Witness Statement Ref. No. 130/1

NAME OF CHILD: ADAM STRAIN

Name: Peter Crean

Title: Dr.

Present position and institution:

Consultant Paediatric Anaesthetist, Royal Belfast Hospital for Sick Children

Previous position and institution:
[As at the time of the child's death]
Consultant in Paediatric, Anaesthesia and Intensive Care- Royal Belfast Hospital for Sick Children ("RBHSC").

Membership of Advisory Panels and Committees:
[Identify by date and title all of those between January 1995 - April 2012]

In N Ireland:

Chairman of the Paediatric Anaesthetic Group in N Ireland 1999-2004

Member of N Ireland Working Group on Hyponatraemia in Children
2001 - 2002

Member of the Human Organs Enquire Implementation Sub-group on the guidance to the HPSS and consent 2002-2004.

Member of the Human Organs Enquiry Implementation Sub-group on Public Information and Communication 2003.

Northern Ireland Regional Paediatric Fluid Therapy Working Group 2006.

Member of 'Paediatric Surgery Working Group Phase 1', Department of Health, N Ireland.
2008

Member of the Paediatric ENT Surgery Group, Department of Health, N Ireland, 2008-9

Guideline and Audit Implementation Network (GAIN). Member of Guideline Development Group on Hyponatraemia in Adults. 2008-9

National:

Member of the Paediatric Group
National Confidential Enquiry into Perioperative Deaths

1998 - 1999

Member of Working Group on Paediatric Anaesthesia and Emergency Care in District General Hospitals 2004-6.
"Care of the acutely ill or injured child: a team response" published 2006

Member of External Reference Group, Children's Hospital Service Pilot Improvement Review, Healthcare Commission. 2004-2005

Member of the Children's Surgical Forum, Royal College of Surgeons, England 2005-07

President of the Association of Paediatric Anaesthetists of Great Britain and Ireland 2005-7

'Joint statement on the provision of general paediatric surgery provision in the District General Hospital', 2006. Member of the working group and co-signatory as President of the APA.

Member of working group revising 'Children's Surgery: a first class service'. 2006-07.
'Surgery for children - delivering a first class service' published July 2007

NICE Guideline Development Group on Sedation in Children 2008 - 2010

NCEPOD Advisor 2009 - 2011 on deaths following surgery in children. 'Are We There Yet?' Published October 2011.

Previous Statements, Depositions and Reports:
[Identify by date and title all those made in relation to the child's death]

OFFICIAL USE:
List of previous statements, depositions and reports:

Ref:	**Date:**	

IMPORTANT INSTRUCTIONS FOR ANSWERING:

Please attach additional sheets if more space is required. Please identify clearly any document to which you refer or rely upon for your answer. If the document has an Inquiry reference number, e.g. Ref: 049-001-001 which is 'Chart No.1 Old Notes', then please provide that number.

If the document does not have an Inquiry reference number, then please provide a copy of the document attached to your statement.

I. QUERIES IN RELATION TO YOUR MEDICAL QUALIFICATIONS, EXPERIENCE, TRAINING AND RESPONSIBILITIES

Please provide the following information:

(a) State your medical qualifications as of 1995;

MB, BCh, BAO, FFARCS

(b) State the date you qualified as a medical doctor;

July 1976

(c) Describe your career history before you were appointed Consultant in Paediatric, Anaesthesia and Intensive Care - Royal Belfast Hospital for Sick children (RBHSC);

I undertook my anaesthetic training in the Northern Ireland under the supervision of the N Ireland Council for Postgraduate Medical Education (1977 - 1982). I then spent two Fellowship years in the Hospital for Sick Children, Toronto, gaining further experience in Paediatric Anaesthesia, Paediatric Intensive Care and Neonatal Intensive Care.

(d) Describe your work commitments at the RBHSC from the date of your appointment to November 1995;

I think at that time I worked seven clinical sessions each week, covering both theatre and the Paediatric Intensive Care Unit. I was also on call for both these areas.

(e) Was there a written job description for your post in 1995? If so please provide copy of the same. If not, what were the functions and responsibilities of the post?

I do not have a job description from 1995.

My post was that of a paediatric anaesthetist delivering the clinical commitment as outlined in 1(d).

(f) Describe the accountability of a Consultant in Paediatric, Anaesthesia and Intensive

Care - RBHSC at that time.

Such an individual was accountable to his or her employer through the management team.

(g) What was your experience of renal paediatric transplant surgery in 1995?

I had been involved in renal transplantation while in Toronto.

I anaesthetised two children in 1995 for their renal transplant surgery.

II. INTERNAL CONTROL

Were professional Codes of Conduct incorporated into the contracts of those healthcare professionals involved in the care and treatment of Adam Strain in 1995?

I do not know.

III. HEALTH AND SAFETY

From a 1995 risk management perspective, what should have been expected in respect of:

The composition of a paediatric operating theatre team;

(h) The minimum staffing requirements thereof;

I have no recollection of this.

(i) The experience of anaesthetist and surgeon in paediatrics;

Both anaesthetist and surgeon should be adequately trained with the requisite skills and competencies to deliver care to children.

(j) The appraisal of anaesthetic staff after an unexpected death;

I have no recollection of this.

(k) The monitoring of anaesthetic set up and drug administration;

The anaesthetic machine should have been checked daily and appropriate doses of drugs administered.

(l) The documentation and record keeping in respect of anaesthetic equipment;

I have no recollection of this.

(m) The content of operation notes.

A full record of the anaesthetic should have been completed .

IV. KINGS FUND ORGANISATIONAL AUDIT

What knowledge did you have of the King's Fund accreditation process?

I remember about its existence but have no further recollection.

If you participated in that process, specify in what way;

V. CLINICAL/MEDICAL AUDITS

In 1995, what arrangements did the RBHSC have in place for ensuring that regular and systematic medical and/or clinical audits took place?

Mortality meetings were held at that time.

If the RBHSC did have a system in place for conducting medical and/ or clinical audits, please address the following:-

(n) Was there a Clinical Audit Committee? If so, what was its remit?

(o) What were the rules that regulated the operation of the Clinical Audit Committee?

(p) Who formed the Clinical Audit Committee?

(q) Did you play a role in connection with the Clinical Audit Committee, and if so what?

(r) Who was responsible for ensuring that medical and/or clinical audits were carried out?

(s) Who was responsible for carrying out medical and/or clinical audits?

(t) Under what procedures were medical and/or clinical audits carried out?

(u) To whom were the results of medical and/or clinical audits sent?

(v) What kinds of action could be taken on foot of the results of medical and/or clinical audits?

Please particularise all steps taken by the RBHSC to investigate the unexpected death of Adam Strain.

I have no recollection of this.

Was there any procedure or system in place in 1995 to audit the quality, clarity and completeness of clinical case notes?

I have no recollection of this.

If there was no system in place for conducting medical audits in 1995, please clarify whether there was any other system in place for quality assuring the safe provision of clinical care?

I have no recollection of this.

Was there a system of independent external scrutiny in place to review patterns of performance in the RBHSC, and if so please provide details of the same?

I have no recollection of this.

VI. CONSENT

(2) In 1995 did the RBHSC have guidance, policy or procedures in place which governed the issue of patient 'consent'?

I have no recollection of this.

If so,

(a) Provide a copy of the guidance, policy or procedure;

(b) Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(c) Describe its main features;

(d) State how the guidance, policy or procedures was distributed to clinical staff;

(e) State how the guidance, policy or procedures was monitored for compliance.

(3) With respect to the recommendations deriving from:

(a) Guide HC (90) 22, a Guide to Consent for Examination or Treatment;

(b) Circular HSS (GHS) 2/95.

Please state what steps the Trust took to:

(i) Disseminate this guidance and to whom;

(ii) Monitor and record compliance with the same;

(iii) Enforce compliance.

I do not know.

What arrangements were in place in order to notify the Trust that **Circular HSS (GHS) 2/95** had been disseminated, and that there was a system in place to monitor compliance with the Circular?

I do not know.

If it is correct that the RBHSC did not commence using the new model consent forms recommended in **HSS (GHS) 2/95** until early in 2000, please state the reasons for this delay. If not, please advise date of introduction of new consent forms.

I have no recollection of this.

VII. RECORD KEEPING

In 1995 did the RBHSC have guidance, policy or procedures in place which governed the issue of clinical record keeping?

I have no recollection of this.

If so,

(c) Provide a copy of the guidance, policy or procedures;

(d) Describe its main features;

(e) Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(f) State how the guidance, policy or procedures were distributed to clinical staff;

(g) State how the Trust satisfied itself that the guidance, policy or procedures was being complied with by members of clinical teams;

(h) State whether there was/ is any protocol or procedure governing the destruction of any clinical records created in 1995, and if so please identify the same;

(i) Whether there is/ was any protocol or procedure governing the identity of those individuals permitted to sign for and signify safe receipt of transplant organs;

(j) In respect of the composition and documentation of clinical and surgical teams engaged in specific operations.

What guidance was provided to medical/ nursing staff in respect of:

(k) The monitoring and recording of intra-operative fluid balance?

