ADAM STRAIN

SUPPLEMENTAL REPORT

PREPARED BY SALLY G. RAMSAY

Introduction

I have been asked to respond to the Supplemental Queries arising from my report dated 10th February 2011 and evidence that the Inquiry has received and to note the basis for my views. The queries were recorded in a document dated 26th May, 2011.

In order to respond to these queries I sought advice from Ms T. Durack an experienced theatre nurse. Her CV is attached.

1. General Queries

(i) Was there any protocol and/or guidance on the composition of the 'nursing team' for a paediatric renal transplant (or transplant surgery in general) in 1995 and now? If so, identify the relevant protocol and/or guidance and provide a copy or advise from where a copy may be obtained.

A renal transplant has the same requirements as other major abdominal operations and consequently, general standards for operating theatres are applicable. I understand the National Association of Theatre Nurses (NATN) published guidance on nurse staffing during the 1990's, but copies appear to be no longer available.

In 2008, the Association for Peri-operative Practice (AfPP), the NATN's successor organisation, published "Staffing for Patients in the Peri-operative Setting" (AfPP – ISBN – 978-1-904290-10-0). This included a formula for calculating total staffing numbers, but only the template "Management of Operating Sessions for Scheduled Surgery" is readily available through the internet.

The NATN was a charity providing education and support to nurses and consequently could only issue guidance. While the NATN publication may have been a useful document, it is my opinion that there was no requirement for hospitals to take account of the recommendations.

(ii) ***Who would normally have the responsibility for completing the five sheets comprising the Anaesthetic Record [Ref: 058-003-004 to 058-003-008], and the basis for this view. If a different person is responsible for signing different parts of the Record, set this clearly and explain it.***

The Anaesthetist would have been responsible for completing and signing the Anaesthetic Record. If s/he has a junior anaesthetist working alongside, then both staff could make entries. The anaesthetist was the registered practitioner responsible for the anaesthetic.

(iii) In relation to the place for the Nurse's signature [Ref: 058-003-004] (which is not completed), please identify which of the Nurses in the theatre should have signed that sheet (scrub, runner or Anaesthetic or the Medical Technical Officer).

It is likely that document ref 058-003-004 is the record for the post-anaesthetic period as it included information in relation to the discharge of the patient from the recovery room. Consequently, the signature relates to the recovery room nurse. None of the nurses in the operating theatre would have been expected to complete this section.

(iv) Does the absence of the various signatures required on the Anaesthetic Record comply with acceptable practice in 1995 (and comply with such practice now).

It is and was poor practice to fail to sign any records. This problem was recognised in the NCEPOD report "Who Operates When?" (1997) by the statement "*Records were often poorly kept and inadequate.*" The omission of a nurse's signature was probably due to Adam's transfer directly from theatre to PICU. Problems with record keeping have persisted. In 2010 the Practice and Education Council for Northern Ireland (NIPEC) published a document and programme aimed at improving record-keeping (Evidencing Care: Improving Record-Keeping Practice).

(v) Was there any protocol and/or guidance on recording the personnel in the operating theatre for a paediatric renal transplant (or transplant surgery in general) in 1995 and now?

To my knowledge, there were no protocols or guidance in 1995 for recording personnel for any operation. The NCEPOD document "Who operates when?" (1997) stated, "*all hospitals should record the grade of anaesthetists and surgeons present in the anaesthetic room and their responsibilities.*"

For all other staff the duty rotas and staff allocation lists were the mechanisms for recording the staff on duty and their allocated work schedule.

(vi) Identify the relevant protocol and/or guidance and provide a copy or advise from where a copy may be obtained.

See (a) above.

(vii) In 1995 (and now) would it have been necessary, usual or advisable to record the presence of all personnel in the operating theatre during a

paediatric renal transplant (or surgery generally)? Should at least the presence of an Anaesthetic Nurse or a Medical Technical Officer (whether or not performing the role of an Anaesthetic Nurse) have been recorded? Where should the identity of the personnel in the operating theatre have been recorded?

It was not standard practice in 1995 for the non-registered practitioner (Operating Department Assistant or locally trained technician) to be recorded in official documentation. In addition, it was not standard practice for an anaesthetic nurse (a registered practitioner) to record his/her participation.

Now, with the introduction of peri-operative care plans/integrated care pathways or instrument tracking systems, all non-medical participants, registered or non-registered (such as health care support workers/assistants) are expected to have their contribution documented.

(viii) In 1995 (and now) would it have been necessary, usual or advisable to record the presence of all personnel in the operating theatre during a paediatric renal transplant (or surgery generally) in circumstances where the patient had failed to wake from anaesthesia and had subsequently died.

Today, if a child fails to recover from anaesthesia, this would be regarded as a serious untoward incident (SUI). The rigour with which these are investigated has changed considerably since the introduction of Clinical Governance in the late 1990's in England and possibly later in Northern Ireland. An important milestone was the publication in 2000 by the UK Department of Health of the document "An Organisation with a Memory". Serious untoward incidents are now investigated in depth by a patient safety team in the first instance and statements from all participants collected. This requires all those present during the operation to be identified.

The situation in 1995 was different and it is possible, in my view, that occurrences as described above were not reported and investigated to the same level as today.

2. Queries arising from witness statements

(i) What were the qualifications and training (including experience) necessary in 1995 (and now) for a nurse to be properly described as an 'Anaesthetic Nurse'.

Several courses were available for registered nurses in England and accredited by the English National Board for Nursing, Midwifery and Health Visiting - ENB 176 Anaesthetics, Theatres & Recovery; ENB182 Anaesthetics only; ENB 183 post-anaesthetic care. The English National Board and its equivalent for Northern Ireland (National Board for Nursing Midwifery and Health Visiting for Northern Ireland) were

dissolved some years ago. I have been unable to find information on the locally available courses for nurses in Northern Ireland during the 1990's.

A one year Level 6 degree pathway carrying 60 CATs (Credit Accumulation and Transfer Scheme) in Anaesthetic Care Practice has replaced these courses in England. I am aware that

Queen's University, Belfast, currently runs a Peri-operative nursing course. (www.qub.ac.uk)

In 1995, it was common for nurses to be given a title based on their experience. Their training may have been "in-house" rather than through a formal course as courses were often difficult to access. It is, therefore, likely, in my opinion, that someone using the title Anaesthetic Nurse may not have completed a specific course.

(ii) What was the typical role of an Anaesthetic Nurse in 1995 (and now).

An anaesthetic requires the minimum of two people. Passing a breathing tube (endotracheal tube) into a child's airway requires someone to pass to the anaesthetist essential pieces of equipment such as endotracheal tubes or anaesthetic circuitry in order to connect the patient to the anaesthetic gases. The anaesthetist cannot let go of an endotracheal tube that has been passed until it has been secured in place by either adhesive tape or a material tie so a second pair of hands is always needed. In addition, there would have been equipment and/or drugs to be collected during the course of the procedure and the anaesthetist should not leave the patient unsupervised during the length of the anaesthetic.

The role of assistant to the anaesthetist was also performed by operating department assistants or technicians. Currently more Operating Department Practitioners (see below) than nurses undertake this role. It is likely that in 1995 there were more ODA's/technicians assisting anaesthetists than registered nurses.

(iii) Would it have been necessary, usual or advisable in 1995 to have an Anaesthetic Nurse involved in paediatric renal transplant surgery? What was the level of the 'involvement' of an Anaesthetic Nurse in 1995 (and now) including the extent to which this involvement was typically:

- ***when anaesthesia was introduced;***
- ***for the duration of the surgery (or part of it, in which case which part); and***
- ***when the patient was being wakened***

The assistant to the anaesthetist helped in preparing the patient for the anaesthetic – talking to the child, taking and recording baseline pre-operative observations, helping with the insertion of intravenous catheters and assisting with induction/airway management. During surgery, I believe that a registered nurse may have had a role in assisting with the monitoring of intravenous and other fluids.

There was also a requirement to fetch and carry for the anaesthetist, then calling for and preparing for the next patient if there was one.

The assistant would usually help the anaesthetist with the withdrawal of anaesthesia (replacement of endotracheal tube with oral airway and oxygen facemask; security of intravenous access) and preparation of the patient for transfer to recovery. There was no specific role in the recovery room. If the patient was to be transferred to ICU, the anaesthetic assistant would assist with transferring the monitoring to an appropriate portable device. S/he would also accompany the anaesthetist and scrub staff to the unit in case the anaesthetist required assistance during the transfer.

