Witness Statement Ref. No. 077/2

NAME OF CHILD: ADAM STRAIN

Name: Ian Carson

Title: Dr.

Present position and institution:

Retired.

Non-Executive Chairman, Regulation & Quality Improvement Authority (Part-time Public Appointment).

Previous position and institution:
[As at the time of the child's death]
Medical Director, Royal Belfast Hospital for Sick Children ('RBHSC') – INCORRECT

Medical Director, Royal Group of Hospitals & Dental Hospital HSS Trust.

Membership of Advisory Panels and Committees:
[Identify by date and title all of those since your Witness Statement dated 8th July 2005]

Nothing outside my role as Deputy CMO up to my retirement in April 2006, and my appointment as Chairman, RQIA (June 2006 to present date).

Previous Statements, Depositions and Reports:
[Identify by date and title all those made in relation to the child's death since your Witness Statement dated 8th July 2005]

None.

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

Ref:	Date:	
077/1	08.07.2005	Witness Statement to the Inquiry

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

(1) Please provide the following information:

(a) State your medical qualifications as of 1995;

MB, BCh, BAO (1968); FFARCSI (1972); MD (Hons) (1974)

(b) State the date you qualified as a medical doctor; *1968*

(c) Describe your career history before you were appointed Medical Director, RBHSC (Incorrect) *Royal Group of Hospitals HSS Trust;*

Pre-registration House Officer, Royal Victoria Hospital, 1968-69; Post-graduate training posts in anaesthesia within the rotational scheme organised by the N.Ireland Council for Post-Graduate Medical & Dental Education 1969-1974; Visiting Professor of Anesthesiology, Stanford University Medical Center, California, USA; Consultant Anaesthetist, Cardiac Surgical Unit, Royal Victoria Hospital, 1975-2002.

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

I did not have any contractual commitments in the RBHSC, although I would have seen paediatric patients pre-operatively and post-operatively following cardiac surgery in the Royal Victoria Hospital.

(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 have provided a copy of my Eastern Health & Social Service Board 'contract of employment' dated 11 Nov 1975 on appointment as a Consultant Anaesthetist with a major interest in Cardiac Surgery Anaesthesia. I do not have a copy of the job description.

I do not have a copy of the job description covering my appointment as Medical Director, for the Royal Group of Hospitals & Dental Hospital HSS Trust in April 1993.

This was a part-time appointment (4 days per week), and I continued with my clinical duties (1 day per week, plus emergency on-call). In 1993 the principle role of the Medical Director was to provide medical leadership within the Trust; at a corporate level to advise the Chief Executive and the Board of the Trust on all medical policy and strategy matters; and to deputise for the Chief Executive in his absence.

(f) Describe the accountability of the Medical Director at that time.

I reported to and was accountable to Mr William McKee, Chief Executive, Royal Group of Hospitals & Dental Hospital HSS Trust.

II. QUERIES ARISING FROM YOUR PREVIOUS STATEMENT (WS-077/1)

"My understanding is that Dr. George Murnaghan (Director of Medical Administration, Royal Hospitals) and I had discussed the finding of H.M Coroner's Inquest on or around 17th to 21st June 1996" (Ref: 059-001-001).

(a) What issues were discussed?

I am unable to recall the detail of this discussion.

(b) Was a record kept of these discussions?

Not by me.

(c) Were the findings of the Coroner regarded by you as a risk management issue?

I am unable to recall my views on the matter at that time, but in general it would be expected that the Coroner's findings and report would be considered to make a contribution to risk management arrangements.

(d) What did you do as a result of these discussions?

I am unable to recall the outcome following this discussion.

(e) Did you attend any further review or seminar arising from the same?

Not that I can recall.

(f) Was a further review or seminar held? If so when and where?

I am unable to recall if anything further was held or where.

(g) Did you have any further discussions with Dr. Murnaghan in relation to matters arising from the Inquest, and if so please provide full details.

I am unable to recall any further discussions with Dr. Murnaghan.

III. INTERNAL CONTROL

(2) What systems for internal control were in place within the Trust in 1995 to monitor clinical quality?

I cannot recall when 'Controls Assurance Standards', and which ones were introduced for Trusts. There was no statutory 'duty of quality' in place for HSS Trusts in 1995. This was introduced w.e.f 25th April 2003.

(3) Please state whether there were any procedures, protocols and/ or practices governing paediatric renal transplant surgery at the RBHSC, and if so what procedures for periodic review and updating for such protocols were there?

I am unable to provide this information. If these existed, they would have been drawn up by, reviewed by, and updated by the clinical professionals within RBHSC, and maybe in conjunction with the EHSSB as Commissioner.

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

Healthcare professionals would have been individually expected to follow the guidance on standards issued by their respective professional regulatory body, in the case of doctors, this would be the GMC. The GMC's guidance "Good Medical Practice" was first published in 2001.

(5) How did clinical based management operate in 1995?

In 1995 the Royal Group of Hospitals & Dental Hospital HSS Trust management structure was based on a system of Clinical Directorates, each with its Clinical Director and supporting management team. The Clinical Director, usually a senior consultant in the Directorate, was in direct line management and accountable to the Chief Executive. The Clinical Director post was part-time with usually 1-2 'notional half-days' allocated for management responsibilities.

IV. HEALTH AND SAFETY

(6) In its **Health and Safety Report for 1995/96,** the Trust reported that *"a full internal investigation"* had been conducted into an incident in which a patient had died in November 1995 (DLS letter to the Inquiry dated 22nd December 2011). If this patient died in the RBHSC please address the following:

The patient did not die in the RBHSC.

(a) Why was a full internal investigation conducted in relation to this death?

(b) In what circumstances had the patient died?

(c) Who was responsible for conducting the investigation?

(d) Under what procedures was the investigation conducted?

(e) What particular steps were carried out as part of the investigation?

(f) Who was the report presented to, and circulated to?

(7) Had the RBHSC taken any steps to implement guidance for children, including that in:

(a) **Welfare of Children and Young People in Hospital'**, Department of Health (1991), HMSO IBSN 0113213581?

It is unlikely that guidance issued by the DoH in England would have been acted on by the RBHSC without prior consideration by the DHSSPS. However, the Paediatric Directorate RBHSC may be able to comment.

(b) **'Children First – A Study of Hospital Services'**, Audit Commission (1993) HMSO IBSN 0118860968?

It is unlikely that guidance issued by the Audit Commission in England would have been acted on by the RBHSC without prior consideration by the DHSSPS. However, the Paediatric Directorate RBHSC may be able to comment.

If so:

(i) What were those steps?

(ii) When were they instituted?

(iii) Was their implementation monitored and if so please provide record of the same?

(iv) Who was responsible in the RBHSC for implementing such guidance for children?

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

(a) The composition of a paediatric operating theatre team;

Appropriately trained or supervised medical, nursing and ancillary staff.

(b) The minimum staffing requirements thereof;

This is outside of my knowledge and would be more appropriately addressed to the Paediatric and Anaesthetic Directorates.

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

It depends on the complexity of the procedure being undertaken, and the pre-operative condition of the patient.

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

Unexpected or unexplained deaths during or following anaesthesia and surgery would be reported externally to HM Coroner, and internally to Dr G.Murnaghan in his capacity as Director of Medical Administration. Any issues specifically for anaesthetic staff would be a matter initially for the Anaesthetics Directorate.

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

Guidelines issued by professional bodies such as the Association of Anaesthetists of GB & Ireland, or the Royal College of Anaesthetists would be followed.

(f) The documentation and record keeping in respect of anaesthetic equipment. *Guidelines issued by professional bodies such as the Association of Anaesthetists of GB & Ireland, or the Royal College of Anaesthetists would be followed.*

V. KINGS FUND ORGANISATIONAL AUDIT

(9) What knowledge do you have of the King's Fund accreditation process?

I am aware that many hospitals in Northern Ireland (including the Royal Hospitals) participated in the King's Fund accreditation process in the 1990s.

(10) If you participated in that process, specify the steps that you took?

I was not responsible for commissioning the review process, but I recall being interviewed by members of the review team.

(11) Identify any changes in practice which occurred as a result of engaging with the Kings Fund process, both in respect of improving systems of risk management at a clinical and corporate level, and in any other respect?

Unable to recall the outcome of the review process, but it would have contributed in some way to the improvement of risk management arrangements.

(12) Were these steps considered sufficient to obtain full accreditation and if not, why not?

I am unable to recall the outcome.

VI. CLINICAL/MEDICAL AUDITS

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

In 1995 clinical audit would have been conducted within the clinical directorates of the Royal Hospitals Trust. This would be more appropriately addressed with the Paediatric Directorate RBHSC.

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

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

Yes – but this would be more appropriately addressed with the Paediatric Directorate RBHSC.

(b) Did you play a role in connection with the Clinical Audit Committee? *No.*

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

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

(d) Who formed the Clinical Audit Committee?

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

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

Each Clinical Directorate would have had a lead clinician for clinical audit, and usually a Clinical Audit Committee.

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

Every consultant would have professional responsibility to participate in clinical audit, but there would be no stipulated minimum or maximum number of audits to be undertaken. Clinicians would have had limited 'protected time' to undertake clinical audit, and there were limited resources centrally to support clinical audit.

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

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

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

Results may have been disseminated nationally in a number of specialties (e.g.

Stroke, Cardiac Surgery), or regionally to Area or Regional Audit Committees, and to the Trust Clinical Audit Department for possible inclusion in the Trust Audit Report. I cannot recall when the first Trust Audit reports were produced.

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

Medical/clinical audit provided an opportunity for education and learning. It could also result in change of clinical practice where necessary.

(14) Please particularise all steps taken by the Trust/ RBHSC to investigate the unexpected death of Adam Strain.

I cannot recall what steps were taken by the Trust, and it would be more appropriately addressed with the Paediatric Directorate RBHSC.

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

Some Clinical Directorates may have included case note reviews as part of their audit programme, but there was no regular trust-wide systematic review of case notes.

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

Clinical Audit was in place within the Trust.

(17) What steps were taken to achieve the objectives outlined in **HPSS Management Plan 1995/96-1997/98** with particular reference to paragraph 4.4.11 and the adoption of a policy of clinical audit as part of a program to improve service quality and state when each such step was taken?

I am unable to recall the outcome following the publication of these objectives; but what was recognised generally was that very limited resources were available to support clinical audit in HSS Trusts. In the Royal Hospitals, the Audit Department had at the most 5 or 6 trained audit assistants to work across all 12 clinical directorates.

VII. CONSENT

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

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

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 were distributed to clinical staff;

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

(19) 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;

DHSSPS Circulars were received in the Office of the Chief Executive, and then forwarded to clinical directorates for action/implementation.

(ii) Monitor and record compliance with the same;

I do not recall any formal system to monitor or record compliance at that time.

(iii) Enforce compliance.

I do not recall any formal system to enforce compliance at that time.

(20) 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 recall any formal system to monitor compliance at that time.

(21) 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.

This *would be more appropriately addressed with the Paediatric Directorate RBHSC.*

VIII. RECORD KEEPING

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

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

If so,

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

(b) Describe its main features;

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

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

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

(f) 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;

(g) 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;

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

(23) In 1995, had the RBHSC established a Medical Records Committee?

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

If so, please address the following:

(a) Who formed the membership of this committee?

(b) Did you play a role in connection with the committee? *No.*

(c) What rules regulated the operation of this committee?

(d) What was the purpose of the committee?

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

(24) With respect to the recommendations deriving from:

(a) **Department of Health Circular HC (89)20;**

(b) **Department of Health Circular HSG (94)11;**

(c) **HSC 1999/053- 'For the Record-Managing Records in NHS Trusts and Health Authorities;**

(d) **The 1995 Audit Commission study 'Setting the Records Straight, a study of hospital health records';**

(e) **The Royal College of Surgeons of England Guidelines for Clinicians on Medical Records and Notes (1990, revised 1994).**

Please state what steps the Trust took to:

(i) Disseminate this guidance and to whom;

I cannot recall what steps might have been taken. There was no mechanism whereby DoH (England) circulars would have been circulated. Awareness of Audit Commission or publications from professional bodies would have been for information only, and would have required direction by the DHSSPS.

(ii) Monitor and record compliance with the same;

I do not have this information, and I do not recall any formal system to monitor and record compliance at that time.

(iii) Enforce compliance.

I do not recall any formal system to enforce compliance at that time.

(25) What guidance was provided to medical staff in respect of:

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

I do not have this information and this would be more appropriately addressed with the Paediatric Directorate RBHSC.

(b) Recording weights in children?

I do not have this information and this would be more appropriately addressed with the Paediatric Directorate RBHSC.

(c) Monitoring effectiveness of peritoneal dialysis?

I do not have this information and this would be more appropriately addressed with the Paediatric Directorate RBHSC.

(d) The completion of patient records?

I do not have this information and this would be more appropriately addressed

with the Paediatric Directorate RBHSC.

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

I am not aware of any system or systematic checklist whereby the Trust would have assured itself that Clinical Directors/Directorates had disseminated guidance, policy or procedures, yet alone compliance by individual clinicians. A system of directorate 'accountability reviews' was introduced much later (late 1990's / 2000) as 'performance management' was developed within the Trust

IX. COMMUNICATION

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

I do not have this information. This would be more appropriately addressed with the Paediatric Directorate RBHSC.

(28) If so please provide:

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

(b) Describe its main features;

(c) 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;

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

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

I am not aware of any system or systematic checklist whereby the Trust would have assured itself that Clinical Directors/Directorates had disseminated guidance, policy or procedures, yet alone compliance by individual clinicians. A system of directorate 'accountability reviews' was introduced much later (late 1990's / 2000) as 'performance management' was developed within the Trust.

(29) 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 am unable to recall any formal Trust guidance on this matter at that time; it is more likely that this would have been seen as the professional responsibility of the senior doctor/consultant in charge of the case.

X. **BLOOD GAS MACHINES**

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

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

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 were being complied with by members of clinical teams.

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

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

(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.

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

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

If so, please address the following:

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

(b) Did you play a role in connection with the committee, group or team? *No*

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

(d) What was its purpose?

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

(33) With respect to the recommendations deriving from:

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

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

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

(d) **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;**

(e) **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;

I do not have this information

(ii) Monitor and record compliance with the same;

I do not recall any formal system to monitor or record compliance at that time.

(iii) Enforce compliance.

I do not recall any formal system to enforce compliance at that time.

XI. LABORATORY TESTING

(34) In 1995 did the RBHSC have guidance, policy or procedures in place which governed the conduct of biochemical laboratory testing during major surgery? If so, please provide the same.

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

XII. THEATRE EQUIPMENT

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

(a) The purchase;

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC or the Anaesthetics Directorate.

(b) Maintenance; and

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC or the Anaesthetics Directorate.

(c) Replacement of theatre equipment,

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC or the Anaesthetics Directorate.

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 were distributed to clinical staff;

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

I am not aware of any system or systematic checklist whereby the Trust would have assured itself that Clinical Directors/Directorates had disseminated guidance, policy or procedures, yet alone compliance by individual clinicians.

(36) 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?

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

If so, please address the following:

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

(b) Was the guidance, policy or procedure 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 were being complied with by members of clinical teams.

(37) 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:

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

(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?

(38) What steps were taken in Adam's case in relation to the following:

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC.

(a) To identify the theatre equipment used during his renal transplant surgery;

(b) To inspect that equipment;

(c) To report on it.

Describe fully any steps that were taken in respect of any of these matters and state,

(i) When the steps were taken; and

(ii) By whom they were taken.

(39) In relation to the Coroner's direction that steps should be taken to ensure that the Siemens Monitor used during Adam's surgery was the subject of independent examination, please address the following:

I do not have this information. This would be more appropriately addressed with the Paediatric Directorate RBHSC, or with Dr G.Murnaghan.

(a) Who was responsible for acting on the Coroner's direction?

(b) What steps did this person take?

(c) When did s/he take them?

(d) Who carried out the examination of the equipment?

(e) Were these persons independent?

(f) Were these persons able to examine the equipment used at the time of Adam's surgery?

(g) Did they produce a report?

(h) Who was the report directed to?

(i) What conclusions did they reach?

(j) Was any action taken by the RBHSC/ Trust on foot of the report?

(k) Was the Coroner provided with a copy of the report?

(l) What steps did the RBHSC/ Trust take to ensure that the Coroner's requirements were complied with?

(40) **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?

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC; or the Trust Estates Department or Dr G.Murnaghan.

If so,

(a) Explain fully how it was applied;

(b) Who applied it?

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

XIII. DISSEMINATION AND INSTITUTIONAL LINKS

(41) 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?

This is outside of my knowledge and this would be more appropriately addressed with the Paediatric Directorate RBHSC.

