The Process of Consent within the Intensive Care Unit
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Draft Proposals for Consultation

Introduction

The following document examines current guidance on consent and the incompetent adult and considers the difficulties in applying these to the field of intensive care. The key goals in the interface between professional and patient/next-of-kin are provision of information, direct communication, involvement in decision-making and documentation. This draft proposal is intended to demonstrate how these goals can be accommodated for the protection of all concerned without converting that interface into a potentially destructive form-filling exercise. It is accepted that certain clinical or family scenarios will fall outside a rather prescriptive approach and the proposal can be considered just one approach to the problem and the starting point for debate rather than a definitive solution.

Professional and political directives

Within English law, the status of valid consent is complex and the ‘next-of-kin’ is not regarded as proxy decision-maker for the incompetent adult in healthcare matters. Nevertheless, it is clear that the current guidance from professional bodies\(^1\) and central government\(^2\) indicate a variety of duties for clinicians. No aspect of care is seemingly excluded from this requirement, it being stated that ‘valid consent must be obtained before starting treatment or physical investigation, or providing personal-care, for a patient’. It should be noted that this requirement applies to ‘all healthcare professionals (including students)’ embracing therefore within intensive care; nursing, physiotherapy, occupational therapy, radiology, dietetics, pharmacy, reviews by the parent specialty or other disciplines and conceivably the chaplain.

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\(^{1}\) ‘Seeking Patients Consent: The Ethical Considerations’ GMC

\(^{2}\) Good Practice in Consent HSC 2001/023
The ‘model consent to treatment policy’ should have been adopted by 1 October 2002 and although there are no direct penalties for non-compliance, the possibility of action through litigation or by both employer and professional bodies should not be underestimated.²

The designated ‘Consent Form 4; Form for Adults who are Unable to Consent to Investigation or Treatment’ requires completion of four principal sections, followed by the signature of the health professional proposing treatment, with designated space for the additional identification and signature of a second opinion. The principal sections are as follows:

A  Details of procedure or course of treatment proposed
B  Assessment of patient’s capacity
C  Assessment of patient’s best interests
D  Involvement of the patient’s family and others close to the patient

A: Treatment proposed

Although there is nothing contentious or difficult about section A, it is clear that if every component of examination, monitoring, prescribing, intervention, basic nursing care and the involvement of the above personnel, required completion of every section and the counter-signature of a second opinion, medical care and indeed communication with relatives would grind to a halt. The form is clearly not intended therefore to be used for all aspects of treatment and care, but is directed at those where the documentation of decision-making could be important. What could be considered important will however differ between staff and patient and between different professional groups and such lack of specificity does not lend itself to staff confidence.

B: Assessment of Capacity

Section B requires qualification of incapacity and whilst this is simple if the patient is unconscious through pathology or sedative therapy, this is more problematic when the patient is in a

³ Dyer C. Consultant suspended for not getting consent for cardiac procedure. BMJ 1998; 316:955
transitional phase between competence and incapacity, a scenario which may change over very short periods of time. Within intensive care the patient may be non-compliant due to a primary cerebral insult, the impact of drugs, sepsis, hypoxia or metabolic disorder on higher functions, or emergence or withdrawal from drugs or alcohol. It can be particularly difficult to categorise agitation or aggression in the circumstances as reflecting a lack of capacity and this raises concerns as to the legitimacy of using chemical or mechanical restraint. It should be noted that unless the patient is unconscious there is an implied requirement to consult with colleagues and to detail the component considerations.

C: Assessment of Best Interests
Most practitioners currently and legitimately provide care for the incompetent adult on the basis that the consent requirements are be deployed in certain (perhaps ideal) circumstances and in the absence of the family, treatment can and should be administered as necessary, especially where urgency is a clear factor. Section C, which refers to ‘best interests’, is potentially problematical since intensive care is not one specific intervention for one well-defined pathology, but a myriad of monitoring, supportive care, investigations, normalisation of various parameters and therapeutic interventions, all of which can change in a very short period of time. Monitoring modalities and treatment strategies will vary between institutions and individual practitioners and are not unequivocally endorsed by evidence or the representative professional bodies. The ‘debates’ on the pulmonary artery catheter, nitric oxide, or transfusion triggers illustrate this point. Many options within intensive care are tried in the hope of an improvement rather than expectation, or from the perspective of medico-legal defensibility such that in the event of death it could not be construed that any treatment option had been omitted or withheld. Such a spectrum of opinion and diversity of practice does not sit easily with the concept of ‘best interests’, certain key cases bringing this consideration to the fore.\(^4\) A potential consequence of the new requirements may be that certain treatment options for which there is no consensus view as above are either delayed or not