(iv) Would an experienced Medical Technical Officer with 18 years experience and whose duties and role were stated to be "to assist the anaesthetists in their duties and if needed to act as a second runner", could reasonably have been used to perform the role of an Anaesthetic Nurse?

It is my understanding that prior to the introduction of Operating Department Assistants, anaesthetic technicians who were usually trained in the department assisted anaesthetists. ODA's undertook City & Guilds or National Vocational Qualifications (NVQ). This was replaced in the 1990's by NVQ (National Vocational Qualification) Level 3 Operating Department Practitioner (ODP) training.

In 2000 the it became a requirement for hospitals in England to work towards only employ registered ODP's in these roles. The role of Operating Department Practitioner became a registered profession in 2007

There were differences between the role and responsibility of an Anaesthetic Nurse and any other assistant to the anaesthetist. Nurses by virtue of their registration are accountable for their actions, whereas an unregistered member of staff would work under the direct supervision of the anaesthetist. A registered nurse would have undergone training in physiology and psycho-social care. Registered nurses could prepare and administer medicines and hold the keys to the medicine cabinet. The latter is important as the nurse could administer controlled drugs and hold the key to the controlled drug cupboard.

There should no longer be ODAs working in operating departments as they must be registered practitioners (ODP). They cannot join the register until they have undergone a 'conversion' course to bring them up to the current standard (Higher National Diploma). It is anticipated that their course will change to a degree level course sometime in the next 18 months.

The majority of anaesthetic staff are now Operating Department Practitioners.

3. Other queries

(i) In 1995 (and now) was any requirement to have three nurses present before an anaesthetic was commenced and if so explain the source of that requirement.

The NATN guidance is no longer available. In my opinion it was not a requirement for 3 registered nurses to be present before an anaesthetic was commenced. Three practitioners were needed – anaesthetic assistant, scrub nurse and circulating nurse. Current guidance as described by the Association for Peri-operative Practitioners includes roles that can be fulfilled by varying levels of practitioner.

(ii) Comment on the advisability or otherwise in 1995 (and now) of proceeding with paediatric renal transplant surgery with a 'Scrub Nurse', 'a Runner' and an experienced 'Medical Technical Officer'. Please address also circumstances (if any) in which it would have been reasonable to do so in 1995 (and now).

I believe it was acceptable for this urgent procedure to proceed with a minimum number of staff in 1995. However, it did not allow for staff having to leave the room for such reasons such as collecting additional equipment or toilet breaks.

In 2003 the Northern Ireland Audit Office found a "*shortage of theatre nurses in most hospitals*" and high sickness and staff turnover rates. It is likely that in 1995 there was a similar situation. This resulted in operating theatres working at times on minimum staffing levels. It is likely, however, that other staff were available in the event of an emergency, for example the senior sister. The transplant was performed during the day when it is likely more staff were on duty.

Current guidance (AfPP) is that there should be a "*registered anaesthetic assistant practitioner*", "*two scrub practitioners*" (can be ODP or Registered Nurse) unless dependency requires more or less and a "*circulating staff member*". Renal transplants can take several hours to complete and therefore other staff should be available to relieve or assist the operating team.

References

Association for Peri-operative Practitioners (2007) Staffing template www.afpp.org.uk

Davey A Ince C. (eds) (1999) Fundamentals of Operating Department Practice, Cambridge University Press

Department of Health (2000) An Organisation with a Memory www.dh.gov.uk

Department of Health (2000) The Employment of Operating Department Practitioners in the NHS www.dh.gov.uk

National Confidential Enquiry into Patient Outcome and Death (1997) Who Operate When? www.ncepod.org.uk

NIPEC (2010) Evidencing Care:Improving Record Keeping Practice www.nipec.n-i.nhs.uk

Information sources used

Health Professions Council – www.hpc-uk.org

Practice and Education Council for Northern Ireland www.nipec.n-i.nhs.uk

Teresa Patricia Durack

I am an experienced senior nurse with a range of abilities, clinical and managerial. Constantly curious and interested to learn and share new information and skills, I believe that the maximum value of knowledge of any kind is realised by sharing it with others and enabling it to become part of routine working practice. I am optimistic, enthusiastic and hard-working with a good sense of humour and endeavour to maintain a healthy balance of work and outside interests.

Employment record

Posts held in Great Ormond Street Hospital for Children NHS Trust

Modern Matron, Corporate Facilities/Head of Materials Management – Band 8a – August 2009 – Present
I lead the team that supplies medical/surgical consumables to the clinical areas and act as clinical adviser to all areas of the Corporate Facilities Directorate, particularly the Decontamination Services. I work closely with the Procurement Department and clinical units on the introduction, standardisation and rationalisation of clinical products used in the Trust and provide support to the Medical Equipment and Supplies Group. This Group is expected to make significant progress to support clinical units to meet their annual cash-releasing efficiencies savings.

In addition to this, I participate in the Trust's Induction programme for clinical staff on a monthly basis by speaking about the care and staff responsibilities for the use of medical devices. As the local resource nurse, I also impart information about the impacts of latex allergy for staff and patients. I continue to work with the Estates team on Redevelopment projects, including the planning/commissioning of the next phase of the hospital's major rebuilding programme.

In addition, I carry out projects on behalf of the Chief Nurses' Unit and work on a regular basis with the local practice educators in areas such as preceptorship and the creation of speciality-specific clinical competencies, guidelines and protocols. I have been a member of the hospital's Clinical Practice Committee for a number of years and am the current co-chair. This has included the development of the new 'Clinical Guidelines' section of the GOSH Internet site incorporating updated clinical procedure guidelines and newly developed Integrated Care Pathways.

Modern Matron – Estates & Facilities – I Grade/Band 7 – September 2005 – August 2009 - Clinical link between the Trusts' Estates & Facilities Directorate and the clinical units. I liaised with all areas of the Directorate, from the Project Team and the current 'Enabling Works' as well as the clinical planners and the Redevelopment team to facilities-based services such as domestic contract and decontamination. Within the Directorate, I provided a range of educational sessions such as basic anatomy and physiology for the materials management staff to infection control for security, site services and sterile services teams. I also arranged ad hoc training for the new security contract in child protection, health and safety and care and safe transport of blood products.

Competency Development Programme Coordinator (secondment) – I Grade/Band 8a – September 2003 – August 2005
Role established by the Chief Nurse to identify and agree generic competencies for qualified nursing staff at GOSH and the managed network and to coordinate and pilot the development of a primary practitioner core competency portfolio. This included incorporating the pending NHS Knowledge and Skills Framework (KSF) within the

portfolio and the integration of the resulting Clinical Skills Toolkit into the existing Preceptorship programme and workbook. Another project that I helped to facilitate during this time was the rollout of a small number of Patient Group Directions across the Trust after its successful pilot in nephrology.
During this secondment, I was one of four trainers for the Trust in the NHS KSF project to facilitate the rollout out this part of Agenda for Change for staff with appraisal responsibility. I worked with the Assistant Chief Nurse, Recruitment & Retention, to establish the KSF profiles for generic Band 5, 6 & 7 nursing staff and assisted several groups of senior staff (such as PICU/NICU and neurosciences) to work through the profiles in order to make them relevant to their specialist skills.

Clinical Supplies Advisor- H Grade – October 2000 – August 2003 – Re-established role within the Trust to manage the clinical supplies review project in order to rationalise, standardise and benchmark clinical products throughout the hospital where possible and to develop a strategy for the introduction and audit of new products. This included the establishment of a multidisciplinary Product Knowledge Management Group to facilitate this rationalisation and the creation of a product formulary. During this role, I also assumed managerial responsibility for the Materials Management team and provided in-house training session for the whole of the supplies team, including team building exercises as well as some basic clinical information to enhance their understanding of the needs of the clinical teams when purchasing goods. I revised the Trust's Latex Allergy Policy (for staff) and wrote the 'Latex Allergy – care of the child' clinical procedure guideline. I was one of the founder members of the London Clinical Procurement Specialists group which lead to the establishment of the national CPS group supported by the NHS Purchase & Supply Agency.