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 were being complied with by members of clinical teams;

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

(42) 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?

This is outside of my knowledge and this *would be more appropriately addressed with the Paediatric Directorate RBHSC.*

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?

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

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

(d) When were those steps taken?

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

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

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

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

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

(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?

(43) The Trust published a statement on the 21 June 1995 indicating changes in practice following Adam's death which had been endorsed by the Consultant Paediatric Anaesthetists (011-014-107a).

Please address the following:

(a) Who endorsed this statement?

I am unaware of it being 'endorsed' formally by the Trust or by any other outside panel of experts.

(b) To whom was the statement distributed?

I do not have this information.

(c) If it was not distributed outside of the RBHSC/ Trust, please explain the reasons for that?

I do not have this information.

(d) If applicable, who decided that the statement would not be distributed outside of the RBHSC/ Trust?

I do not have this information.

(e) Had you read the *'paper by Arieff et al (BMJ 1992)'* at the time this statement was published?

I cannot recall.

(f) What date was it published and by what means?

I do not have this information.

(44) Following the Inquest into Adam's death it was agreed that the *"other issues identified"* at the Inquest would be dealt with and that a seminar would be arranged for that purpose and would involve the following clinicians: Doctors Mulholland, Gaston, Savage, Taylor, Hicks, O'Connor and Mr. Keane (Ref: 059-001-001).

Please address the following:

(a) Did that seminar take place? If it did not take place, please explain why it didn't take place?

I cannot recall whether a seminar did or did not take place.

(b) Upon the assumption that it did take, place please provide any record associated with the meeting or its conclusions and address the following:

(c) When did it take place?

I do not have this information.

(d) Who attended?

I do not have this information.

(e) What was discussed?

I do not have this information.

(f) What conclusions were reached?

I do not have this information.

(g) Were these conclusions disseminated, and if so, when and to whom?

I do not have this information.

(45) 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?

This would be more appropriately addressed with the Paediatric Directorate RBHSC or the Anaesthetics Directorate. I am not aware of any formal steps being taken by the Trust.

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?

(e) Did you formally appraise Dr. Taylor's management of the Adam Strain case? *No.*

(46) 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?

Every adverse incident, including deaths whether expected or unexpected, provide an opportunity for learning. Medical professionals have used 'Morbidity & Mortality Case Conferences' as learning opportunities for many years.

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

Not that I can recall, deaths (even unexpected deaths) in the Royal Group of Hospitals were not formally reported to the Medical Director as a routine.

(48) Please state whether there existed, in the period both before and after the death of Adam Strain in 1995, a formal approach to:

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

No formal approach existed that I can recall.

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

No formal approach existed that I can recall.

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

No formal approach existed that I can recall.

XIV. INTERNAL REVIEW

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

I do not have this information. This would be more appropriately addressed with the Paediatric Directorate RBHSC.

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

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

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

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

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

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

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?

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

I do not recall. This would be more appropriately addressed with the Paediatric Directorate RBHSC.

(51) With reference to:

(a) **'Reporting of Accidents in hospitals' (1955)** guidance;

(b) **'Risk Management in the NHS' (1993)** guidance;

(c) **'EL (94) Report 'The Allitt Inquiry' (1994)** recommendations;

Please particularise how the above were taken into consideration when formulating the RBHSC response to the unexpected death of Adam Strain?

I was not involved in formulating 'the RBHSC response' to the death of Adam Strain. This *would be more appropriately addressed with the Paediatric Directorate RBHSC.*

XV. OTHER

(52) In respect of the clinical negligence action commenced 25th April 1996 and settled 29th April 1997 please state:

(a) Why was a confidentiality clause was made a term of settlement?

This is outside of my knowledge and may be more appropriately addressed with Dr G.Murnaghan.

(b) Did the litigation restrict the scope of explanation offered to Adam's parents?

As above

(c) Did the litigation restrict the scope of dissemination of information in respect of learning both internally and externally?

As above

(d) Were the clinical staff involved in Adam's case kept informed of all aspects of the outcome of the clinical negligence case?

I don't know. It would have been common practice to inform those staff who provided statements in regard to the outcome of the case. This would be more appropriately addressed with Dr G.Murnaghan.

(53) Has any consideration been given to viability of the RBHSC renal transplant facility and if so:

I cannot recall any such consideration being undertaken, but this *would be more appropriately addressed with the Paediatric Directorate RBHSC, and with the EHSSB and the DHSSPS.*

(a) When?

(b) Why?

(c) By whom?

(d) What was considered?

(e) With what outcome?

(f) In light of the publication of the *'Provision of Services for Children and Adolescents with Renal Disease'* (Working Party Report in March 1995)

(54) 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:

This would be more appropriately addressed with the Paediatric Directorate, RBHSC and with the EHSSB, who would have to approve and fund such a transfer.

(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.

(55) What progress was the RBHSC making in 1995 to comply with extant guidance in respect of both general and specialist children's services?

This is outside of my knowledge and would be more appropriately addressed with the Paediatric Directorate RBHSC

(56) Were there any procedures, protocols or practices in 1995 governing paediatric renal transplant surgery? If so, please address the following:

This is outside of my knowledge and would be more appropriately addressed to the Paediatric Directorate, RBHSC.

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

(b) Was the guidance, policy or procedure 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 were being complied with by members of clinical teams;

(e) Was there a system for periodic review and updating of any such policy, protocol or guidance?

(57) Please describe and particularise the experience gained by the RBHSC by 1995 as a paediatric renal transplant centre in relation to other UK centres?

I do not have this information; this would be more appropriately addressed with the Paediatric Directorate RBHSC.

(58) In respect of the UTV Insight documentary (*'When Hospitals Kill'*- 21st October 2004) please state:

I do not have this information – all contacts with the media were handled by the Mr. Gerry Carson, who was the responsible Director (Corporate Affairs) at that time for the Royal Hospitals HSS Trust.

(a) What requests for information and comment were received from UTV;

(b) What information and comment were given to UTV, specifying by whom, to whom and when;

(c) Please identify those individuals engaged in this process;

(d) Who bore responsibility for this process;

(e) What internal responses were generated by any such requests;

(f) What internal responses were generated by the broadcast of the documentary;

(g) Whether any record or documentation of this process was made, and if so please provide the same;

(h) If same was created, but is now no longer available please state what became of it.

(59) 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 cannot recall what formal protocols were in place in 1995 to respond to the following issues, but it would have been customary practice for the Trust Medical Director to contact (usually by telephone) the Director of Public Health in the local HSS Board, and possibly, if the circumstances justified it, the Chief Medical Officer at DHSSPS. Dissemination to the wider medical community would not normally be the responsibility of the Trust following (a) or (b) below, rather it usually fell to the Health Board through the DPH, or the Department through the CMO.

(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 were 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.

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

I do not have this information; Undergraduate teaching was the responsibility of Queen's University, Belfast, and regulated by the General Medical Council. Post-graduate training was the responsibility of the Northern Ireland Post-graduate Medical & Dental Training Council and the respective Medical Royal Colleges.

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

(b) Record keeping.

(61) 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 cannot recall what steps, if any, were taken to implement NCPOD recommendations; this would be more appropriately addressed with the Paediatric Directorate RBHSC, the EHSSB and/or the DHSSPS.

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

Other than my discussion with Dr. Murnaghan on or around 17th to 21st June 1996, I am unable to recall what action I took following the Inquest, if any.

(63) Please state what steps you took during your time as special advisor to the Chief Medical Officer (CMO) on clinical governance, to address the issue of hyponatraemia. If you took no action please explain why.

My secondment as Special Adviser on Clinical Governance to the CMO commenced in Oct 1999. It was a part-time appointment (I was still an employee of the Royal Hospitals' HSS Trust) and I was principally involved in the development of a consultative document on the prevention, recognition and management of poor performance of doctors in Northern Ireland, entitled "Confidence in the Future". This document was published on 11 Oct 2000. A key outcome from the consultation was the introduction of arrangements for appraisal of all doctors working in Northern Ireland. "Confidence in the Future" also proposed that a framework for clinical governance be introduced in Northern Ireland as a matter of urgency.
I do not recall what steps, if any, were taken by myself during my time as Special Advisor to address the specific issue of hyponatraemia.

(64) 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.

Presumably, because RBHSC was the regional centre for all complex paediatric surgery and intensive care – these cases would not have been done elsewhere in Northern Ireland.

(65) Please explain why you did not inform other hospitals of this amendment on your appointment as special advisor to the CMO on clinical governance in 1999.

My role was that of a 'Special Advisor' to the CMO, and the purpose was to undertake specific work in regard to clinical governance. I had no authority to 'inform other hospitals' - this would have been the responsibility of the CMO.

(66) Were there, in 1995, any procedures, protocols or guidelines governing:

This is outside of my knowledge and would be more appropriately addressed to the Paediatric Directorate, the EHSSB or the DHSSPS.

(a) Transplant ward arrangements for renal transplant?

(b) Receipt, care and management of transplant organs?

(c) Documentation and record keeping in relation to transplant organs?

(d) And if not, why not?

(67) When the RBHSC assumed responsibility for paediatric renal transplant in patients under the age of 14 years from the Belfast City Hospital, why:

I do not have this information; this would be more appropriately addressed to the Paediatric Directorate RBHSC

(a) Did it not create new protocols to govern this new responsibility?

(b) Did it not adopt the Belfast City Hospital's protocols drawn up in July/ August 1992 governing the respective roles of nursing staff on the transplant ward and the donor transplant services?

(c) Did it not formalize procedures and arrangements with the Northern Ireland Organ Donor Services Team Manager?

XVI. EDUCATION, TRAINING AND EXPERIENCE.

(68) 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;

Fluid & electrolyte shifts as part of physiology course in 1963/64 (2nd/3rd year); I am unable to recall much else apart from the importance of maintaining fluid balance and correcting fluid and electrolyte loss with the appropriate replacement fluid. I cannot remember any specific education/training on record

keeping.

(b) Postgraduate level;

Physiology was part of the postgraduate training scheme for Part I of FFARCSI examination 1970/71; I am unable to recall details of training for Part II of the FFARCSI. I am unable to recall the extent of training in record keeping.

(c) Hospital induction programs;

As a junior doctor, probably nothing in regard to fluid management/hyponatraemia; probably some advice in regard to record keeping.

As far as I recall, induction programs for consultants did not exist in 1975.

(d) Continuous Professional Development;

Unable to recall any detail

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

I cannot recall having encountered the problem specifically.

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

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

(c) The nature of your involvement;

(d) The outcome for the children.

XVII. GENERAL

(70) Please provide any further comments you may wish to make.

THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF
Signed:  **Dated:** 14 May 2012

Eastern Health and Social Services Board

Telephone enquiries in connection with this letter should be directed to the Board at

LONDONDERRY HOUSE
CHICHESTER STREET
BELFAST BT1 4RH

Telephone 33811

EHSSB

65 University Street
Belfast BT7 1HN
Telephone 44811
Telegrams EHSSB, Belfast

Secretary & Chief Administrative Officer
William Harvey, O.B.E., M.A.

IN CONFIDENCE

our ref: 5623/52
your ref:

11th November, 1975

Dear Sir,

Appointment as Consultant Anaesthetist with a major interest in Cardiac Surgery Anaesthesia

I am instructed by the Eastern Health and Social Services Board to offer you a whole-time appointment from 24th October, 1975 as Consultant in Anaesthetics with a major interest in Cardiac Surgery Anaesthesia subject to -

(a) the provisions of the Health and Personal Social Services (Northern Ireland) Order 1972 and the Regulations made thereunder;

(b) the terms and conditions of Memorandum S/1/1949 (Revised) dated 30th September, 1973 (as subsequently amended) in so far as they are applicable to whole-time Consultants; and

(c) the terms and conditions of appointment as set out hereunder:

1. The duties attached to the appointment are as follows:-

(a) Regular attendance at the Royal Victoria Hospital and the Northern Ireland Radiotherapy Centre.

You will undertake such duties in your specialty in the above hospitals as may be allocated to you including duties in respect of any patients placed in your care who are admitted under the provisions of Article 31(1) or Article 33 of the Health and Personal Social Services (Northern Ireland) Order 1972.

(b) Attendance as required at Clinics held at or in connection with the above hospitals.

(c) So far as is consistent with your specialty and the proper discharge of the above duties, any additional duties undertaken from time to time as substitute for other members of the staff of the above hospitals during their temporary absence.

(d) Duties arising on call in an emergency at other hospitals administered by the Eastern Health and Social Services Board.

(e) Domiciliary consultations within such periods and areas as may be laid down by the Board from time to time.

31(f) As a Consultant employed at, or for the purpose of, a hospital recognised by the Queen's University of Belfast as a hospital in which undergraduate students in the Faculty of Medicine receive clinical instruction and education, you will give such service as a clinical teacher of students as may be required by the Faculty of Medicine and as may reasonably be undertaken by you in association with, or in addition to, your duties as an officer of the Board. Payment will be made by the University in respect of any such teaching you may be asked by the University to undertake, in accordance with the University's approved arrangements for the making of such payments.

2. The appointment shall not be terminated, except by agreement between the Board and yourself, unless either party has given the other at least three months' notice of the date on which the termination is to take place.

3. You will be required to reside within a reasonable distance of the principal centre at which you undertake duties.

4. An appropriate charge will be made for any board and lodging provided for you in connection with the appointment offered. The amount of this charge will be determined by the Board.

5. Membership of a medical protection or defence organisation must be maintained by you.

6. You will be remunerated at the appropriate rate in accordance with Memorandum S/1/1949 (as amended) in so far as applicable to your grade. Such remuneration will be applied on the basis of whole-time service (including travelling time) and your commencing salary will be at the rate of [redacted] payable monthly, and your incremental date will be 1st October.

7. The salary will be subject to a deduction in accordance with the provisions of the Health Services (Superannuation) Regulations made by the Department of Health and Social Services.

8. This offer of appointment is conditional on your passing a medical examination in accordance with Memorandum S/1/1949, paragraphs 186/187 and on the required Medical Certificate being received by the Board.

9. If you agree to accept the appointment on the terms specified above, please sign the form of acceptance at the foot of the enclosed copy of this letter and return that copy (completed) to me.

Yours faithfully,

[redacted]

Secretary and Chief Administrative Officer

Dr. I.W. Carson, F.F.A.R.C.S.,

[redacted]

I hereby accept the appointment mentioned in the letter to me dated 11th November, 1975 from the Secretary and Chief Administrative Officer, Eastern Health and Social Services Board, of which the above is a copy, on the terms and subject to the conditions of service referred to in that letter.

Signed: [signature]

Date: 27th November 1975

/mr

THE ROYAL GROUP OF HOSPITALS AND DENTAL HOSPITAL HSS TRUST

Clinical Governance : a framework for continuous improvement in quality of clinical services and the maintenance of high standards of care within the Royal Hospitals Trust.

I.W.CARSON
Medical Director

April 1999

Summary

1. Clinical governance sets out to ensure:

that systems to monitor the quality of clinical practice are in place and are functioning properly that clinical practice is reviewed and improved as a result that clinical practitioners meet standards, such as those issued by the national professional regulatory bodies. Clinical governance puts in place a controls assurance function for the systems of clinical quality management.

2. The systems embraced by clinical governance include:

* Systems to achieve quality improvement

plus:

- Systems to ensure lessons learnt are implemented

plus:

- A mechanism to ensure all systems are in place and functioning effectively.

3. Clinical governance must build on the good and effective systems already in place, and must be integrated fully into all aspects of care.

4. There are major implications for individuals, organisations and for the NHS in introducing clinical governance. Chief among these are:

- Development of leadership skills and knowledge amongst clinicians.
- Development of mechanisms to ensure the 'audit loop' is closed - that is, to ensure that change in clinical practice takes place in the

light of audit, research, evidence, risk management and complaints findings.

- Development of appropriate accountability structures in both primary and secondary care.
- Creation of effective links between primary care and secondary care.
- Implementation of evidence-based practice across organisations.
- Improvement of the clinical information infrastructure of the NHS.
- Development of effective multidisciplinary and interagency working.
- Integration of continuing medical education and continuing professional development into quality improvement programmes.

