

Clinical Governance & Risk Management:

Achieving safe and effective, patient-focused care

Consultation on draft national standards

April 2005

Contents

1	Background on NHS Quality Improvement Scotland	2
2	Development of Clinical Standards	3
3	An Introduction to Clinical Governance and Risk Management	5
4	Development of the Draft Standards for Clinical Governance and Risk Management	8
5	How to Participate in the Consultation Process	11
6	Overarching Principles	12
7	Draft Standards for Clinical Governance and Risk Management	13
	Standard 1 – Safe and effective care	14
	Standard 2 – The health and care experience	16
	Standard 3 – Assurance and accountability	18
8	Appendices	20
	Appendix 1 Membership of the Clinical Governance and Risk Management Standards Project Group	21
	Appendix 2 Evidence Base	23
	Appendix 3 Background to the Draft Standards	28
	Appendix 4 Glossary of Terms	29

© NHS Quality Improvement Scotland 2005

First published April 2005

NHS Quality Improvement Scotland (NHS QIS) consents to the photocopying, electronic reproduction by 'uploading' or 'downloading' from the website, retransmission, or other copying of these draft clinical standards for the purpose of implementation in NHSScotland and educational and 'not-for-profit' purposes. No reproduction by or for commercial organisations is permitted without the express written permission of NHS QIS.

www.nhshealthquality.org

1 Background on NHS Quality Improvement Scotland

NHS Quality Improvement Scotland (NHS QIS) was set up by the Scottish Parliament in 2003 to take the lead in improving the quality of care and treatment delivered by NHSScotland.

We achieve our objectives through four key functions that link together:

- setting standards
- reviewing and monitoring performance
- providing advice and guidance on effective practice
- supporting staff to improve services.

We deliver our commitments to the public and to NHSScotland by following an approach that is:

- **independent** – we reach our own conclusions and report on what we find
- **open and transparent** – we explain what we do, how and why we do it, and what we find, using language and formats that are easy to understand and to access
- **sensitive and professional** – we recognise needs, beliefs and opinions and respect and encourage diversity.

Our work is:

- **partnership-focused** – we work with patients and the public, NHSScotland and many organisations to improve the quality of care and avoid duplication
- **evidence-based** – we base our conclusions and recommendations on the best evidence available
- **quality-driven** – we make sure our own work is monitored and evaluated, internally and externally.

2 Development of Clinical Standards

Basic principles

A major part of the remit of NHS Quality Improvement Scotland (NHS QIS) is to develop and run a national system of quality assurance of clinical services. Working in partnership with healthcare professionals and members of the public, NHS QIS sets standards for clinical services, assesses performance throughout NHSScotland against these standards, and publishes the findings. The standards are based on the patient's journey as he or she moves through different parts of the health service. A wide range of diseases and services have already been addressed including diabetes, breast screening and stroke services.

The standards set by NHS QIS are clear and measurable, based on appropriate evidence, and written to take into account other recognised standards and clinical guidelines. The standards are:

- written in simple language and available in a variety of formats
- focused on clinical issues and include non-clinical factors that impact on the quality of care
- developed by healthcare professionals and members of the public, and consulted on widely
- regularly reviewed and revised to make sure they remain relevant and up to date
- achievable but stretching.

Process

For each project in the work programme, NHS QIS appoints a group comprising appropriate healthcare professionals and members of the public to:

- oversee the development of, and consultation on, the draft standards and self-assessment framework
- recommend an external peer review process.

The way in which standards are developed is a key element of the quality assurance process. Project groups working on behalf of NHS QIS are expected to:

- adopt an open and inclusive process involving members of the public, voluntary organisations and healthcare professionals
- work within NHS QIS policies and procedures
- test the measurability of draft standards by undertaking pilot reviews.

Assessment of performance against the standards

The framework for the NHS QIS review process is as follows.

- Once the standards have been finalised, each relevant NHS Board/service is asked to undertake a self-assessment of its service against the standards.
- A review team visits the NHS Board/service on behalf of NHS QIS to follow up this self-assessment exercise with an external peer review of performance in relation to the standards.
- NHS QIS reports the findings for the NHS Board/service, based on the self-assessment exercise and on the external peer review.

All the processes being developed by NHS QIS are subject to review and evaluation, to help improve the quality assurance system.

3 An Introduction to Clinical Governance and Risk Management

Clinical governance

The system for making sure that healthcare is safe and effective and that patients and the public are involved.

As described in *Building a Better Scotland (2001)* NHSScotland needs to 'improve the health and quality of life of the people of Scotland and the delivery of integrated health and community care.'

The concept of clinical governance was introduced to NHSScotland in *Designed to Care (SEHD 1997)*, the White Paper on improving Scotland's healthcare. It was described as 'corporate accountability for clinical performance' and has more recently been described as the system for making sure that healthcare is safe and effective and that patients and the public are involved.

These standards have been set in the context of healthcare governance in NHSScotland. NHS Boards are statutory bodies and have clearly defined governance arrangements in place to cover financial, staff and corporate governance and this is collectively described as healthcare governance. The elements of governance which NHS QIS has a responsibility for are the assessment and monitoring of clinical governance and risk management.

A number of bodies are involved in assessment and monitoring of healthcare governance arrangements within NHSScotland. In order to minimise duplication and to develop comprehensive profiles of NHS Boards, the Scottish Executive Health Department (SEHD) is establishing a national governance reference group and all bodies involved in monitoring governance will be represented on this.

The themes of clinical governance are:

- clinical effectiveness
- patient focus
- risk management
- information management
- professional/staff development.

These themes are underpinned by effective systems of organisational learning and development.

Principles of good governance

The following principles have been adapted for use from *The Good Governance Standard for Public Services (2004)*:

Good governance means:

- focusing on the organisation's purpose and on outcomes for patients and service users
- performing effectively in clearly defined functions and roles
- promoting values for the whole organisation and demonstrating the values of good governance through its practices
- taking informed, transparent decisions and managing risk
- developing the capacity and capability of the governing body to be effective
- engaging stakeholders and making accountability real.

Risk management

Risk management is the systematic identification, assessment and reduction of risks to patients, staff and the organisation.