Fluid intake and loss (blood loss and urine output) would be recorded on the anaesthetic record.

(l) Recording weights in children?

Children should be weighed, if possible, when admitted to hospital. Renal patients were weighed frequently, depending on their medical condition and treatment.

(m) Monitoring effectiveness of peritoneal dialysis?

I have no recollection of this.

(n) The completion of patient records?

I have no recollection of this.

What procedures or protocols were in place in 1995 for monitoring compliance with professional standards for record keeping?

I have no recollection of this.

VIII. COMMUNICATION

In 1995 did the RBHSC have guidance, policy or procedures in place which governed the issue of communications with next of kin and the provision of information during, before and after surgery; and after an unexpected death?

I have no recollection of this.

If so please provide:

(o) A copy of the guidance, policy or procedures;

(p) Describe its main features;

(q) Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so please identify this guidance;

(r) State how the guidance, policy or procedures were distributed to clinical staff;

(s) State how the Trust satisfied itself that the guidance, policy or procedures was being complied with by members of clinical teams.

Were there any procedures in place in 1995 for communication with next of kin when aspects of care had not gone to plan and had resulted in harm to the patient?

I have no recollection of this.

IX. BLOOD GAS MACHINES

In 1995 did the RBHSC have guidance, policy or procedures in place which governed the use of blood gas machines?

I have no recollection of this.

If so, please address the following:

(t) Provide a copy of the relevant guidance, policy or procedures.

(u) Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(v) State how the RBHSC's guidance, policy or procedures were distributed to clinical staff;

(w) State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams.

(4) In 1995 what did the guidance, policy or procedures associated with the use of blood gas machine say about the following matters:

I have no recollection of this.

(a) Maintenance;

(b) Inspection;

(c) Risk assessment;

(d) Quality control checks;

(e) The personnel entitled to use the machines;

(f) Documenting and recording keeping in respect of same.

In 1995 was there established within the RBHSC a committee, group or team to oversee the safe use of blood gas machines?

I have no recollection of this.

If so, please address the following:

(g) Who formed the membership of this committee, group or team?

(h) Did you play a role in connection with the committee, group or team?

(i) What rules regulated the operation of this committee, group or team?

(j) What was its purpose?

(k) Was its operation governed by any policy/procedure?

With respect to the recommendations deriving from:

(l) **DHSS NI (Hazard Notice 24/89/76);**

(m) **Joint Working Group Guidance on Quality Assurance (1993);**

(n) **HEI 98- Management of Medical Equipment And Devices (revised 1991);**

(o) **Guidelines for implementation of Near-Patient Testing (September 1993)**, Joint Working Party of the Association of Clinical Biochemists and the Royal College of Pathologists, ACB, London;

(p) **Management Executive Circular of 27th July 1994 Ref: PEL (93)36 Annex B.**

Please state what steps the Trust took to:

(i) Disseminate this guidance and to whom;

(ii) Monitor and record compliance with the same;

(iii) Enforce compliance.

I have no recollection of this.

X. LABORATORY TESTING

(5) In 1995 did the RBHSC have guidance, policy or procedures in place which governed the conduct of biochemical laboratory testing during major surgery?

I have no recollection of this.

If so, please address the following:

(a) Provide a copy of the relevant guidance, policy or procedures;

(b) Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(c) State how the RBHSC's guidance, policy or procedures were distributed to clinical staff;

(d) State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams;

(e) Did the RBHSC seek to apply a response time in respect of biochemical laboratory testing during major surgery, and if so, what was this response time?

(f) If so, what guidance, policy or procedure informed such attempts?

XI. THEATRE EQUIPMENT

In 1995 did the RBHSC have guidance, policy or procedure in relation to,

(g) The purchase;

(h) Maintenance; and

(i) Replacement of theatre equipment, and if so,

(i) Provide a copy of the relevant guidance, policy or procedure;

(ii) Was the guidance, policy or procedure adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(iii) State how the RBHSC's guidance, policy or procedures was distributed to clinical staff;

(iv) State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams.

I have no recollection of this.

In 1995 did the RBHSC have guidance, policy or procedure in relation to equipment which had been used in theatre when a patient had died?

I have no recollecton of this.

If so, please address the following:

(j) Provide a copy of the relevant guidance, policy or procedure;

(k) Was the guidance, policy or procedure adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(l) State how the RBHSC's guidance, policy or procedures was distributed to clinical staff;

(m) State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams.

(6) If, in 1995, the RBHSC did have guidance, policy or procedures in relation to equipment which had been used in theatre when a patient had died, please also address the following:

I have no recollection of this.

(a) How was that guidance, policy or procedures applied in relation to the theatre equipment used during Adam's surgery;

(b) In Adam's case, what steps were taken in relation to the guidance, policy or procedures;

(c) Who took those steps;

(d) What conclusions were reached?

(7) **Professional Estate Letter (93)36 (27th July 1994)** provided the HSS Trusts with a hazard reporting procedure. Was this procedure applied in Adam's case?

I have no recollection of this.

If so,

(a) Explain fully how it was applied;

(b) Who applied it?

(c) What steps were taken by reference to this procedure?

(8) Did the RBHSC comply with the guidance contained in **HEI 98- Management of Medical Equipment and Devices (revised January 1991)** and referenced in *'Anaesthetic related equipment, purchase, maintenance and replacement, the Association of Anaesthetists of Great Britain and Ireland in November 1994 (PEL (93) 36)'*, and if so what steps did it take to comply?

I have no recollection of this.

XII. DISSEMINATION AND INSTITUTIONAL LINKS

(9) In 1995 did the RBHSC have guidance, policy or procedures in place governing issues arising out of a serious untoward incident or an adverse incident such as the death of a patient following surgery?

I have no recollection of this.

If so, please address the following:

(a) Provide a copy of the relevant guidance, policy or procedures.

(b) Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(c) State how the RBHSC's guidance, policy or procedures were distributed to clinical staff;

(d) State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams;

(e) How was the guidance, policy or procedures applied in Adam's case?

(10) Did the RBHSC take any steps, whether by way of an internal investigation or otherwise, to establish whether lessons could be learned from the death of Adam Strain?

If no such steps were taken, please explain why not?

If steps were taken, please address the following:

(a) What steps were taken to learn lessons from the death of Adam?

A statement was prepared for Adam's Inquest.

(b) Under what policy or procedures were these steps taken?

I have no recollection of this.

(c) Identify the person(s) who took steps to establish whether lessons could be learned from Adam's death?

Dr Joe Gaston had prepared a draft statement and requested that I sign it.

(d) When were those steps taken?

At the time of Adam's Inquest.

(e) What lessons were learned from the death of Adam?

An inappropriate amount of hypotonic fluid was administered to Adam.

(f) What lessons were learned from the Inquest into the death of Adam?

I have no recollection of this.

(g) What measures were taken to review matters arising from the Inquest?

I have no recollection of this.

(h) What steps, if any, were taken to disseminate outcomes and lessons internally (within the RBHSC/ Trust)?

I have no recollection of this.

(i) What steps, if any, were taken to disseminate outcomes and lessons externally (outside the RBHSC/ Trust)?

I have no recollection of this.

(j) What steps, if any, were taken to assess and develop the competence of staff involved in the treatment that led to Adam's death?

I have no recollection of this.

(11) Dr. Taylor indicated his disagreement with the cause of death indicated on Adam's death certificate. State whether any steps were taken by the RBHSC/ Trust to address Dr. Taylor's views?

I have no recollection of this.

If so, please address the following:

(a) What steps were taken to address Dr. Taylor's views?

(b) When were those steps taken?

(c) Who took those steps?

(d) What conclusions emerged from this process?

(12) Please state your view on whether it would have been easier to use Adam Strain's case history as a vehicle for learning had there been agreement as to the role dilutional hyponatraemia played in Adam's death?

Yes it would have been easier.

(13) Please confirm whether or not you received a report in writing of or into the death of Adam Strain in 1995?

No I did not.

(14) Please state whether there existed a formal approach to:

(a) Assessing and developing the competence of the staff involved in the treatment that led to Adam's death;

(b) Disseminating outcomes and lessons learned internally both before and after the Inquest;

(c) Disseminating outcomes and lessons learned externally both before and after the Inquest?

I have no recollection of this.

In respect of Dr. Murnaghan's fax of 19th June 1996 (Ref: 060-014-025):

(d) Did you approve the draft statement and if so is it document Ref: 060-018-036 (if not please identify the document you approved)?

Yes and it is document 060-018-036.

(e) On what basis and for what purpose did you approve this statement?

I was asked to approve the statement by Dr Joe Gaston for Adam's Inquest.

(f) Did you suggest any amendments to this statement?

No

(g) Was this document ever finalized?

I have no recollection of this.

(h) Was it distributed?

I have no recollection of this.

(i) If so to whom was it distributed, how and when?

(j) If it was not distributed why not?

(k) What were the relevant considerations in respect of dissemination of these recommendations?