\(^4\) Re B (Adult: Refusal of Medical Treatment) [2002] 2 All England Reports 449
initiated once it is decided that consent is advisable on the grounds of no consensus. If the family is not available, communication is problematical because of the added dimension of explaining a lack of consensus, or there are other time restraints on the professionals involved which prevent them embarking on a clearly time-consuming process, the default option may be to simply withhold certain care options.

It should be observed that the requirement for formal involvement of the families in seeking their assent for aspects of care is not explicitly mirrored when it is intended to limit escalation of care, withdraw care or not embark on resuscitation manoeuvres. Logically the process should apply to all such significant decisions, particularly given the recommendations of the professional bodies on the involvement of the next of kin in this area.  

D: Involvement of the patient’s family and others close to the patient

The obvious difficulties in the above three areas are compounded by the problem of deciding who has a legitimate interest to warrant breaches of confidentiality or influence care decisions. Regardless of the lack of a uniform definition of ‘next-of-kin’, differences under English and Scottish law as to their role and a paucity of evidence on the expectations of the next of kin with regard to responsibility for decision-making, it is apparent that a universally applicable approach to the above questions should be sought. The relevance of the consultation document from the Department of Health, ‘Human Bodies, Human Choices’, in which questions are raised as to the suitability of the term ‘next-of-kin’ and as to whether this should be defined in legislation, is not certain. Clinical practice demonstrates that the term spans spouse to friend, with varying degrees of ‘closeness’, a range of intellectual capacity and desire to be involved or take responsibility, may include any number of other individuals and may not always be considered to reflect the patient’s genuine best interests. These factors do not lend themselves to a prescriptive approach or legislation and are best approached on an individual basis.

Possible solutions

5 BMA. Withholding and Withdrawing Life-Prolonging Medical Treatment (1999)
6 GMC. Withholding and Withdrawing Life-Prolonging Medical Treatments: Good Practice in Decision-Making (August 2002)
The principles behind the guidelines for consent are of:

1. respect for patient autonomy,
2. provision of information (including for the next-of-kin when a patient lacks capacity) and
3. formal documentation of the decision-making and rationale for treatment in any circumstance.

**Respect for autonomy**

It is documented within Consent Form 4 that ‘“best interests” go far wider than “best medical interests” and include factors such as the patient's wishes and beliefs when competent, their current wishes, their general well-being and their spiritual and religious welfare’.

Respect for autonomy, should where possible, therefore, involve engagement with the patient long before deterioration due to critical illness renders them incompetent for the purposes of consent. It is unrealistic to expect every individual whilst well to consider treatment options during critical illness, to formulate an advance directive that can be applied to all clinical scenarios, and to nominate a next-of-kin who would not only understand the wishes and beliefs of the patient but would be willing to act as a proxy decision maker in the event of incompetence. Such an exercise would ultimately however help to clarify these key issues for health carers and next-of-kin alike.

In certain clinical scenarios, such as worsening medical illness or the need for major surgery, a requirement for intensive care can be predicted in advance of incapacity. Involvement of the ICU/outreach team in determining suitability for intensive care would not only be in line with current recommendations but in seeking prior consent for the inherent key components would go some way towards promoting autonomy and reducing the later burden on both staff and next-of-kin.

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7 *Functioning as a Team? The 2002 Report of the National Confidential Inquiry into Perioperative Deaths*
If the outreach team were to have such an explicit expanded role, having been referred the at-risk patient, it would clearly be important to ensure good training, coordination and monitoring of the process.

In the context of planned major surgery with an obvious requirement for postoperative intensive care there appears little excuse for not informing the competent patient pre-operatively as to what this will entail.

If the anaesthetist in such circumstances were to have such an explicit expanded role, it would be unclear who would take responsibility for ensuring that they had sufficient understanding of the implications, and were able to communicate and answer all relevant questions, etc. Liaison with the intensive care team would appear to be the natural default option.