Risk management is defined as 'the culture, processes and structures that are directed towards realising potential opportunities whilst managing adverse effects'.
(*Australia/New Zealand Risk Management Standards 4360: 2004*)

To be most effective, risk management must become part of an organisation's culture. It should be embedded into the organisation's philosophy, practices and business processes rather than be viewed or practiced as a separate activity. When this is achieved, everyone in the organisation becomes involved in the management of risk. Furthermore, as an integral component of the Statement on Internal Control, it is a mandatory requirement that NHS Boards have systems and processes in place to manage risk.

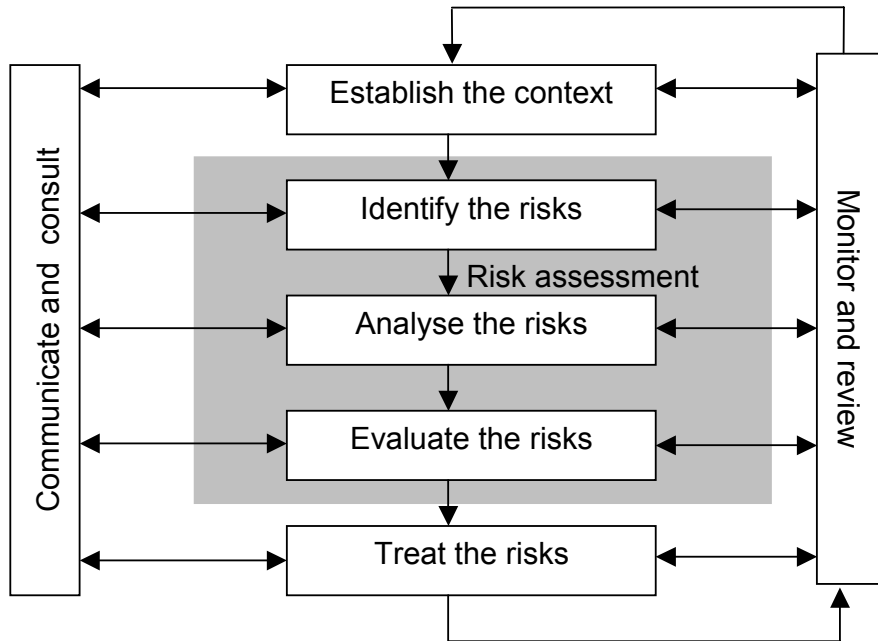
Risk management proactively reduces identified risk to an acceptable level by creating a culture founded on assessment and prevention rather than reaction and remedy. It plays a vital role in supporting and informing decision-making in providing a safe and secure environment for patients, staff and visitors.

Organisations that manage risk effectively and efficiently are more likely to achieve their objectives and do so at lower overall cost.

NHS QIS has responsibility for overseeing the standard setting and assessment processes associated with these standards for NHSScotland. NHS QIS is also

supporting a national standard methodology for the management of risk, building on the Australia/New Zealand Risk Management Standards, within NHSScotland.

The Australia/New Zealand Risk Management Standards define the generic risk management process as follows:



Note: Risk treatment plans involve the assessment and implementation of controls – ‘treat’ could equally be defined as ‘control’.

4 Development of the Draft Standards for Clinical Governance and Risk Management

In order to take work forward in developing the draft standards for clinical governance and risk management, NHS Quality Improvement Scotland (NHS QIS), appointed a project group, chaired by Dr John Browning Medical Director, NHS Lanarkshire. The Clinical Governance and Risk Management Project Group is multidisciplinary and includes healthcare professionals and members of the public. The Group first met in September 2003 and its membership can be found in Appendix 1. Additional information on the background to these draft standards can be found in Appendix 3.

In January 2004, *Draft Standards for Healthcare Governance: Working Towards Safe and Effective, Patient-Focused Care* were issued for consultation and a pilot exercise was undertaken. The key messages taken from the consultation were to reclaim the patient and clinical focus of the standards. The draft standards have therefore been revised to focus on clinical governance and risk management from the perspective of patient outcomes.

The purpose of the draft standards

The *Draft Standards for Clinical Governance and Risk Management* will help everyone concerned with clinical governance and risk management to not only understand and apply common principles of good clinical governance, but also to assess the strengths and challenges of current clinical governance practice and improve it. Hopefully, the standards will be useful to non-executives, the executive team and all staff who are aiming to do a difficult job better, and to individuals and groups who have an interest in exploring the effectiveness of governance.

The standards focus on the ways different functions of clinical governance can support each other. Governance is dynamic: good clinical governance encourages public trust and participation that enables services to improve; bad clinical governance fosters low morale and adversarial relationships that lead to poor performance or events, and ultimately, to dysfunctional organisations.

Scope of the draft standards

The *Draft Standards for Clinical Governance and Risk Management* will be used by NHS QIS to assess performance in NHS Boards and are intended for use by NHS Boards and Special Health Boards throughout Scotland.

These standards have been set at a strategic level and are to be implemented by all NHS Boards in collaboration with their constituent parts (eg community health partnerships) and community partners. It is intended that the standards apply to all aspects of the work of NHS Boards, including the public health function. NHS QIS will assess these standards at board level (top down approach). In addition, governance arrangements at operational level (bottom up approach) will also be assessed using the NHS QIS condition and service specific standards.

These standards are supported by a self-assessment framework which contains the operational detail, measurable criteria and outcome indicators which will be used to assess performance. This framework will be published as a separate document.

Relationship with other standards and guidance

These standards do not seek to duplicate standards and guidance from other organisations. We hope that those who develop and set these other standards and guidance will refer to these draft standards in updating and reviewing their own documents.

These standards cross refer to the *Standards for Staff Governance (2004)* but do not duplicate this assessment, which will meet the requirements of staffing issues of the *Draft Standards for Clinical Governance and Risk Management*. Other specific staffing elements which require more in-depth information for the purpose of risk management, but are not explicitly referred to in the *Staff Governance* self-assessment audit tool, such as registration checks, will be included within these standards.

The standards also draw on the *National Standards for Specialist Practice in Public Health (2001)* as it is recognised that clinical governance arrangements within NHS Boards must address the health improvement agenda alongside ensuring that healthcare is safe and effective.

To date, NHS QIS has also published standards covering other aspects of governance: *Healthcare Associated Infection (2001)* and *Food, Fluid and Nutritional Care in Hospitals (2003)* and these will be monitored separately. There may be further governance issues which arise and these will be taken into account in future revisions of these standards.

The *Draft Standards for Clinical Governance and Risk Management* should be read alongside NHS QIS condition and service specific standards.