Project Nurse – H Grade – November 1999 – October 2000 - This was a short secondment for the Director of Nursing to create and agreed local procedural guidelines for the Trust's operating department staff to aid recruitment and retention of staff in the area. During this time, I also revised the Trust's Perioperative Care Record that is still in current use.

Senior Sister, Theatres – H Grade – June 1993- November 1999 – Senior member of the nursing team responsible for providing surgical services to the Trust and deputy to the Clinical Nurse Manager. I lead and facilitated the amalgamation of two separate teams of staff with the move to the new Variety Club Building theatres as well as the subsequent expansion of the department. This role incorporated recruitment, appraisal and fiscal responsibilities in addition to maintaining clinical expertise and I established and regularly participated in teaching within the department as part of the staffs weekly 'protected teaching time'.

Sister, Theatres – G Grade – January 1985 – June 1993 – One of a team of sisters within the department that provided scheduled and emergency general, orthopaedic, urology and plastic & reconstructive surgical services to the Trust and also provided emergency cover for ENT, ophthalmic and dental surgery. The role was mainly clinically based with budgetary responsibility for the relevant specialities and appraisal responsibility for junior staff. It also incorporated teaching and mentoring peer and junior staff and I was responsible for the re-establishment of student nurse rotation to the department after a successful clinical placement audit carried out by the Charles West School of Nursing.

Other posts

Senior Staff Nurse, Theatres – Royal Ear Hospital – May 1984 – December 1984
Senior member of the staff nursing team providing ENT, dental and some general surgical services in University College Hospital. Clinically based with teaching /

mentoring responsibilities for peer, junior and student nurses in the department in all aspects of theatre nursing including anaesthetic, scrub and recovery roles.

Clinical Nurse Tutor, Theatres (maternity leave cover) – University College Hospital – October 1983- April 1984 – Provided clinical nurse training and assessment for all student and pupil nurses with the UCH group of hospitals. This included assessing course work as well as carrying out assessments in the clinical situation.

Staff Midwife – North Middlesex Hospital – May 1983 – October 1983 – based mainly in the labour ward as part of the staff midwife team but also spent some time in the SCBU and, for a brief period, was also in charge of the antenatal clinic.

Staff Nurse, Theatres – University College Hospital – September 1980 – April 1981 – worked as part of the scrub nurse team within the main clinical building and was in charge (maternity leave cover) of the plastic surgical theatres based in St Pancras Hospital

Finance Officer – Walton Hospital – 1973 -1974

Clerical officer – Barclays Bank – 1972 – 1973

Qualifications

State Registered Nurse training – Radcliffe School of Nursing, Oxford – July 1977-August 1980

State Certified Midwife training – North Middlesex School of Midwifery, Edmonton, London – April 1981 – May 1982

English National Board course 176 – Operating Department Nursing – October 1982 – October 1983

Diploma in Nursing – Royal College of Nursing (University of London) – September 1988 – August 1991

English National Board course 998 – Teaching and Assessing in Clinical Practice- October 1992 – December 1992

Postgraduate Diploma in Interprofessional Health and Community Studies – Canterbury Christchurch University College (University of Kent) – September 1995 – March 2001

Master of Science in Interprofessional Practice (Embodying Leadership) – City University London – September 2002 – July 2004

Other Education/Seminars

GOSH Assessment and Facilitation for Student Nurses - 1989
GOSH Trust – Management Development Programme –1994
Midas Rex® Advanced Pneumatic Instrumentation –1999
SureStock Procurement training – 2001
Clinical Governance for Nurses – NHS Modernisation Agency- 2004
Competence in New & Extended Nursing Roles – RCN – 2004
PGDs and Nurse Prescribing – Nursing Times – 2004
Selecting the right gloves – for Healthcare & PPE – London - 2005
Infection Control Nurses Association Joint Study Day – 2006
Fire Safety and Management in Hospitals – BRE – 2006

Pan London Patient Environment Network – NHS Estates – 2006
GS1Standards for Coding and Identification – GS1 - 2007
GOSH Update for Clinical Staff
GOSH Basic Life Support for Clinical Staff
Various general office courses including Word and Excel, minute taking
Various operating department based seminars such as electrosurgical safety, endotracheal suctioning and chemical decontamination

General Education
Early education split between schools in USA and England
CSE – Mathematics
GCE 'O' levels in English Language, English Literature, Economic History, Biology, French,
'A' Level English
Institute of Bankers – English

Other information
NMC Registration – 77G0413E exp. July 2008
RCN membership number – 860302
Honorary member of the Latex Allergy Support Group (national charity)

Address: [redacted]
Telephone: [redacted]
Email: [redacted]

Date of Birth – 19 October 1954
Place of Birth – New York City, USA
Marital status – Married
Car driver

Interests
Singing/music
Reading
Gardening
Cooking
Walking
Travel
Palaeontology
Astronomy
Needlepoint
Member of National Trust
English Heritage
Royal Horticultural Society

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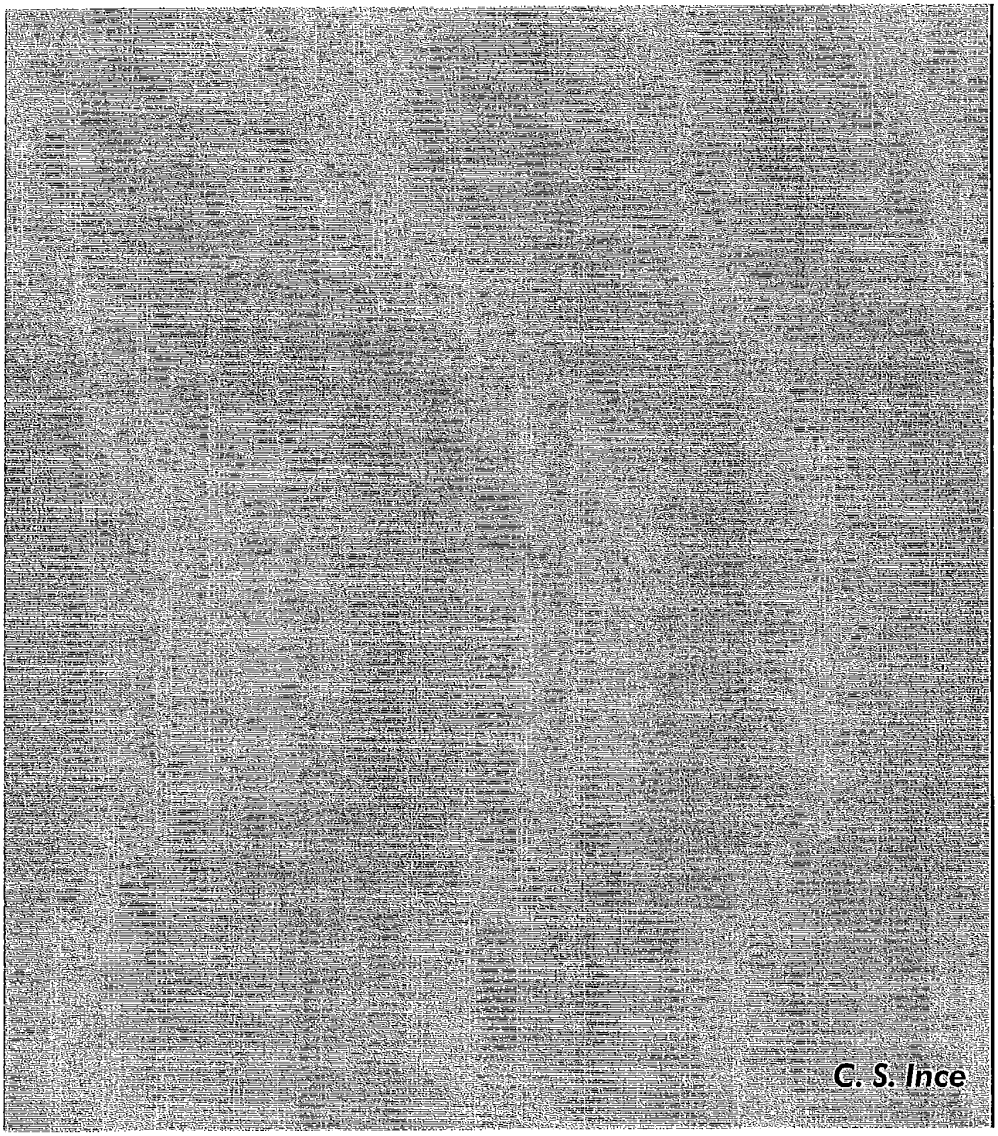
INTRODUCTION



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Major advances in anaesthesia and surgery may only occur when the understanding of a principle or discovery is linked to its practical application and the potential usefulness of this development is realized. Even then, progress is limited by the technical ability of the time.

