



**Business Services
Organisation**

Directorate of Legal Services

— PRACTITIONERS IN LAW TO THE
HEALTH & SOCIAL CARE SECTOR —

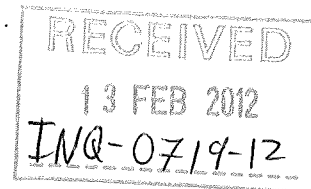
2 Franklin Street, Belfast, BT2 8DQ
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Your Ref:
BC-0063-11

Our Ref:
HYP B4/1

Date:
13.02.12

Ms Bernie Conlon
Secretary to the Inquiry
Arthur House
41 Arthur Street
Belfast
BT1 4GB



Dear Madam,

RE: INQUIRY INTO HYPONATRAEMIA RELATED DEATHS

I refer to the above and your letter of 2nd November 2012 (BC-0063-11).

With reference to annex 1 c thereof I am instructed that the Trust has not retained a copy of the Trust procedures which it was required to produce and believes it was the Royal Hospitals Policy on Consent (TP 21/98) or possibly an earlier version. This was superseded by Trust Policy TP 5/04 "Consent" dated April 2004. I enclose a copy of same for your attention.

Yours faithfully,

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Providing Support to Health and Social Care



INVESTOR IN PEOPLE

**THE ROYAL GROUP OF HOSPITALS AND DENTAL HOSPITAL
HEALTH AND SOCIAL SERVICES TRUST**

Trust Policy

**TP 5/04
Supersedes TP 21/98**

Consent

Why consent is crucial

Patients have a fundamental legal and ethical right to determine what happens to them. Valid consent to treatment is therefore absolutely central in all forms of health care, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health care professionals and patients.

The policy

The Department has issued a range of guidance documents on consent, and these should be consulted for details of the law and good practice requirements on consent. This policy sets out the standards and procedures which aim to ensure that health professionals are able to comply with the guidance. While this document is primarily concerned with health care, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those which involve touching the patient or client.

What consent is – and isn't

“Consent” is a patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing. For the consent to be valid, the patient must

- be competent to take the particular decision,
- have received sufficient information to take it, and
- not be acting under duress

The context of consent can take many different forms, ranging from the active request by a patient of a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health professional's advice. In some cases, the health professional will suggest a particular form of treatment or investigation and after discussion the patient may agree to accept it. In others, there may be a number of ways of treating a condition, and the health professional will help the patient to decide between them. Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments. In many cases, ‘seeking consent’ is better described as ‘joint decision-making’ – the patient and health professional need to come to an agreement on the best way forward, based on the patient's values and preferences and the health professional's clinical knowledge.

Where an adult lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, **no-one else can give consent on their behalf**. However, treatment may be given if it is in their best interests, as long as it has not been refused in advance in a valid and applicable advance directive. For further details on advance directives see the Department of Health, Social Services and Public Safety's *Reference Guide to Consent for Examination, Treatment or Care* (chapter 1, paragraph 16)

Guidance on consent

The Department of Health, Social Services and Public Safety is issuing a number of guidance documents on consent, and these should be consulted for advice on the current law and good practice requirements in seeking consent. Health professionals must also be aware of any guidance on consent issued by their own regulatory bodies

- *Reference Guide to Consent for Examination, Treatment or Care* provides a comprehensive summary of the current law on consent, and includes requirements of regulatory bodies such as the General Medical Council where these are more stringent. Copies are available at division offices and may also be accessed on the internet at
- Specific guidance, incorporating both the law and good practice advice is available for health professionals working with children, with people with learning disabilities and with older people. Copies of these booklets are available at division offices and on the internet at

Documentation

For significant procedures, it is essential for health professionals to document clearly both a patient's agreement to the intervention and the discussions which led up to that agreement. This may be done either through the use of a consent form (with further detail in the patient's notes if necessary), or through documenting in the patient's notes that they have given oral consent.

Written consent

Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is evidence that the patient has given consent, but is not proof of valid consent. If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract.

It is rarely a legal requirement to seek written consent,¹ but it is good practice to do so if any of the following circumstances apply

¹ The Mental Health (Northern Ireland) Order 1986 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances

- the treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications')
- the procedure involves general/regional anaesthesia or sedation
- providing clinical care is not the primary purpose of the procedure
- there may be significant consequences for the patient's employment, social or personal life
- the treatment is part of a project or programme of research approved by the Royal Hospitals

If the individual is illiterate, the individual may be able to make their mark on the form to indicate consent. It would be good practice for the mark to be witnessed by a person other than the clinician/practitioner seeking consent, and for the fact that the individual has chosen to make their mark in this way to be recorded in the case notes. Similarly, if the individual has capacity, and wishes to give consent, but is physically unable to mark the form, this fact should be recorded in the notes, or on the consent form.