(l) Was any consideration given to the potential relevance of this document to other hospitals and the wider medical community given the lessons learned in the light of the Adam Strain case and the Arieff et al paper?

The Arieff paper highlights children who developed hyponatraemia, caused by extensive extrarenal loss of electrolyte containing fluids and replacement with intravenous hypotonic fluids, in the presence of increased antidiuretic hormone activity.

Adam's case was extremely complex.

I believe it differed from the Arieff cases in that Adam had end stage renal failure and his calculated renal losses were replaced with a large volume of hypotonic fluid. Also his kidneys would not have responded to anti-diuretic hormone.

At the time we believed that surgery such as Adam's would only have taken place in RBHSC.

(m) Did this draft document become a policy? If so was it substantive? If not why not?

I have no recollection of this.

(n) Had you read the Arieff et al paper (BMJ 1992) at the time you approved this document?

Yes

(o) Please state why, given the content of the Arieff et al paper and its relevance to hyponatraemia in healthy children, the recommendations were confined to children undergoing major surgery?

See my response in (i).

(p) Please state whether consideration was given to drafting guidance for managing hyponatraemia in healthy children?

I have no recollection of this.

(q) What was the primary purpose of drafting this document?

It was to be produced for Adam's Inquest.

(r) Did you consult with others in drafting this document? If so please identify those individuals and state their areas of expertise?

No.

XIII. INTERNAL REVIEW

(15) Did the RBHSC conduct an internal review in respect of any of the following matters after Adam's death:

(a) The procedures governing consent, and whether they were complied with in Adam's case;

I have no recollection of this.

(b) The records kept/made relating to the pre, intra and post operative care of Adam;

I have no recollection of this.

(c) The records kept/ made of communications with Adam's parents;

I have no recollection of this.

(d) The use of equipment before and during Adam's surgery;

I have no recollection of this, however, I now know that this took place as I have seen the assessment of the anaesthetic equipment by Dr Fiona Gibson and others on the Inquiry website.

(e) Lessons to be learned from the treatment which led to his death;

I have no recollection of this.

(f) The competence and training needs of those who cared for Adam.

I have no recollection of this.

If so, please address the following:

(i) What steps were taken in respect of each matter?

(ii) When were those steps taken?

(iii) Who took those steps?

(iv) What policies or procedures were used when taking those steps?

(v) What conclusions emerged in respect of any of these matters?

(16) Did the RBHSC have a policy for investigating adverse incidents in 1995?

I have no recollection of this.

XIV. OTHER

(17) Were any child patients transferred from the RBHSC to any other hospital in the UK for surgery before Adam's death, and if so please state:

I have no recollection of this.

(a) Date of transfer;

(b) Hospital to which child was transferred;

(c) Age of child when transferred;

(d) Identity of Consultant in charge of child prior to transfer;

(e) Reason for the transfer;

(f) Whether there existed any policy, protocol, procedure or guidelines in relation to the transfer of children to hospitals outside of Northern Ireland for surgery.

(18) Please identify those procedures and protocols governing the reporting and dissemination of information to the DHSSPS and the wider medical community in 1995 and now relating to:

I have no recollection of these.

(a) Unexpected/ unexplained deaths in RBHSC;

(b) Outcomes of Coroner's Inquests

and further please address the following:

(i) Identify those individuals responsible for the implementation of the same;

(ii) Was the procedure/ protocol as adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(iii) State how the Trust satisfied itself that the procedures and protocols where complied with;

(iv) To what extent were the procedures and protocols followed in Adam's case?

(v) What information was supplied in Adam's case?

(vi) Whether the procedures and protocols were consistent with guidance in both Northern Ireland and the UK in 1995.

(19) Please indicate what teaching and/ or training was provided to nursing and/ or medical teams in and before 1995 in respect of:

(a) Fluid management (with particular reference to hyponatraemia);

(b) Record keeping.

I have no recollection of this.

(20) Please state what steps had been taken by November 1995 to implement the recommendations of the NCPOD report in respect of out of hours paediatric surgery.

I think that one or possibly two theatre sessions each week were available in-hours to carry out emergency surgery.

(21) Please state what action you took following the Inquest into Adam's death. If you took no action please explain why.

I ensured that I continued to adequately monitor and assess children undergoing major surgery.

A new blood gas analyser was purchased for near patient testing. Quality control measures were implemented to ensure accuracy of this device.

(22) Explain why no contact was made by the RBHSC with other hospitals to inform them of the amendment of the renal transplant guidelines by the anaesthetic, theatre and intensive care directorate.

I am unable to recollect the amended guideline.

XV. EDUCATION, TRAINING AND EXPERIENCE.

(23) Describe in detail the education and training you received in fluid management (with particular reference to hyponatraemia) and record keeping through the following, providing dates and names of institutions/ bodies:

(a) Undergraduate level;

(b) Postgraduate level;

(c) Hospital induction programs;

(d) Continuous Professional Development;

I have no recollection of this.

Prior to 26th November 1995, describe in detail your experience of dealing with children with hyponatraemia, including:

(e) The estimated total of such cases, together with the dates and where they took place;

(f) The number of children who were aged under 6 years;

(g) The nature of your involvement;

(h) The outcome for the children.

I have no recollection of this.

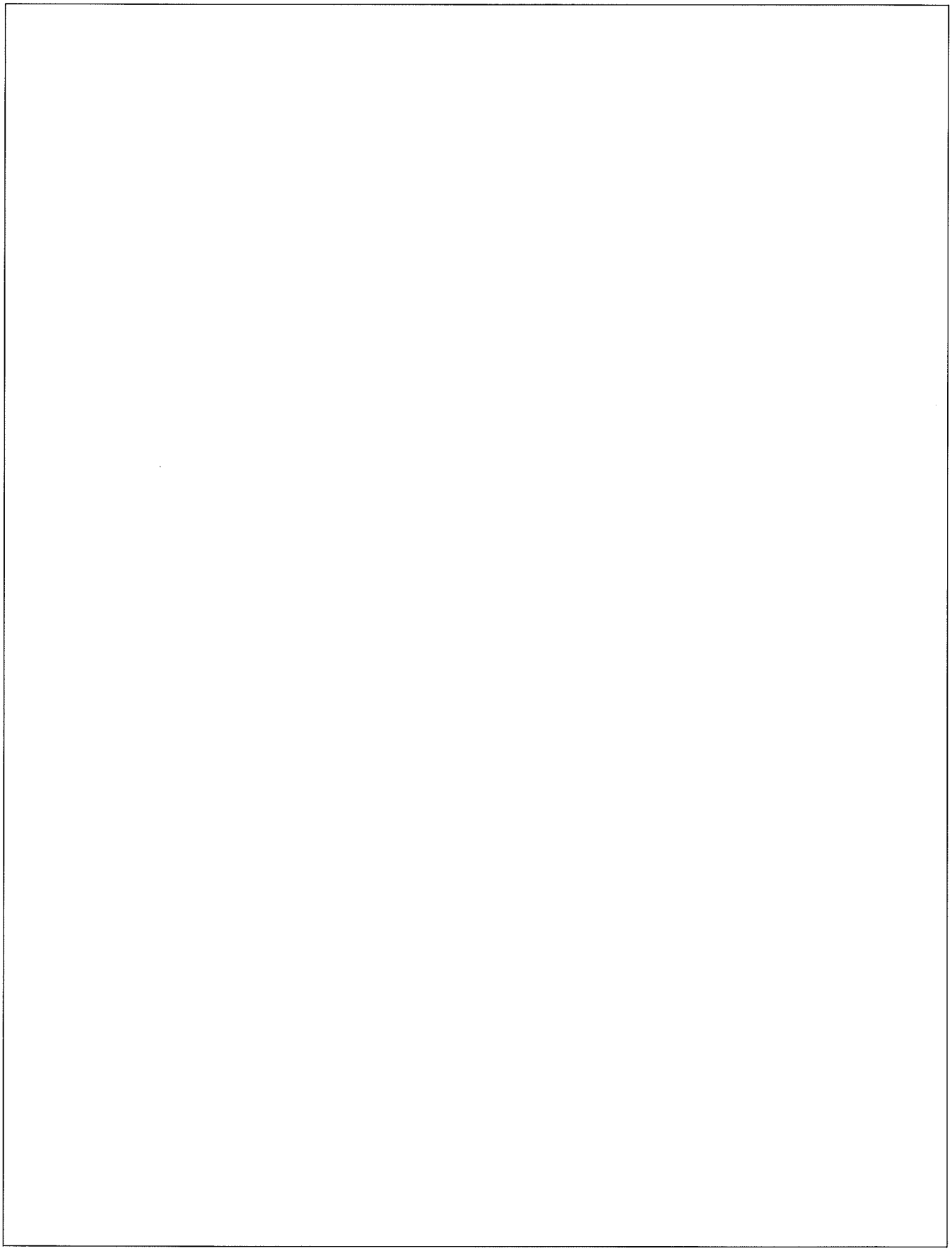
XVI. GENERAL

Please provide any further comments you may wish to make.

I have in my possession two document that I would like to bring to your attention.