Thus, before the discovery of anaesthesia surgery was generally limited to amputations, the removal of bladder stones, the repair of fistulas and fairly superficial operations. Celcus, a Roman physician in AD 30, was probably the first to remove a bladder stone and the procedure changed little over 1800 years. This type of surgery was, however, made respectable when, in 1686, Charles François removed a stone from Louis XIV by cutting into the perineum.

The Massachusetts General Hospital in Boston only recorded 43 operations from 1821 to 1823 because the real prospect of death and the incredible pain suffered meant that only hopeless cases or patients in severe distress would consider the risk worthwhile. Surgeons therefore tried to introduce instruments into the bladder in order to crush these stones. Jean Civiale experimented on cadavers and on his own bladder stone. In 1823 he used forceps introduced through the urethra to hold his stone which was then drilled, causing it to break into pieces. His record showed that it was virtually painless.

Without anaesthesia, surgeons needed to practise with skill and speed. Susruta, an Indian physician in the 5th century AD, recorded the first operation for nasal reconstruction. A similar operation was performed on a bullock driver by a Mahratta surgeon, using a forehead skin flap modelled on a wax reconstruction of the nasal defect. This was first published in "The Gentleman's Magazine" in October 1794. Joseph Carpue, who trained at St George's Hospital London, researched the method and performed his first operation that lasted 37 minutes on October 23 1814.

Major developments in surgery only became possible with the discovery that inhaling certain chemical gases could produce insensitivity to pain. The possibility had existed for over 300 years because in 1540 Valerius Cordus used ether to successfully anaesthetize and then recover chickens. Joseph Priestly discovered nitrous oxide in 1772 and in 1800 Sir Humphry Davy used it to relieve the pain of an infected tooth.

On December 10 1844 Gardner Quincy Colton, a travelling lecturer in chemistry, demonstrated nitrous oxide inhalation at his 'laughing gas show' and Horace Wells, a Connecticut dentist, noticed that, while inhaling the gas, Samuel Cooley banged his shin but felt no pain. He realized its potential and on December 11 1844 Riggs, Wells' assistant, successfully extracted one of Wells' teeth under nitrous oxide administered by Colton. This was repeated on 15 patients in his practice and only two felt pain. On January 17 1845 he gave a demonstration at Harvard Medical School in the presence of John Collins Warren, a respected surgeon, but the patient felt pain and he was branded a fraud.

Meanwhile, Dr Crawford Long used ether to operate on the neck of James Venable on March 20 1842, having similarly observed that individuals engaged in "ether frolics" could injure themselves without experiencing pain. William T. G. Morton, an apprentice of Horace Wells, was present at the failed nitrous demonstration and gave the first recorded ether anaesthetic on October 16 1846 at the Massachusetts General Hospital, Boston, to Gilbert Abbott.

By December the news reached Dr Francis Boott who told Robert Liston, the Professor of Clinical Surgery at University College London. The technique was tried on a young woman undergoing dental extraction. On December 21 1846 an amputation performed by Robert Liston on Frederick Churchill was the first pain-free surgical procedure in England. Peter Squire gave the ether.

In 1847 Professor James Young Simpson introduced chloroform into obstetric practice. No mention was made, however, of James Waldie, the Liverpool chemist who suggested the method to Simpson and whose apothecary shop subsequently burned down.

In 1847 John Snow, the first full-time British anaesthetist, wrote '*On the Inhalation of Ether*'. He realized that the common methods of ether and chloroform administration were faulty and developed both ether and chloroform inhalers. Snow gave chloroform to Queen Victoria during the birth of Prince Leopold. Although the first death from ether occurred in 1847 and from chloroform in 1848, Snow administered over 4000 anaesthetics without a death. Both ether and chloroform had significant disadvantages and newer agents (Cyclopropane 1930, Trichlorethylene 1941 and Halothane 1956) were introduced. The further development of vaporizers made administration more controllable.

Hewitt, McKesson and Boyle introduced anaesthetic machines from 1898 and in 1928 a circle circuit which incorporated carbon dioxide absorption using soda lime was developed by Brian Sword. (Joseph Priestly first described the absorption of carbon dioxide by alkalis in 1754 but it took nearly 200 years for this discovery to be utilized.)

The development of endotracheal anaesthesia allowed surgeons to perform more complicated procedures. Endotracheal insufflation was described in 1667 and in

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1880 MacEwen passed a tube into the trachea using his fingers as a guide. Magill and Rowbotham further developed this concept in 1920, although cuffed tubes were not introduced until 1928. The first direct vision laryngoscope was used in 1896, with the Macintosh curved blade described in 1942.

Muscle relaxants made a great difference to surgical practice but were first used to control spontaneous ventilation rather than for paralysis. The South American arrow poison, curare, was described by Sir Walter Raleigh in 1596 but, although its physiological action was ascertained in 1850, it was first used as a full muscle relaxant on January 23 1942 by Griffith and Johnson in Montreal. Professor Gray and Dr Jackson Rees established its use in Britain and developed the Liverpool School of Anaesthesia using the triad of analgesia, muscle relaxation and narcosis. Suxamethonium was first used in Sweden and Italy in 1951 and still has an important place in anaesthesia. The development of newer muscle relaxants has been rapid but the ideal agent has still to be produced. Guedel and Treweek developed control of respiration by respiratory depression in 1934 and Crafoord used the first ventilator in 1940.

The ability to cannulate a blood vessel allowed the intravenous injection of anaesthetic agents and analgesics. Sir Christopher Wren gave the first intravenous injection of opium to a dog in 1657, using a bladder attached to a sharpened quill, but the first glass hypodermic syringe and needle were not developed until 1853. Chloral hydrate was used in 1874 to induce anaesthesia but, although barbitone was synthesized in 1903, it was not until 1927 that the first barbiturate was routinely used to induce anaesthesia. In 1934 Lundy introduced thiopentone which paved the way for many other intravenous anaesthetics.

The discovery of local anaesthetic agents permitted surgery to take place without general anaesthesia. Cocaine, which occurs in coca leaves, was isolated by Gaedicke in 1855 and was further purified by Nieman in 1860. It was Koller, however, in 1884 who demonstrated its use in the eye. In the same year Stewart Halsted performed a mandibular nerve block using cocaine and the following year an accidental subarachnoid injection of the drug produced regional analgesia. Lumbar puncture was shown to be a practical clinical procedure in 1891 and August Bier produced successful spinal analgesia in 1898, with extradural analgesia described in 1901. Cocaine was known to be toxic and the first alternative, tropocaine, preceded the development of procaine which was produced by Einhorn in 1903 and used by Braun two years later. Bier used this drug intravenously as an analgesic in 1908. Nupercaine was introduced in 1929 and became popular as a spinal analgesic. Later, the spinal route was less used because of nerve damage resulting from phenol, which leaked into the anaesthetic ampoules from the sterilizing fluid. Spinal and epidural analgesia now have an established place in the anaesthetist's repertoire. (Harvey Cushing coined the term 'Regional anaesthesia' to describe pain relief resulting from a nerve block.) Lignocaine came into use in 1948 followed by prilocaine and bupivacaine.

One of the factors limiting major surgery was the ability to replace blood and fluid loss. Richard Lowther, in 1665, transfused the blood of one animal into another but the first attempt at fluid replacement was in 1832 when intravenous saline was used to treat the dehydration of cholera. Only after the discovery of ABO blood groups in 1900 by Landsteiner at the University of Vienna could major advances in blood transfusion occur and in 1914 Hustin used citrate in blood transfusion.

Although anaesthesia allowed surgical techniques to advance, large numbers of patients died from surgical wound fever. In February 1846 Ignaz Semmelweis, a Hungarian, became the assistant at the First Obstetrical Clinic in Vienna. In the 'lying in' section of the Vienna General Hospital 36 of the 208 mothers had died. Semmelweis discovered that, whereas 10% of mothers died in the ward where medical students were trained, only 1% died in the ward where midwives attended. The wards were next to each other in the same building.

