

**'LEARNING FROM EXPERIENCE'
HOW TO IMPROVE SAFETY FOR PATIENTS IN
SCOTLAND**

A CONSULTATION PAPER

Deadline for responses: **28th February 2003**

Responses to be sent to:

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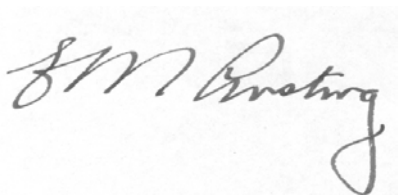
FOREWORD

It has been said that medicine in the past was simple, safe and ineffective. Health care in the 21st century is, by comparison, complex and very effective but not without risk. Some patients are actually harmed in the process of care. The ethical framework which guides the work of all health professionals recognises the need to balance the risks and benefits of any intervention or treatment. Similarly, maximising benefit and minimising risk is a key element of clinical governance for the NHS. We know, however, that much of the harm suffered by patients in the process of care is preventable.

The first step in making things better is to raise the consciousness of safety and harm prevention among all those who provide services for patients. Many of the incidents which harm patients happen recurrently in the NHS. To avoid repeating mistakes we need to recognise and learn from them and to ensure that the lessons are communicated across the whole NHS. We need to move away from finding someone to blame when things go wrong to a culture which is open and fair to staff and which supports learning from what took place and why. We need to do everything we can to encourage a "reporting culture" and a "safety culture" amongst all staff in NHS Scotland.

This document identifies the necessary next steps to improve safety for patients in Scotland. These include linking with the work of the new National Patient Safety Agency and providing education which supports staff to work together to identify, learn from and solve the problems.

I would very much welcome your comments on the ideas developed in this document. All comments will be considered as we work with NHS Quality Improvement Scotland, our lead agency for patient safety, in taking these important matters forward.

A handwritten signature in black ink, appearing to read 'E M Armstrong', is written over a light grey rectangular background.

DR E M ARMSTRONG
Chief Medical Officer

‘Learning from experience’ How to Improve Safety for Patients in Scotland: A Consultation paper

1 THE IMPORTANCE OF SAFETY FOR PATIENTS

1.1 Promoting patient safety by reducing error has become a key priority for major health services around the world. In June 2000, the Department of Health (DH) published the report *An Organisation with a Memory*.¹ This report, commissioned by English Health Minister from an expert group under the chairmanship of Professor Liam Donaldson, Chief Medical Officer for England, reviewed:

"....the scale and nature of serious failures in NHS health care, to examine the extent to which the NHS has the capacity to learn from such failures when they do occur and to recommend measures which could help to ensure that the likelihood of repeated failures is minimised in the future."

1.2 The report set out ten recommendations for improving the way in which the NHS can learn from adverse events and near misses. In April 2001, the Department of Health published a follow-up report, *Building A Safer NHS For Patients*,² which detailed how the recommendations of the earlier report should be implemented, namely:

- the promotion of a culture of patient safety within local services as an integral part of clinical governance;
- practical steps to be taken to introduce a comprehensive system of adverse event reporting to enable effective learning and action to reduce risk at local and national level;
- a new independent Special Health Authority – the **National Patient Safety Agency (NPSA)** – to run and oversee the arrangements for the reporting system;
- a new streamlined system for investigation and inquiries into failures of standards of care in the NHS.

2 THE COMMITMENT TO IMPROVING PATIENT SAFETY IN SCOTLAND

2.2 In January 2001, the report *An Organisation with A Memory* was discussed at the meeting of the Clinical Effectiveness Strategy Group which until recently advised the Scottish Executive Health Department on the strategic direction of the clinical effectiveness agenda. Subsequently, Scottish Ministers endorsed the Group’s recommendation that the report’s principles and recommendations should be implemented in Scotland.

¹ DoH 2000 *An Organisation with a Memory*

² DoH 2001 *Building a Safer NHS for Patients*

- 2.3 In addition, the Report of the Bristol Royal Infirmary Inquiry in July 2001 called for systems to ensure that patient care is safe and of good quality, including systems of clinical governance and risk management.³
- 2.4 A commitment was made in *Our National Health: A Plan for Action a Plan for Change*⁴ to achieve better integration and co-ordination of national organisations with an interest in clinical quality. This is being taken forward with the establishment of a new Special Health Board, NHS Quality Improvement Scotland (formerly Quality and Standards Board for Health in Scotland).⁵ One of the functions of the new Board is Patient Safety. It is expected to manage a service agreement with the NPSA, inform NHSScotland of its recommendations and monitor their implementation across Scotland.

3 ROLE OF THE NPSA

- 3.1 The primary purpose of the body is to implement, operate and oversee all aspects of a national system for learning from adverse events and near misses in all sectors of the NHS in England.⁶
- 3.2 The Joint Chief Executives of the NPSA, Sue Osborn and Susan Williams have written to say:

“We are very pleased that Ministers in Scotland have endorsed the recommendations of the Clinical Effectiveness Strategy Group that the principles set out in *An Organisation with a Memory* should be adopted in Scotland. Patient safety is clearly an issue for the whole of the health service in the UK and the involvement of Scotland will strengthen our work to improve safety of patients across the NHS. We look forward to developing a strong partnership with *NHS Quality Improvement Scotland*.”