CLINICAL GOVERNANCE - THE TEN 'C's

CLINICAL PERFORMANCE
CLINICAL LEADERSHIP
CLINICAL AUDIT
CLINICAL RISK MANAGEMENT
COMPLAINTS
CONTINUING HEALTH NEED ASSESSMENT
CHANGING PRACTICE THROUGH EVIDENCE
CONTINUING EDUCATION
CULTURE OF EXELLENCE
CLEAR ACCOUNTABILITY

with acknowledgement to North Thames Department of Postgraduate Medical and Dental Education

1.0 What is clinical governance?

'Clinical governance can be defined as a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. "

"A First Class Service: Quality in the new NHS"; p.33

The systems embraced by clinical governance include:

systems to achieve quality improvement, such as -

- clinical audit
- risk management
- evidence based clinical practice
- implementation of clinical effectiveness evidence
- development of clinical leadership skills
- continuing education for all clinical staff
- audit of consumer feedback
- management of the clinical performance of colleagues
- effective management of poorly performing clinical colleagues
- developing guidelines and protocols
- accreditation of hospitals, community providers and primary care groups
- continuing professional development for all staff

plus:

systems to ensure lessons learnt are implemented

plus:

a mechanism to ensure all systems are in place and functioning effectively.

1.1 Clinical governance within health care organisations provides a clear framework for the achievement of quality improvement. Quality in this context means quality of clinical care as well as customer care. Clinical governance brings together all the processes needed to achieve the highest quality clinical practice possible, within the constraints of

the resources available, thereby forming a major contribution to the local health improvement programme.

1.2 Clinical governance is not simply a set of systems: far more important is the culture and attitude of all who work in the NHS clinical practitioners and managers alike. All must understand the underlying principle of clinical governance, which is that clinical standards and quality improvement are to be monitored and reported in the same way that financial probity and value for money are currently monitored and reported; they are, at the very least, of equal status. The success - or otherwise - of trusts will be judged on the basis of clinical performance, as well as on financial performance. For this to succeed, however, basic systems must be in place.

1.3 Clinical governance integrates processes for clinical audit, risk management, processes for identifying and helping poorly performing practitioners, systems for re-certifying practitioners, supporting those who function well to be even better, promoting clinical effectiveness and continuous professional development along with audit of consumer feedback - into a single system for quality improvement. It can be described as an agreed, collective stewardship for the clinical services, within a framework of corporate governance, governed by the same principles and exercised through systems and processes.

All clinical practitioners will be expected to meet the standards set out by their professional bodies;
Good Medical Practice (GMC) for doctors, and
Nurses, Midwives and Health Visitors (Professional Conduct) Rules 1993 (UKCC) for nurses, and organisations will be expected to demonstrate systems for ensuring this.
Increasingly Royal Colleges and other professional bodies are issuing specific guidance on standards. With the introduction of clinical governance, there will be a single focus of accountability, along with a range of mechanisms to ensure implementation. This will mean that the aspiration to a serious, explicit and "monitorable" approach to quality improvement - currently evident in only a small number of health care organisations - becomes a mandatory and achievable requirement for all trusts and primary care groups. Clinical governance should be aligned with, and inform, service development so that

organisational and directorate-level investment decisions are based on assessment of clinical performance as well as need. Professional development should be aligned to achieving clinical governance.

1.4 In order to deliver clinical governance, a number of cultural changes must take place. Principal amongst these is the development of leadership skills amongst hospital clinical staff of all disciplines and all clinical trainees. Systems to identify talented individuals, at every level, must be put in place, so that these clinicians are developed and appropriately educated. Systems of appraisal, including potentially revalidation of clinical professionals and accreditation of services, should be developed and introduced. Professional development programmes must be taken seriously and must clearly reflect the principles of clinical governance.

1.5 A culture must be developed in which lessons learnt from clinical audit programmes, from adverse event monitoring and 'near miss reporting', from patient feedback and complaints - as well as desired quality improvements - are routinely and explicitly translated into action. A commitment must be made by organisations to invest the necessary human and material resources to deliver these changes. The implementation of lessons learnt must be monitored and reported to the Trust management board or equivalent structure within primary care. The responsibility for implementing change as a result of clinical governance does not merely rest with specific individuals. Governance is the duty of the entire organisation, not just a few enthusiastic practitioners.

1.6 The White Paper proposes that a clinical governance committee, a sub-committee of the trust board or primary care group, incorporating the patient perspective, is set up to ensure that appropriate systems are in place and that they function effectively. This sub-committee would perform a role similar to that which the audit committee performs in relation to financial systems, which is, in effect, a controls assurance role. The trust or primary care group board can then be assured, through its two sub committees and their reporting, of the overall management of both clinical quality and finance. The totality of such systems, integrated through the board, provides the controls assurance framework for the organisation.

1.7 Many of the basic systems for quality improvement are already in place in trusts and general practices, although the degree of implementation, quality and effectiveness, vary widely. Clinical governance demands that the systems for monitoring and improving quality - clinical audit, risk management, evidence based practice - are *themselves* of excellent quality, are interlinked and co-ordinated to form a single comprehensive system. Such systems will be highly dependant on accurate and timely clinical information. In many trusts this will require a review of currently diverse, scattered, discrete information systems and an acknowledgement of the need for appropriately rewarded, trained and supported specialist information staff. This is clearly a considerable issue for PCG's looking to link together practice based on information. The recently released strategy for IM&T within the NHS, "Information for Health" provides a platform for this work. Increasingly local systems will function within a national framework in which the National Institute for Clinical Excellence reviews and disseminates evidence based clinical guidelines and the Commission for Health Improvement routinely reviews local arrangements, providing a benchmark for local implementation of clinical governance.

1.8 Clinical governance demands that good practice, ideas and innovation are widely disseminated and adopted both within and outside the organisation. It requires an explicit recognition of the role of research and development and mechanisms for reviewing evidence. It is an open and transparent process, which seeks a partnership with other stakeholders including the general public, to involve them with the organisation and delivery of services and the monitoring of performance.

The organisation and management of clinical knowledge is a key issue for clinical governance. To function optimally, clinicians need appropriate relevant and timely information. Only if adequate, culturally relevant support is offered to clinicians in maintaining and improving their own clinical practice can their support be expected in managing performance issues be realistically expected.

1.9 Clinical governance has major implications for clinical leaders, for chief executives, for trust boards, for the public - in terms of structures, roles, processes, accountabilities - and for R&D and education. The patient deserves the best that the NHS can provide and clinical professionals must function to the highest standards. The rest of the organisation, management and support services have a duty to provide the environment to allow this to happen.

1.10 The philosophies and systems encompassed by clinical governance pose a number of questions for the organisation:

i) are we doing the right things?

- development of the evidence base. These questions are likely to be addressed in the development of Health Improvement Programmes, in collaboration with the health authority and other stakeholders

ii) are we doing things right?

- clinical audit (taking a view that clinical audit as it is currently undertaken, must be further developed, to include the implementation of audit findings into everyday clinical practice and a process of continuous review of the effects against locally developed standards) - risk management, outcome measures, complaints management - again including implementation of lessons learnt and review of the effects

iii) how will we know if we are doing it right?

- management of clinical performance, ensuring that clinical practitioners are delivering care to the standards laid out in "Good Medical Practice" and other national codes of clinical practice.

iv) do we have the capacity and capability?

- managing people clinical mentoring, leadership development, CPD, organisational development, appraisal and review processes.

v) how do we know if we are keeping up with new developments?

-regularly reviewing R&D and existing evidence for service and professional development and investment and / or disinvestment decisions

vi) how are we going to demonstrate that what we are doing is right?

-production and dissemination of an annual quality report, working with CHIMP

1.11 The process of controls assurance demands that an organisation and its constituent elements; directorates, and ultimately clinical teams, undertakes self assessment to identify and manage the risks it faces in achieving its objectives. As part of this, health care organisations need to provide the public and government with assurances that they have appropriate control procedures in place. In trusts clinical governance will 'happen' at the level of specialty based multidisciplinary clinical management teams or directorates. The clinical governance committee of the board will perform a controls assurance role, ensuring that the appropriate procedures and systems are in place, and functioning effectively. In addition, the board and its sub-committee groups, will ensure that the results of clinical governance reviews are addressed and acted upon at practice level.

2.0 The Context

2.1 Clinical governance is a mechanism by which the public, trust and PCG boards, health authorities and the NHS Executive and Department of Health can be sure that provider organisations have a cohesive set of management systems, embracing all aspects of clinical quality and financial management. It provides a controls assurance mechanism, just as the financial audit process provides a controls assurance function for financial systems. The introduction of clinical governance is intended to allow the quality of clinical care to be monitored and valued equally with the financial performance of the trust or primary care organisation.

2.2 Clinical governance must be clearly defined. Its principles must be sufficiently robust to be transferable between primary and secondary care, between acute and community units, and between district general and teaching hospitals.

2.3 Many trusts and primary care practices have some or indeed all of the necessary systems in place already, although the quality, effectiveness and consistency of these throughout the service is variable. The introduction of clinical governance means that all providers of healthcare will be expected to build on and develop those systems that are working well, and put in place those that are lacking.

2.4 Providers of healthcare in the UK vary widely, in terms of leadership qualities, managerial competence and the change management skills of both managers and clinicians. Guidance and support should take the form of:

a) an explicit statement of functions and systems that need to be in place, with desired outcomes
b) suggested mechanisms to achieve these outcomes
c) practical examples of good practice, for each of the various systems required.

2.5 Governance arrangements within the trusts need to build on and work with existing structures and processes; both formal and informal. In trusts, the role of managers, particularly clinical

directors, in relation to clinical governance needs to be developed and clarified.

Responsibility for supporting, developing and enabling clinical governance needs to be clear, as does the relationship between clinical teams, including the primary health care team, and the management process.

This support will need to review the management information system and its ability to support clinical governance as well as training and development programmes for staff.

Clinical governance will not only be about the clinical services in the trust or PCG, but also about the governance component of the clinical education which is supported by the PCG or trust.

2.6 PCGs & Trusts are increasingly working within a complex web of relationships. Just as individual practitioners work in clinical teams, so the NHS works with a wide variety of other agencies to improve the health of the nation.

Recognising these external relationships will be an important element of clinical governance arrangements. How will these bodies influence debates within the trust, how will the trust communicate with them?

2.7 Local relationships can all be characterised in one way or another, as relationships with the public. Central will be the relationship with the health authority or health board and the other stakeholder agencies drawn together through the health improvement programme. Clinical governance will require formalising relationships with partners in service provision; not only the local authority but also charitable and voluntary organisations.

2.8 National agencies also play a role in local governance arrangements. Providers will want to be clear about the way in which they relate to CHI and NICE (or bodies like SIGN and CRAGG in other parts of the UK). Other bodies also have a role and local documents will want to refer to bodies like the Royal Colleges, GMC, UKCC, Audit Commission and the CNST.

2.9 Finally clinical governance will require clinical leadership at all levels of the NHS.

3.0 What will clinical governance mean?

Clearly the implementation of clinical governance will have major implications for clinicians and managers alike. Clinical leaders, if not already well established and developed, will need to be identified, educated and trained. However to do this in isolation from their colleagues is folly; educational activities for quality improvement must stretch across the entire organisation. To do otherwise will result in leaders but no followers and no real change in the organisation. Some trusts and primary care practices have made real progress in this area. It is vital that such exemplary practice is identified, analysed and disseminated, so that the NHS as a whole learns from these approaches.

3.1 Clinical governance depends on effective working between clinicians, clinician/managers and managers. In trusts the key to this will be effective team working between the medical director, director of nursing, clinical directors and other clinical leaders. Similarly, with PCG'S, it will be critical for all clinical managers to work together. Clinical governance is very much a matter for all clinical professionals and the whole management team. Trusts and PCG's will need to devise the model most appropriate to the organisation. In practical terms it is difficult to envisage how any system other than one which involves the medical director, director of nursing, other clinical leaders and other senior managers working extremely closely together, would be effective. Resources will need to be committed: including time for clinical staff, information/ analytical staff support and the IT infrastructure. Such investment will need to be related to existing investments in clinical and professional audit programmes and continuing professional development (CPD/CME) so that additional funding can be secured on a robust basis.

3.2 Currently the majority of doctors in medical director roles and all those in clinical director roles take on their management responsibilities on a part-time basis. This is also likely to be true of GP's who take on management roles in PCG'S. The implementation of clinical governance is likely to increase the load on the medical director, and consideration must be given to this role and to alternative models of delivering and strengthening it (for example, appointment of associate medical directors, jobsharing arrangements, allocation of protected time to medical andclinical

directors, education of junior doctors and appointment of full-time medical directors).

Similarly, the role of clinical director is likely to develop and place more demands on the clinicians taking on these jobs. Currently, the average clinical director devotes two contracted sessions each week to management and it is probable that this will be sufficient to meet the demands of clinical governance. It will be important to look closely at the organisational support to clinical leaders, both in staff terms and more generally in the way the organisation works. It is important to be clear that a paid time commitment within trusts and primary care groups will be required.

3.3 At board, directorate and practice levels, managers, doctor/managers, nurse managers and other clinical leaders will increasingly work together. They share the responsibility for the clinical service and for delivery of quality improvement. In effect, these individuals will need to "job share" the responsibility for leading the clinical workforce towards achieving the highest quality possible. It is vital that the opportunity presented to achieve effective multidisciplinary working is fully exploited and adequately resourced.

3.4 In primary care the responsibility for the development of clinical governance will rest with the Primary Care Group. In order to achieve primary care trust status, primary care groups will need to demonstrate that they have a systematic approach to monitoring and developing clinical standards. Individual practices will be encouraged to identify lead responsibility on the same basis. Each group will nominate a senior professional to take the lead.

3.5 Chairmen, non-executive directors, chief executives and nonclinical executive directors must also address and adapt to the reality of clinical quality having equal status with financial probity and value for money. They must develop their relationships with the clinical leaders and establish clearly how responsibility and reporting will work. There will inevitably be variation in the way this is implemented - there is a need to encourage local flexibility, whilst ensuring that the outcomes are in line with the principles of clinical governance.

4.0 How will clinical governance work in secondary care?

This section describes clinical governance as it might apply to the secondary care system. A system for primary care is put forward in section 5.0, although this poses rather more of a challenge, since the organisational structures in primary care are currently evolving.

The building blocks of clinical governance are multidisciplinary teams at every level of the organisation, working from ward, clinic or care team upwards. A high quality service can only be delivered by a real commitment to individual professional standards at the level of treating patients. Clinical governance is a real opportunity for trusts to invest in people and systems and to prioritise quality.

4.1 Hearts and minds

Although it is easier to focus on tangible structures and processes to implement clinical governance, it is vital to understand the necessity to engage clinicians of every discipline wholeheartedly in the concept. The clinical workforce in most organisations faces increasing demands and frequent change. Yet most professional staff are already working to high standards and trying to do their best. Few doctors, nurses and other clinical professionals would *not* like to do better - yet many feel frustrated and weary. It is essential that the change in culture involved in clinical governance builds on the good work that is already going on, and is integrated into those systems that are already working well. Clinical knowledge management is essential to involving clinicians, allowing them to develop their skills towards clinical excellence throughout the organisation. It must not be a bolted on added extra - it must become the way the organisation is run.

To achieve this, clinical champions and leaders are needed to enthuse and motivate colleagues locally. Support for these champions and development of their leadership skills are both essential. A culture of continuous education, of lifelong learning, must be fundamental to the organisation.

4.2 Accountability

In order to achieve clinical governance, clear understanding is needed of the lines of accountability for clinical practice. Clinical accountability for patients

rests with the consultant or general practitioner, who is ultimately responsible for clinical decisions.

In trusts, consultants and other clinical practitioners are accountable to the clinical director or equivalent specialty leader for the quality of the clinical care provided, as well as to the patients themselves. Clinical directors are in turn accountable in most trusts directly to the Chief Executive, for the quality of clinical care provided by the directorate. The concept of accountability of one practitioner to another for the quality of clinical care is complex. It presents considerable challenges to professionals accustomed to clinical autonomy. However the greater challenge of clinical governance may be the concept of accountability for clinical matters to non-clinicians. Nevertheless the need to demonstrate consistent and high quality clinical practice demands that systems for quality monitoring, quality improvement and accountability be put in place.

4.3 Levers and sanctions

One key to successful achievement of clinical governance will be the development of systems, which ensure changes in clinical practice on the basis of identification of quality failures. This 'closing the loop' has not, in the main, been achieved by existing systems of clinical audit. One major concern is the lack of involvement of junior doctors and other professional staff in clinical audit. Audit must support health care teams in reviewing their delivery of clinical care. Central to clinical governance will be the development of mechanisms to make sure that lessons are learnt from system and process failures. These mechanisms might include:

- inducements and rewards - organisational and individual, financial and non-financial.
- identification and high profile dissemination of best practice.
- sanctions - for example reporting of poorly performing colleagues, in the longer term, recertification of clinical practitioners are in place and functioning properly.
- defects identified are systematically reviewed to ensure that remedial action has been implemented into everyday clinical practice
- all aspects of the clinical service and all management systems subjected to routine and rigorous review.