At postmortem he found that these women had a picture of suppuration and inflammation throughout the body resembling surgical or wound fever. He and the medical students followed this with ward visits to carefully examine the mothers to try and find the cause. As a result the death rate increased but only on the days when women were admitted to the division attended by the doctors and medical students. Professor Kolletshka, who had given Semmelweis much support, died after being cut during a postmortem and at his own autopsy a similar pattern of suppuration was seen. Semmelweis then realized that examining patients after performing postmortems could be the cause.

On May 15 1847 Semmelweis made all doctors and students wash their hands in chlorine water before entering the maternity wards. Over the next month the mortality decreased from 12.34% to 3.04%. When this practice was extended to washing between examinations by the end of 1847, the death rate was 1.33%. Publications in 1847 and 1848 were met with derision by Semmelweis's professor who prevented him from

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further study, arranged for his removal from his post and abolished all his handwashing protocols.

Semmelweis left Vienna in 1848 and became a GP obstetrician in Budapest. On May 20 1851 he took the post of Honorary Head of Obstetrics at St Roch's Hospital in Budapest and over the next eight years reduced the mortality rate to less than 1%. On July 18 1855 he was appointed Professor of Obstetrics at Budapest University but his ideas were still rejected by the foremost obstetricians in Europe. Semmelweis died on August 14 1865 at the age of 47 of septicaemia following a cut at a postmortem, with his work largely unrecognized.

In 1863 Louis Pasteur discovered that microorganisms caused fermentation and putrefaction and that this process could be stopped by heat. Joseph Lister, who was Professor of Surgery at the University of Glasgow, read of this work and also that a Dr Crooks had eliminated the smell of the Carlisle drainage fields by treating the sewage with carbolic acid (phenol). Realizing the significance of the discovery, he introduced handwashing with carbolic and also soaked the dressings in this substance. His main argument was that the carbolic prevented germs from entering the clean wound. On June 17 1867 he performed a radical mastectomy on his sister without significant suppuration and the wound was healed in a few weeks. He also discovered that catgut ligatures, that were soaked for four hours in carbolic, did not cause suppuration and were absorbed by the body. These findings were presented to a sceptical audience at the British Medical Association's 35th annual meeting but Professor Simpson lead a vehement opposition, until his death in 1870. Although his ideas were widely implemented in Europe, it was not until the 1920s that 'Listerism' was accepted worldwide.

In the latter part of the 1870s a German doctor named Robert Koch identified rods and cocci under the microscope, observed them multiplying and used the organisms, which he named bacteria, to infect mice that subsequently died. He found ways of dyeing and photographing them and in this way identified the bacteria responsible for anthrax, cholera and tuberculosis.

Research soon showed that steam killed bacteria more efficiently than carbolic and Schimmelbusch and Terrier introduced the steam sterilization of instruments, sutures and dressings. Although it was known that bacteria collected under fingernails, rubber gloves were introduced by coincidence. John Halsted, the Professor of Surgery at Johns Hopkins Medical School, had a nurse assistant who developed severe eczema due to handwashing in carbolic. In 1890 he developed a thin rubber glove, which could be steam sterilized to protect her hands. When she became his wife and retired from work, his assistants took it in turns to use the gloves for surgical practice. Thus, not only were the causal agents of infection identified but also a means was found to protect the clean wound from contamination.

The final part of this introduction traces the evolution of theatre training, reviews the current position and looks forward to new developments that will lead to safer practice. As anaesthesia and surgery developed, so did the need for non-medical assistance. A dedicated assistant to the surgeon and the anaesthetist is now vital for the delivery of safe surgical and anaesthetic practice. Initially learning was by experience, the anaesthetist often pressing into service a 'Box Boy' or a friendly theatre porter, with this role later developing into that of the Theatre Technician. Some anaesthetic departments, however, preferred to employ informally trained nurses. At first, surgical assistants were, invariably nurses who were trained in a similar manner.

The City and Guilds of London Institute (CGLI) 752 examination was introduced in 1976 as part of the recommendations of the Lewin Report. During the course, which concluded with a final examination, there was a single practical assessment in both surgery and anaesthesia. The emphasis was on theory and all parts had to be passed within three attempts. Apart from the recovery of patients from anaesthesia, most surgical and anaesthetic topics were well covered in the syllabus. Thus, qualified Operating Department Assistants were able to assist both the surgeon and the anaesthetist, although generally employers did not take full advantage of the dual capability.

The Regional Health Authorities were responsible for coordinating the training through regionally based and funded training schools, with support from a local steering or management committee, which was charged with the implementation of the syllabus, and training standards that were identified by the National Health Service Training Authority (later to become the National Health Service Training Directorate NHSTD). The NHSTD approved training schools for periods of up to five years, using visits by Approval Panels. The day-to-day quality assurance was the responsibility of City and Guilds of London Institute.

Although this represented a great advance, there was undue emphasis on theory. Students whose performance was poor under the pressures of formal examination conditions, although they may have been practically excellent, often fared badly. Similarly, practical ability was judged in a "one-off" situation in anaesthesia and surgery and students sometimes passed

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More information

even though their overall performance did not justify this result.

Surgical assistants were either Registered General Nurses (RGNs) or State Enrolled Nurses (SENs). Theatre training was usually informal in the first instance but locally certificated awards were introduced in the late 1950s. In 1969 the Joint Board of Clinical Nursing Studies (JBCNS) was established with the aim of bringing uniformity and professional credibility to postregistration courses for nurses and midwives. In 1983 The English National Board for Nursing, Midwifery and Health Visiting (ENB) encompassed the JBCNS and additional courses were introduced. Although emphasis was placed on ethical issues and research as well as the acquisition of practical skills, the courses have been shortened and are now considered by many inadequate to cover the range of skills required. The ENB 998 Teaching and Assessing course for RGNs and the CGLI 730 Teaching Course are available for postbasic study.

Prior to the introduction of the concept of the 'Theatre Person', there were five main non-medical staff groups working in theatre: ancillary staff; surgical nurses; operating department assistants (ODAs) and anaesthetic and recovery nurses. Traditionally, nurses usually assisted the surgeon while anaesthetic nurses and ODAs (despite being multiskilled) supported the anaesthetist. ODAs were not permitted to have responsibility for controlled and scheduled drugs and therefore nurses had a much greater responsibility in postoperative recovery areas. This inflexibility reduced the efficiency of operating departments.

The Department of Health asked Professor P. G. Bevan to carry out a detailed study of the management of operating theatres. He recommended that the ENB and the NHSTD should look at the possibility of developing a common training for those involved in theatre work and that levels of competence should be defined for anaesthetic and surgical support personnel. Thus developed the concept of the "Operating Department Practitioner" (ODP), who would supersede but not replace the traditional roles of the nurse and the ODA and would have the knowledge and ability to practise in all theatre situations. (It must be stressed that this is only a generic definition describing somebody that practises in theatre and should not be confused with (Health Care) Operating Department Practice Level 3, which is a qualification.)

Meanwhile, the Department of Health proposed that National Vocational Qualifications (NVQs) should be developed for theatre staff as soon as it was practically possible. The Government set up the National Council for Vocational Qualifications (NCVQ) in 1986: together with the Scottish Vocational Education Council (SCOTVEC), it was responsible for approving all vocational qualifications.

The Lead Industry Body, the Care Sector Consortium, now known as the Occupational Standards Council, analysed the work practices which were required by the employer and which should be included in the award. After developing draft standards, determining the evidence requirements and developing an assessment system, the draft proposals were piloted within operating theatres. The Awarding Body was identified as the 'Joint Awarding Body' (JAB) with the CGLI being the active member and the award was submitted to the NCVQ for approval. This award, known as "Health Care: Operating Department Practice Level 3", is available to all personnel who wish to practise as the equivalent of assistants to the anaesthetist and/or surgeon or who wish to work in the recovery area. It has now replaced the CGLI 752 qualification but in no way disadvantages holders of this or any ENB certificate.