Applying the standards to different governance structures and NHS Boards

We encourage all organisations to show that they are putting these draft standards into practice in a way that reflects their structure and is proportionate to their size and complexity. We recognise that not all parts of the standards will appear to be directly applicable to all types of NHS Board. In particular, it is acknowledged that the mandatory governance requirements do not always apply to Special Health Boards who do not deliver direct patient care. None-the-less, the principles of effective governance are recognised as good practice for any organisation and as such act as a useful tool for assessing their governance arrangements.

The draft standards produced by the Group have been split into three broad areas.

Standard 1 – Safe and effective care

Standard 2 –The health and care experience

Standard 3 – Assurance and accountability

Once finalised, the standards will be used by NHS QIS to assess performance in these areas in NHS Boards and Special Health Boards throughout Scotland.

Format of standards and definition of terminology

All standards set by NHS QIS follow the same format.

- Each standard has a **title**, which summarises the area on which that standard focuses.
- This is followed by the **standard statement**, which explains the level of performance to be achieved.
- The **rationale** section provides the reasons why the standard is considered to be important.
- The standard statement is expanded in the section headed **criteria**, which states exactly what must be achieved for the standard to be reached. The criteria are numbered for the sole reason of making the document easier to work with, particularly for the assessment process. The numbering of the criteria is not a reflection of priority.

Evidence base

The evidence base for the *Draft Standards for Clinical Governance and Risk Management* can be found in Appendix 2.

5 How to Participate in the Consultation Process

NHS Quality Improvement Scotland (NHS QIS) will use several different methods of consultation during the development of the draft standards:

- wide circulation of the draft standards document to relevant professional groups, health service staff, voluntary organisations and individuals
- public consultation exercises involving distribution of comment forms and/or questionnaires
- focus group discussions
- pilot review visits.

If you would like to know how you can participate in the consultation process, please contact:

Mrs Angela Balharrie
Project Officer
NHS Quality Improvement Scotland
Elliott House
8-10 Hillside Crescent
EDINBURGH
EH7 5EA

Tel: 0131 623 4310

Fax: 0131 623 4299

Email: angela.balharrie@nhshealthquality.org

Submitting your comments

Responses to the *Draft Standards for Clinical Governance and Risk Management* should be submitted (by post, phone, fax or email) to the above address by Friday 10 June 2005.

Consultation feedback

At the end of the consultation period all responses will be collated and the Project Group will respond to all comments received on the draft standards. The response will explain how the comments were taken into account.

The response will be made available on the NHS QIS website (www.nhshealthquality.org) and from Mrs Angela Balharrie, Project Officer.

6 Overarching Principles

NHS Quality Improvement Scotland's *Draft Standards for Clinical Governance and Risk Management* have been developed to ensure that:

- systems are in place to ensure that patient safety is a core principle underpinning all aspects of healthcare delivery
- patients' views and experiences are taken into account in the planning and delivery of services
- patients are involved in, and informed about, all decisions made during their journey of care
- information is used appropriately to maximise benefit in all sectors of healthcare
- policies and procedures are in place to encourage and enable continuous quality improvement
- staff from across NHSScotland are fully supported and adequately trained, both personally and professionally, to provide high quality health services
- quality systems are in place to enable employees to play a full and active role in providing effective and efficient healthcare services for patients
- structures and processes are in place for the adequate review of service delivery
- the principles of equality and diversity are embedded in the values, culture and behaviour of NHSScotland.

The standards must be interpreted and implemented in ways which:

- challenge discrimination
- promote equality of access and quality of services
- support the provision of services appropriate to individual needs, preferences and choices
- respect and protect human rights.

These standards underpin all clinical services provided by NHSScotland. They provide the broad context for all NHS QIS condition and service specific standards. Condition and service specific standards should be read in conjunction with the *Draft Standards for Clinical Governance and Risk Management*.

7 Draft Standards for Clinical Governance and Risk Management

Standard 1 – Safe and effective care

Standard 2 – The health and care experience

Standard 3 – Assurance and accountability

Standard 1 – Safe and effective care

Standard Statement 1: Patient care is safe and effective and based on available evidence.

Rationale

Healthcare services are safer and more effective when continuously monitored and systematically reviewed to improve all activities that directly affect the safety of all those using and providing healthcare services. This will be achieved where staff are enabled and encouraged to learn from their experience and that of others, and members of the public have an opportunity to contribute to this process.

The review of clinical practice through research and audit is a well-established means of monitoring and improving the quality of care and supporting the implementation of changes in practice.

References: 2, 5, 19, 21, 25, 26

Essential Criteria

1a Risk management and emergency/continuity planning

- 1a.1 There is an open and responsive approach to risk management.
- 1a.2 Clear strategic objectives and a robust operational framework are in place.
- 1a.3 Potential threats and weaknesses in systems are identified at strategic and operational levels and an assessment of their impact is undertaken.
- 1a.4 Effective risk management and adverse event reporting are integrated into the organisation's decision-making arrangements to create a framework for learning and improvement .
- 1a.5 There is assessment of risks and evaluation of a range of control options throughout the organisation.
- 1a.6 Prioritised action plans are used to control unacceptable risks.
- 1a.7 The effectiveness of the risk management system is reviewed and modifications made as necessary.
- 1a.8 Emergency planning arrangements are in place to deal with major incidents.
- 1a.9 Service continuity plans are in place to promote resilience to significant adverse events.
- 1a.10 Information generated from national and local experience is used to improve practice and reduce risk.

1a.11 The adequacy of risk assessments, together with existing control measures, is periodically reviewed.

1b Clinical effectiveness

1b.1 A prioritised, approved, co-ordinated and supported programme of clinical effectiveness activity is in place that reflects the Health Plan and the scope of services provided by the NHS Board.

1b.2 A system is in place to prioritise, implement and review national and local standards and guidance.

1b.3 There is evidence of improved patient care and ongoing improvement in the health of the population.

1b.4 Formal and informal methods are used to seek information from patients, the public, and staff to inform improvements in practice.

Standard 2 – The health and care experience

Standard Statement 2: Health care is provided in partnership with patients, their carers and relatives, and the public, meeting their individual needs, preferences and choices and treating them with dignity and respect at all times.

Rationale

Every individual is entitled to fair and equal access to healthcare and has the right to opportunities for better health.

People expect to be involved in deciding about their own healthcare as responsible partners in care.