- education and CPD support
- development of appraisal systems

In addition it must be recognised that clinical governance will flourish and gain wider commitment and support within a clear "no blame culture", where professionals can feel comfortable in openly sharing their views and practices.

4.4 Structures, processes and models

4.4.1 From multidisciplinary clinical teams, a directorate (or-other appropriate grouping terminology) structure is built, led by a clinician and supported by management. It is the responsibility of the directorate management team to put systems in place to ensure that:

- directorate strategy and trust strategy are aligned.
- comprehensive clinical and financial management systems are in place; including clinical audit, monitoring of clinical practice against evidence based national guidelines, and adverse event reporting
- systems to improve clinical practice are in place; particularly clinical effectiveness and protocol development.

An important part of the clinical services provision are the diagnostic services such as pathology and radiology. In the case of pathology the clinical pathology accreditation system has done much to improve standards within laboratories.

4.4.2 Essentially trusts will need to adopt a performance management style in which the goals, objectives, milestones and outcomes are agreed between the trust management group and the clinical directorates. Regular review and monitoring towards these targets, which will include clinical governance issues, takes place regularly during the year. It is a fully decentralised model of management, which is implemented in some but not all UK hospitals. The clinical management or directorate team holds full management responsibility for all resources; financial, staff, equipment and facilities of the clinical specially. It is held accountable to the trust management team, for the quality of clinical practice delivered by the directorate and for the proper use of these resources.

This model places responsibility and decision making with directorates and through them clinical teams. It also provides a mechanism for directorate accountability.

4.4.3 The clinical management team is led by a clinician, often referred to as the clinical director, who is usually accountable directly to the chief executive. Communication needs to be in both directions; trusts will need to ensure that existing and future contributions to the evidence base are disseminated to appropriate clinicians and acted upon. To support monitoring of clinical governance, the directorate team will provide regular reports to the trust management team. In many trusts these processes are already being put in place but will require some development and refinement.

A summary report based on all clinical directorate reports, will be required by the Trust Board executive sub-group.

The reports will demonstrate:

- the outcomes of clinical audit, with lessons learnt and an action plan for their implementation.
- monitoring of adverse events, with lessons learnt and action plans for their implementation.
- specific improvements in clinical care that have been introduced into day to day practice.
- The outcomes of clinical complaints, and analysis of patterns of complaints and action undertaken.
- Evidence that risk assessment has been understood and adopted
- patient feedback - good and bad - and its management
- implementation of guidelines and protocols
- action taken to develop leadership skills
- action taken to support CME and CPD
- CME and CPD undertaken
- the outcomes of appraisal of clinical colleagues
- action taken to develop the directorate team

Poorly performing clinical colleagues should be managed by clinical directors within established trust policies, including policies on disciplinary procedures and the right of appeal. Clinical directors

should keep the appropriate clinical lead at trust board level informed, (medical director in the case of a poorly performing doctor, director of nursing in the case of a poorly performing nurse). The process of dealing with the poorly performing colleague should then be handled according to the trust's procedures, preserving the appropriate degree of confidentiality as laid out in the relevant professional body's guidance document (GMC, UKCC etc.) on handling difficult colleagues. It is very important that poorly performing clinical staff and directorates are aware that remedial programmes are available.

4.4.4 Management arrangements within trusts vary. The organisational structure should be developed so as to facilitate clinical governance. Each trust must have an appropriate structure to ensure that all directorates or specialities are properly involved in decision-making. Accountability, governance and decision making should all be undertaken through a single management system.

4.4.5 The trust management group is the forum at which all aspects of the trust's activity, clinical and managerial, are brought together and at which all major decisions are made. In terms of delivery of clinical governance, the management group must ask a number of questions of the organisation;

- Are systems in place to monitor quality of clinical care?
- Does the service provided by the trust or primary care group match the strategic objectives?
- Does the service provided meet national standards?
- Are adverse events identified? Are complaints handled effectively? Are the lessons learnt from surveillance and audit processes translated into changes in clinical practice and reviewed regularly?
- Are there areas where quality could be improved?
- Are there developing approaches to the monitoring of outcomes to identify areas of concern?
- Is litigation monitored and used as a management tool? What are the outcomes of litigation and the use of expert witnesses and their deliberations?
- Are there appropriate numbers of adequately trained and developed staff to run the service?

- Are systems in place to identify and manage the poorly performing clinician?
- Is education and development of staff approached seriously?
- Are clinical leaders being identified at all levels of the organisation and are they being developed?
- Is a true commitment to CPD evident throughout the organisation?

4.4.6 The trust management group reports regularly to the trust board, providing a clinical quality and a finance report. The trust board has responsibility for assuring effective internal control. To achieve this, systems must be established, maintained and monitored to give reasonable assurance that:

* assets, including the human resource asset of professional staff,
  are safeguarded
- waste or inefficiency is avoided
- reliable financial information is provided
- value for money is continuously sought
- cost effectiveness is maintained

To this list of responsibilities, clinical governance must be added: The board will have the responsibility for ensuring that quality systems have been implemented and are maintained. and developed.

The board must ensure that those systems are based on clear standards, where appropriate set at a national level, for example, by the National Institute of Clinical Effectiveness. The systems must be open and transparent. The board must also ensure that there is a system for accountability, with the outcomes of clinical governance subject to public and governmental scrutiny.

4.4.7 To bring about clinical governance, a sub-committee of the trust board should be formed. The purpose of the clinical governance committee is to provide the board with a means of independent and objective review of:

- clinical quality monitoring and improvement systems

- effective implementation of the lessons learnt from these systems
- quality of the information used by these systems
- compliance with national guidelines and protocols
- the capacity of the organisation to deliver the required quality of service in terms of

- quality of clinical performance
- educational systems and commitment to continuing professional development
- leadership development of clinicians and managers
- commitment to organisational development.

The clinical governance committee will be set up by the trust board. The committee should make a regular report on its activities to the trust board which will be as important as the finance report. The committee will also provide an annual report on clinical governance.

It is suggested that the following individuals would, in most trusts sit on the clinical governance committee:

A non-executive director of the trust
Medical Director
Director of Nursing
Director of Human Resources

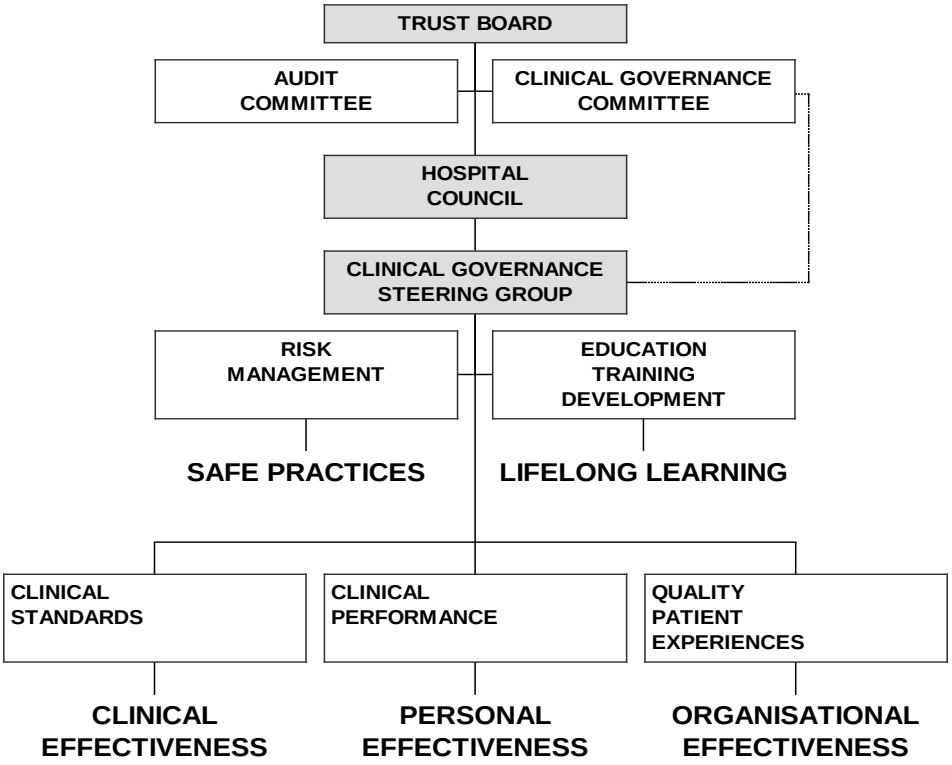
In addition the following might attend the committee:

Community Health Council Member, with recognition of the need for confidentiality.
Other lead clinical staff
Director/head of clinical effectiveness/clinical quality
Head of clinical risk management

4.4.8 Models

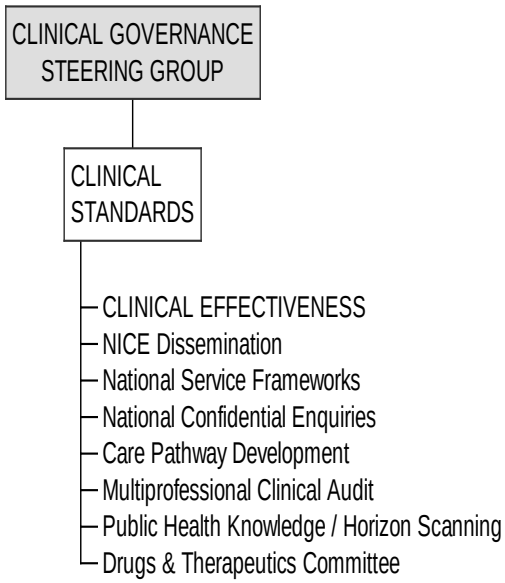
The structure for individual trusts will vary - it is very much the trust's responsibility to decide how best to implement and deliver clinical governance.

Royal Hospitals Organisational Structure for Clinical Governance :

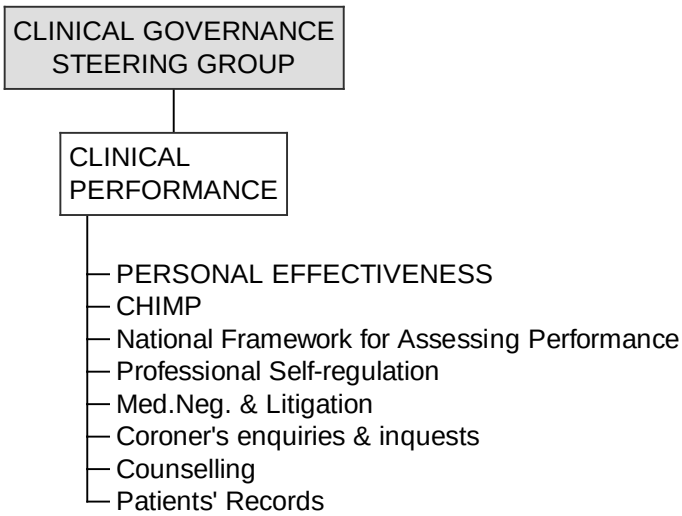


Clinical Governance Components:

Clinical Standards



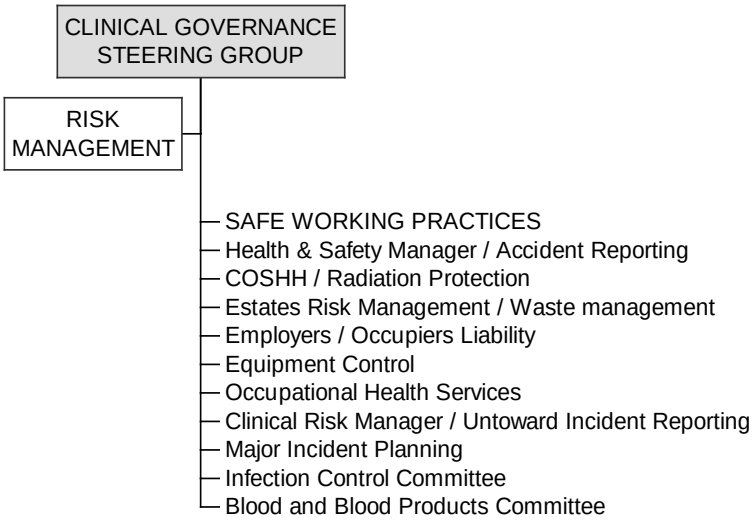
Clinical Performance



Clinical Governance Components (Continued) :

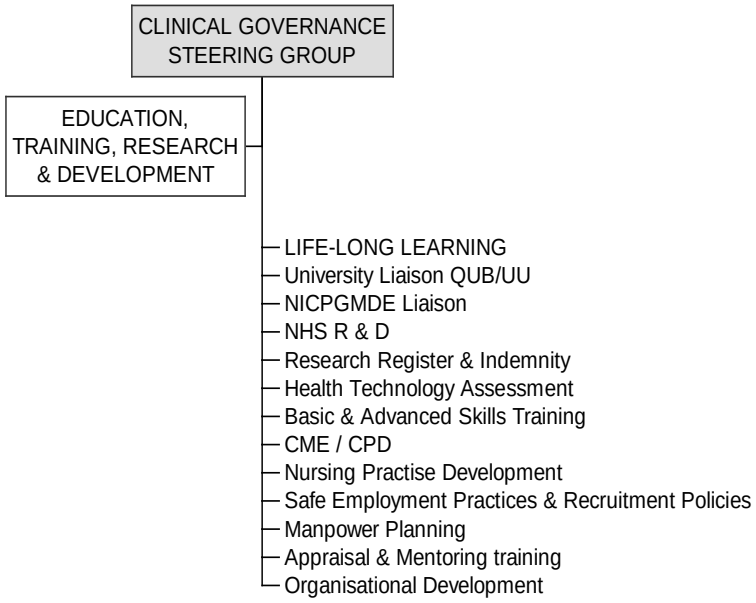
Quality & Patient Experience

Risk Management



Clinical Governance Components (Continued) :

Education, Training & Development



Clinical effectiveness is primarily a clinical directorate function - the department or directorate of clinical effectiveness co-ordinates activity across the trust and provides a forum for bringing together clinical quality, leadership development, continuing professional development and organisational development.

5.0 Where are we now?

Throughout the NHS there is considerable variation between organisations.
Many trusts and practices would state that clinical audit and other quality assurance or improvement programmes are in place. There is, however, little evidence of effective mechanisms in place to make these systems work or that the mechanisms are appropriately supported in terms of personnel and other resources. Evidence based practice is well developed in some trusts and primary care practices - but not in others. There is a real gap in clinical leadership development in many organisations. Research is needed as to what the barriers have been and how they might be addressed.

Embryonic systems for adverse events reporting are in place in a considerable number of organisations. However, translation of the findings into changed clinical practice is patchy or non-existent at present. The identification of poor clinical performance varies considerably, although the GMC's new performance procedures will go some way towards reducing this variation.

Of great concern is the underlying quality of information upon which clinical care can be monitored. There remains considerable improvement to be made in the provision of appropriate, accurate and timely data for monitoring clinical care. NICE and the national service frameworks are potential tools for improving quality of information. There is a need to talk more openly about clinical performance and become used to openly sharing data, which implies organisational development.

6.0 What needs to happen?

For some trusts and primary care practices, the introduction of clinical governance will mean radical change. For others, the changes will be less challenging, as much of the work has already been done. It is clear that it will only be possible to provide specific guidance on implementing clinical governance following detailed research to determine current best practice. Trusts, practices, regional offices and professional national bodies are currently developing ideas for implementing clinical governance. In order to harness these ideas, reduce wasted effort and avoid numerous alternative approaches, thought should be given to how best to develop guidance. In terms of the steps for implementation, the following list identifies the issues:

at the level of the individual:

1) Commitment - first and foremost a change in culture and attitude must be brought about in both the clinical and the managerial worlds. Without changing hearts and minds, none of the various strands of implementation can be put in place. Considerable educational effort will be required both to develop skills in clinical staff already in post whilst concurrently ensuring that staff in training are appropriately educated to take on leadership roles.

at trust and primary care group level; and at directorate and practice level

2) The information base, on which judgements can be made on the quality of clinical service, must be improved. This is fundamental, without the information, real improvement in clinical quality cannot be achieved.

3) Relevant structures and processes must be put in place and reviewed very regularly to ensure that they are appropriate and functioning. Organisations will need to undertake a 'stocktake' of their various clinical governance functions, and assess how these will be integrated with the requirements of the clinical

governance committee - and what actions are required to bring these functions up to the required quality.

4) Organisations must be able to demonstrate a commitment to effective multi-disciplinary decision making, devolved down the organisation as near as possible to the point at which professional staff have direct contact with the patient.