A vocational qualification is based on the achievement of competence. Defined as "the ability to perform the practical skills of the occupation", it encompasses everything a person should be able to do at work if they are to be effective in their job, including the necessary background knowledge (theory) and understanding to produce a safe practitioner. The NVQ framework currently has five levels of work practice, based on the complexity of the activities performed in the work area and the ODP qualification is at Level 2 for the support worker and at Level 3 for the assistant to the surgeon and/or the anaesthetist.

NVQ training differs from the more traditional methods in the following important ways: there must be open access for students of any sex, sexual orientation, race, religion or creed and training must not be 'Time Banded'. This means that no limit may be placed on the length of time taken to qualify but, in practice, the employing authorities limit this by Training Contracts. Access to Health Care: ODP Level 3 is through clearly defined entry criteria.

The qualification is divided into major parts known as Units, each of which deals with a specific area of experience, and these are further subdivided into Elements. Each Element has its own Performance Criteria and the range of clinical settings over which these apply. Sections of Elements and Units are completed as and when competence is consistently established and this is formally documented. On completion of all Units, the student may apply for the qualification but, should the student so wish, Units may be individually certificated.

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Work experience takes place in the local hospital under the guidance of Work-Based Trainers and Assessors and the underpinning knowledge is taught within the hospital and at approved Assessment Centres. Work-Based Assessors (WBAs) are responsible for ensuring that the student generates sufficient and relevant evidence of competence, both practically and at a theoretical level. The Local Assessment Coordinator, who is competent in all areas of the qualification, collates and evaluates evidence from many different sources.

ODP Level 3 must be creditable to the Awarding Body and to the employer. The Assessment (Training) Centres, which consist of the schools and the related hospitals, are subject to a rigorous quality assurance process coordinated by the Awarding Bodies using External Verifiers, both at initial approval and at regular intervals throughout the year. It is possible, therefore, for centre approval to be withdrawn at any time.

Internal Verifiers, usually senior theatre staff, are responsible for the internal quality assurance relating to the National Standards of the qualification. An award can only be as creditable as those who are responsible for its administration and assessment. Thus the JAB places great emphasis on the training of WBAs, Internal and External Verifiers. Assessment Centres are responsible for the training of WBAs and Internal Verifiers and the JAB trains its External Verifiers and continuing appointment is dependent on satisfactory performance. These assessors must be seen to be competent and, therefore, the Training Development Lead Body (TDLB) has provided National Standards, which lead to a range of assessing awards. All verifiers and assessors must have achieved this award within 12 months of taking up their post.

Existing theatre staff who wish to obtain this ODP Level 3 award may be assessed against the National Standards or demonstrate their current competence and underpinning knowledge using witness statements from their employers. This is known as "Accreditation of Prior Learning or Experience" (APE or APL) and allows assessment of competence without the need for formal practical evaluation. No Unit may be totally acquired through APL.

In order to develop further the role of the theatre practitioner a series of Additionally Accredited Units (AAUs) have been introduced. The content relates to the high levels of skill and responsibility appropriate to the practitioners. The AAUs are intended to cover skills not specified by the standards contained within existing levels. Areas that have been assessed in Level 3 are only repeated if it is considered essential. These free-standing Units may be separately certificated and candidates may not have achieved the ODP 3 award prior to accessing the AAUs. In order to maintain the highest standards set by ODP Level 3, performance has been structured to ensure that candidates reach an equivalent level of competence before they are awarded unit recognition.

The AAUs are divided into two main groups. The seven Clinical Specialisms cover performance within the specific surgical and anaesthetic areas of ophthalmology, plastic surgery and burns, cardiothoracic surgery, vascular surgery, orthopaedic surgery, maxillofacial surgery and the neurosciences. The Generic Skill Units have been developed for those areas of technical ability which are applicable within the Extended ODP Role wherever this is perceived to be relevant by the candidate or the employer. This may not always relate to theatre practice. The units cover the following skills: venepuncture and intravenous cannulation; the administration of drugs; intubation and extubation; and basic and advanced cardiac life support.

Although there have already been great changes, this does not mean that the qualification in its current form is without fault. The need for modification was identified early on and a first revision is currently in place. During 1996–7 a fundamental review of the award has been carried out to make it more relevant to today's requirements. An additional AAU for surgical assistance will also be introduced and others are under consideration.

In these days of frequent litigation a nationally recognized qualification such as ODP Level 3, which is hopefully supported by the medical Royal Colleges and hopefully, in the near future, by professional registration for the ODA and the ODP, must give the same credibility to the non-medical practitioner as the medical profession has possessed for many years.

RECOMMENDED READING

Lee J, Alfred J. Atkinson, R.S. 1992 *A Synopsis of Anaesthesia*: Bristol: John Wright

Ince C.S. 1995 *The Training of non-medical theatre personnel*: Health Trends 27(3):80.)

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1

THE OPERATING DEPARTMENT PRACTITIONER, THE PATIENT AND THE LAW

J. Ballance & P. Duxbury

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More information

INTRODUCTION

Each patient passing through an operating department has a right to be dealt with in a sympathetic and professional manner. This care extends throughout the perioperative period, a term that describes the time around and including surgery and anaesthesia. Theatre professionals are becoming involved at all stages of this process and in some hospitals only operating department staff look after the day-case patients. Management of this care is discussed in Chapter 3 and many individuals are involved in what may be a lengthy process.

It is, however, important that care meets the highest moral, ethical and legal standards that have been introduced to protect not only the patient and the patient's rights but also those of the theatre worker. This chapter seeks to clarify some of this legislation but also tries to explain why it was introduced in the first place. Some of these topics are dealt with in greater detail elsewhere in the book and will only be mentioned in passing. It is important for the reader to understand that this section deals with English Law and must only be interpreted in this context.

THE LAW AND ETHICS

A principle may be defined as a theoretical base which can and must apply to all people in order to maintain a stable society. There are four main principles guiding the actions of the health-care worker:

1. Autonomy – the right to self-determination.
2. Beneficence – to act in a way to do good.
3. Non-maleficence – to act in a way to do no harm.
4. Justice – to be fair to all individuals.

Ignoring these principles may not necessarily be illegal because breaking the law and breaking an ethical code are not the same and it is for this reason that codes of practice have been introduced by the professional organizations. It is not illegal for a doctor to divulge confidential information about a patient, without that patient's consent, to a person not involved with their medical management but it does break the medical code of practice. If this action came to light the doctor would be disciplined and, depending on the seriousness of the complaint, may be suspended from practice. Examples include revealing a diagnosis such as HIV to a patient's relative or friend and informing the parent of a 17-year-old that she was taking the contraceptive pill.

In Britain we are all presumed to know the law and ignorance of the law is no excuse for breaking it. It is therefore most important that the health worker is aware of actions or omissions that may have legal consequences and that individuals may well be required to account for their actions in a court of law. This also applies to the professional organizations such as the General Medical Council and the UKCC because legal judgements take precedence over any professional disciplinary matter.

DOCTRINE OF JUDICIAL PRECEDENT

The Doctrine of Judicial Precedent states that cases must be decided in the same way when the material facts are the same. How, then, does this affect the health-care worker? Unfortunately or perhaps fortunately, the law is not a static function but its interpretation may change as it is tested by the courts.

One of the best examples of this is the 'Neighbour Principle' that was formulated in the case of Donoghue v Stevenson in 1932. Lord Atkin had to make a judgement on what was considered to be the duty of care. He defined it as:

> 'You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour. Who is then my neighbour? The answer seems to be persons who are so closely and directly affected by my acts that I ought reasonably to have them in my contemplation as being affected when I am directing my mind to the acts or omission which are called in question.'

Until that judgement, there may have been some doubt as to what the duty of care meant but this is no longer the case and this statement now forms a yardstick by which all actions are judged. It is a definition that every health-care worker would do well to learn and always keep in mind.

RIGHTS AND OBLIGATIONS

The rights of an individual may be defined as 'that to which a person has a just or lawful claim' and it is an interest which will be recognized and protected by a rule of law. There are therefore some rights that each of us should expect and some which the State or an employer has a duty to provide. Examples include the following.

- Basic goods and services such as clean water, housing and food.
- Voting rights.
- An employer must provide a safe and healthy environment for their workers. This should be physically, psychologically, emotionally and spiritually sound.
- Employees have a right to be protected and to feel safe.