Better outcomes are achieved when both the patient and healthcare staff share in making decisions about treatment and care.

References: 17, 18, 20, 23, 25, 26, 27, 29, 30, 35, 37, 39, 44, 45

Essential Criteria

2a Access, referral, treatment and discharge

- 2a.1 Accessible information on services in the NHS Board area is readily available to patients, carers and the public.
- 2a.2 Services are provided to meet the needs of the population and there is a system in place to ensure service accessibility that includes consideration of individual needs, waiting and response times, location and availability.
- 2a.3 Comprehensive referral guidance is available to enable timely and appropriate admission/transfer within/between healthcare providers and their community partners, and this guidance is monitored and fed back on a regular basis to those referring.
- 2a.4 There is a multidisciplinary assessment process which includes diagnosis, and considers each individual's needs and preferences for care and treatment throughout his/her care experience.
- 2a.5 The needs of carers are identified and responded to at each stage in the patient journey.
- 2a.6 Patients, and with their consent relatives/carers/advocates, are provided with a range of appropriate, timely and accessible information about their condition, treatment options, outcomes, risks, side effects and rights.
- 2a.7 Patients are enabled to make decisions throughout diagnosis and treatment, and staff are guided by a consent policy which includes an explanation of relevant legislation and best-practice guidelines.

2a.8 Discharge is planned in partnership with the patient, carers and other agencies, and addresses the need for aids, adaptations and support, and arrangements are in place to ensure that these needs are met.

2a.9 Patients are supported in making decisions about their healthcare and this includes the provision of independent advocacy services.

2b Equality and diversity

2b.1 All new and existing systems are developed, or improved, to ensure that every person has fair and equal access to healthcare and associated services.

2b.2 Systems are in place to identify, assess and respond to the needs of groups and individuals within its population, who have particular requirements or preferences.

2c Communication

2c.1 There is a strategy in place that guides, monitors and improves the way that NHS staff communicate with patients, carers and service users.

Standard 3 – Assurance and accountability

Standard Statement 3: The public and NHSScotland are confident about the safety and quality of NHS care.

Rationale

NHS bodies are legally obliged to establish effective governance arrangements that provide public assurance in the services they provide.

Improving services is enhanced by engaging with a public who have confidence in the services they receive.

The effectiveness of collaborative working is enhanced where the scope of roles and responsibilities is clearly defined.

References: 6, 12, 14, 15, 16, 22, 25, 26, 31, 32, 33, 38

Essential Criteria

3a Clinical governance

- 3a.1 Clinical governance arrangements are in place which satisfy the statutory mandatory requirements including a formal scheme of delegation.
- 3a.2 Patients, carers and the public are informed, engaged and consulted when the NHS Board is planning, monitoring and improving services.
- 3a.3 There are effective organisational structures and processes for monitoring and reporting on the effectiveness of quality assurance and improvement processes at individual team, operational unit/service (i.e. CHP, Divisions) and corporate level.
- 3a.4 Systems are in place to assure the quality of services provided by the NHS Board and those provided jointly with other agencies.
- 3a.5 Systems are in place to seek feedback on services and this informs the planning, monitoring and improvement of services.
- 3a.6 There are arrangements for ethical review and research governance which follow national guidance and are assured through clinical governance arrangements.

3b Staff governance/professional support and development

- 3b.1 There is a system to ensure that all appropriate employment checks are undertaken and that all employed or contracted professionally qualified staff are registered with the appropriate bodies.

3b.2 Clear arrangements are in place to ensure that issues impacting on patient care and treatment arising from staff governance arrangements are reported and managed through the clinical governance structure.

3b.3 There is a clear policy and standards on clinical supervision for all professional groups.

3c External communication

3c.1 There is an external communication strategy in place which is systematically monitored and reviewed.

3d Performance management

3d.1 There are clear arrangements for performance management which link to local, regional and national planning and enable the NHS Board to manage performance across the organisation.

3d.2 Performance management is underpinned by explicit organisational objectives, targets and indicators ensuring prioritisation of decision-making.

3d.3 Performance improvement is achieved through continuous monitoring of performance.

3e Information governance

3e.1 A governance framework is in place which promotes the ethical and lawful use of information in enhancing decision-making to support and improve the quality of patient care, choice and services.

3e.2 A comprehensive system is in place to ensure the secure and confidential management of personal information including how it is obtained, recorded, used, shared, stored and disposed of in line with current legislation.

3e.3 Patients are effectively informed about how their personal health information is collected and used, how to access their personal health information, and about their rights to determine how their personal information is shared.

3e.4 Formal policies are in place to manage situations where patient consent to share information is withheld, and where disclosure of personal health information is required without consent.

3e.5 Information management links clearly into clinical governance arrangements and engages clinicians and patients in the development and application of information and communication technology.

3e.6 Systems are in place to ensure that staff have appropriate access to relevant and understandable clinical information to support clinical decision-making and facilitate delivery of quality services to patients.

8 Appendices

Appendix 1 Membership of the Clinical Governance and Risk Management Standards Project Group

Appendix 2 Evidence Base

Appendix 3 Background to the Draft Standards

Appendix 4 Glossary of Terms

Appendix 1

Membership of the Clinical Governance and Risk Management Standards Project Group

Name	Title	NHS Board Area/ Organisation
Dr John Browning (Chair)	Medical Director	Lanarkshire
Mr Alan Barn (until April 2004)	CNORIS Scheme Manager	Willis Ltd
Mrs Margo Biggs	Member	Forth Valley Health Council
Dr A Fiona Bisset (from August 2004)	Consultant in Public Health Medicine	Scottish Executive Health Department
Ms Hazel Brooke	Chair of Clinical Governance Committee	Yorkhill Division
Ms Claire Brennan (from March 2004)	Partnership Associate	Scottish Executive Health Department
Ms Anne Bryce	Chief Internal Auditor	Argyll & Clyde
Dr Doreen Campbell (until April 2004)	Senior Medical Officer	Scottish Executive Health Department
Mr Andy Crawford	Clinical Governance Manager	Greater Glasgow Primary Care Division
Mrs Deb den Herder (until September 2004)	Project Director, Planned Healthcare	Grampian
Ms Kay Eastwood (until March 2005)	Director of Nursing	Lomond & Argyll Division
Ms Heather Fiskien (from August 2004)	Practice Development Officer	Disability Rights Commission
Mr Wayne Gault	Head of Risk Management	Grampian
Mr Steve Jack	Director of Patient Services	Shetland
Mr Brian Kennedy	Former CNORIS Assessor	Willis Ltd
Mr Adrian Lucas	Chief Executive	Scottish Ambulance Service
Ms Liz Macdonald (from April 2004)	Policy Manager	Scottish Consumer Council
Mr Hector MacKenzie (from May 2004)	Head of Public and Patient Focus and Quality Branch	Scottish Executive Health Department
Ms Diane Murray (from March 2004)	Partnership Associate	Scottish Executive Health Department