5) The resource implications for R&D, education, training and CPD should be identified and systems to monitor these resources should be established at health authority level.

at regional level:

6) Resources that are required to ensure the development of clinical leaders must be identified and made available. The role of the post graduate deans and their networks in facilitating the necessary changes must be clarified. Expectations in terms of quality reports must not be imposed but should be the result of debate and dialogue with providers.

at national level:

7) Resources in terms of time, people and finance should be identified for proper implementation. Different approaches, for example the relative benefit of targeted leadership development programmes and wider CPD might usefully be compared.

8) Processes to ensure effective training, continuing professional development programmes and leadership development programmes must be put in place.

9) The tools and mechanisms that currently support quality improvement, in particular clinical audit, must be reviewed and changed where necessary.

10) The energies and input of CHI, NICE and the professional bodies must be harnessed and co-ordinated. The roles of the Royal Colleges, the General Medical Council and the UKCC and

other statutory professional bodies must be clarified in relation to clinical governance. These bodies will have a major role in setting standards of good clinical practice. The mechanism by which trusts, primary care groups and their clinical governance committees relate to these national and professional bodies must be established.

11) Clinical teams, practices and directorates must provide a culture in which all staff engage in creating development and where lifelong learning is supported. The concepts of the "learning practice" and "learning directorates" will need to become firmly established to develop and maintain clinical governance

12) The components of a "successful" outcome must be analysed from the perspective of both the patient and of the professionals.

13) The development of educational programmes at undergraduate and early postgraduate levels for all clinical disciplines must be considered, to ensure that the clinical professionals of the future have the appropriate leadership and quality management skills for the NHS of the future.

14) Work must be undertaken to establish the value of recertification of clinicians and the impact this system will have on improving the quality of clinical care.

15) Work must be undertaken to identify:

(i) effective joint working between medical directors, directors of nursing, other clinical leaders and managers
(ii) multidisciplinary and interagency works
(iii) the developing roles of the medical director and director of nursing
(iv) a stronger and more effective role for the clinical director
(v) the various clinical leadership roles within a PCG.

Steps towards clinical governance :

1.Organisational stocktake - the trust or primary care group must establish the state of health of the current systems, which contribute to clinical governance.

2.Establish an action plan to implement systems that are lacking and revise those in place, which are not functioning effectively.

3.Undertake an organisational review - to determine whether the current management arrangements support clinical governance? Is the system truly decentralised? If not, put in place plans to change.

4.Establish a clinical governance committee as a sub-committee of the trust board, educating and training its members.

5.Develop and implement an awareness raising campaign throughout the organisation. Use this as an opportunity to address staff concerns as well as discuss with them what is to be done.

6.Clinical leaders - medical director, director of nursing, clinical directors in secondary care and GP partners and lead nurses in primary care to discuss in considerable detail how clinical governance will be implemented and achieved throughout the organisation.

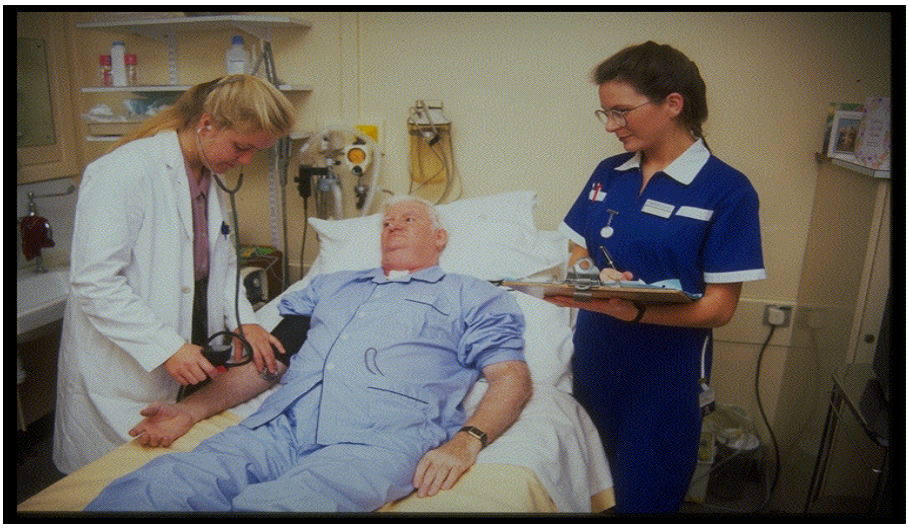
7.Establish plans for identifying and developing clinical leaders within the organisation.

8.Ensure that new systems for clinical governance are piloted and evaluated.

9.Ensure a considered approach to the development of reporting systems

10. Link all of the above to the development of plans for organisational development.

THE ROYAL GROUP OF HOSPITALS AND DENTAL HOSPITAL HSS TRUST



Clinical Governance Report - 1999 / 2000

Clinical Governance Action Plan - 2000 / 2001

I.W.CARSON
Medical Director

September 2000

Clinical Governance Report – 1999 /2000

Contents:

Foreword by the Chief Executive

This is the first report to be published by the Royal Hospitals on clinical governance – a term which describes the action taken by a trust to ensure that there are proper processes in place for continuously monitoring and improving clinical quality and care of patients.

However, while it is the first time that much of what is contained in this document is being made public, the information detailed and the subjects covered are, or have become, crucial to our continuing commitment to evaluate patient care, and the systems and processes that deliver care.

It is also important that the public know openly, what we do to ensure quality of care, how we evaluate treatment and services, what weaknesses and failures we find, the problems we face and how we plan to overcome these.
We are committed to quality and continuing efforts to minimise and eliminate any short-comings.

We plan to produce a report along the lines of this publication annually. You, the public, our patients, and indeed our own families, can judge the progress we make.
We hope that people will share with us in our achievements, and understand our frustrations when we experience on occasions the difficulties faced by a health service still suffering from the effects of long-term chronic under-funding.

William McKee

Chief Executive

Introduction

'A First Class Service: Quality in the new NHS' was published in July 1998, almost at the same time as events were taking place to mark the 50 years of progress since the inception of the NHS. It underlined Government's determination to work with staff and patients to deliver high quality care.

The Royal Hospitals have determined that it is in the best interests of patients, staff and the wider service to pursue an active approach to the development of systems and processes that could be used to underpin quality assurance. Many of these activities are already in place within our organisation, but they need to be brought together and co-ordinated with clearer reporting relationships to our Trust Board.

Despite the absence of a statutory framework in Northern Ireland for the introduction of clinical governance, we have made a great deal of progress. Our staff, who recognise the benefits of continuously monitoring and improving clinical quality, understand their individual and collective responsibility in delivering patient care, and they are to be commended sincerely for their commitment.

We cannot stand still, and our performance must continue to improve. It is our aim to ensure steady progress in the quality of patient care, and it is for that reason this document also sets out our action plan for the year 2000 / 2001.

Review of Clinical Governance and its implementation in the Royal Hospitals

Following the publication in July 1998 of the consultative document ***A First Class Service: Quality in the new NHS*** and the circular HSC 1999(33) in February 1999, NHS trusts and health authorities in England and Wales were tasked with undertaking preparatory work on clinical governance. They were also asked to consider, in advance of further guidance, how they could use the proposals set out in that document to take forward work on quality improvement locally. Similar guidance was issued for trusts and health boards in Scotland.

Given the scale and ambition of the agenda presented, and the importance of ensuring that all professional groups could identify with, and 'own' the quality agenda, the Royal Hospitals decided to embrace the initiative at an early stage, and in advance of any local guidance for the HPSS. Extensive steps were taken to brief staff groups throughout the Trust by the use of formal and informal presentations.

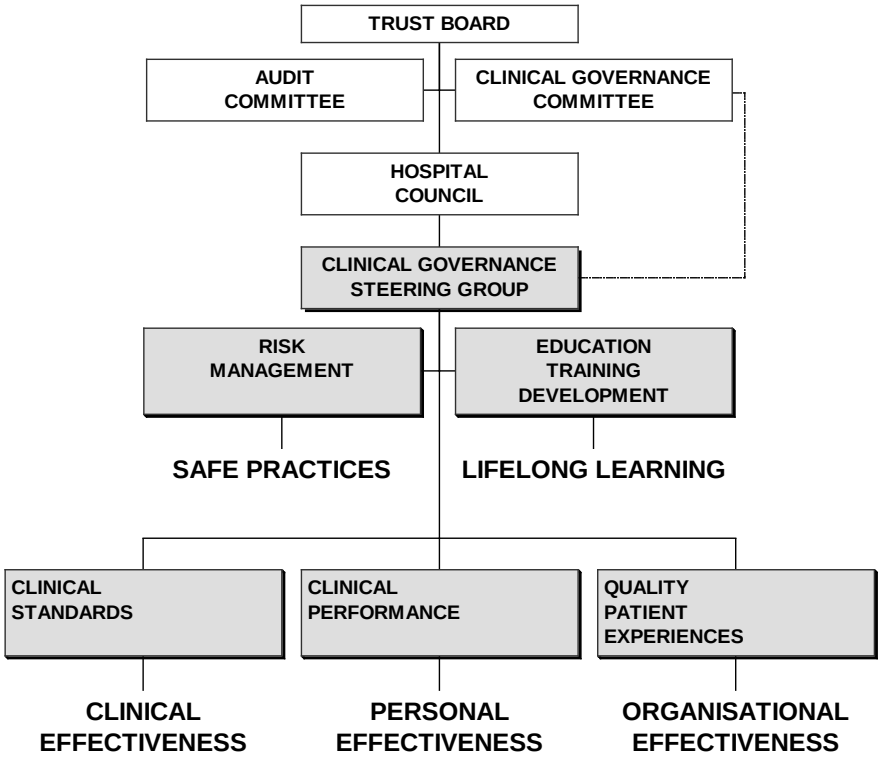
The NHS Executive provided further guidance (HSC 1999/065) on the implementation of clinical governance and set out a programme for the year 1999/2000.
This was to include the following action:

- By April 1999, identify lead clinicians for clinical governance and set up appropriate structures for overseeing clinical governance within their organisation;
- Agree with the relevant NHS Executive Regional Office or health authorities, a process and timescale for conducting a baseline assessment of capability and capacity for implementing clinical governance;
- Formulate an action plan in the light of this assessment;
- Report on clinical governance arrangements within their Annual Reports for the year 1999/2000.

The Royal Hospitals have followed, where appropriate, the above guidance and put in place the necessary structures and arrangements. Additional information in the form of the document, ***"Clinical Governance: a framework for continuous improvement in quality of clinical services and the maintenance of high standards of care within the Royal Hospitals Trust"*** has been prepared, approved by the Trust Board and in April 1999 was made available to all staff.

It is not possible to detail all of the initiatives being undertaken within the Trust. However, this report marks the commencement of a programme of concerted clinical quality improvement which will bring benefit to patients, and as such will be welcomed whole-heartedly by all staff across the Trust.

Royal Hospitals Organisational Structure for Clinical Governance



The chair of the Clinical Governance Steering Group and the lead professional for clinical governance is the Medical Director, Dr I W Carson.

The following Directors have responsibility for leadership and co-ordination of the activities encompassed by the five clinical governance sub-groups:

Dr H C Mulholland	(Associate Medical Director) – Clinical Standards
Mr A P Walby	(Associate Medical Director) – Clinical Performance
Mrs D O'Brien	(Director of Nursing & Patient Services) – Quality and Patient Experiences.
Dr A B Stevens	(Director of Occupational Health) – Risk Management
Prof. A G H Love	(Director of Education, R & D) – Education, Training and Development

The following reports summarise some of the activities and information being used to underpin the quality agenda within the Royal Hospitals.

Clinical Governance Components:

Clinical Standards - CLINICAL EFFECTIVENESS

- **Clinical Audit**

The Royal Hospitals 5th Annual Report on Clinical Audit was published and circulated. A strategy for audit planning has been developed, approved and shared with directorates to focus attention on:

a. Trust, Area Board and DHSS audit agendas
b. Implementation and monitoring of changes as a result of clinical audit
c. The involvement of trainees in local directorate audits.

The attendance of consultant staff at audit meetings is variable and is often less than 30%. Their example tends to be followed by doctors in training.
Sustaining present department activity is difficult and there is a waiting list of 6 months for new audit projects.

- **Care Pathways**

Progress is continuing with further pathways being developed. There are now nine care pathways integrated into clinical activity, another nine are currently being piloted and a further 12 are proposed. A small number have been suspended or discontinued.

The main qualitative step forward has been the development of a number of integrated pathways that incorporate the full medical record and in some cases part of the nursing record.
A significant number of doctors are still very reluctant to participate in the Care Pathway programme, seeing it as additional paperwork. It is imperative that more integrated records are developed. A mechanism for rapid audit is required to allow access to progress on a trust wide basis.

- **National Confidential Enquiries and National Sentinal Audits**

The appropriate clinical departments contribute to the National Confidential Enquiries. Annual reports are received and disseminated throughout the directorates by the Audit Department.

Follow-up monitoring is not easily achieved. Information is not available centrally about the degree of implementation of recommendations and the effects on directorate care. Systems need to be developed which will ensure that information having been received is used where necessary to implement change and that the effect of that change is identified and shared.

A list of completed or ongoing national audits in which staff have or are participating is appended at the end of this section.

- **National Institute of Clinical Excellence**

Relevant directives from NICE have been issued to directorates and appropriate action is being taken. The resources to enable these directives to be applied trust wide have not yet been identified within the Trust or within the region

The Royal Hospitals are part of a group working with the comparative health informatics consultancy – CHKS, to develop detailed protocols for the management of patients with ischaemic heart disease.

- **Blood and Blood Products Utilisation**

A review is underway throughout the Trust of utilisation of blood and blood products. A significant reduction in requests has occurred in some directorates with some associated reduction in the percentage of the units returned to the Blood Bank. Each directorate is to audit this activity.
Delays in transportation of blood products throughout the site give rise to over ordering with subsequent wastage. A more efficient transportation system with a bar-coding mechanism to trace products from the time of ordering to usage or return to the Blood Bank is required.

- **Drug and Therapeutics Committee**

The development of antibiotic resistance due to inappropriate prescribing is under study. Several protocols have been developed and disseminated throughout the Trust. Prescribing in general is largely performed by junior medical staff, and the system remains paper-based and usually hand-written. The need for an electronic prescribing system with decision support is a very high priority.
prescribing system linked to the Pharmacy system is needed in the very near future.

Dr H.C. MULHOLLAND
Associate Medical Director

Completed or on-going national audits:

A & E - Major Trauma Outcomes Study

Regional Intensive Care Unit - ICNARC

National Vascular Audit - (Elective Open Aortic Aneurysm Surgery)

Adult Interventional Activity - British Cardiovascular Interventional Society

British Pacing and Electrophysiology Group - National Pacemaker ICD Database

Prospective Registry of Acute Ischaemic Syndromes in UK

Survey of Nuclear Cardiology Procedures - British Nuclear Group

Cardiac Surgery Results - Society of Cardiothoracic Surgeons of Great Britain and Ireland

National Orthodontic Working Party audit

Royal College of Ophthalmologists - National Audit of Trabeculectomy

Royal College of Surgeons (London) - Tonsillectomy Audit
- Otitis Media with Effusion Management

Royal College of Physicians (London) - Evidence-based Prescribing in Older People
- National Sentinel Audit of Stroke

DOH National Audit of Service and Management of Atopic Eczema

National Pituitary Database and National Acromegaly Database

Neurosurgery - National Shunt Registry

Royal College of Obstetricians & Gynaecologists - Audit of Management of RhD Negative Women

British Paediatric Respiratory Group/British Thoracic Society - Audit of Acute Asthma Admissions

British Association for Paediatric Nephrology - End Stage Renal Failure Audit Database

UK CCSG - Solid Tumour Audit
- Leukaemia Audit

British Association of Paediatric Surgeons - Neonatal Surgical Audit
- Laparoscopic Surgical Audit

Paediatrics - National Growth Hormone Audit
- National Diabetic Audit

UKTSSA - Organ Transplantation

Royal College of Paediatrics and Child Health - British Paediatric Surveillance Scheme

National ‘Care’ Cleft Lip Birth Database

Clinical Standards Advisory Group - National Audit of Cleft Lip and Palate

Clinical Performance - PERSONAL EFFECTIVENESS

- **Clinical Negligence and Litigation**

During the period 1/4/99 to 31/3/00, 109 clinical negligence claims files were opened naming the Royal Hospitals as the defendant or co-defendant. The figure must be seen in the context of the total activity levels of work carried out in the Trust (over 67,000 inpatients and daycases, and over 320,000 outpatient attendances), and compares to 81 claims in 1998/99, 109 claims in 1997/98 and 83 claims in 1996/97.
Notification of a claim does not necessarily indicate that the Trust has incurred any liability. Contingent liability for 1999/2000 has been set at £1,112,700.00 (inclusive of legal and associated costs).
There are no comparative data for similar sized trusts.