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- The right of the individual to have an equal opportunity in any aspect of life (employment, training, facilities, etc.) is a fundamental right for everybody, irrespective of race, creed, gender, sexual persuasion or physical disability.

THE RIGHTS OF THE PATIENT

The health-care professional has a duty to care for the patient and the patient has a right to be cared for. Duty of Care may only centre round an individual patient or it may include the much broader concept of the whole caring environment. The basic rights that are relevant to health care are discussed below.

Health care and treatment were defined in the National Health Service Act 1947, which gives every patient the right to have medical treatment that is free at the point of delivery.

The right to choose, e.g. the choice of a doctor, hospital, carer or treatment although in practice this is a limited concept within the NHS.

The right to know is not always enforced. For example, a terminally ill patient may not wish to know the true facts. In this context the skill of the carer is paramount in trying to decide what the patient really wants, but it is very easy to make the wrong decision.

To be informed relates particularly to consent and the different effects of available treatments to which the patient may be subjected.

Patients have a right to be treated but also have the fundamental right.

To refuse treatment, both surgical and therapeutic. The patient does not, however, have the right to demand a certain method of treatment. Sometimes there may be a choice between an expensive drug, which may be marginally better, and a cheap drug and this may be very controversial. Equally controversial is the right of a Jehovah's Witness to refuse blood and blood products in a life-threatening situation. They do have this right but this does not apply to their children who are below the age of consent.

To take one's own discharge is a right but it must be clearly established that the patient has the mental capacity to understand the consequences of that action.

The right to life deals with issues such as protection of the unborn child but also raises such questions as 'When does a fetus become viable?'

Children also have the right of protection under the Children Act and this may potentially bring the carer into conflict with the parent(s). Thus there are clearly defined guidelines relating to the management of suspected child abuse.

The right of the patient to privacy may sometimes be difficult to implement in an open ward and the interpretation of what is meant by privacy may also lead to potential patient/carer conflict.

Perhaps the right of confidentiality is one of the most difficult to deal with. If a carer is given information that will affect the treatment of a patient but is sworn to secrecy, should they reveal it to the appropriate person? A patient who is about to have an operation but has concealed the diagnosis of HIV may put the safety of the theatre staff at risk and these individuals also have rights. This subject will be discussed in more detail later in this chapter.

Both patients and carers have the right of protection from harm. This includes such things as protection from infection (the Department of Health has ruled that all staff working in an environment that potentially exposes them to hepatitis B must be vaccinated) and the Control of Substances Hazardous to Health (COSHH – see Chapters 2 and 4 relating to the Safety at Work Act).

OBLIGATIONS

An obligation is a duty, usually legal or moral, arising from one's choosing to undertake a course of action. If this obligation is legal it is known as a contract and is legally binding. Contracts may be oral, written or implied and arise from the assumed intentions of the parties concerned. Compensation is the payment for loss or injury sustained and is part of common law – the Law of Tort (an evil wrong independent of contract), which allows for unqualified damages (compensation) to be paid if a contract is broken.

Compensation may be awarded for:

- Trespass, which also involves issues around consent.
- Defamation, which is the publishing of statements tending to lower a person in the estimation of right-thinking members of society. Every patient is entitled to protection against defamatory remarks but if the remark is true the patient has not been defamed. Slander is spoken defamation and the plaintiff must prove that special damage has occurred before guilt is established. It is therefore important that the care worker is discreet at all times. Communication in good faith for the benefit of the patient is permissible but gossip is not.
- Negligence, which will be dealt with later in the chapter.

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More information

CONSENT TO INVASIVE TREATMENT OR SURGERY

THE RIGHTS OF THE PATIENT

With regard to the consent of patients for invasive clinical procedures, ethical and legal points must be considered as these have a bearing on the professional judgements made in consent.

There are six main legal points that influence the obtaining of consent.

1. Under Common Law, a doctor may only administer treatment when a patient gives consent.
2. Under the Law of Trespass, a doctor who proceeds to act in the absence of consent will be liable for trespass, assault or battery.
3. For the consent to be legally valid, the patient must know in broad terms what is involved in the clinical treatment. English law imposes the higher obligation of providing information if the suggested procedure has any potentially significant risks or side effects.
4. Under the Law of Negligence, there is a similar obligation to provide information with the identification of potentially significant risks or side effects (breach of the duty of care).
5. Patient autonomy is a guiding principle of medical law.
6. The principle of self-determination will, in most circumstances, overrule the medicolegal principle of the sanctity of life. This principle entitles a competent adult to reject a specific treatment or select an alternative even at the risk of death, for reasons which may be rational, irrational, unknown or non-existent.

Informed consent to operation has three components as judged by the Thorpe Test (after Lord Thorpe):

1. Understanding and retaining information.
2. Believing the information.
3. The ability to weigh up and decide on the basis of that information.

Patients are entitled to receive sufficient information in a way that they can understand about the proposed treatments, the possible alternatives and any substantial risks so that they can make a balanced judgement. In some circumstances an interpreter may be needed. Patients must be allowed to decide whether they agree to treatment and may refuse or withdraw consent at any time. Guidance on the amount of information and warnings of risk to be given to patients can be found in the judgement of the House of Lords – Sideway v Gov. of Bethlem Royal Hospital (1985).

Patient autonomy is sacrosanct in law but the problem doctors and other carers face is what to tell patients: how much, how little or exactly what? In this regard, perhaps the following should be considered when providing information to the patient:

- The reasons for the procedure.
- The nature of that procedure including such things as the anaesthetic, duration of stay and physical/mental incapacity.
- The benefits.
- The discomforts.
- The substantial risks.
- The alternatives.
- The consequences of not having the procedure.

It is for this reason that NHS Trusts are now producing specific information sheets for the most common operative procedures and these include the main complications of the operation. The Clinical Negligence Scheme for Trusts (CNST) has replaced the now removed Crown Immunity and is the current standard for indemnification within Trusts. It has advised that only doctors who are capable of performing a procedure should explain that procedure to the patient and subsequently obtain the consent. In practice, the phrase 'by an appropriately qualified and experienced person' is more commonly used. This has radically changed the way that many surgical departments function because traditionally the houseman and not the surgeon was the individual charged with completing the consent form. Patients who are now admitted on the day of surgery often do not receive premedication because consent may not be obtained if the patient is under the influence of drugs.

The wishes of the patient should always be respected and this is particularly important when patients may be involved in the training of clinical students. Although information is sent out to the patient prior to admission, further explanation is often necessary. It should, however, be made clear that a patient may refuse to agree to a student being present without detriment to their care.

Unfortunately, it would appear that many patients are unaware of the nature of their operation or of the importance of informed consent. 'Ethical Issues in Anaesthesia' (see Recommended Reading) deals with this subject in detail and so we have only provided a few examples.

- Byrne et al (1988) – 45% of patients could not recall the basic details of the operation and 45% did not know the reason for their operation.
- Askew et al (1990) – 40% of patients could not name one risk or complication of the procedure.

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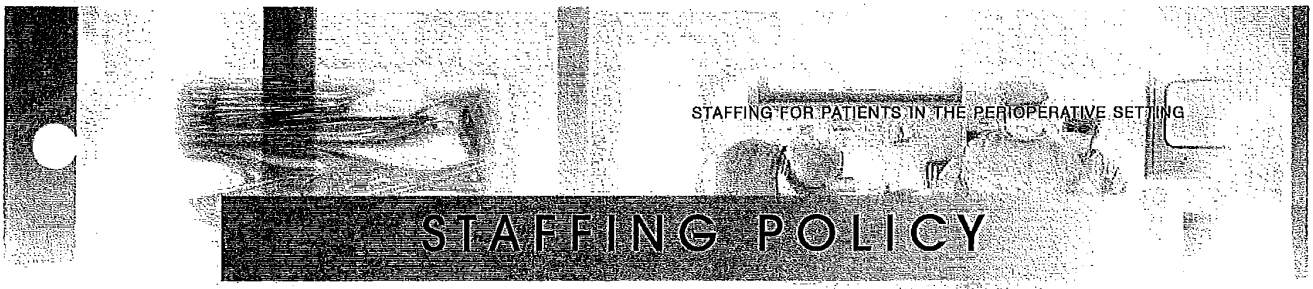

STAFFING POLICY

Name of organisation:

Subject: Management of operating sessions for elective and scheduled surgery

Date of implementation:

Date of review:

Person responsible for policy implementation and review:

Policy location:

1 Introduction

Effective organisation by all members of the perioperative caring team is essential for the efficient management of elective and scheduled operating sessions. This template policy has been devised to facilitate the effective use of resources in order to enhance clinical efficiency within the operating department. Adherence to this policy should prevent the overrunning of elective and scheduled operating lists and will provide guidance to all theatre users.