Ms Donna O'Boyle	Former CNORIS Assessor	C3healthsolutions Ltd
Ms Pat O'Connor	Head of Risk Management	Tayside
Mr John Orr	Associate Medical Director	Lothian – University Hospitals Division
Mr Ross Scott	Head of Policy Implementation & Development Branch	Scottish Executive Health Department
Dr Lesley Anne Smith	Clinical Risk Manager	Highland
Mrs Rona Webster	Director of Human Resources	Fife
Mr Ian Williamson (until May 2004)	Head of Planning and Risk Management	Borders
Mrs Andrea Wilson	Clinical Governance Lead	Fife

NHS Quality Improvement Scotland (NHS QIS) gratefully acknowledges the important contribution made by Ms Ann Clark, Project Manager, Scottish Health Council, Mr Derek Feeley, Head of Planning, SEHD, and Mr Douglas Philp, Principal Inspector of Health & Safety, H&S Executive, during the development of these draft standards.

The Board member specifically working with the Clinical Governance and Risk Management Standards Project Group is the Very Reverend Graham Forbes.

Support from NHS QIS is provided by Ms Jan Warner (Director of Performance Assessment and Practice Development), Mrs Hazel Borland (Head of Clinical Governance & Patient Safety), Ms Elaine McRae (Clinical Governance Co-ordinator), Mrs Anne Hanley (Team Manager), Ms Karen Tarn (Senior Project Officer), Mrs Angela Balharrie (Project Officer), Mrs Margaret Brown (Project Officer), and Mrs Wendy Forbes (Project Administrator).

Appendix 2

Evidence Base

1. Business Continuity Institute (BCI). 2003. *10 Certification Standards for Professional Practitioners*. BCI.
<http://www.thebci.org/10%20Standards%20Intro.htm> URL accessed 20/04/01.
2. Clinical Negligence and Other Risks Indemnity Scheme (CNORIS). 2003. *(CNORIS) Risk Management Standards for NHSScotland. Risk: Finance; Transfer; Management ; Advice; Assessment; Accreditation [Version 4]*. Edinburgh: Scottish Executive.
www.cnoris.com/pdfs/riskmanagement/rmstandards/2003%20_rm_standards.pdf [full document] URL accessed 16/03/05.
3. Clinical Standards Board for Scotland (CSBS). March 2002. *Clinical Standards: Generic [See Patient Focus Section]*. Edinburgh: CSBS.
4. Clinical Standards Board for Scotland (CSBS). December 2001. *Clinical Standards: Healthcare Associated Infection (HAI) Infection Control*. Edinburgh: CSBS.
5. Department of Health (DoH) and National Patient Safety Agency (NPSA). August 2001. *Doing Less Harm: Improving the Safety and Quality of Care through Reporting, Analysing and Learning from Adverse Incidents Involving NHS Patients – Key Requirements for Health Care Providers*. London: DoH and NPSA.
6. Institute of Chartered Accountants in England and Wales (ICAEW). 1999. *Internal Control - Guidance for Directors on the Combined Code of Practice on Good Corporate Governance (Turnbull Report)*. London: ICAEW.
7. NHS in Scotland Property and Environment Forum. August 2000. *Scottish Hospital Technical Note 3 (Version 3): Management and Disposal of Clinical Waste*. Borders General Hospital NHS Trust, Melrose.
8. Reason J. 1990. *Human Error*. New York: Cambridge University Press.
9. Reason J. 2000. Human Error: Models and Management. *British Medical Journal*, 320 (7237): 768-770.
[http://bmj.bmjournals.com/cgi/content/full/320/7237/768?](http://bmj.bmjournals.com/cgi/content/full/320/7237/768) URL accessed 20/01/04.
10. Royal Institute of Public Health. 2001. *National Standards for Specialist Practice in Public Health*. London: Royal Institute of Public Health.
www.riph.org.uk/detailed.html [full document] URL accessed 16/03/05.
11. Scottish Executive. 2002. *Building a Better Scotland. Spending Proposals 2003-2006: What the Money Buys*. Edinburgh: Scottish Executive.
www.scotland.gov.uk/library5/government/babs-00.asp [full document] URL accessed 17/03/05.

12. Scottish Executive. 2001. *Clinical Governance Arrangements. Amendment to MEL(1998)75 and MEL(2000)29. NHS HDL(2001)74*. Edinburgh: Scottish Executive. www.show.scot.nhs.uk/sehd/mels/HDL2001_74.htm [full document] URL accessed 16/03/05.
13. Scottish Executive. 2000. *Clinical Negligence and Other Risks Indemnity Scheme (CNORIS): Amendment Regulations and Scheme Standards. NHS HDL(2000)2*. Edinburgh: Scottish Executive. www.show.scot.nhs.uk/sehd/mels/HDL2000_02.pdf [full document] URL accessed 16/03/05.
14. Scottish Executive. 2002. *Corporate Governance: Statement on Internal Control (SIC). NHS HDL(2002)11*. Edinburgh: Scottish Executive. www.show.scot.nhs.uk/sehd/mels/HDL2002_11.pdf [full document] URL accessed 16/03/05.
15. Scottish Executive. 2000. *Data Protection Act 1998. NHS MEL(2000)17*. Edinburgh: Scottish Executive. www.show.scot.nhs.uk/sehd/mels/2000_17.doc [full document] URL accessed 16/03/05.
16. Scottish Executive. 2003. *Draft Guide to the Production and Provision of Information About Health and Healthcare Interventions*. Edinburgh: Scottish Executive. www.scotland.gov.uk/library5/health/gppi-00.asp [full document] URL accessed 16/03/05.
17. Scottish Executive. 2000. *Equality Strategy: Working Together for Equality*. Edinburgh: Scottish Executive. www.scotland.gov.uk/library3/social/wtem-00.asp [full document] URL accessed 16/03/05.
18. Scottish Executive. 2002. *Fair for All: Working Together Towards Culturally Competent Services. NHS HDL(2002)1*. Edinburgh: Scottish Executive. www.show.scot.nhs.uk/sehd/mels/HDL2002_51.pdf [HDL] www.scotland.gov.uk/library3/society/ffar-00.asp [full report] URLs accessed 16/03/05.
19. Scottish Executive. 1999. *Goals for Clinical Effectiveness. NHS MEL (1999)76*. NHS MEL. Edinburgh: Scottish Executive. www.show.scot.nhs.uk/sehd/mels/1999_76.doc [full document] URL accessed 16/03/05.
20. Scottish Executive. 2003. *Improving Health in Scotland - the Challenge*. Edinburgh: Scottish Executive. www.scotland.gov.uk/library5/health/ihis-01.asp [full document] URL accessed 16/03/05.
21. Scottish Executive. 2002. *'Learning from Experience'. How to Improve Safety for Patients in Scotland. A Consultation Paper*. Edinburgh: Scottish Executive. www.scotland.gov.uk/consultations/health/learnexperience.pdf [full document] URL accessed 16/03/05.