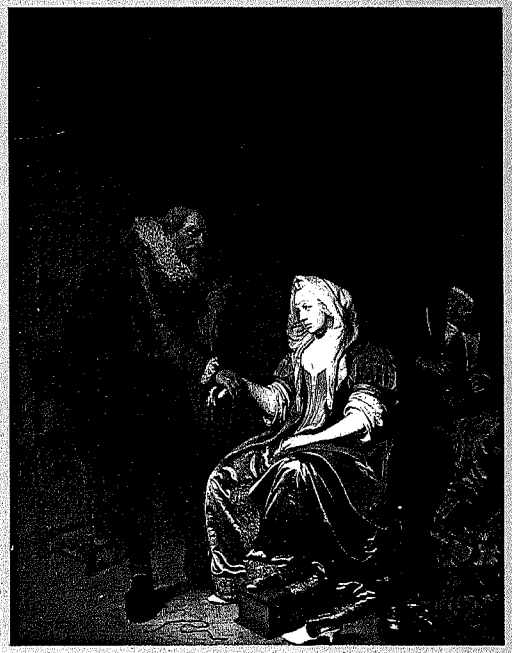
The first is 'A guide to consent for examination or treatment'. This is dated October 1995 and printed in N Ireland for HMSO (Dd8445096). However I have no recollection when I received this.

The second is a document 'Good Medical Practice', produced by the General Medical Council, that states clearly the duties of a doctor. This is dated October 1995, however, I have no recollection when I received this.



THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF

Signed: [signature] **Dated:** 15.5.12.



Cover shows a detail from the painting

by Michiel van Musscher (1645-1705)
Private collection

Picture courtesy of the Bridgeman Art Library, London

General Medical Council
Protecting patients, guiding doctors
178-202 Great Portland Street London W1N 6JE

Good medical p

Guidance from the General Medical Council

The duties of a doctor registered with the General Medical Council

Patients must be able to trust doctors with their lives and wellbeing. To justify that trust, we as a profession have a duty to maintain a good standard of practice and care and to show respect for human life. In particular as a doctor you must:

- make the care of your patient your first concern;
- treat every patient politely and considerately;
- respect patients' dignity and privacy;
- listen to patients and respect their views;
- give patients information in a way they can understand;
- respect the rights of patients to be fully involved in decisions about their care;
- keep your professional knowledge and skills up to date;
- recognise the limits of your professional competence;
- be honest and trustworthy;
- respect and protect confidential information;
- make sure that your personal beliefs do not prejudice your patients' care;
- act quickly to protect patients from risk if you have good reason to believe that you or a colleague may not be fit to practise;
- avoid abusing your position as a doctor; and
- work with colleagues in the ways that best serve patients' interests.

In all these matters you must never discriminate unfairly against your patients or colleagues. And you must always be prepared to justify your actions to them.

Guidance to doctors

Being registered with the General Medical Council gives you rights and privileges. In return, you must meet the standards of competence, care and conduct set by the GMC.

This booklet sets out the basic principles of good practice. It is guidance. It is not a set of rules, nor is it exhaustive. The GMC publishes more detailed guidance on confidentiality, advertising and the ethical problems surrounding HIV and AIDS.

Providing a good standard of practice and care

1. Patients are entitled to good standards of practice and care from their doctors. Essential elements of this are professional competence, good relationships with patients and colleagues and observance of professional ethical obligations.

Good clinical care

2. You must take suitable and prompt action when necessary. This must include:

   - an adequate assessment of the patient's condition, based on the history and clinical signs including, where necessary, an appropriate examination;
   - providing or arranging investigations or treatment where necessary;
   - referring the patient to another practitioner, when indicated.

3. In providing care you must:

   - recognise the limits of your professional competence;
   - be willing to consult colleagues;
   - be competent when making diagnoses and when giving or arranging treatment;
   - keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, information given to patients and any drugs or other treatment prescribed;

   - keep colleagues well informed when sharing the care of patients;
   - pay due regard to efficacy and the use of resources;
   - prescribe only the treatment, drugs, or appliances that serve patients' needs.

Treatment in emergencies

4. In an emergency, you must offer anyone at risk the treatment you could reasonably be expected to provide.

Keeping up to date

5. You must maintain the standard of your performance by keeping your knowledge and skills up to date throughout your working life. In particular, you should take part regularly in educational activities which relate to your branch of medicine.

6. You must work with colleagues to monitor and improve the quality of health care. In particular, you should take part in regular and systematic clinical audit.

7. Some parts of medical practice are governed by law. You must observe and keep up to date with the laws which affect your practice.

Teaching

8. The GMC encourages you to help the public to be aware of and understand health issues and to contribute to the education and training of other doctors, medical students, and colleagues.

9. All doctors should be prepared to supervise less experienced colleagues.

10. If you have special responsibilities for teaching you should develop the skills of a competent teacher. If you are responsible for training junior colleagues you must make sure they are properly supervised.

Maintaining trust

Professional relationships with patients

11. Successful relationships between doctors and patients depend on trust. To establish and maintain that trust you must:

- listen to patients and respect their views;
- treat patients politely and considerately;
- respect patients' privacy and dignity;
- give patients the information they ask for or need about their condition, its treatment and prognosis;
- give information to patients in a way they can understand;
- respect the right of patients to be fully involved in decisions about their care;
- respect the right of patients to refuse treatment or take part in teaching or research;

- respect the right of patients to a second opinion;
- ask patients' permission, if possible, before sharing information with their spouses, partners, or relatives;
- be accessible to patients when you are on duty;
- respond to criticisms and complaints promptly and constructively.

12. You must not allow your views about a patient's lifestyle, culture, beliefs, race, colour, sex, sexuality, age, social status, or perceived economic worth to prejudice the treatment you give or arrange.

13. If you feel that your beliefs might affect the treatment you provide, you must explain this to patients, and tell them of their right to see another doctor.

14. You must not refuse or delay treatment because you believe that patients' actions have contributed to their condition, or because you may be putting yourself at risk.

15. Because the doctor-patient relationship is based on trust you have a special responsibility to make the relationship with your patients work. If the trust between you and a patient breaks down either of you may end the relationship. If this happens, you must do your best to make sure that arrangements are made promptly for the continuing care of the patient. You should hand over records or other information for use by the new doctor as soon as possible.

Confidentiality

16. Patients have a right to expect that you will not pass on any personal information which you learn in the course of your professional duties, unless they agree. If in exceptional circumstances you feel you should pass on information without a patient's consent, or against a patient's wishes, you should read our booklet 'Confidentiality' and be prepared to justify your decision.

Abuse of your professional position

17. You must not abuse your patients' trust. You must not, for example:

- use your position to establish improper personal relationships with patients or their close relatives;
- put pressure on your patients to give money or other benefits to you or other people;
- improperly disclose or misuse confidential information about patients;
- recommend or subject patients to investigation or treatment which you know is not in their best interests;
- deliberately withhold appropriate investigation, treatment or referral.

Your duty to protect all patients

18. You must protect patients when you believe that a colleague's conduct, performance or health is a threat to them.

19. Before taking action, you should do your best to find out the facts. Then, if necessary, you must tell someone from the employing authority or from a regulatory body. Your comments about colleagues must be honest. If you are not sure what to do, ask an experienced colleague. The safety of patients must come first at all times.

If your health may put patients at risk

20. If you have or are carrying a serious communicable condition, or if your judgment or performance could be significantly affected by a condition or illness, you must take and follow advice from a consultant in occupational health or another suitably qualified colleague on whether, and in what ways, you should modify your practice. Do not rely on your own assessment of the risk to patients.

21. If you think you have or are carrying a serious communicable condition you must have all the necessary tests and act on the advice given to you by a suitably qualified colleague about necessary treatment and/or modifications to your clinical practice.

If in doubt...

22. The GMC publishes further advice on what to do when you believe that you or a colleague (including a health care worker for whom you are providing medical care) may be placing patients at risk in a note about the GMC's health procedures, and in its booklet 'HIV infection and AIDS: the ethical considerations'.

Working with colleagues

23. You must not discriminate against colleagues, including doctors applying for posts, because of your views of their lifestyle, culture, beliefs, race, colour, sex, sexuality, or age.

24. You must not make any patient doubt a colleague's knowledge or skills by making unnecessary or unsustainable comments about them.

Working in teams

25. Health care is increasingly provided by multi-disciplinary teams. You are expected to work constructively within such teams and to respect the skills and contributions of colleagues.

26. If you are leading a team, you must do your best to make sure that the whole team understands the need to provide a polite and effective service and to treat patient information as confidential.

27. If you disagree with your team's decision, you may be able to persuade other team members to change their minds. If not, and you believe that the decision would harm the patient, tell someone who can take action. As a last resort, take action yourself to protect the patient's safety or health.

Delegating care to non-medical staff and students

28. You may delegate medical care to nurses and other health care staff who are not registered medical practitioners if you believe it is best for the patient. But you must be sure that the person to whom you delegate is competent to undertake the procedure or therapy involved. When delegating care or treatment, you must always pass on enough information about the patient and the treatment needed. You will still be responsible for managing the patient's care.