**Provision of information for the next of kin when a patient lacks capacity**

Clearly in the majority of cases the patient will be admitted to an ICU with no possibility of the above exercises being conducted. Staff will then be placed in the position of answering the above questions with regard to how much information the relatives expect and how formally the consent process should be invoked for which components of care.

The most applicable solution appears to be one in which the relatives are;

1. given information about the process of intensive care,
2. given information on their role with regard to decision-making for the incompetent patient, and
3. asked to designate a next-of-kin.

If it was considered advisable or essential, Consent Form 4 could be completed on admission therefore with ‘intensive care’ as a generic inclusive process being specified as the treatment but with reference to supplementary documentation.

It would be reasonable to introduce the concept of medical futility at this stage as a prelude to later discussions on resuscitation status.
It may well be that the next-of-kin is unable to comprehend the information or simply wishes that the staff do what they consider best for the patient. In such circumstances it would be inappropriate to coerce that individual to sign an informed disclaimer and a senior member of staff should take responsibility for confirming that this situation pertains.

Regardless of the approach taken by the next-of-kin, the onus is on staff to document within the clinical records all the major treatment decisions, the rationale for these decisions and communication with the next-of-kin. A generic consent form or a disclaimer does not excuse any individual from their professional responsibilities in this regard.

It should be apparent however that there will be a very limited indication for the use of the full consent form other than on admission. Interventions of a more major nature and with inherent risk, such as a tracheostomy, which cannot be said unequivocally to be of immediate therapeutic benefit, certainly warrant discussion with the next-of-kin. It could be argued that this procedure thereby provides a benchmark against which a need to formally discuss other interventions can be judged. The next-of-kin does not however have a decisive role and it would create uncertainty if a formal consent form were to be used for these interventions. The decision should be taken on the basis of ‘best interests’, consideration of which should include discussion with the next of kin, and documentation in the medical records should describe that decision-making process.
Information for Relatives of Patients on the ICU (Intensive Care Unit)

Which patients need admission to an ICU?
Patients may be admitted to an ICU as a precautionary measure, or because they are so ill, that without a higher level of medical care, death would become inevitable. Although these patients may be the sickest in the hospital, the doctors would not usually have admitted them to the ICU if they did not believe that there was a realistic chance of both survival and a return to a reasonable quality of life. Occasionally, patients are admitted when death appears to be inevitable to provide time for assessment or to move them from a clinical area such as the operating theatre or A&E department where it is difficult for the family to be in attendance.

What care will they receive and who will deliver it?
The care that they will receive whilst on the ICU is a complicated combination rather than one single treatment and often changes over very short periods of time. Care is delivered by many different professional groups, such as doctors, nurses and physiotherapists, some of which will still be in training. Staff may change from day-to-day. Care is often described as supportive, that is, helping the systems of the body that are under stress, whilst time allows healing from major injury or surgery, or drugs such as antibiotics help the body to fight infection.

What are the different aspects of care?
The goal of care is to ensure that during this time of critical illness the body is kept as near to normal as possible in terms of lung function, performance of the heart and circulation, removal of waste products, provision of food and body chemistry. These critically ill patients need to be examined regularly, be monitored by machines and have various investigations such as blood tests or x-rays performed to check whether the patient is responding appropriately to care. Quite often the patients need to be sedated to rest the body and keep them comfortable whilst care is being delivered. They may be on a breathing machine to help the lungs, drugs to support the heart and circulation, an artificial kidney and may be receiving food via a tube.
into the stomach or into the veins. They may need various drugs, **drips** to keep the body chemistry normal, or **blood** or plasma. Monitoring the patient often means putting a **catheter** into the bladder or inserting plastic tubes into some of the major blood vessels of the body.

This **supportive care** sometimes needs to be supplemented by more active **interventions** such as putting a telescope down the breathing tube into the lungs or draining collections of fluid or pockets of infection. The patient may need to be taken to the **x-ray department** for special scans or to the operating theatre for **surgery**. Occasionally staff need to act in an **emergency** if the patient starts to bleed, the heart rhythm deteriorates or the lung leaks into the cavity of the chest.

Sometimes the patient will appear **agitated** or even distressed. This is because staff are trying to have the patient awake, responsive and cooperative and off their sedative drugs which can have harmful side-effects. Since restarting sedation is not a long-term answer the staff may sometimes bandage the patient's hands to prevent the patient harming themselves or indeed the staff.