22. Scottish Executive. 1999. *Learning Together. A Strategy for Education, Training and Lifelong Learning for All the National Health Service in Scotland: December 1999*. Edinburgh: Scottish Executive.
www.scotland.gov.uk/learningtogether/leto-00.htm [full document] URL accessed 16/03/05.
23. Scottish Executive. 2003. *A New Public Involvement Structure for NHSScotland. Patient Focus and Public Involvement. A Draft for Consultation*. Edinburgh: Scottish Executive. www.scotland.gov.uk/library5/health/npis.pdf [full text] URL accessed 16/03/05.
24. Scottish Executive. 2003. *Occupational Health and Safety Self Assessment Audit Tool for NHS Scotland Occupational Health and Safety Services 2003/2004. Draft*. Edinburgh:
www.show.scot.nhs.uk/sehd/publications/DC20030827ohsSelfAssess.pdf [full document] Explanatory letter at:
www.show.scot.nhs.uk/sehd/publications/DC20030827ohs.pdf URLs accessed 16/03/05.
25. Scottish Executive. 2000. *Our National Health: a Plan for Action, a Plan for Change*. Edinburgh: Scottish Executive.
www.scotland.gov.uk/library3/health/onh-00.asp [full document] URL accessed 16/03/05.
26. Scottish Executive. 2003. *Partnership for Care: Scotland's Health White Paper*. Edinburgh: Scottish Executive Health Department (SEHD).
www.scottishexecutive.gov.uk/library5/health/pfcs-00.asp [full document] URL accessed 16/03/05.
27. Scottish Executive. 2001. *Patient Focus and Public Involvement*. SEHD.
www.scotland.gov.uk/library3/health/pfpi-00.asp [full text] URL accessed 16/03/05.
28. Scottish Executive. 2002. *Performance Assessment Framework. NHS HDL(2002)78*. Edinburgh: Scottish Executive.
www.show.scot.nhs.uk/sehd/mels/HDL2002_78.pdf [full document] URL accessed 16/03/05.
29. Scottish Executive. 2003. *Reforming the NHS Complaints Procedure. Patient Focus and Public Involvement. A Draft for Consultation*. Edinburgh: Scottish Executive. www.scotland.gov.uk/library5/health/rtcp-00.asp [full document] URL accessed 16/03/05.
30. Scottish Executive. 2002. *Spiritual Care in NHSScotland. NHS HDL(2002)76*. Edinburgh: Scottish Executive.
www.show.scot.nhs.uk/sehd/mels/HDL2002_76.pdf [full document] URL accessed 16/03/05.
31. Scottish Executive. 2002. *Staff Governance - Self Assessment Audit Tool. NHS HDL(2002)84*. Edinburgh: Scottish Executive.

32. Scottish Executive. 2003. *The Use of Personal Health Information in NHSScotland to Support Patient Care. NHS HDL(2003)37*. Edinburgh: Scottish Executive. www.show.scot.nhs.uk/sehd/mels/HDL2003_37.pdf [full document] URL accessed 16/03/05.
33. Scottish Executive Health Department (SEHD). 2000. *Clinical Governance. NHS MEL(2000)29*. Edinburgh: SEHD. www.show.scot.nhs.uk/sehd/mels/2000_29final.htm [full document] URL accessed 16/03/05.
34. Scottish Executive Health Department (SEHD). 2000. *Guidance on Volunteering in the NHS: Implementation. NHS MEL(2000)4*. Edinburgh: SEHD. www.show.scot.nhs.uk/Publications/ME/dt_involve/2000_4.htm [full document] URL accessed 16/03/05.
35. Scottish Executive Health Department (SEHD). September 2000. *Independent Advocacy: a Guide for Commissioners: a Guide for Health Boards, NHS Trusts, Local Authorities and Anyone Involved with Advocacy*. Edinburgh: SEHD. www.scotland.gov.uk/library3/health/iagc-00.asp [full document] URL accessed 16/03/05.
36. Scottish Executive Health Department (SEHD). 1999. *Towards a Safer Healthier Workplace. NHS MEL(1999)85*. NHS MEL. Edinburgh: SEHD. www.show.scot.nhs.uk/sehd/mels/1999_85.doc [full document] URL accessed 16/03/05.
37. Scottish Intercollegiate Guidelines Network (SIGN). 2003. *SIGN Guideline 65: The Immediate Discharge Document*. Edinburgh: SIGN. www.sign.ac.uk/guidelines/published/index.html [access to full document] URL accessed 16/03/05.
38. Scottish Office. Department of Health. NHS Management Executive. 1998. *Clinical Governance. NHS MEL(1998)75*. Edinburgh: Scottish Office. www.show.scot.nhs.uk/sehd/mels/1998_75.htm [full document] URL accessed 16/03/05.
39. Scottish Parliament. *Adults with Incapacity (Scotland) Act 2000*. Edinburgh: HMSO. www.scotland.gov.uk/health/cmo/incapacity_act_toc.asp [official website for the incapacity act] / www.scotland-legislation.hmso.gov.uk/legislation/scotland/acts2000/20000004.htm [full document] www.scotland.gov.uk/Topics/Justice/Civil/16360/5005 [Code of Practice].
40. Scottish Parliament. 2002. *Freedom of Information (Scotland) Act 2002*. Edinburgh: HMSO. www.scotland-legislation.hmso.gov.uk/legislation/scotland/acts2002/20020013.htm [full document] URL accessed 16/03/05.
41. Standards Australia International Limited. AS/NZS 4360: 2004 Risk Management. Melbourne: Standards Australia International Limited (2004).