Completed forms should be kept with the patient's notes. Any changes to a form, made after the form has been signed by the patient, should be initialled and dated by both patient and health professional.

It will not usually be necessary to document a patient's consent to routine and low-risk procedures, such as providing personal care or taking a blood sample. However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined, or become very distressed about, similar care in the past), it would be helpful to do so.

Procedures to follow when patients lack capacity to give or withhold consent

Where an adult patient does not have the capacity to give or withhold consent to a significant intervention, this fact should be documented in **form 4** (form for adults who are unable to consent to investigation or treatment), along with the assessment of the patient's capacity, why the health professional believes the treatment to be in the patient's best interests, and the involvement of people close to the patient. The standard consent forms should never be used for adult patients unable to consent for themselves. For more minor interventions, this information should be entered in the patient's notes.

An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. You should involve appropriate colleagues in making such assessments of incapacity, such as specialist learning disability teams and speech and language therapists, unless the urgency of the patient's situation prevents this. If at all possible, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate.

Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. Where the consequences of having, or not having, the treatment are potentially serious, a court declaration may be sought.

Availability of forms

Standard consent forms and forms for adults who are unable to consent for themselves are available as a stock item. There are three versions of the standard consent form: **form 1** for adults or competent children, **form 2** for parental consent for a child or young person and **form 3** for cases where it is envisaged that the patient will remain alert throughout the procedure and no anaesthetist will be involved in their care. The use of form 3 is optional but may be thought more appropriate than form 1 in situations where patients do not need to be made aware of issues surrounding general or regional anaesthesia and do not need to make any advance decisions about additional procedures because they will be in a position to make any such decisions at the time if necessary. **Form 4** is for adults who are unable to consent to treatment or care.

Availability of Patient Information leaflet about the consent form "Consent – it's up to you"

The patient information leaflet about the consent form "Consent – it's up to you" is available from Stores. It should be made available to patients in advance of their being asked to sign a consent form, and may be published in any appropriate format. Text should only be omitted if it will never be relevant (for example the section on anaesthesia could be omitted if the organisation involved would never be seeking consent for anaesthesia).

When should consent be sought?

When a patient formally gives their consent to a particular intervention, this is only the *endpoint* of the consent process. It is helpful to see the whole process of information provision, discussion and decision-making as part of 'seeking consent'. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition.

Single stage process

In many cases, it will be appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. For example, during an ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient's condition and whether there are any significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given orally.

If a proposed procedure carries significant risks, it will be appropriate to seek written consent, and health professionals must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the health professional may then proceed.

Two or more stage process

In most cases where written consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital out-patient clinic), or it might be over a whole series of consultations with a number of different health professionals. The consent process will therefore have at least two stages: the first being the provision of information, discussion of options and initial (oral) decision, and the second being confirmation that the patient still wants to go ahead. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.

Patients receiving elective treatment, intervention or investigations for which written consent is appropriate should be familiar with the contents of their consent form before they arrive for the actual procedure, and should have received a copy of the page documenting the decision-making process. They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in out-patients, at a pre-admission clinic, or when they arrive for treatment. If a form is signed before patients arrive for treatment, however, a member of the healthcare team **must** check with the patient at this point whether they have any further concerns and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure. When confirming the patient's consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example beginning with "tell me what you're expecting to happen", rather than "is everything all right?"

While administrative arrangements will vary, it should always be remembered that for consent to be valid, the patient must feel that it would have been possible for them to refuse, or change their mind. It will rarely be appropriate to ask a patient to sign a consent form after they have begun to be prepared for treatment (for example, by changing into a hospital gown), unless this is unavoidable because of the urgency of the patient's condition.

Seeking consent for anaesthesia

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks. However, in elective treatment it is not acceptable for the patient to receive no information about anaesthesia until their pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position genuinely to make a decision about whether or not to undergo anaesthesia. Patients should therefore either receive a general leaflet about anaesthesia in out-patients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient's notes or on the consent form. Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then he or she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia. Information for patients' relatives and friends on anaesthesia have been produced by the Royal College of Anaesthetists and Association of Anaesthetists of Great Britain and Ireland.

In addition, where general anaesthesia or sedation is being provided as part of dental treatment, the General Dental Council currently holds dentists responsible for ensuring that the patient has all the necessary information. In such cases, the anaesthetist and dentist will therefore share that responsibility.

Emergencies

Clearly in emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other, and it may often be appropriate to use the patient's notes to document any discussion and the patient's consent, rather than using a form. The urgency of the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

Treatment of young children

When babies or young children are being cared for in hospital, it will not usually seem practicable to seek their parents' consent on every occasion for every routine intervention such as blood or urine tests or X-rays. However, you should remember that, in law, such consent is required. Where a child is admitted, you should therefore discuss with their parent(s) what routine procedures will be necessary, and ensure that you have their consent for these interventions in advance. If parents specify that they wish to be asked before particular procedures are initiated, you must do so, unless the delay involved in contacting them would put the child's health at risk.