Claims categorised by Directorate:

Surgical	31	Medicine	7
Obs/gyn/neo	27	Cardiology	3
Paediatrics	12	ENT	3
Ophthalmology	10	Dental	1
Neurosciences	7	Laboratory	1
Anaesthetics, Theatres and Intensive Care Services (ATICS)			4
Insufficient information to allocate against a specific clinical directorate			3

Review of the allegations raised shows that ‘failure to diagnose or delay in diagnosis’ was the most common cause of claim during the period, followed by ‘complication of treatment’, ‘intra-operative problems’ and ‘injury caused during examination’.

- **Clinical Negligence files closed during the period**

There were 23 files closed during the above period. Of these:

- six were withdrawn or discontinued by plaintiffs;
- six were closed on the advice of the Royal Hospitals’ solicitors, as there had been no activity on the part of the plaintiff for some considerable time;
- nine were settled out of court;
- two cases were taken to court – both were withdrawn by the plaintiffs on the morning of the hearing and some legal costs were incurred/accepted by the Royal Hospitals.

The costs to bring these claims to settlement were:

Awards to Plaintiffs:	£171,250.00
Third Party/Legal Costs:	£ 71,862.70
Total:	£243,112.70

- **Coroner's Cases**

The Trust is obliged to report all sudden, unexplained, or suspicious deaths to HM Coroner. This includes, all deaths resulting from road accidents, industrial injury or due to violence. During 1999/2000 there were 47 new files opened in response to requests for information from HM Coroner relating to deaths which occurred in the Royal Group of Hospitals. Of these, 40 cases did not relate to services provided by the Trust. Seven cases did raise issues in regard to patient services, and while the Coroner has yet to decide whether an inquest is to be held, the Trust has reviewed the cases to ensure that those services were delivered appropriately.
For the period covered by this report there were a further two cases directed by the Coroner. One hearing was adjourned and one completed. The Trust has addressed the clinical risk management issues involved in the completed case.

- **Medical Staff Inquiries**

During the year seven doctors with performance difficulties have been the subject of internal local investigation by the Trust. In two cases this resulted in their referral to the Occupational Health Department. Close liaison with the N.Ireland Council for Postgraduate Medical and Dental Education has also been necessary in relation to those doctors with performance problems during their training attachment to the RGH. The RUC have been involved in two investigations and the Trust imposed appropriate restrictions of medical practice where and when necessary. All these cases were closely monitored to protect patients and yet maintain doctors' privileges. There are no doctors currently suspended by the Trust, nor have any cases been referred for prosecution. Liaison is maintained with the General Medical Council in regard to case management.

- **Junior Doctors' Hours**

The Royal Hospitals comply fully with New Deal targets for 68% of posts, compared with a Northern Ireland average of 77% compliance. For Pre-Registration House Officers compliance is better at 81% (NI average 73%) with less satisfactory figures for SHOs at 71% (NI average 78%) and Specialist Registrars at 63% (NI average 75%). The reasons for lack of compliance are mostly not now related to hours of work, which have been reduced to within the New Deal targets. Work intensity without adequate rest periods is the current reason for non-compliance. Additional resources would help some directorates by the employment of additional staff, however in others this would produce too many trainees for the needs of the speciality at senior level. Employing career grade staff is a solution in this situation however the expense is much greater.

Other areas of work for the Clinical Performance group in future will include communication with the Commission for Health Improvement (CHI) and/or the equivalent monitoring body for N.Ireland.

Mr. P. WALBY
Associate Medical Director

Quality and Patient Experience - ORGANISATIONAL EFFECTIVENESS

Progress made on quality improvement can be demonstrated through:

- Consultation with our users
- Training of our staff to bring about a well-motivated workforce.
- Complaints management

➢ **Consultation with our users:**

In 1999/2000 the Royal Hospitals has used a two-pronged approach in consulting users. An annual corporate patient satisfaction survey is carried out and use is made of focus groups.

- **Patient Satisfaction Survey (PATSAT)**

This the fourth year of PATSAT and has shown an improvement in satisfaction with many aspects of service delivery. The survey was carried out during two weeks in February. Inpatients, outpatients and daycase patients were all surveyed. A total of 2,500 surveys were issued with a 40% return. The key elements of this survey covered:-
information giving, discharge information, catering and staff attitude.

Improvements were evident in areas such as -

- Information sent prior to arrival
- Promptness of admission
- Attitude of visitors
- Care attitude of nurses/midwives
- Listening and explaining by doctors
- Leaflets - relevant/use of
- Overnight facilities for parents.

98% of respondents said they would recommend the hospital to others.

- **Focus Groups:**

In the past year various focus groups have taken place. Examples of the use of these groups were in haematology, 'carers', diabetic education and pain management. The following table illustrates some of the recommendations and benefits that have been welcomed by the Royal Hospitals in its pursuit of excellence.

	Recommendations	**Action**
Children's Haematology	Better information for parents of children with haemophilia.	Produce new leaflets in consultation with parents.
Carers	To include carers more in patients' care, information giving and discharge.	Heighten staff awareness of carers role through the use of: - leaflets and seminars

➢ **Training of our nursing staff:**

Following the launch of the clinical governance agenda within the Royal Hospitals, the Director of Nursing appointed a practice development nurse. Clinical education facilitators were then appointed in most directorates. Their remit was to provide a more comprehensive nursing induction programme, develop framework documents for the different grades of nurses, set up a database for all nurse training. The new induction programmes have commenced, feedback is positive and staff already in post have requested an opportunity to attend.

The first mandatory training day covering blood products, manual handling, CPR and administration of medicines have been planned. Staff are required to attend annually. Other trusts have requested information on our clinical education facilitators and their work, and some are already replicating it.

➢ **Complaints:**

Quality in healthcare is a key element of current policy initiatives for reform within the NHS. Bearing in mind these changes and the wishes and needs of users while pursuing a complaint, it is important that we manage complaints impartially and efficiently. It is both daunting and challenging for many to make a complaint, therefore it is our responsibility to ensure that our procedure is open, accessible and effective. To improve complaints management an audit of complaints satisfaction has been carried out.

During the year the site has undergone tremendous change. It was anticipated that the number of complaints relating to this would increase. This was not so. Disruption has been minimal and has caused patients and their families little inconvenience.

- ***Local Resolution/Independent Review:*** The importance of handling complaints as soon as they arise is recognised by all directorates. This stage of the complaints procedure is being managed very well as only two complaints were referred to the Independent Review stage and one to the Commissioner for Complaints during this first stage.

- *Services and performance improvements:* One of the principal aims of the complaints procedure is to ensure that lessons are learnt from complaints, thus improving services, not only for complainants but also for all potential users. While the new clinical governance arrangements will bring improvements, there is a lack of information being provided by directorates. Not all complaints do require action, but focus on lessons learnt must be given a higher priority at directorate level.

➢ **Charter Marks**

To date the Royal Hospitals have been awarded seven Charter Marks –

- Regional Intensive Care Unit
- Genito-urinary Medicine
- Dermatology
- Speech and Language

- Children's Haematology
- HRT Clinic, RMH
- Acute Pain Service

➢ **Clinical Ethics**

As a result of research and consultation by a special task group on ethical dilemmas the Trust has established a Clinical Ethics Committee. The remit is:

® to advise the Trust in all matters relating to ethical issues in the clinical domain.

® to raise and maintain ethical standards in clinical practice in the Royal Hospitals.

The committee consists of 12 members, six of whom are current members of the Royal Hospitals staff and six lay members from outside the hospital. The membership is broad based to reflect a range of experience, interest, gender as well as racial, religious and cultural attitudes.

Mrs. D. O'BRIEN
Director of Nursing and Patient Services

Risk Management - SAFE WORKING PRACTICES

➢ **Risk Management Strategy:**

The Royal Hospitals has identified risk management as a key tool in developing its clinical governance framework. The emphasis on effective risk management, in all aspects of the Trust's undertakings, is highlighted and described in the Royal Hospitals risk management strategy. This document has been endorsed by Trust Board and Hospital Council in July 2000, following wide consultation at all levels within the organisation.

The strategy outlines the Royal Hospitals objectives in this area and identifies established external standards of best practice to which the Trust will work. The strategy also outlines the Royal Hospitals organisational arrangements for risk management (See Figure 1). It identifies directorates as the key management units for the assessment, control and elimination of risk. To ensure the effective implementation of the risk management strategy a multi-disciplinary steering group has been established that will monitor progress, establish priorities and provide expert advice.

➢ **Standards for risk management:**

Until local guidance is available the Royal Hospitals have adopted the following standards against which to benchmark progress:

- Clinical risk management standards developed in England and Wales to support risk pooling arrangements among NHS trusts (CNST Standards)
- Controls Assurance Standards as published by NHS Executive
- Current best practice in health & safety as defined by authoritative guidance.
- In addition, all professional staff have been reminded of their duty to main the standards of practice laid down by the respective regulatory bodies.

➢ **Developing an open and honest culture:**

The Trust is working to establish a culture that encourages staff to report adverse events so that lessons can be learnt and practices and policies changed accordingly. To assist in this the Trust has published a risk management policy statement and has also clarified what staff may expect to happen when they report incidents. This is enshrined within a definition of what the Royal Hospital means by an "open and honest culture".

➢ **External controls:**

The Royal Hospitals has secured the services of Marsh Risk Consulting to externally validate its risk management methods and the outcome of risk audits.

➢ **Progress to date:**

- *Incident reporting:*
  The Royal Hospitals established a single incident reporting system, in April 2000 that covers all adverse events both clinical and non-clinical, and including near misses. This is supported by a bespoke IT system that allows the recording, tracking, trending and compilation of data on adverse events. Management at all levels of the organisation

receive regular reports. In the first quarter of this financial year 695 adverse incident reports have been received. Sixty percent of these relate to clinical events. In the majority of these no harm accrued but we are now able to identify trends and highlight problem areas, such as prescription and administration of drugs and difficulties with consent. The high rate of incident reporting is encouraging, suggesting acceptance by staff of the Trusts risk management strategy and the benefits of incident reporting.

- *Risk Management Team:*
  Trust management and staff are supported by a dedicated Risk Management Team that includes a clinical risk manager, a health & safety manager, ergonomics advisers, an emergency planning officer and an occupational hygienist.

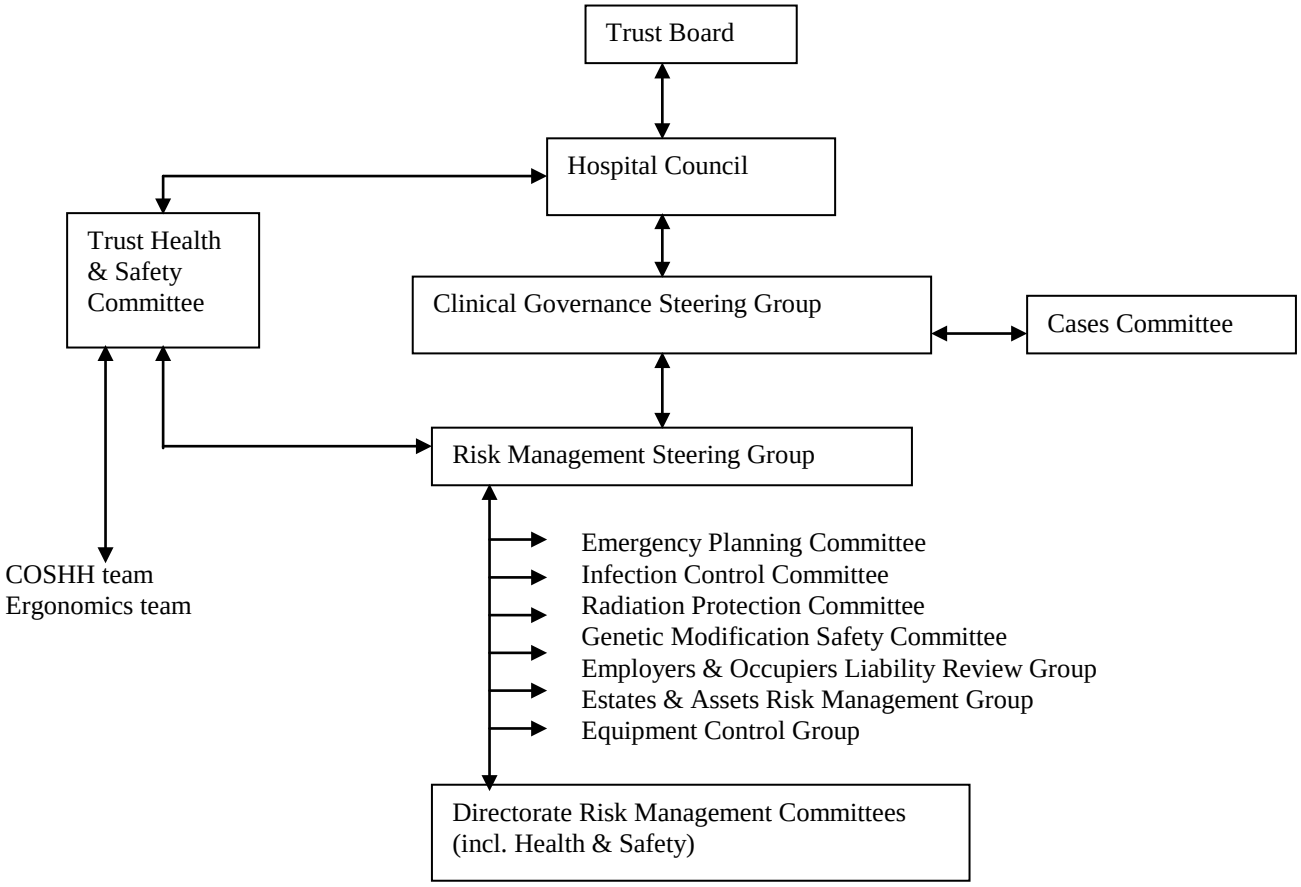
- *Controls Assurance:*
  The Trust is currently undertaking a baseline audit against five of the NHS executive controls assurance standards and as part of this is compiling a risk register. The audit process has been validated by an external consultant.

- *Annual Health & Safety Report:*
  The Royal Hospitals published its 4th annual health & safety report in July 1999. Sharps injuries and slips/trips/falls have been identified as the main causes of accidental injuries.
  Physical violence to staff is of growing concern. In 1995/96 there were 33 reported incidents, but by 1999/2000 there were 191 reported incidents. This increase may in part represent improved awareness and reporting by staff. We are taking a proactive approach to dealing with this problem using awareness and training programmes, improved surveillance and close co-operation with the police.

- *Risk Audit & Assessment:*
  The Trust has developed a risk audit and assessment process that will enable departments and directorates to assess all the risks associated with their undertakings and set priorities for control. This process will help to co-ordinate, risk assessments as required by Controls Assurance the Management of Health and Safety at Work Regulations, into a single process.

- *Infection Control:*
  The Royal Hospitals infection control team provides expert advice and maintains a number of surveillance programmes. As part of the risk management arrangements there is an established Infection Control Committee. Regular infection control reports are produced for Hospital Council.

Figure 1. Organisational Arrangements for Risk Management



Other areas of work for the Risk Management group in conjunction with the Directorate of Human Resources include the development and application of safe employment and recruitment practices.

Dr A.B. STEVENS
Director of Risk Management and Occupational Health

Education, Training and Development - LIFE-LONG LEARNING

- **University Liaison**

Liaison between the universities and the Royal Hospitals happens at many levels. Issues in relation to undergraduate medicine are contained in the SUMDE contract and are also represented by the Undergraduate Clinical Tutor. Particular issues in relation to accommodation for medical students, and doctors in training, have been highlighted through an accommodation report commissioned by the Directorate. The Directorate has also been working with Queens University on a proposal to develop a minimal access training and clinical simulation facility.

A number of joint posts with Queen's University and the University of Ulster will facilitate research and practice development within individual professional groups and contribute to wider healthcare research and education. Under the Memorandum of Agreement with the University of Ulster two partnership boards have been established, one for research and development, the second for training and personal development. These will take forward specific initiatives within professional groups across the Trust.

- **Postgraduate Liaison**

The Northern Ireland Council for Postgraduate Medical and Dental Education (NICPGMDE) and the Royal Hospitals have signed a training agreement contract. New systems have been designed and implemented by the Directorate to assist with the necessary recording and monitoring of rotation programmes and study leave activities. The NICPGMDE's plans to introduce a central study leave register will be piloted in the Royal Hospitals and the Postgraduate Tutors continue to represent the Council's views within the organisation.