Whilst this process of care is continuing, the **physiotherapists** will be involved in preventing or dealing with problems with the chest and keeping the patient mobile. Nursing staff, in addition to all of the above, perform **personal-care** to keep the patient clean and prevent pressure sores developing.

All of these aspects are **basic to intensive care** and are only undertaken if staff believe that they would be beneficial to the patient and that the patient would have wanted this care to be started and continued. Although many treatments are associated with certain risks, the potential **benefit** should always outweigh that **risk** and staff will do all possible to prevent that risk developing. The staff furthermore will always be available to **discuss** the patient's **condition**, the **care** she/he is receiving, the **outlook**, and the **plan** for the patient, particularly if there is some risk involved.
Who decides on all these aspects of care?

The ultimate responsibility for deciding on care when an adult cannot answer for themselves rests with the medical team, since they have the best knowledge of whether the patient is likely to benefit from any particular component of care. In most cases furthermore, it would be unfair to put responsibility for decision-making on the next of kin. We would however always discuss more major interventions such as surgical procedures, and aim to get your agreement that this was in the patient’s best interests except in an extreme emergency. The process of ‘consent’ cannot however be applied to all of the above aspects of care and particularly so when the final responsibility rests with the staff.

As such, we would like you to sign a form that indicates you are aware of these considerations and you can list any aspect that you would wish to know about before staff embarked upon this.

What happens if the patient does not respond positively to intensive care?

It is an unfortunate fact of life that not every patient will respond to the care we provide and death may occur despite maximal support. In such circumstances the clinical staff may consider that it would not be appropriate to embark on resuscitation measures (CPR - cardiopulmonary resuscitation) since this would not only be unsuccessful but physically harmful and unpleasant to the patient, thereby preventing a death with dignity. In other circumstances the staff may consider that full support should continue, but if the patient were to deteriorate further, that it would be inappropriate to increase the levels of support or to consider aggressive resuscitation. In certain patients there may be evidence of such severe damage that in the event of survival the patient's quality-of-life would be unacceptable. In these cases it may be appropriate to concentrate on keeping the patient comfortable, reducing the amount of artificial support they are receiving, and letting nature take its course.

If unfortunately, any of the above situations were to develop, the ICU staff will aim to fully involve you in these considerations, explaining the reasons for this approach to care and asking for your perspective on what the patient would have wanted if circumstances permitted this. The form that we will ask you to sign draws attention to resuscitation decisions.
Are there any other aspects of care that the next of kin should be aware of?

All staff have a duty to audit their activity and thereby demonstrate that the patients they are responsible for are receiving the best possible care. Information about the patient’s condition, care and outcome are collected on a computer database and analysed centrally. This allows an individual unit to compare their outcomes for certain conditions against national figures. Any information that is published carries no details that could identify an individual patient, thereby complying with a duty to respect confidentiality.

Research may also be ongoing in the intensive care unit to which the patient has been admitted, with the goal of always striving to improve the quality-of-care we deliver. Just as your family member or friend will hopefully be benefiting from previous research, these projects are more likely to benefit future patients with a similar condition and this will be explained to you along with the specific details of any study. Research will only be conducted within professional guidelines, and with the approval of a Research Ethics Committee. Research would not involve withholding any treatment or intervention that is known to be effective. We do understand how difficult it is to have to deal with these issues in addition to all of the above whilst worried and concerned, and would hope to minimize any burden to you.

If there is any aspect of this information booklet that is not clear please speak to any member of staff. Medical and nursing staff are present round-the-clock and would wish you to speak to them if any aspect of care is not clear or troubling to you at any stage.

Do not worry that staff might think your concern is trivial or silly.

You are also perfectly free to reconsider any decisions you may have made previously.
Information for patients expected to require intensive care postoperatively

It has been decided that you will need to be cared for on the ICU (intensive care unit) after your operation. This may be because the operation is so major or so long that your body needs time to recover when the operation is over. You may also need to be admitted when you already have medical problems that put you more at risk of complications from the operation and anaesthetic.