2 Aims of the policy

2.1 To optimise the effective use of human and physical resources through proactive coordination, in order to facilitate the delivery of high quality patient care to patients admitted for elective and scheduled surgery.

2.2 To reduce and prevent the cancellation of elective and scheduled surgery by ensuring that allocated theatre time is planned effectively and that perioperative personnel are deployed appropriately to meet the identified service demand.

3 Objective of the policy

To ensure that all theatre users are aware of the optimal means of utilising allocated theatre time, and its associated resources, for the delivery of an elective/scheduled operating session.

4 Definitions used

THEATRE COORDINATOR/TEAM LEADER: The most senior Registered Nurse/Operating Department Practitioner. The theatre coordinator/team leader is in charge of the theatre team on a particular shift.

ELECTIVE: Operating list organised and delivered at a time that is planned within the operating schedule/contract as agreed by the Theatre Users' Committee or relevant forum.

EMERGENCY: The requirement for an operative procedure or collection of procedures that is judged to be life threatening, or requires prioritising over and above meeting the needs of patients scheduled for a designated elective list.

5 Times of operating sessions

5.1 The operating session should allow for three and a half hours of operating time, and half an hour for the postoperative recovery of a patient and the effective decontamination of the operating theatre.

5.2 The morning session may be defined as:

09:00–12:30 hrs operating time

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12:30–13:00 hrs recovery and cleaning time.

5.3 The afternoon session may be defined as:

13:30–17:00 hrs operating time

17:00–17:30 hrs recovery and cleaning time.

AfPP acknowledges that many operating departments, especially within the independent sector, are managing three operating sessions a day where capacity permits. AfPP also acknowledges that all day operating lists with the same operating consultant are becoming increasingly popular due to increasing efficiency of theatre utilisation. In this situation the principles of indicators stated in 5.1 will still apply.

5.4 In the case of a planned all day operating list the allocated sessions may be from 09:00–16:00.

5.5 It is the responsibility of the consultant operating surgeon or nominated theatre scheduler when planning elective and scheduled operating lists to ensure that as far as is reasonably practicable, allocated operating session times are not exceeded. Theatre resources can then be utilised appropriately.

6 Cancellation of elective/scheduled patients

6.1 In situations where the operating surgeon is about to, or has actually run out of allocated session time, the coordinator or designated team leader of the theatre concerned, in collaboration with the consultant anaesthetist should cancel any further cases to prevent the operating list from overrunning.

6.2 The surgical team responsible for the operative list should ensure that all patients affected by the decision to curtail the list receive an explanation as to why it was deemed necessary to postpone or cancel their planned surgery.

6.3 The appropriate clinical incident form must be completed by the coordinator or designated team leader, stating the reason for cancellation and who was involved in making this decision.

6.4 In the absence of a coordinator or designated team leader the anaesthetic assistant should seek advice from the most senior member of staff on duty within the operating department.

6.5 To ensure effective management of perioperative resources it must be accepted by all staff that only the coordinator or designated team leader have the authority to authorise the collection of/sending for patients.

6.6 All cancellations should be audited monthly to determine whether theatre scheduling has been effective. This process should include Anaesthetic and Surgical Directorates, the main coordinator/scheduler and medical secretaries, as recommended by the National Confidential Enquiry into Perioperative Deaths (NCEPOD 2001).

7 Planned overrunning of sessions

The Audit Commission (2003) estimated that in about 5% of hospitals in the UK, the majority of operating lists were consistently over running. Some operating lists are predictably over booked which is unacceptable. Research by Pandit and Carey (2006) recommends that when planning the operating list estimates of operating times to plan lists would reduce the incidence of predictable overruns and cancellations.

7.1 In situations where it is anticipated that the complexity of a procedure or the nature of the operative case will result in a longer than scheduled operating time, it is the responsibility of both the consultant surgeon and the anaesthetist to liaise with the coordinator/designated team leader. The priority is to ensure that the appropriate physical and staff resources can be organised and secured.

7.2 In circumstances where a consultant surgeon or anaesthetist may wish to commence the scheduled operating list at an earlier time than that allocated or published, they must liaise with the coordinator or designated team leader to ensure that appropriate human and physical resources are available. If the necessary resources are not available then the coordinator/designated team leader should inform both the consultant surgeon and the anaesthetist as soon as is reasonably practicable.

8 Ensuring an effective response to emergency situations

8.1 If the organisation wishes to provide a responsive emergency service, then a designated 24 hour operating theatre, managed by trained and competent staff, must be resourced (NCEPOD 1997).

8.2 The staff rostered/designated to provide emergency cover must not be used to supplement the staffing establishment that service/support elective or scheduled cases. It must be ensured that they are available to provide an immediate response to emergency incidents.

8.3 In situations where emergency teams comprise a minimum of three registered personnel, and a risk assessment regarding prioritisation of service and patient dependency has been conducted, one individual may, at the discretion of the coordinator or

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designated team leader, be directed to assist where a significant staffing problem has occurred. This is acceptable only on the understanding that the individual will be recalled in the advent of an emergency situation.

8.4 Anaesthetists and surgeons rostered for emergency work should be free from other commitments (NCEPOD 1997).

9 Cancellation/changes to the operating list

9.1 All operating lists should arrive in the operating department 16—24 hours in advance of a scheduled session, in order to ensure patient safety and the effective utilisation of resources (AfPP 2007).

9.2 Any changes or cancellations to the operating list must be relayed immediately to the person in charge of the operating list.

9.3 All copies of the operating list or send-for slips must be amended as appropriate by the person making the changes and all appropriate members of staff must be notified (AAGBI 1995).

9.4 The persons making the amendments must sign and add a note to the side of the list: 'Note change to order'. The appropriate untoward incident form should be completed detailing the reasons why the change in order was indicated.

9.5 All relevant staff should be informed, including the wards, radiological departments and support services as appropriate.

9.6 It must be acknowledged by all staff that to change the order of an operating list creates the potential for error and that changes to a published schedule should only occur in extreme circumstances and only when absolutely necessary. The importance of documenting the circumstances of any change, via the appropriate untoward incident form, should be viewed as fundamental to securing improvements in future scheduling practice.

10 Staffing of elective/scheduled operating lists

It is the responsibility of the coordinator or designated team leader to ensure that every elective and emergency operating list is staffed by a team of appropriately trained and competent personnel who are equipped with the skills and abilities to administer high quality patient care and who are able to identify and minimise any risks to the patient as they journey through the perioperative environment. It is recommended that the formula for calculating staffing establishment advocated by AfPP (see pages 18–22 of this document) are utilised.

The recommendations include:

- ONE REGISTERED ANAESTHETIC ASSISTANT PRACTITIONER for each session involving an anaesthetic
- TWO SCRUB PRACITIONERS as the basic requirement for each session, unless patient dependency and/or clinical service demand more or less. Two practitioners are recommended for a list of major surgery unless there is only one case. Two practitioners are recommended for a list of minor surgery that demands a quick throughput or has several cases on it such as for an elective day surgery list
- ONE CIRCULATING STAFF MEMBER for each session unless there is a requirement for more, i.e. when two cavities are opened, for example anterior and posterior resection.
- ONE PRACTITIONER TO ACT AS ANAESTHETIC ASSISTANT for each session involving an anaesthetic and/or anaesthetist. This includes sessions where local sedation or regional anaesthesia is administered. There may be occasions when more than one assistant is required due to patient dependency/type of anaesthesia.
- ONE RECOVERY PRACTITIONER per patient for the immediate postoperative period. There may be occasions when two recovery practitioners are judged to be required if there is a quick throughput of patients requiring minor procedures, such as in a surgical day unit.
- If the patient is not returning to a special care area such as a High Dependency Unit immediately after surgery, they need to be cared for by practitioners who are trained and experienced in post-anaesthetic care.

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