- **NHS R&D**

The new plans for the management of HPSS R&D funds, led by the R&D Office, are in the process of being rolled out. Five Recognised Research Groups (RRGs) will proceed in this financial year and Royal Hospitals staff are involved with or leading four of the groups.

The Royal Hospitals are working closely with the R&D Office to assist with designing the necessary funding arrangements to support the new arrangements.

The appointment of a Director of Nursing Research will support, promote and direct nursing research activity and contribute to multiprofessional healthcare research.

- **Research Register and Indemnity**

The Royal Hospitals consider research to be a fundamental activity of the organisation, however the protection of patients, staff and resources is also crucial while supporting research. The implementation of a research management process managed through the Research Office will introduce a formal mechanism by which all research is agreed, both locally and organisationally, costed, funded, ethically approved and ultimately indemnified. Another component of the research management process will be the maintenance of a research database of all proposed, current and recently completed research projects.

- **Basic and Advanced Skills Training**

The creation of the Clinical Skills Facility has provided an area to support multiprofessional skills training. The area is used for induction, basic and enhanced clinical skills training.
In relation to advanced skills training the Royal Hospitals is exploring collaboration with the Royal College of Surgeons (England) around shared training and the use of teleconferencing. The first of the programmes is the TeleSTEP feasibility study, which involves 18 other sites in the UK and will deliver the training and education programme for surgeons weekly via teleconferencing to Belfast. This will mean that surgeons in training are spared the expense and time involved in travelling to London.

- **CME/CPD**

The Royal Hospitals recognise the importance of 'lifelong learning' and continuous professional development. Proposals include the creation of a central register to record and monitor Continuing Medical Education for all consultant staff.

- **Nurse Practice Development**

As a requirement of the UKCC regulatory body, nurses must participate in CPD and are required to update nursing practice using an evidence base. The appointment of a practice development nurse and clinical education facilitators will further this process and contribute to excellence in nursing practice.

- **Appraisal and Mentoring Training**

A programme of appraisal and mentoring training for medical staff has been introduced in the Medical Directorate. The aim will be to introduce similar programmes across directorates to support the trust-wide introduction of appraisal for career grade doctors.

Other areas of work for the Education, Training and Development group, in conjunction with the Directorate of Human Resources and the Director of Organisational Development, include workforce planning and the development and application of appraisal and mentoring training

Prof. A.G.H. LOVE
Director of Education, Research and Development

Reports and presentations to Trust Board

6 May 1999

(i) Proposed arrangements for implementation of Clinical Governance in the Royal Hospitals - (Dr I W Carson)

(ii) 5th Annual Report on Clinical Audit - (Dr H C Mulholland)

1 July 1999

4th Annual Report on Health & Safety - (Dr A B Stevens)

2 September 1999

Excellence Report - (Mrs. D O'Brien)

4 November 1999

Clinical Standards & Effectiveness - (Dr H C Mulholland)

13 January 2000

Report on Litigation Management - (Mr A P Walby)

2 March 2000

Excellence Report - (Mrs. D O'Brien)

Quality and Performance Indicators:

- **National Clinical Performance Indicators**

Performance league tables for hospitals in England were first published in May 2000. The collection of data and publication of such tables has not yet been extended to Northern Ireland. However, the Royal Hospitals with the assistance of CHKS – a comparative health informatics consultancy, using quality assured information have benchmarked the Royal's performance against a number of similar acute teaching hospitals in England.
Using patient data from 1997/98 the Royal's performance was either equal to or better than the average of its comparators in the following national indicators:

1. In-hospital perioperative mortality (Non-emergency) within 30 days of surgery
2. In-hospital perioperative mortality (Emergency) within 30 days of surgery
3. In-hospital mortality within 30 days of admission with a fractured neck of femur
4. Discharge home within 56 days of admission with a fracture neck of femur
5. Discharge home within 56 days of admission with a stroke
6. Emergency readmission within 28 days of first treatment

- **Value for Money Review of Anaesthetic and Critical Care Services**

Price Waterhouse and Coopers on behalf of the National Audit Commission in 1999/2000 undertook this in depth assessment of anaesthetic and critical care services. This review assessed the Royal Hospitals anaesthetic and critical care services for both value for money and quality and compared them with other Trusts in UK

- Anaesthetic Services

i) 88% of theatre sessions were consultant led compared to an England and Wales average of 75%.

ii) Trainee anaesthetists were supervised on 98% of the theatre sessions compared with an England and Wales average of 75%.

iii) The average number of theatre sessions worked by consultant anaesthetists was 6.9 per week compared to an England and Wales average of 6 sessions.

- Critical Care Services

In comparing the Regional Intensive Care Unit (RICU) with the intensive care units in the 6 teaching hospitals surveyed by the Audit Commission the review found that:

i) Royal Hospitals' occupancy was 95.5% compared to the English average of 89.2%

ii) Mortality rate for RICU was 20%, as against 21% for comparative units and 22% for all intensive care units reviewed by Audit Commission

iii) Readmission rates for the unit are in line with comparative trusts.

iv) The Royal has one of the highest emergency as against elective admission rates as against comparative trusts

- **Laboratory Accreditation**

The Belfast Link Laboratory Service was inspected by Clinical Pathology Accreditation (CPA) in 1998. Several improvements were required by inspection and conditional approval was granted. Since then, the conditions relevant to the Royal Hospitals site have been met and full accreditation has been granted to the Haematology, Microbiology, Biochemistry and Immunology services. Conditional status has been confirmed for Tissue Pathology. with minor adjustments to be introduced to achieve full accreditation. This confirms that the laboratory service meets the very high standards required to support a major acute teaching hospital. The accreditation will be reviewed in 2001.

Clinical Governance Action Plan 2000 / 2001

The vision for the next five years

The essential building blocks for clinical governance have been put in place during 1999/2000. For clinical governance to be successful into the future, the Royal Hospitals should demonstrate the following generic features:

- An open and participative culture in which education, research and the sharing of good practice are valued and expected.
- A commitment to quality that is shared by clinical staff and managers alike, supported by clearly identified local resources, both human and financial.
- A tradition of active working with the public, users of services and their carers.
- An ethos of multi-disciplinary team working at all levels in the Trust.
- Regular Board-level discussion of all major quality issues for the Trust and strong leadership from the top.
- Good use of information to plan and to assess progress.
- Clear lines of responsibility and accountability for overall clinical care

This action plan specifies the steps that the Trust needs to take during 2000 / 2001 to enable the clinical governance programme in the Trust to progress to the next stage of development. Specifically, it highlights the four targets that the Clinical Governance Steering Group need to work towards, namely:

1. **Ensure that there is clear responsibility and ownership of clinical governance at clinical directorate level, by the establishment of Clinical Governance Teams in each Directorate.**

2. **Ensure that infrastructure support is available to meet the clinical governance requirements**

3. **Institute a programme of familiarisation and training to further develop clinical governance within the Trust.**

4. **To produce the second annual clinical governance report covering the year 2000/2001.**

THE ROYAL GROUP OF HOSPITALS AND DENTAL HOSPITAL HSS TRUST

Medical Excellence - Maintaining good medical practice: the conduct, health and performance of doctors working within the Royal Hospitals Trust.

I.W.CARSON
Medical Director

November 1997

INTRODUCTION

The medical profession is trusted by society to regulate itself. The General Medical Council has statutory responsibility for overseeing self-regulation. In defining the duties of the doctor however, the GMC has made it clear that self-regulation is a responsibility of all doctors. Members of the medical profession have a moral, ethical and professional responsibility for their individual practice and that of their colleagues.

Effective professional self-regulation is fundamental to maintaining the public's confidence in the medical profession. Trust is at the heart of the relationship between patients and their doctors, and between society and the medical profession. Patients trust their doctors to look after them competently and conscientiously, respecting their privacy and dignity. Society trusts the medical profession to make sure that doctors are well trained, and that they maintain good standards of practice and care. Equally, it expects the profession to protect patients from doctors whose fitness to practise gives cause for concern.

The GMC, and in the case of hospital doctors the employer, have key roles in these matters. Both formal and informal arrangements exist to monitor, guide and if necessary intervene in the practice of doctors, where there is concern about their conduct, health or performance. In addition to the responsibilities of the medical profession to the public there is a responsibility placed on Employing Trusts, Purchasers and Training Bodies to protect the health and welfare of doctors at work while providing adequate and appropriate educational opportunities.

We want to prevent poor practice by encouraging and helping doctors to promote, maintain and assure good practice in all fields of medicine through effective local professional self-regulation. If problems do arise, they should be handled promptly by colleagues at a very early stage - before damage is done to patients and the doctor in difficulty.

Professional standards

The GMC - the licensing body - is the fulcrum of the system of self-regulation in the United Kingdom, and as such has set general standards for all doctors. The great majority comply with those standards, providing good quality health care - often under difficult and demanding circumstances.

It is important that doctors have clear standards against which to assess and improve their own practice, and that their professional performance retains the confidence of patients and colleagues. These standards of professional practice and conduct are summarised in the GMC's ***"Duties of a Doctor"*** (Appendix 1). The standards have been endorsed by the profession, medical schools, royal colleges, employers, government, and have been well received by the public.

Fitness to practise

The GMC fitness to practise procedures provide the means for dealing with the exceptions - the small minority of doctors whose conduct, health or performance gives rise to serious concern. This approach depends on effective means, outside the GMC, of identifying and tackling actual or prospective dysfunction at an early stage. The aim is to ensure that immediate local action will be taken when a doctor shows signs of dysfunction, thereby putting patients at risk.

The GMC have been given legal powers by Parliament, covering all doctors, whether in the NHS or in private practice, working in hospital or general practice, and can take action when:

- a doctor is convicted of a crime
- there is an allegation of serious professional misconduct
- a doctor's state of health may pose a threat to patients
- a doctor's professional performance may be seriously deficient.

The GMC now have a range of procedures which allow it to handle effectively the dysfunctional doctor. These arrangements are being integrated closely so that, when a complaint against a doctor is received, there will be a single screening process to determine whether to proceed and which procedure to apply, namely - conduct, health or performance.

New performance procedures

New legislation, under the Medical (Professional Performance) Act 1995, now allows the GMC to significantly increase protection for patients by dealing with doctors who exhibit seriously deficient performance - that is, *repeated or persistent failure to comply with accepted standards of good medical practice - sufficient to call into question a doctor's registration.* It may well include failure to comply with GMC guidance in ***Good Medical Practice.***

The new performance procedures introduced by the GMC from September 1997 make very significant strides towards a culture in which poor performance is prevented wherever possible, identified early if it does exist and all possible attempts to manage the situation effectively and locally without resort to disciplinary action. Where disciplinary action is unavoidable, the appropriate procedures for dealing with the matter must be implemented with the full knowledge and understanding of the doctor concerned.

All doctors have a role to play, not only in identifying the colleague whose performance is not what it should be, but also in ensuring that action is taken. The Medical Director or Clinical directors are often the first to become aware of a colleagues' performance problems, or is the point of contact for other consultants in reporting areas of dysfunctional colleagues. Medical Directors have a key role in implementing the proper procedures, in safeguarding patients and in liaison with other appropriate individuals and professional bodies, including the GMC.

When confronted with a seriously dysfunctional doctor, there are three immediate objectives:

- to take all measures necessary to protect patients
- to try to find out what has gone wrong and why
- to help doctors who are keen to rehabilitate themselves - especially where seriously deficient performance is established - by ensuring that they have good access to the necessary advice, counselling and training.

SCOPE OF THIS DOCUMENT

This document describes the roles, and defines the relationship between local management arrangements and the statutory procedures of the GMC.

Professional Performance:

This document deals with the mechanisms in place for identifying poor practice, demonstrating the means by which doctors with performance problems can be supported and ultimately the actions and processes that may be implemented in the event of persistent under-performance.

Problems of performance may include, for example:

- Failure to keep professional knowledge and skills up to date
- Failure to recognise the limits of professional competence
- Failure to maintain any or adequate clinical records
- Inability to perform a competent physical examination
- Attempting to perform techniques in which the doctor has not been appropriately trained
- Inability or refusal to communicate effectively with patients or their relatives
- Failure to work effectively with colleagues.

Doctor's Health:

This document deals with the problems doctors face in dealing with general health problems. In particular the problems faced by doctors in obtaining confidential medical advice and support. In addition health problems that have an impact on the performance of a doctor are considered in terms of diagnosis, treatment, rehabilitation, accommodation of the disability and retirement.

Ill health which impairs a doctor's fitness to practise is most likely to take the form of:

- A serious mental condition; and / or
- Abuse of alcohol and / or drugs.

Misconduct:

Misconduct is considered an internal issue with reference to existing Trust policies. The relationship of the Trust to the General Medical Council is considered and the function of the GMC with respect to serious professional misconduct is also outlined.

Problems in relation to conduct include, for example:

- Serious neglect or disregard of professional responsibilities to patients
- Certifying as true, information which the doctor knows to be untrue or has taken appropriate steps to verify
- Improper charging of fees to patients
- Any form of dishonesty, including improper claims or fees
- Any abuse by the doctor of his or her position of trust, including a breach of professional confidence
- Any form of indecency or inappropriate sexual conduct towards a patient or colleague.

EXTERNAL ARRANGEMENTS

Role of General Medical Council in relation to :

Performance

The GMC has drawn up procedures for investigating a doctor's performance where there is concern that this may be seriously deficient. The GMC defines seriously deficient as a departure from good professional practice serious enough to call into question the doctor's registration. The primary aim of the performance procedures is to protect patients. Subject to this overriding aim, the procedures will be used to help doctors return to fully effective medical practice. The aim is for the doctor to voluntarily undertake remedial action and the GMC's formal arrangements only come into place if the doctor does not co-operate, or if the performance is so bad that the public has to be protected by giving consideration to the registration of the doctor. The detailed arrangements include -

- assessment of a doctor's professional performance if there is evidence that it is seriously deficient;
- insistence that a doctor take remedial action to address any deficiencies;

- the power to suspend or place conditions on a doctor who is found to be seriously deficient in their practice.

The methods of assessing doctors are being prepared in detail by the GMC, in close co-operation with the royal colleges and faculties. An assessment panel, normally comprising of two medical and one lay member, will visit doctors at their place of work to review records, discuss cases, interview colleagues and, where appropriate, observe consultations. Assessments may also include tests of professional knowledge and skills. On the basis of the assessment, the GMC will decide if further action is required. The GMC may decide to refer the case to the Committee on Professional Performance, (CPP) or allow the doctor to take remedial action without referral to the CPP. The onus will be on the doctor to rectify deficiencies.

If a case is referred to the CPP, the Committee's task will be to determine if the standard of a doctor's professional performance has been seriously deficient and, if so, whether to put conditions on, or suspend, the doctor's registration.

Patients, other members of the public and doctors will be able to make complaints under the new procedures. The Trust and other public bodies such as the Purchasing Authority may also make referrals.

Further details of the performance procedures are contained in Performance Procedures: A Guide to the New Arrangements: July 1997 - available through the Medical Director's Office or directly from the GMC.

Health

The medical profession has higher rates of depression, suicide and drug/alcohol abuse compared to other professional groups. Stress amongst doctors is being increasingly recognised as a problem. The GMC have procedures for dealing with sick doctors. While aimed at protecting patients these procedures are designed to provide help and support to doctors. The GMC's aim is to assist doctors recover from illness and be rehabilitated, in order that they can undertake their duties as a doctor satisfactorily.
In reality the vast majority of cases the GMC deals with are related to mental illness or substance abuse.

The proceedings of the GMC Health Committee are strictly confidential and involve four main stages. These include preliminary consideration of evidence, medical examination of the sick doctor, medical supervision/rehabilitation and intervention by the Health Committee. Most cases are dealt with informally and do not require attendance at the Committee.

The Health Committee does have the power to suspend a doctor from the Medical Register either for a temporary period or indefinitely.

Sick doctors may choose to refer themselves under the health procedures. More probably the case will be referred by an employing authority, concerned colleagues or the advocate of a patient.

Misconduct

The GMC receives many inquiries or complaints about doctors. Only a small number of these are considered serious enough to require a hearing in front of the Professional Conduct Committee. Such hearings are in public.
Where professional misconduct is proven the Committee may erase or suspend a doctor from the Register. Alternatively their registration may have conditions applied.

Whenever doctors commit offences that constitute gross misconduct, they are subject to the same rules and disciplinary procedures as other staff in the Trust.

What constitutes gross misconduct?