29. You must not enable anyone who is not registered with the GMC to carry out tasks that require the knowledge and skills of a doctor.

Arranging cover

30. You must be satisfied that, when you are off duty, suitable arrangements are made for your patients' medical care. These arrangements should include effective handover procedures and clear communication between doctors.

31. General practitioners must satisfy themselves that doctors who stand in for them have the qualifications, experience, knowledge and skills to perform the duties for which they will be responsible. A deputising doctor is accountable to the GMC for the care of patients while on duty.

Accepting posts

32. If you have formally accepted a post, you should not then withdraw unless the employer will have time to make other arrangements.

Decisions about access to medical care

33. You should always seek to give priority to the investigation and treatment of patients solely on the basis of clinical need.

Referring patients between a general practitioner and a specialist

34. A general practitioner referring a patient should give the specialist all relevant information about the patient's history and current condition. Specialists who have seen or treated a patient should, unless the patient objects, tell the general practitioner the results of their investigations, the treatment provided, and any other information necessary for the continuing care of the patient.

35. Specialists should not usually accept a patient without a referral from a general practitioner. If they do, they must inform the patient's general practitioner before providing treatment, unless the patient tells them not to or has no general practitioner. In these cases the specialist must be responsible for providing or arranging any aftercare which is necessary until another doctor agrees to take over.

36. In some areas of practice – accident and emergency, genito-urinary medicine, contraception and abortion services, and refraction – there may be good reasons for specialists to accept patients without referrals from general practitioners. In these circumstances specialists must keep general practitioners informed unless the patient tells them not to. If the general practitioner is not informed the specialist must provide any necessary aftercare until another doctor agrees to take over.

Probity in professional practice

37. You must be honest and trustworthy.

Financial and commercial dealings

38. You must be honest in financial and commercial matters relating to your work. In particular:

- if you charge fees, you must tell patients if any part of the fee goes to another doctor;
- if you manage finances, you must make sure that the funds are used for the purpose they were intended for and are kept in a separate account from your personal finances;
- you must not defraud patients or the service or organisation you work for;
- before taking part in discussions about buying goods or services, you must declare any relevant financial or commercial interest which you or your family might have in the purchase.

Conflicts of interest

39. You must act in your patients' best interests when making referrals and providing or arranging treatment or care. So you must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect your judgment. You should not offer such inducements to colleagues.

40. If you have financial or commercial interests in organisations providing health care or in pharmaceutical or other biomedical companies, these must not affect the way you prescribe for or refer patients.

- *Financial interests in hospitals, nursing homes and other medical organisations*

  If you have a financial or commercial interest in an organisation to which you plan to refer a patient, you must tell the patient about your interest. When treating NHS patients you must also tell the health care purchaser.

- *Accepting gifts or other inducements*

  You should not ask for or accept any material rewards, except those of insignificant value, from companies that sell or market drugs or appliances. You must not ask for or accept fees for agreeing to meet sales representatives.

- *Hospitality*

  You may accept personal travel grants and hospitality from companies for conferences or educational meetings, as long as the main purpose of the event is educational. The amount you receive must not be more than you would normally spend if you were paying for yourself.

Signing certificates and other documents

41. Registered medical practitioners have the authority to sign a variety of documents, such as death certificates, on the assumption that they will only sign statements they believe to be true. This means that you must take reasonable steps to verify any statement before you sign a document. You must not sign documents which you believe to be false or misleading. Similarly, when providing references for colleagues, your comments must be honest and you must be able to back them up.

Advertising – providing information to colleagues and the public

42. If you advertise your services your advertisement must be honest. It must not exploit patients' vulnerability or lack of medical knowledge and may provide only factual information. All doctors' advertisements must follow the detailed guidance in the GMC's booklet 'Advertising'.

Research

43. If you are taking part in clinical trials of drugs or other research involving patients you must make sure that the research is not contrary to the patients' interests. Check that the research protocol has been approved by a properly constituted research ethics committee.

44. You must keep to all aspects of the research protocol and may accept only those payments approved by a research ethics committee. Your conduct in the research must not be influenced by payments or gifts.

45. You must always record your research results truthfully and maintain adequate records. In publishing these results you must not make unjustified claims for authorship.

46. You should read the guidance on confidentiality in research in the GMC's booklet 'Confidentiality'.

You must always be prepared to explain and justify your actions and decisions.

October 1995

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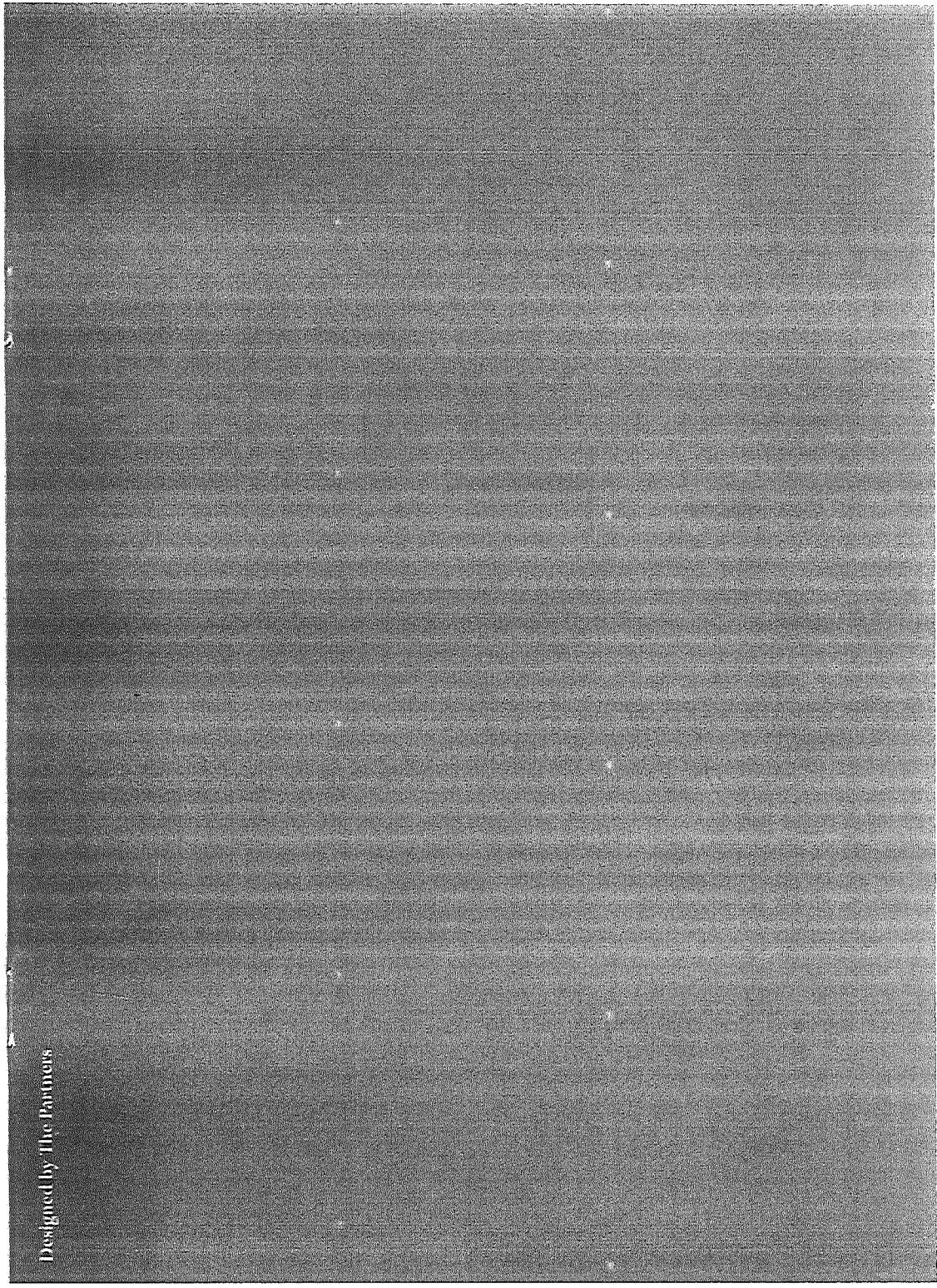
note: numbers refer to paragraphs



A guide to consent for examination or treatment

CHAPTER 1

A patient's rights in accepting treatment

1. A patient has the right under common law to give or withhold consent prior to examination or treatment (except in the circumstances outlined in Chapter 2 paragraph 17, Chapter 3 paragraph 2 and Chapter 4 paragraph 3). This is one of the basic principles of health care. Subject to certain exceptions, the doctor or other health professional and/or Health and Social Services Board/HSS Trust may face an action for damages if a patient is examined or treated without consent.

2. The patient is entitled to receive sufficient information about his or her medical condition, the proposed treatments, the possible alternatives and any substantial risks, in a way he or she can understand, so that he or she can make a balanced judgement. The patient must be allowed to decide whether he or she will agree to the treatment, and may refuse treatment or withdraw consent to treatment at any time. A patient who consents to treatment on the basis of inadequate information may allege that the treatment was negligently given and bring an action for damages alleging failure of duty or care.