42. The Comptroller and Auditor General [Sir John Bourn]. 2003. *Achieving Improvements through Clinical Governance: a Progress Report on Implementation by NHS Trusts*. London: The Stationery Office.
http://www.nao.org.uk/publications/nao_reports/02-03/02031055.pdf [full document] URL accessed 16/03/05.
43. The Independent Commission for Good Governance in Public Services. 2004. *The Good Governance Standard for Public Services*. London: The Independent Commission for Good Governance in Public Services.
www.opm.co.uk/ICGGPS/download_upload/Standard.pdf [full text] URL accessed 17/03/05.
44. UK Parliament. 1995. *Disability Discrimination Act 1995*. London: HMSO.
www.legislation.hmso.gov.uk/acts/acts1995/Ukpga_19950050_en_1.htm [full document] URL accessed 16/03/05.
45. UK Parliament. 2000. *Race Relations (Amendment) Act 2000*. London: HMSO.
www.legislation.hmso.gov.uk/acts/acts2000/20000034.htm [full document] URL accessed 16/03/05.
46. World Health Organisation (WHO). 2003. *Standards for Health Promotion in Health Promoting Hospitals*. WHO.
www.who.dk/healthpromohosp/Publications/20030127_7 [WHO general web pages on this project]. The detailed WHO document 'Developing Standards for Health Promotion in Hospitals - Results of a Pilot Test in Nine European Countries' [Barcelona, April 2003] can be found at:
www.who.dk/Document/IHB/hphstandardsfinrpt.pdf URL accessed 16/03/05
URL accessed 05/01/04.

Appendix 3

Background to the Draft Standards

Standards for generic clinical governance were first published in January 2001. They covered a range of clinical governance areas under the headings of 'patient focus' and 'safe and effective clinical care'. Two rounds of review visits have been completed, culminating in the publication of national overviews and local reports in April 2002 and May 2003.

CNORIS, managed on behalf of the Scottish Executive Health Department by Willis Ltd, was established in April 2000 with the aim of providing financial risk pooling and claims management arrangements for NHSScotland, and standards supporting rigorous risk management were published. In January 2003, updated CNORIS healthcare risk management standards were published. The CNORIS standards were designed to evolve and incorporate good practice as it developed within NHSScotland and elsewhere. Therefore, they referred to the work, amongst others, of NHS QIS, the Royal Colleges, the Health & Safety Executive, and expert working groups.

In August 2002, a short-life working group was set up to revise the generic clinical governance standards, taking into account areas of overlap with other related standards and systems, and with the aim of learning from the experience of reviewing performance against the standards to date. These standards were issued in June 2003 to a limited distribution list as part of a pre-consultation exercise. Following this exercise the decision to integrate the CNORIS standards with the generic clinical governance standards was made (see below) therefore the revised generic clinical governance standards were not widely distributed but were used to inform the development of the *Draft Standards for Clinical Governance and Risk Management*.

In July 2003, the Scottish Executive Health Department issued *HDL(2003)29* which set out the decision to integrate the healthcare risk management standards developed by CNORIS, and the NHS QIS generic clinical governance standards. NHS QIS was given future responsibility for overseeing the standard setting and assessment processes associated with the resulting standards. The financial and claims management aspects of CNORIS will continue to be handled separately.

Appendix 4

Glossary of Terms

adverse event	Any occurrence which is not routine, and which causes physical or psychological harm, loss, or damage.
advocacy	Where an individual acts independently on behalf of, and in the interests of, patients/users who may feel unable to represent themselves in their contacts with a healthcare or other facility.
assessment	The process of measuring patients' needs and/or the quality of an activity, service or organisation.
audit	The measuring and evaluation of care against agreed standards with a view to improving practice and care delivery.
carer	A person who looks after family, partners or friends in need of help because they are ill, frail or have a disability. The care they provide is unpaid.
clinical effectiveness	The extent to which specific clinical interventions, when deployed in the field for a particular patient or population, do what they are intended to do, ie maintain and improve health, securing the greatest possible health gain from the available resources.
clinical governance	The purpose of clinical governance is to make sure that patients receive the highest quality of care possible, putting each patient at the centre of their care. This is achieved by ensuring that those providing services work in an environment that supports them and which places the safety and quality of care at the top of the organisation agenda.
Clinical Negligence and Other Risks Indemnity Scheme (CNORIS)	Financial risk sharing arrangements for both clinical and non-clinical risks. Introduced from 1 April 2000 and outlined in MEL(1999)86, issued in December 1999. More detailed information on the Scheme's coverage and operation is set out in MEL(2000)18, which was issued in April 2000. Website address: www.cnoris.com
clinical risk	Risk arising directly from healthcare delivery. This includes, amongst other things, medication errors, healthcare associated infection, clinical effectiveness issues, failure to obtain consent.
clinical service	Service provided by healthcare professionals.
CNORIS	See Clinical Negligence and Other Risks Indemnity Scheme.
continuing professional development (CPD)	An ongoing commitment to learning in various forms, which maintains and enhances professional standards of work, and develops the ability to recognise good practice.
corporate governance	The system by which an organisation directs and controls its functions and relates to its stakeholders.
CPD	See continuing professional development.
criterion(s)/criteria (pl)	Provide the more detailed and practical information on how to achieve the standard
diagnosis	Identification of an illness or health problem by means of its signs and symptoms. This involves ruling out other illnesses and causal factors for the symptoms.