Depending on these factors and how your body responds to the operation and anaesthetic, you may be transferred to the intensive care unit awake and breathing on your own or still receiving anaesthetic agents and being artificially ventilated by a machine. If this is the case, the sedation will be stopped as soon as all the systems of your body are stable. Once you are breathing adequately on your own the intensive care staff will remove the plastic breathing tube that connects you with the ventilator from down your throat.

You will usually be given pain relief either in the form of a drug like morphine or by an epidural injection. You will be monitored more closely than on a general ward and as soon as it is clear that you are on the road to recovery you will be transferred back to your original surgical ward. Sometimes the body's recovery is quite slow or complications set in and instead of reducing the amount of support you need, the intensive care staff are forced to increase it. If this is the case the staff will keep your designated next-of-kin informed as to your condition, the outlook and the plan of management.

If you have any questions regarding the above, please direct these to the anaesthetist who will visit you before your operation.

If you want to discuss your feelings towards resuscitation in the event of serious complications developing you should arrange to speak to your surgeon or anaesthetist ideally in the presence of your designated next of kin.
Certification of the involvement of the patient's family and others close to the patient

I,……………………………….., being the…………………………………………
of……………………………… and designated next of kin, confirm that I have had the opportunity to read the booklet Information for Relatives of Patients on the ICU (Intensive Care Unit).

I have had the opportunity to ask questions about the care that will be given on the ICU and the role of the next of kin in the decision-making process.

I can think of no objection why the basic care described in the booklet should not be given to the patient in line with good medical practice and the best interests of the patient.

I have signed the consent form 4 to this effect.

I would however like to be informed if the following interventions were planned;

…………………………………………………………………….
…………………………………………………………………….
…………………………………………………………………….

I understand that staff will, where possible, ensure that I am informed and consulted before embarking on surgery or interventions that carry significant risk.

I understand that if the staff consider a favourable outcome is not possible they will explain the reasons for this and a decision may be taken either not to increase or to withdraw certain treatments.

Signed……………………………… Name……………………………. Date……………

In the presence of;
Disclaimer

The designated next of kin is incapable of comprehending the information as to what intensive care constitutes / does not wish to consider all that provided information.

The designated next of kin wishes not to be / to be informed of major health-care decisions.

Signed……………………….. Name……………………….  Designation………………

Date…………………….
Key questions for consideration/consultation

The proposals in this consultation document include;

1.1 provision of comprehensive information for relatives,
1.2 a new formal process of documentation for both consent and disclaimer,
1.3 early discussion on resuscitation status,
1.4 promotion of decision-making before the point of incapacity,
1.5 an expanded role for outreach services, and
1.6 additional duties of an anaesthetist with regard to planned ICU admissions.

Each of these aspects warrants broad consideration.

The following series of questions should be viewed therefore as the starting point for this consultation exercise.

Key questions for any staff involved in intensive care are;

1. What aspects of care should be formally defined as necessary for inclusion in a consent process?
2. What defines incapacity in the diverse circumstances outlined above?
3. What determines that an aspect of care is in a patient's ‘best interests’?
4. Pertinent to all these questions is who decides, who documents, who informs the next of kin and when and from where should a second opinion be sought?
5. Should a decision to limit or withdraw care, or not engage in resuscitation manoeuvres require the same degree of formal written consent?
6. What defines the next of kin?
7. What approach is to be taken when the next of kin do not wish to be burdened with details, information on risk or indeed any responsibility for decision-making?
Key questions for any ICU and responsible trust are;

1. How can the requirements of the central guidance from the Department of Health on consent be met?
2. How can the professional defensibility of all grades and disciplines of staff be assured?
3. Should there be an explicit unit policy?

Key questions for the Intensive Care Society are;

1. Does the society have a primary role in defining principles or standards in this field?
2. Apart from the Department of Health, Royal College of Anaesthetists, Royal College of Nursing and the Chartered Society of Physiotherapists, who are the other key stakeholders in this debate?
3. Are the interests of members best served by defining nationally applicable standards?
4. Are the interests of patients and the public best served by defining nationally applicable standards?

The Intensive Care Society clearly has a role in addressing such issues but the response in terms of guidelines and standards will be dictated by informed opinion from individuals across a range of disciplines, various professional bodies with a legitimate interest, and groups representative of patient and public interest.

Responses should be directed electronically or in writing to the ICS as directed.
The closing date for responses to the consultation exercise will be Friday 26 September 2003.