3. Care should be taken to respect the patient's wishes. This is particularly important when the patient may be participating in the training of students and professionals in various disciplines. An explanation should be given of the need for the trainees to gain practical experience and the patient's agreement must be obtained before proceeding. It should be made clear to the patient that he or she may decline to be observed, examined or attended by those in training without this affecting in any way the care he or she receives.

4. When the patient gives information to doctors or other health professionals he or she is entitled to assume that the information will be kept confidential and will not be disclosed to anyone without the patient's consent other than for the provision of his or her health care. The only exceptions to this general rule are where disclosure is ordered by a Court; required by statute; or considered to be in the public health interest - for example, for some forms of specifically approved research. Where disclosure is made in the public health interest appropriate safeguards must be applied. Departmental guidance on the confidentiality, use, security, and disclosure of Health and Personal Social Services information and on Research Ethics Committees will be issued separately.

CHAPTER 2

Doctor or other health professional's role in advising the patient and obtaining consent to treatment

Advising the patient

1. Where a choice of treatment might reasonably be offered, the doctor or other health professional should always advise the patient of his or her recommendations together with reasons for selecting a particular course of action. Enough information must normally be given to ensure that the patient understands the nature, consequences and any substantial risks of the treatment proposed so that he or she is able to take a decision based on that information. Though it should be assumed that most patients will wish to be well informed, account should be taken of those who may find this distressing.

2. The patient's ability to appreciate the significance of the information should be assessed. For example with patients who:

   i. may be shocked, distressed or in pain;

   ii. have difficulty in understanding English;

   iii. have impaired sight, hearing, speech or understanding;

   iv. are suffering from mental disorder but who nevertheless have the capacity to give consent to the proposed procedure (see also Chapter 4 - Consent by patients suffering from mental disorder);

   v. are under the influence of alcohol or analgesics or other drugs.

3. Subject to the agreement of the patient, it may help if a close family member or a friend can be present at the discussion when consent is sought, or a member of staff may be able to assist the patient in understanding. Where there are language problems or hearing difficulties, it is important that the services of an interpreter should be provided. Agreement to treatment by anyone accompanying the patient is not a valid substitute for the competent patient's conscious informed consent.

4. A doctor will have to exercise his or her professional skill and judgement in deciding what risks the patient should be warned of and the terms in which the warning should be given. However, a doctor has a duty to warn the patient of substantial or unusual risk inherent in any proposed treatment. This is especially so with surgery but may apply to other procedures including drug therapy and radiation treatment. Guidance on the amount of information and warnings of risk to be given to a patient can be found in the judgement of the House of Lords in the case of Sidaway V Gov of Bethlem Royal Hospital [1985] AC 871 described below.

The Sidaway Case

5. In this case, Lord Bridge indicated that a decision on what degree of disclosure of risks is best calculated to assist a particular patient to make a rational choice as to whether or not to undergo a particular treatment must primarily be a matter of clinical judgement. He was of the further opinion that a judge might in certain

circumstances come to the conclusion that the disclosure of a particular risk was so obviously necessary to an informed choice that no reasonably prudent medical man would fail to make it. The kind of case which Lord Bridge had in mind would be an operation involving a substantial risk of grave adverse consequences. Lord Templeman stated that there was no doubt that a doctor ought to draw the attention of a patient to a danger which may be special in kind or magnitude or special to the patient. He further stated that it was the obligation of the doctor to have regard to the best interests of the patient but at the same time to make available to the patient sufficient information to enable the patient to reach a balanced judgement if he chooses to do so.

Obtaining consent

6. Consent to treatment may be implied or express. In many cases a patient does not give express consent but his or her agreement may be implied by compliant actions, such as offering an arm for the taking of a blood sample. Express consent is given when the patient confirms his or her agreement to a procedure or treatment in clear and explicit terms, whether orally or in writing.

7. Oral consent will be sufficient for the vast majority of contacts with patients especially in general practice. Written consent should be obtained for any procedure or treatment carrying any substantial risk or risk of substantial side effect. If the patient is capable, written consent should always be obtained for general anaesthesia, surgery, certain forms of drug therapy, eg cytotoxic therapy and therapy involving the use of ionising radiation. Oral or written consent should be recorded in the patient's notes with relevant details of the doctor or other health professional's explanation. Where written consent is obtained it should be incorporated into the notes.

8. **Standard consent form.** The main purpose of written consent is to provide documentary evidence that an explanation of the proposed procedure or treatment was given and that consent was sought and obtained. The model consent forms *(see Appendices)* set out the requirements for obtaining valid consent to treatment in terms which will be readily understood by the patient. In the majority of cases these forms will be used by doctors or dentists but there may be occasions when other health professionals such as nurses, physiotherapists, or chiropodists will wish to record formally that consent has been obtained for a particular procedure. A separate form is available for their use.

9. It should be noted that the purpose of obtaining a signature on the consent form is not an end in itself. The most important element of a consent procedure is the duty to ensure that the patient understands the nature and purpose of the proposed treatment. Where a patient has not been given appropriate information then full consent may not always have been obtained despite the signature on the form.

10. Consent given for one procedure or episode of treatment does not give any automatic right to repeat that procedure or to undertake any other procedure. A doctor or other health professional may, however,

undertake further treatment if the circumstances are such that a patient's consent cannot reasonably be requested **and** provided the treatment is immediately necessary **and** the patient has not previously indicated that the further treatment would be unacceptable.

SPECIAL CIRCUMSTANCES

Treatment of Children and Young People

11. **Children under the age of 16 years.** Where a child under the age of 16 has a sufficient understanding of what is proposed, that child may consent to a doctor or other health professional making an examination and giving treatment. The doctor or other health professional must be satisfied that any such child has sufficient understanding of what is involved in the treatment which is proposed. A full note should be made of the factors taken into account by the doctor or other health professional in making his or her assessment of the child's capacity to give a valid consent. In the majority of cases children will be accompanied by their parents during consultations. Where, exceptionally, a child is seen alone, efforts should be made to persuade the child that his or her parents should be informed except in circumstances where it is clearly not in the child's best interests to do so. Parental consent should be obtained and will take precedence where a child does not have sufficient understanding and is under age 16 except in an emergency where there is not time to obtain it.

12. **Young people over the age of 16 years.** Section 4 of the Age of Majority Act (Northern Ireland) 1969 relates to "Consent by persons over 16 to surgical, medical, and dental treatment" and states that:-

> "4.-(1) The consent of a minor who has attained the age of sixteen years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian.
>
> (2) In this section "surgical, medical or dental treatment" includes any procedure undertaken for the purposes of diagnosis, and this section applies to any procedure (including, in particular, the administration of an anaesthetic) which is ancillary to any treatment as it applies to that treatment.
>
> (3) Nothing in this section shall be construed as making ineffective any consent which would have been effective if this section had not been enacted".

This means that the consent of the young person who has attained 16 years to any surgical, medical, or dental treatment is sufficient in itself and it is not necessary to obtain a separate consent from the parent or guardian. In cases where a child is over age 16 but is not competent to give a valid consent, then the consent of the parent or guardian must be sought. However, such power only extends until that child is 18.

13. **Children in Care.** When parental consent is necessary for a child who is in care as a consequence of a Court Order (ie Fit Person Order or Parental Rights Order) irrespective of whether he or she is under or over the age of 16 years, account should be taken of the fact that the parental rights in respect of the child will have been transferred from the parents to the appropriate Health and Social Services Board or to a HSS trust acting on behalf of a Board. In the majority of cases, parents will have agreed to the Board or trust giving consent for the child to receive any necessary treatment. Nevertheless, consent should be sought from the parents as well as from the child's social worker. In the event of the parents refusing consent, legal advice should be sought. It should be noted that where a child is a ward of court, authority to give consent rests with the Court itself.

14. **Refusal of parental consent to urgent or life-saving treatment**. Where time permits, court action may be taken so that consent may be obtained from a judge. Otherwise hospital authorities should rely on the clinical judgement of the doctors concerned, normally the consultants, after a full discussion between the doctor and the parents. In such a case the doctor should obtain a written supporting opinion from a medical colleague that the patient's life is in danger if the treatment is withheld and should discuss the need to treat with the parents or guardian in the presence of a witness. The doctor should record the discussion in the clinical notes and ask the witness to countersign the record. In these circumstances and where practicable the doctor may wish to consult his or her defence organisation. If he or she has followed the procedure set out above and has then acted in the best interests of the patient and with due professional competence and according to his or her own professional conscience, he or she is unlikely to be criticised by a court or by his or her professional body.

Adult or competent young person refusing treatment

15. Some adult patients may wish to refuse some or all parts of their treatment. This may include those whose religious beliefs prevent them accepting a blood transfusion. Whatever the reason for the refusal such a patient should receive a detailed explanation of the nature of his or her illness and the need for the treatment or transfusion proposed. He or she should also be warned in clear terms that the doctor or other health professional may properly decline to modify the procedure and of the possible consequences if the procedure is not carried out. If the patient then refuses to agree, and he or she is competent, the refusal must be respected. The doctor or other health professional should record this in the clinical notes and where possible have it witnessed.