discharge	A discharge marks the end of an episode of care. Types of discharge include in-patient discharge, day-case discharge, day-patient discharge and out-patient discharge.
diversity	Diversity is about recognising difference. To benefit from diversity an organisation's culture and practices need to respect, value and harness difference for the benefit of the service users and staff.
equality	Equality is about creating a fair society where everyone can participate and has the opportunity to fulfil their potential. Equality is backed by legislation which aims to stop discrimination. Equality and Diversity are not interchangeable – they need to be progressed together. There is no equality of opportunity if difference is not recognised and valued.
essential (criterion/criteria)	A criterion that must be met wherever a service is provided. See criterion.
evaluation	The study of the performance of a service (or element of treatment and care) with the aim of identifying successful and problem areas of activity.
generic standards	Standards that apply to most, if not all, clinical services.
governance	Governance is the system by which an organisation directs and controls its functions and relates to its stakeholders.
guidelines*	Operational good practice to inform activity.
harm	Injury, disease, suffering, disability, or death.
HDL	See Health Department Letter.
Health & Safety (H&S)	Legislative and regulatory framework designed to safeguard the health and safety of employees and all others who may be affected by work activities.
Health Department Letter (HDL)	Health Department Letter (formerly known as Management Executive Letter - MEL), formal communications from the Scottish Executive Health Department to NHSScotland.
healthcare governance	The organisation of staff, managers, and senior decision makers, and the development of systems and protocols, aimed at minimising risk to patients and maximising the level of effective quality healthcare; the way in which organisations are required to have a framework which ensures their responsibilities to deliver safe and effective services are met.
healthcare professional	A person qualified in a health discipline.
implementation	Putting into practical effect; carrying out a task or project.
informed consent	The principle by which a patient/user is informed about the nature, purpose and likely effects of any treatment or investigation proposed, before being asked to consent to it.
legislation	Laws passed by a parliament.
mandatory	Where something must be done, or is required by law.

monitoring	The systematic process of collecting information on the performance of clinical or non-clinical activities, actions or systems. Monitoring may be intermittent or continuous. It may also be undertaken in relation to specific incidents of concern or to check key performance areas. Monitoring is used to appraise strengths, weaknesses, opportunities and threats.
multidisciplinary	A multidisciplinary team is a group of people from different disciplines (both healthcare and non-healthcare) who work together to provide care for patients with a particular condition. The composition of multidisciplinary teams will vary according to many factors. These include: the specific condition, the scale of the service being provided, and geographical/socio-economic factors in the local area.
NHS Board	NHS Boards are responsible for the strategic planning, service delivery, performance management and governance of each of Scotland's 15 local health systems.
NHS QIS	See NHS Quality Improvement Scotland.
NHS Quality Improvement Scotland (NHS QIS)	NHS Quality Improvement Scotland is a statutory body, established as a Special Health Board in January 2003. Its role is to focus on improving the quality of patient care and the health of patients. It has a particular emphasis on the quality of care and the patient journey for vulnerable groups. Website: www.nhshealthquality.org
NHSScotland	The National Health Service in Scotland.
outcome	The end result of care and treatment and/or rehabilitation. In other words, the change in health, functional ability, symptoms or situation of a person, which can be used to measure the effectiveness of care and treatment, and/or rehabilitation.
patient	1. A person who is receiving care or medical treatment. 2. A person who is registered with a doctor, dentist, or other healthcare professional, and is treated by him/her when necessary. Sometimes a patient is referred to as a service user.
patient journey	The pathway through the health services taken by the person who is receiving treatment, and as viewed by that person.
peer review	Review of a service by those with expertise and experience in that service, either as a provider, user or carer, but who are not involved in its provision in the area under review. In the NHS Quality Improvement Scotland approach, all members of a review team are equal.
plan*	An operational tool to manage activity in the quest to achieve objectives.
policy*	The highest level statement of intent and objectives within an organisation.
procedure*	Operational instructions to regulate activity.
protocol*	See procedure
quality assurance (QA)	Improving performance and preventing problems through planned and systematic activities including documentation, training and review.
rationale	Scientific/objective reason for taking specific action.
record	Any instrument which contains information, personal or non-

	personal, in any medium, which has been created, gathered, or retained as a result of any aspect of the work of NHS organisations.
referral	The process whereby a patient is transferred from one professional to another, usually for specialist advice and/or treatment.
risk	The chance of something happening (an opportunity or hazard) that will have an impact (good or bad) upon objectives. Risk is measured in terms of its consequences and likelihood.
risk assessment	A systematic process to determine risk management priorities through finding out the frequency of an outcome, and its consequences.
risk management	A systematic approach to the management of risk, staff and patient/client/user safety, to reducing loss of life, financial loss, loss of staff availability, loss of availability of buildings or equipment, or loss of reputation. Risk management involves identifying, assessing, controlling, monitoring, reviewing and auditing risk.
Scottish Executive Health Department (SEHD)	The Scottish Executive Health Department is responsible for health policy and the administration of NHSScotland. Website address: www.show.scot.nhs.uk/sehd
SEHD	See Scottish Executive Health Department.
self-assessment	Assessment of performance against standards by individual/clinical team/Trust providing the service to which the standards are related.
service continuity plan	Arrangements to maintain provision of services in the event of a sudden and severe incident which degrades resource of whatever type and so affects the capability of the organisation to operate in the usual way.
stakeholders	Those people and organisations who may affect, be affected by or perceive themselves to be affected by a decision or activity.
standard statement	An overall statement of agreed performance.
statement on internal control	A description of the process designed to identify and prioritise risks to the achievement of an organisation's policies, aims, and objectives, to evaluate the likelihood of those risks being realised and the impact should they be, and to manage them efficiently, effectively and economically.
statutory	1. Enacted by statute 2. depending on statute for its authority as a statutory provision. 3. Required by law.
strategy*	A high level document indicating a framework for achieving objectives and perhaps incorporating a plan.
systematic	Methodical, according to plan and not casually or at random.
treatment plan	Protocol of care which specifies what should be done, when and with what aim.

* With regard to the terms 'guidelines'; 'plan'; 'policy'; 'procedure'; 'protocol'; and 'strategy', it is recognised that organisations may use different definitions. The above definitions are not intended to be prescriptive. The contents and attributes of a document, eg high-level statement of intent, record of objectives, are more important than the fact of its being called a 'strategy' or 'policy'.

You can look at this document on our website. It is also available, if you ask:

- in electronic format
- in audio format
- in Braille
- in large print
- in community languages

NHS Quality Improvement Scotland

Edinburgh Office

Elliott House, 8-10 Hillside Crescent, Edinburgh, EH7 5EA

Phone 0131 623 4300

Glasgow Office

Delta House, 50 West Nile Street, Glasgow G1 2NP

Phone 0141 225 6999

E-mail: comments@nhshealthquality.org website: www.nhshealthquality.org