Only people with 'parental responsibility' are entitled to give consent on behalf of their children. You must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it). If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check.

Provision of information

The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about their condition and about possible treatments/investigations and their risks and benefits (including the risks/benefits of doing nothing). They also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue. Once a decision to have a particular treatment/investigation has been made, patients need information about what will happen, where to go, how long they will be in hospital, how they will feel afterwards and so on.

Patients and those close to them will vary in how much information they want and in a form the patient understands, from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the presumption must be that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

Clinicians are responsible for providing information on their procedures. This includes different formats such as audio tapes, Braille or video tapes. Interpreters are available and can be arranged as per the Trust Policy on Interpreters (TP 4/02)

Provision for patients whose first language is not English

The Royal Hospitals is committed to ensuring that patients whose first language is not English receive the information they need and are able to communicate appropriately with healthcare staff. It is not appropriate to use children to interpret for family members who do not speak English.

The policy on the use of interpreters guides staff on the various types of interpreters and how to contact one.

Access to more detailed or specialist information

Patients may sometimes request more detailed information about their condition or about a proposed treatment than that provided in general leaflets. This should be provided by the clinician and any sources such as the Cochrane Library listed.

Access to health professionals between formal appointments

After an appointment with a health professional in primary care or in out-patients, patients will often think of further questions which they would like answered before they take their decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or to wait until the date of an elective procedure (by which time it is too late for the information genuinely to affect the patient's choice). A contact number should be provided which will allow the patient to seek further information if desired.

Open access clinics

Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment. You should ensure that they have the information they need before proceeding with an investigation or treatment.

Who is responsible for seeking consent?

The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done. It is they who will be held responsible in law if this is challenged later.

Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the health professional responsible. However, team work is a crucial part of the way the HPSS operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent. If the person cannot write or is physically unable to sign a form, a record that the person has given verbal or non-verbal consent should be made in their notes or on the consent form.

Completing consent forms

The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit.

If the patient signs the form in advance of the procedure (for example in out-patients or at a pre-assessment clinic), a health professional involved in their care on the day should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered. It will be appropriate for any member of the healthcare team (for example a nurse admitting the patient for an elective procedure) to provide the second signature, as long as they have access to appropriate colleagues to answer questions they cannot handle themselves.

The Royal Hospitals will continue to provide rolling programmes of training on consent. It is the responsibility of the divisional staff to ensure that staff involved in obtaining consent for a procedure are appropriately trained to do so.

Responsibility of health professionals

It is a health care professional's own responsibility

- to ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so, and
- to work within their own competence and not to agree to perform tasks which exceed that competence.

If a health care professional is feeling pressurised to seek consent when they do not feel competent to do so they should contact their line manager or professional head.

Refusal of treatment

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's/client's options. A competent adult person is entitled to refuse any treatment (See paragraph 2 regarding mental health legislation). The situation for children is more complex see the Department of Health Social Services and Public Safety *Seeking consent working with children* for more detail. The following paragraphs apply primarily to adults.

Mental health legislation does provide the possibility of treatment for a person's mental disorder and its complications without their consent. This legislation does not give power to treat unrelated physical disorders without consent. If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in their notes. If the patient has already signed a consent form, but then changes their mind, you (and where possible the patient) should note this on the form.

Where a patient has refused a particular intervention, you must ensure that you continue to provide any other appropriate care to which they have consented. You should also ensure that the patient realises they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.

If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient the possible consequences of their partial refusal. If you genuinely believe that the procedure cannot be safely carried out under the patient's stipulated conditions, you are not obliged to perform it. You must, however, continue to provide any other appropriate care. Where another health professional believes that the treatment can be safely carried out under the conditions specified by the patient, you must on request be prepared to transfer the patient's care to that health professional.

Tissue

The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises very difficult issues and is currently under review. Such tissue can be very valuable in education and research, and its use may lead to developments in medical knowledge and hence improvements in healthcare for all. At present, The Royal Hospitals requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedure to be used for education or research purposes.

Explicit consent is not necessary for public health surveillance using the unlinked anonymous method.

The Department of Health, Social Services and Public Safety, in line with what is happening elsewhere in the UK, is currently undertaking a review of the law on the removal, retention and use of organs and tissue. Pending the outcome of the review the Department will issue an interim statement on the use of tissue.

Clinical photography, audio and video recordings

Photographic, audio and video recordings made for treatment purposes form part of a patient's record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic, audio or video recording will result from that procedure.

Photographic, audio and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in paragraph 3 below. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.