Teaching

16. Detailed guidance about medical students in hospital is given in circular HSS(TC8) 13/91 'Medical Students in Hospitals'. It should not be assumed, even in a teaching hospital, that a patient has consented to be available for teaching purposes.

Examination or Treatment without the patient's consent

17. The following are examples of occasions when examination or treatment may proceed without obtaining the patient's consent:

i. For life-saving procedures where the patient is unconscious and cannot indicate his or her wishes. Exceptions to this may be:

a. Where the patient has previously indicated that he/she does not wish to have the particular treatment; or

b. This can be reliably deduced from the patient's immediate family.

ii. Where there is a statutory power requiring the examination of a patient, for example, under the Public Health Act (Northern Ireland) 1967. However an explanation should be offered and the patient's co-operation should nevertheless be sought.

iii. In certain cases where a minor is a ward of court and the court decides that a specific treatment is in the child's best interests.

iv. Treatment for mental disorder of a patient liable to be detained in hospital in circumstances permitted under the Mental Health (Northern Ireland) Order 1986 (see Chapter 4 below, and Chapter 5 of the Code of Practice, Mental Health (Northern Ireland) Order 1986).

v. Treatment for physical disorder where the patient is incapable of giving consent by reason of mental disorder, and the treatment is in the patient's best interests (see Chapter 4).

CHAPTER 3

Examples of treatments which have raised concern

Maternity Services

1. Principles of consent are the same in maternity services as in other areas of medicine. It is important that the proposed care is discussed with the woman, preferably in the early antenatal period, when any special wishes she expresses should be recorded in the notes, but of course the woman has a right to change her mind about these issues at any stage, including during labour.

2. Decisions may have to be taken swiftly at a time when the woman's ability to give consent is impaired, eg as a result of medication, including analgesics. If the safety of the woman or child is at stake the obstetrician or midwife should take any reasonable action that is necessary. If, in the judgement of the relevant doctor or other health professional, the woman is temporarily unable to make a decision, it may be advisable for the position to be explained to her husband or partner if available, but his consent (or withholding of consent) cannot legally over-ride the clinical judgement of the doctor or other health professional, as guided by the previously expressed wishes of the woman herself.

Breast Cancer

3. The usual principles of explaining proposed treatment and obtaining the patient's consent should be followed in treating cases of breast cancer. Breast cancer does not normally require emergency treatment. The patient needs reassurance that a mastectomy will not be performed without her consent, and that unless she has indicated otherwise the need for any further surgery will be fully discussed with her in the light of the biopsy and other results. This is a particular case of the principle, set out in para 10 of Chapter 2, that consent to an initial treatment or investigation does not imply consent to further treatment.

Tissue and Organ Donation: Risk of Transmitted Infection

4. Where tissues or organs are to be transplanted, the recipient should be informed, prior to consent to the operation being obtained, of the small but unavoidable risk of the transplant being infected. Further guidance is available in a CMO letter, "HIV Infection, tissue banks and organ donation" (HSS(MD)8/90).

CHAPTER 4

Consent by patients suffering from mental disorder

NOTES:

(i) Mental disorder is defined in Article 3 of the Mental Health (Northern Ireland) Order 1986

(ii) Consent to treatment by patients suffering from mental disorder is discussed in more detail in Chapter 5 of the "Code of Practice Mental Health (Northern Ireland) Order 1986".

1. The principles of common law apply to treatment for mental disorder (except in the circumstances permitted by the Mental Health (Northern Ireland) Order 1986) as well as to medical or surgical treatment which may be required by mentally disordered patients. Consent to treatment must be given freely and without coercion and be based on information about the nature, purpose and likely effects of treatment presented in a way that is understandable by the patient. The capacity of the person to understand the information given will depend on his or her intellectual state, the nature of his or her mental disorder, and any variability over time of his or her mental state. The ability of a mentally disordered person to make and communicate decisions may similarly vary from time to time.

2. The presence of mental disorder does not by itself imply incapacity, nor does detention under the Mental Health (Northern Ireland) Order 1986. Each patient's capability for giving consent has to be judged individually in the light of the nature of the decision required and the mental state of the patient at the time.

Mental Health Legislation - treatment for mental disorders

3. The Mental Health (Northern Ireland) Order 1986 makes specific provisions for giving medical treatment for a mental disorder without the patient's consent. These are contained in Part IV of the Order and are discussed fully in Chapter 5 of the Mental Health (Northern Ireland) Order 1986 Code of Practice published by the Department in 1992.

Mental Incapacity and treatment for physical conditions

4. The Mental Health (Northern Ireland) Order 1986 does not contain provisions to enable treatment of **physical disorders** without consent either for detained patients or those people who may be suffering from mental disorder but who are not detained under the Order. The administration of treatment for physical conditions to people incapable of giving consent and making their own treatment decisions is a matter of concern to all involved in the care of such people, whether they are detained in hospital; or in hospital on a voluntary basis; in residential care; or in the community.

The House of Lords decision in Re F [1989] 2 WLR 1025; [1989] 2 All ER 545

5. This decision helped to clarify the common law in relation to general medical and surgical treatment of people who lack the capacity to give consent. No-one may give consent on behalf of an adult but the substantive law is that a proposed operation or treatment is lawful if it is in the best interests of the patient and unlawful if it is not. Guidance given in that case is set out below.

   i. In considering the lawfulness of medical and surgical treatment given to a patient who for any reason, temporary or permanent, lacks the capacity to give or to communicate consent to treatment, it was stated to be axiomatic that treatment which is necessary to preserve the life, health or well-being of the patient may lawfully be given without consent.

   ii. The standard of care required of the doctor concerned in all cases is laid down in Bolam v Friern Hospital Management Committee [1957] 1 WLR 582, namely, that he or she must act in accordance with a responsible body of relevant professional opinion.

   iii. In many cases it will not only be lawful for doctors, on the ground of necessity, to operate or give other medical treatment to adult patients disabled from giving their consent, but it will also be their common law duty to do so.

   iv. In the case of the mentally disordered, when the state is permanent or semi-permanent, action properly taken may well transcend such matters as surgical operation or substantial medical treatment and may extend to include such (mundane) matters as routine medical and dental treatment and even simple care such as dressing and undressing and putting to bed.

   v. In practice, a decision may involve others besides the doctor. It must surely be good practice to consult relatives and others who are concerned with the care of the patient. Sometimes, of course, consultation with a specialist or specialists will be required; on other occasions, especially where the decision involves an opinion with wider issues than medical ones, an inter-disciplinary team will in practice participate in the decision.

Documentation

6. Proposals for treatment should, as a matter of good practice, be discussed with the multidisciplinary team and where necessary other doctors and, given the consent of the patient where this is possible, with their nearest relative or friend. The decisions taken should be documented in the clinical case notes. In cases involving anaesthesia and surgery, or where the treatment carries substantial or unusual risk it would also be advisable for documentation to record that the patient is incapable of giving consent to treatment and that the doctor in charge of the patient's treatment is of the opinion that the treatment proposed should be given and that it is in the patient's best interests. A model form is suggested to register medical opinion - where a patient is incapable of giving consent *(Appendix B)*.

Sterilisation

7. In Re F, referred to in para 5 above, it was said that special features applied in the case of an operation for sterilisation. Having regard to those matters, it was stated to be highly desirable as a matter of good practice to involve the court in the decision to operate. In practice an application should be made to a court whenever it is proposed to perform such an operation. The procedure to be used is to apply for a declaration that the proposed operation for sterilisation is lawful, and the following guidance was given as to the form to be followed in such proceedings:

   i. applications for a declaration that a proposed operation on, or medical treatment for, a patient can lawfully be carried out despite the inability of such a patient to consent thereto should be by way of originating summons issuing out of the Family Division of the High Court;

   ii. the application should normally be made by those responsible for the care of the patient or those intending to carry out the proposed operation or other treatment, if it is declared to be lawful;

   iii. the patient must always be a party and should normally be a respondent. In cases in which the patient is a respondent the patient's guardian *ad litem* should normally be the Official Solicitor. In any cases in which the Official Solicitor is not either the next friend or the guardian *ad litem* of the patient or an applicant he/she will be a respondent;

   iv. with a view to protecting the patient's privacy, but subject always to the judge's discretion, the hearing will be in chambers, but the decision and the reasons for that decision will be given in open court.

Appendices

Specimen consent forms

A(1) – For medical or dental investigations, treatment or operation

A(2) – For sterilisation or vasectomy

A(3) – For treatment by a health professional other than doctors or dentists

B – Medical or dental treatment of a patient who is unable to consent because of mental disorder

The wording of these forms has been agreed with professional associations and medical defence organisations.

However, these forms are models only and alternatives may be agreed locally. The responsibility for the form used rests with the health professional concerned.