The following list is neither exclusive nor exhaustive, but illustrates the range of misdemeanours which require investigation: -

- Theft
- Fraud
- Malicious damage to property which belongs to the Trust, a patient or other employee
- Falsification of expense claim forms, time sheets or other important personal records
- Misuse of employee's official position for personal gain
- Unauthorised use or removal of the Trust's property
- Drug trafficking or misuse / abuse
- Fighting or physical assault
- Deliberate disregard of safety rules
- Unauthorised absence from work
- Using abusive or obscene language
- Repeated refusal to obey lawful orders or gross insubordination
- Serious neglect of duties
- Improper disclosure of confidential information
- Sexual / racial harassment or discrimination
- Sexual misconduct
- Working under the influence of alcohol or other substances
- Any breach of the Trust's Equal Opportunities Policy.
- Providing an applicant for a job with an inaccurate reference, not mentioning the fact that the applicants' conduct or performance has been below what would be expected
- Putting patients at risk by not declaring knowingly the presence in the doctor of an infectious disease. The infections have been HIV or Hepatitis B, but this would apply to any other infections.

Role of the Local Director of Public Health:

With the advent of Trusts the role of the Director of Public Health has become less pivotal. It is recognised that a Trust as the employer of a doctor has assumed many of the responsibilities of the local Director of Public Health. In the case of the Royal Hospitals Trust the Medical Director has assumed these responsibilities (see internal arrangements below).

"Three Wise Men":

This procedure for the management of the 'sick doctor or dentist' whose clinical performance was well below accepted standards was established by the Department of Health in 1982. Details were contained in a Department of Health circular (HC[82]13) . This procedure was designed to function within the old NHS management structure prior to the establishment of Trusts. The procedure was not well understood, and was not always effective.
The new GMC Performance Procedures effectively replace the "Three Wise Men", although the concept may be adopted by the Medical Director, where appropriate, at an early stage of the informal local mechanism.

Role of Northern Ireland Council for Postgraduate Medical & Dental Education :

The NICPMDE, through the Postgraduate Dean, has a role in the management of doctors in training. Where concern arises about the performance, health or conduct of such doctors the Medical Director of the Trust will notify the Postgraduate Dean and liaise regarding appropriate action.

Role of Queen's University of Belfast (for joint appointments):

The Trust has inherited the agreement between the Eastern Health and Social Services Board and Queen's University, that "when action has to be taken by either the Trust or the University, in relation to the health, performance or conduct of jointly appointed members of staff, the other employer will honour the decision which will affect the total contract of the joint appointee. The other party will be informed that proceedings are taking place but the procedures will be carried out by the employer which appears most responsible in relation to the complaint".

Role of Health and Social Service Councils:

Health and Social Service Councils and the Ombudsman offer a route for patients and users of our services to highlight problems, make complaints and seek further information. They will act as advocates for patients and others who avail of our services.

The Trust's existing complaints procedure describes the mechanism for dealing with issues raised by Health and Social Service Councils and other advocates of patients' rights.

Role of the British Medical Association:

The BMA has an important role in representing doctors collectively, through the Local Negotiating Committee. The BMA will also advise and represent individual members in their dealings with the Trust.

BMA Counselling Service: - This service is available to doctors and their families on a 24 hour basis. It provides a confidential facility for discussing personal, emotional and work related problems. The service is free except for the cost of the telephone call, charged at the local rate. Tel: 0645 200 169

The National Counselling Service for Sick Doctors:

This service was set up in 1985. It is supported by the medical Royal Colleges, the Joint Consultant Committee and the BMA.

This service can be accessed by individual doctors or their colleagues or relatives. A local adviser will deal initially with the client but will have support from psychiatric counsellors who can provide advice and treatment. The service is confidential and is not linked to the GMC or any other statutory authority.

The service is advertised in the BMJ, and is accessed by telephone (0171 935 5982).

Defence Organisations:

Other Confidential Help Lines

The Sick Doctor Scheme, Association of Anaesthetists of Great Britain and Ireland.
Tel. 0171 631 1650

Doctors Support Network.
Tel. 0171 727 3738

Drinkline (National Alcohol Helpline).
Tel. 0345 320202

Sick Doctor's Trust (Helpline for addicted physicians).
Tel. 01252 345163

BMA Stress Counselling Service for Doctors.
Tel. 0645 200169

INTERNAL ARRANGEMENTS

Health:

It is generally recognised that doctors do not always respond well to their own ill-health. There may be problems with admitting an illness exists or to seek help, particularly from colleagues. Doctors may differ from other people in the way that they access health services. The corridor consultation in particular may cause a problem, with doctors seeking advice informally, from colleagues they work with. The loss of confidentiality and lack of a structure for action and follow up may result in sub-optimal or inappropriate treatment within the context of this document. With respect to work, health issues can be divided into those that are relevant to a doctor's occupation and those that are of more general concern.

General Health Problems:

Where the doctor does not feel able to access health services through his General Practitioner, confidential advice is available through the Occupational Health Service. The Consultant or Occupational Physician can arrange for medical colleagues to be seen by a relevant Specialist either in the Occupational Health Department or at a site separate from the Trust's premises. It will also be possible to access a specialist who works at another hospital. Both senior and junior doctors should feel able to approach the Consultant Occupational Physician for advice either about themselves or colleagues.

Occupational Health Problems:

It is a duty of all doctors to deal with their own health problems appropriately where these may affect the safety and care of patients. In this situation any member of the Trust medical staff should contact the Consultant Occupational Physician for advice. Clinical information will always remain confidential to the Occupational Health Department. The Consultant Occupational Physician will provide clinical and occupational advice to medical staff. Only where advice is not taken and there is a risk to patients or colleagues will the Occupational Physician advice the Medical Director of a problem. In this situation the advice will be of a non-clinical nature. This would take the form of advice to the Medical Director regarding somebody's fitness or otherwise for work.

Health and Safety:

Where doctors are concerned about the working environment or working arrangements and a risk to health, safety or welfare can be identified, then these issues should be

brought to the attention of the Director of Risk Management or the Trust Health and Safety Officer. Issues can be dealt with in a confidential way in order that the source of information is not identified.

All doctors have the responsibility to co-operate with the Trust's management arrangements for health and safety. These are detailed within the Trust's Health and Safety policy and various procedural documents.

Doctor and Blood Born Viruses:

HIV - All doctors within the Trust should have received a letter from the Medical Director dealing with their responsibilities should they believe that they have HIV infection or may be at risk of infection. Guidance on the duties of a doctor who may be in this situation are contained in GMC publication - ***"HIV and AIDS: the ethical considerations"***. This has been distributed to all doctors registered with the GMC. A copy can be obtained from the GMC Tel. 0171 915 3507.

The GMC says that it is unethical for doctors who know or believe themselves to be infected with HIV to put patients at risk by failing to seek appropriate counselling or by failing to act upon advice when given.

The GMC also says that a doctor who knows that a health care worker is infected with HIV and is aware that that person has not sought or forwarded advice to modify his or her professional practice, has a duty to inform the appropriate regulatory body and an appropriate person in the health care worker's employing authority, who will usually be the Medical Director.

Within the Royal Hospitals Trust any doctor who is concerned about infection with HIV can seek confidential advice from the Consultant in Occupational Medicine or from a Consultant in Genito-urinary Medicine.

Hepatitis B - All doctors involved in exposure-prone procedures are required by the Department of Health and the Trust to submit to antibody testing for Hepatitis B after appropriate vaccination. Where vaccination has not been carried out or where a satisfactory antibody response to vaccination has not been achieved, doctors must submit to a Hepatitis B surface antigen test to ensure that they are not carriers of Hepatitis B. The Trust will follow current Department of Health guidance with respect to the employment of doctors who may be chronic carriers of Hepatitis B.

Doctors who are non-responders to vaccine or who have not had vaccination, will be required to undertake annual serology testing.

Performance:

The Trust is committed to providing safe and effective care for patients. Assuring the performance of individual doctors is essential to achieving this commitment. Appropriate measures to promote and maintain professional performance have been put in place. These include:

- Recruitment and selection procedures
- Induction programmes for new staff
- Review of Job Plans
- Clinical audit
- Risk Assessments and Risk Management Reviews
- Untoward clinical incident and accident reporting
- Study Leave arrangements, and
- New reporting procedures for doctors concerned about colleagues' performance (Appendix 2)

Further information on any of these matters is available through your Clinical Director.

All doctors also have responsibilities for ensuring their performance and that of colleagues. Doctors are expected to keep up to date their professional knowledge and skills. The Trust expects all career grade medical and dental staff to undertake continuing medical and dental education (CME). The requirements and standards for CME are set by the Royal Colleges. All senior staff must be familiar with the standards set by their respective College and are required by the Trust to meet these standards.

Individual doctors must act appropriately to protect patients at risk where there is reason to believe that their own performance or that of a colleague is deficient. The procedure for dealing with this situation is detailed in Appendix 2.

Conduct:

All medical staff are expected to maintain the highest levels of professional conduct. Examples of misconduct are given in the section entitled 'Scope of this Document'. With respect to conduct, medical staff are expected to comply with the policies and procedures of the Trust, particularly with respect to:

- Absenteeism
- Equal Opportunities
- Harassment
- Recruitment and Selection
- Health & Safety
- Alcohol and Substance Abuse Policy
- Complaints

Details of all Trust Policies are contained in the Trust Policy Manual or Health & Safety Manual.
The standards of professional conduct expected of staff are dictated by the GMC (Appendix 1 and Duties of a Doctor, GMC October 1995)

Where misconduct has an impact on performance the procedures described in Appendix 2, for dealing with deficient performance will apply.

APPENDIX 1

The Duties of a Doctor registered with the General Medical Council (Oct 1995)

Patients must be able to trust doctors with their lives and well-being. 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
- 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.

APPENDIX 2

ROYAL HOSPITALS TRUST PROCEDURE

Procedures for doctors to report concerns about the conduct, performance or health of medical colleagues.

1. The Royal Hospitals Trust is committed to providing safe and effective care for patients and must ensure that medical staff have a mechanism that enables them to report concerns about the conduct, performance or health of medical colleagues. (Chief Medical Officer, 10th January, 1997)

Procedure:

1.1 Any doctor concerned about his/her fitness to practise or the fitness of a colleague, due to concerns about conduct, performance or health, should discuss the matter with his consultant, the Clinical Director or the Medical Director, whichever is appropriate.

1.2 Generally concerns about trainee doctors should first be discussed with the supervising consultant and the relevant Clinical Tutor.

1.3 If a trainee is involved, the Postgraduate Dean and where appropriate, the chairman of the relevant training committee will be consulted.

1.4 If report is received about a locum then the Clinical Director must be informed. If the locum is sourced from an agency, they will need to be involved.

1.5 In every case, irrespective of the circumstances, reports should be brought to the attention of the Medical Director.

1.6 The Medical Director should make formal note of the report.

1.7 Concerns about the clinical performance of the Medical Director should be raised with the Chief Executive by the Clinical Director.

1.8 The Medical Director, or in the case of the Medical Director the Chief Executive, will institute an inquiry by appointing an appropriate investigating officer. Support should be provided by a senior member of the Personnel Department and the Director of Risk Management (if appropriate). This may be a preliminary enquiry and outside the Trust's formal disciplinary mechanisms. It should normally be led by the Medical Director.

1.9 Every care will be taken to ensure the confidentiality of the parties while any allegation is being investigated.

1.10 If there are concerns about the safety of patients the doctor may have to be suspended while an enquiry is pursued. If disciplinary action is contemplated suspension may also be required. Suspension should be seen as a neutral act,

rather than a disciplinary sanction. It is intended to protect the interests of patients, other staff, or the practitioner him/herself. It does not imply 'guilt' and is not punitive. Alternatives to suspension, e.g. the practitioner continuing to work on limited or alternative duties where practicable, will be carefully considered.

1.11 Upon receipt of the report it is for the Medical Director to make a decision as to how the matter should be pursued and report his decision promptly to the Chief Executive of the Trust, and in the case of a trainee to the Postgraduate Dean. This should normally be within one month of receiving the complaint.

1.12 The Medical Director will consider whether to report the matter to the GMC. The stage at which this should be done will depend upon the nature of the concerns expressed and formal guidance issued by the GMC.

1.13 The doctor complained against should be kept informed of proceedings at all stages.

2. The GMC publication 'Duties of Doctor' maintains that all doctors must 'act quickly to prevent patients from risk if you have good reason to believe you or a colleague may not be fit to practise'. This procedure is applicable to all doctors within the Trust, senior career grade or trainee, substantive or locum.

3. **Please return the acknowledgement slip on the next page to Mrs. Barbara Martin, KEB**

Please complete and return to:
Mrs. Barbara Martin,
Chief Executive's Office,
KEB.

NAME:

GRADE:

DIRECTORATE:

I have read and understand the procedure for reporting concerns about the conduct, performance and health of colleagues.

Signed: DATE:

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LETTER TO ALL CURRENT MEDICAL STAFF

Procedures for reporting concerns about the conduct, performance or health of medical colleagues.

Dear Colleague,

I wrote to all consultant staff on 9 June 1997, when I outlined new arrangements that would come into place with effect from 1 September 1997. Detailed rules to govern the new performance procedures have gone through parliament and are now in place. You will note that the introduction of such procedures have been required by the Chief Medical Officer, have been agreed by the Central Consultant and Specialists Committee of the BMA, and will become an established component of the General Medical Council's performance monitoring process.

The GMC has now clarified its procedures and has conducted a series of 'roadshows' for representatives of health authorities, health boards, trusts and local health councils, at regional centres throughout the UK to publicise the new arrangements.

I intend to hold a number of brief presentations for medical staff to help provide further information, your attendance at one of these sessions would be appreciated.

Venue: Sir Samuel Irwin Lecture Theatre, RVH

Dates and Times: .....
.....

Venue: MacAfee Lecture Theatre, RMH

Date and Time: .....

Venue: RBHSC Conference Room

Date and Time: .....

I enclose a detailed document entitled ***Medical Excellence - Maintaining good medical practice: the conduct, health and performance of doctors working within the Royal Hospitals Trust.*** This outlines the principles governing good medical practice and some additional information in respect of formal and informal arrangements to monitor, guide and if necessary intervene in the practice of doctors, should concerns arise. A number of doctors have asked me for further information on these matters, and I hope you find this helpful.

Also appended to the document (Appendix 2) is a copy of the Trust Procedure for reporting concerns about medical or dental colleagues. This procedure has been agreed with the Local Negotiating Committee, and approved by the Provost, College of Medicine and Health Sciences, QUB, and the Postgraduate Medical Dean.

Will you please read this important communication and return the acknowledgement slip attached to the procedure, to my secretary - Barbara Martin (KEB), as soon as possible.

A number of you have applied to the GMC to be considered as clinical members of their panel of assessors. As Medical Director, it would be helpful if I was aware of all those consultants so appointed, and who will accumulate experience and skills in this area of work.

Yours sincerely,

IAN W. CARSON
Medical Director.

Clause for incorporation in the Job Descriptions of all Medical Staff appointed after 1 November 1997.

The following paragraph should be inserted into the job descriptions of all medical staff.

'The Trust is committed to providing safe and effective care for patients. To ensure this there is an agreed procedure for medical staff that enables them to report, quickly and confidentially, concerns about the conduct, performance or health of medical colleagues (Chief Medical Officer, 10th January, 1997). All medical staff, practising in the Trust, should ensure that they are familiar with the procedure and apply it.'

Clause for incorporation in the Job Description of the Medical Director.

As Medical Director you are responsible for ensuring that procedures are in place throughout the Trust for doctors to report concerns about the conduct, performance or health of medical colleagues. These must apply to substantive and temporary (locum) appointments, career or trainee grades. This procedure must include directions for the appropriate investigation of issues and resulting action.

Letter for all locum doctors who might not receive a contract before commencing work.

NAME

Locum Post

Dear Doctor,

Enclosed is a copy of the procedures agreed with the Local Negotiating Committee for reporting concerns about medical colleagues. You will note that the introduction of such procedures have been required by the Chief Medical Officer, agreed by the Central Consultant and Specialists Committee and will become an established component of the General Medical Council's performance monitoring process.

Will you please read and acknowledge. This must be done before you commence work in the Trust.

OR

Dear Doctor,

The Trust is committed to providing safe and effective care for patients. To ensure this there is an agreed procedure for medical staff that enables them to report, quickly and confidentially, concerns about the conduct, performance or health of medical colleagues (Chief Medical Officer, 10th January, 1997). If you have any concerns about a colleague (senior or junior) you must tell someone in authority in the Trust. This may be

- a consultant
- the Clinical Director
- the Medical Director
- the Director of Risk Management
- the Clinical tutor

Will you please read and acknowledge. This must be done before you commence work in the Trust.