CONSENT FORM

APPENDIX A(1)

For medical or dental investigation, treatment or operation

Board/HSS Trust..... Patient's Surname.....

Hospital..... Other Names.....

Unit Number..... Date of Birth.....

Sex: *(please tick)* Male ❑ Female ❑

DOCTORS OR DENTISTS *(This part to be completed by doctor or dentist. See notes on the reverse).*

Type of operation, investigation or treatment for which written evidence of consent is considered appropriate

I confirm that I have explained the operation, investigation or treatment, and such appropriate options as are available and the type of anaesthetic, if any (general/local/sedation) proposed, to the patient in terms which in my judgement are suited to the understanding of the patient and/or to one of the parents or guardians of the patient.

Signature..... Date ...../...../.....

Name of doctor or dentist.....

PATIENT/PARENT/GUARDIAN

1. Please read this form and the notes overleaf very carefully.

2. If there is anything that you don't understand about the explanation, or if you want more information, you should ask the doctor or dentist.

3. Please check that all the information on the form is correct. If it is, and you understand the explanation, then sign the form.

I am the patient/parent/guardian *(delete as necessary)*

I agree	■	to what is proposed which has been explained to me by the doctor/dentist named on this form.
	■	to the use of the type of anaesthetic that I have been told about.
I understand	■	that the procedure may not be done by the doctor/dentist who has been treating me so far.
	■	that any procedure in addition to the investigation or treatment described on this form will only be carried out if it is necessary and in my best interests and can be justified for medical reasons.
I have told	■	the doctor or dentist about the procedures listed below I would **not** wish to be carried out without my having the opportunity to consider them first.

.....

.....

.....

Signature .....

Name .....

Address .....

(if not the patient) .....

.....

NOTES TO:

Doctors, Dentists

A patient has a legal right to grant or withhold consent prior to examination or treatment. Patients should be given sufficient information, in a way they can understand, about the proposed treatment and the possible alternatives. Patients must be allowed to decide whether they will agree to the treatment and they may refuse or withdraw consent to treatment at any time. The patient's consent to treatment should be recorded on this form (further guidance is given in HSS(GHS)2/95: A Guide to Consent for Examination or Treatment).

Patients

- **The doctor or dentist is here to help you. He or she will explain the proposed treatment and what the alternatives are. You can ask any questions and seek further information. You can refuse the treatment.**
- **You may ask for a relative, or friend, or a nurse to be present.**
- **Training doctors and dentists and other health professionals is essential to the continuation of the health service and improving the quality of care. Your treatment may provide an important opportunity for such training where necessary under the careful supervision of a senior doctor or dentist.**
- **You may, however, decline to be involved in the formal training of medical, dental and other students without this adversely affecting your care and treatment.**

CONSENT FORM

APPENDIX A(2)

For sterilisation or vasectomy

Board/HSS Trust..... Patient's Surname.....

Hospital..... Other Names.....

Unit Number..... Date of Birth.....

Sex: *(please tick)* Male ❑ Female ❑

DOCTORS *(This part to be completed by doctor. See notes on the reverse).*

Type of operation: Sterilisation or Vasectomy

Complete this part of the form.

I confirm that I have explained the procedure and any anaesthetic (general/local) required, to the patient in terms which in my judgement are suited to his/her understanding.

Signature..... Date ...../...../.....

Name of doctor.....

PATIENT

1. Please read this form very carefully.

2. If there is anything that you don't understand about the explanation, or if you want more information, you should ask the doctor.

3. Please check that all the information on the form is correct. If it is, and you understand the explanation, then sign the form.

I am the patient

I agree	■	to have this operation, which has been explained to me by the doctor named on this form.
	■	to the have the type of anaesthetic that I have been told about.
I understand	■	that the operation may not be done by the doctor who has been treating me.
	■	that the aim of the operation is to stop me having any children and it might not be possible to reverse the effects of the operation.
	■	that sterilisation/vasectomy can sometimes fail, and that there is a very small chance that I may become fertile again after some time.
	■	that any procedure in addition to the investigation or treatment described on this form will only be carried out if it is necessary and in my best interests and can be justified for medical reasons.
I have told	■	the doctor about the procedures listed below I would **not** wish to be carried out straightaway without my having the opportunity to consider them first.

.....

.....

.....

For vasectomy I understand	■	that I may remain fertile or become fertile again after some time.
	■	that I will have to use some other contraceptive method until 2 tests in a row show that I am not producing sperm, if I do not want to father any children.

NOTES TO:

Doctors

A patient has a legal right to grant or withhold consent prior to examination or treatment. Patients should be given sufficient information, in a way they can understand, about the proposed treatment and the possible alternatives. Patients must be allowed to decide whether they will agree to the treatment and they may refuse or withdraw consent to treatment at any time. The patient's consent to treatment should be recorded on this form (further guidance is given in HSS(GHS)2/95: A Guide to Consent for Examination or Treatment).

Patients

- **The doctor is here to help you. He or she will explain the proposed procedure, which you are entitled to refuse. You can ask any questions and seek further information.**

- **You may ask for a relative, or friend, or a nurse to be present.**

- **Training doctors and other health professionals is essential to the continuation of the health service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor.**

- **You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.**

CONSENT FORM

APPENDIX A(3)

For treatment by a health professional other than doctors or dentists

Board/HSS Trust..... Patient's Surname.....

Hospital..... Other Names.....

Unit Number..... Date of Birth.....

Sex: *(please tick)* Male ❑ Female ❑

HEALTH PROFESSIONAL *(This part to be completed by health professionals. See notes on the reverse).*

Type of treatment proposed for which written evidence of consent is considered appropriate

Complete this part of the form

I confirm that I have explained the treatment proposed and such appropriate options as are available to the patient in terms which in my judgement are suited to the understanding of the patient and/or to one of the parents or guardians of the patient.

Signature..... Date ...../...../.....

Name of doctor or dentist.....

Job Title of health professional .....

PATIENT/PARENT/GUARDIAN

1. Please read this form and the notes overleaf very carefully.

2. If there is anything that you don't understand about the explanation, or if you want more information, you should ask the health professional who has explained the treatment proposed.

3. Please check that all the information on the form is correct. If it is, and you understand the treatment proposed, then sign the form.

I am the patient/parent/guardian *(delete as necessary)*

I agree ■ to what is proposed which has been explained to me by the health professional named on this form.

Signature .....

Name .....

Address .....

(if not the patient) .....

.....

NOTES TO:

Health Professionals, other than doctors or dentists

A patient has a legal right to grant or withhold consent prior to examination or treatment. Patients should be given sufficient information, in a way they can understand, about the proposed treatment and the possible alternatives. Patients must be allowed to decide whether they will agree to the treatment and they may refuse or withdraw consent to treatment at any time. The patient's consent to treatment should be recorded on this form (further guidance is given in HSS(GHS)2/95: A Guide to Consent for Examination or Treatment.

Patients

- **The health professional named on this form is here to help you. He or she will explain the proposed treatment and what the alternatives are. You can ask any questions and seek further information. You can refuse the treatment.**
- **You may ask for a relative, or friend, or another member of staff to be present.**
- **Training doctors, and dentists and other health professionals is essential to the continuation of the health service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a fully qualified health professional.**
- **You may however decline to be involved in the formal training of medical, dental and other students without this adversely affecting your care and treatment.**

CONSENT FORM

APPENDIX B

Medical or dental treatment of a patient who is unable to consent because of mental disorder

Board/HSS Trust..... Patient's Surname.....

Hospital..... Other Names.....

Unit Number..... Date of Birth.....

Sex: *(please tick)* Male ☐ Female ☐

NOTE:

It is the personal responsibility of any doctor or dentist proposing to treat a patient to determine whether the patient has capacity to give a valid consent.

It is good practice to consult relatives and others who are concerned with the care of the patient. Sometimes consultation with a specialist or specialists will be required.

The form should be signed by the doctor or dentist who carries out the treatment.

DOCTORS/DENTISTS

Describe investigation, operation or treatment proposed.

Complete this part of the form

In my opinion ..... is not capable of giving consent to treatment. In my opinion the treatment proposed is in his/her best interests and should be given.

The patient's next of kin have/have not been so informed. *(delete as necessary)*

Date .....

Signature .....

Name of doctor or dentist who is providing treatment:.....

Belfast Health and Social Care Trust

Litigation Management Office
Royal Victoria Hospital

Our Ref: A.49/04/33/Inquiry
Your Ref: NSC B04/1

15th May 2012

Ms Joanna Bolton
Directorate of Legal Services
2 Franklin Street
BELFAST
BT2 8DQ

Dear Joanna

Re: Inquiry into Hyponatraemia-related Deaths

I refer to previous correspondence regarding the above and now enclose original signed statement from Dr Peter Crean (130/1).

Yours sincerely

Amanda Lennon
Litigation Officer

Enc.

Litigation Management Office, 4th Floor, Bostock House, Royal Victoria Hospital, Belfast, BT12 6BA
Tel: 028 9063 3526 Fax: 028 9023 6122 E-mail: amanda.lennon@belfasttrust.hscni.net