4 KEY ELEMENTS OF A STRATEGY TO REDUCE HARM IN NHSSCOTLAND

- 4.1 Experience from USA and Australia and the risk management literature suggests the following are required to reduce harm:-
- An awareness of risk and patient safety has to be promoted amongst staff. An open and fair culture is required.
 - Honest reporting of incidents should be encouraged, whether the incidents are events causing harm or ‘near misses’. Learning can then follow which will require changes to local practices through explicit policies which are embedded into the usual way of working.
 - When adverse events or near misses occur, the whole system should be investigated instead of simply finding someone to blame.
 - Staff must have confidence that learning and change, which reduce the chance of future harm, will follow from investigating incidents. This will

³ Learning from Bristol: the report of the public inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984-85. Command paper 5207 (2001)

⁴ SEHD December 2000 *Our Nation Health: A Plan for Action a Plan for Change*

⁵ Consultation on NHS Quality Improvement Scotland, NHS Quality Improvement Scotland, formerly entitled Quality and Standards Board for Health in Scotland, March-June 2002

www.show.scot.nhs.uk/public/publicindex.htm

⁶ Details of the work of the NPSA are at www.npsa.org.uk

encourage reporting and opportunities for learning. It is the responsibility of management to ensure that risk management structures and communication channels enable this.

- Staff education and training will be a key success factor in improving patient safety. We need to build knowledge about identifying, analysing and controlling risk. And in particular we need to develop capacity to:
 - learn from incident reporting
 - deliver safer services as a result of the learning.

4.2 Clinical Governance, as part of a sound system of internal control⁷, already provides the framework in NHSScotland to support these requirements. Clinical Governance Committees have the responsibility to review and recommend action on the patient safety agenda as part of their assurance that health services have systems in place to provide patients with high standards of care.

4.3 Some systemic solutions are most appropriately dealt with at a Scotland-wide or UK level. This work will build on the work of existing agencies but will be co-ordinated for Scotland by NHS Quality Improvement Scotland working closely with the NPSA.

4.4 We recognise a need for action in Scotland in five key areas explored in this consultation paper:-

- Implementing a reporting and learning system
- Developing an open and fair culture in the NHS and skills for analysing incidents
- Developing solutions
- Disseminating Patient Safety Alerts
- Investigating issues of serious concern.

5 PATIENT SAFETY IN SCOTLAND – THE CURRENT SITUATION

5.1 Much work in patient safety is currently underway:-

5.1.1 Risk management standards developed by the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS) and linked to both the Clinical Standards Board for Scotland (CSBS) generic clinical governance standards and to the Performance Assessment Framework are monitored and reported to the public.

5.1.2 The Healthcare Associated Infection Action Plan was published in October 2002.⁸ Healthcare Associated Infection is a significant risk to patients, public and to staff and the action plan links the work of several agencies to reduce the risk and improve practice. The Action Plan reflects good practice in the management of patient safety.

⁷ HDL(2002)11 Corporate Governance: Statement on Internal Control (SIC)

⁸ Preventing Infections Acquired while Receiving Health Care: The Scottish Executive's Action Plan to Reduce their Risk to Patients, Staff and Visitors. 2002-2005. on Scottish Executive Website at www.scotland.gov.uk/library5/health/preventinfect.pdf

- 5.1.3 GPs undertake practice-level “critical incident analysis” as part of the Royal College of General Practitioners’ practice accreditation programme, which is supported financially by Clinical Resource and Audit Group (CRAG) and by CSBS who have recently published a Progress Report.⁹
 - 5.1.4 CRAG will publish, in December 2002, a ‘Good Practice Statement on the Preparation of Medicines for Injection in Near Patient Areas including Clinical and Home Environments.’ This gives detailed advice on safe practice.
 - 5.1.5 In July 2002, the NPSA published their first Patient Safety Alert on preventing accidental overdose with intravenous potassium.¹⁰
 - 5.1.6 The ‘Effective Use of Blood’ project is being taken forward by the Scottish National Blood Transfusion Service. This follows the Serious Hazards of Transfusion (SHOT) Report 2000/01¹¹ and the UK CMOs’ Better Blood Transfusion 2 Seminar, which took place in October 2001.
 - 5.1.7 The Simulator in Stirling is supported by NHS Education for Scotland so that staff can learn new practices in a simulated environment to establish safe practice in teams.
 - 5.1.8 Scottish Healthcare Supplies manages the investigation of adverse incidents in NHSScotland in relation to medical devices. The Scottish Executive Health Department and Scottish Healthcare Supplies have an agreement with the Medical Devices Agency and issue hazard notices to alert staff to problems with devices.
 - 5.1.9 The Medicines Control Agency has well-established systems for reporting suspected adverse reactions to medicines (the ‘yellow card’ scheme) and for suspected defective medicinal products.
- 5.2 It will be the role of NHS Quality Improvement Scotland to co-ordinate and develop these initiatives in conjunction with the NPSA and other agencies as appropriate.

6 IMPLEMENTING A REPORTING AND LEARNING SYSTEM

What is in place in Scotland

- 6.1 Trusts and Boards in Scotland are working towards the CNORIS risk management standards which are backed by comprehensive guidance and formal assessment from a scheme manager¹². Non-clinical and clinical risks are managed together in Scotland. Risk management co-ordinators are located in all Trusts and usually come from clinical or Health and Safety backgrounds. All Trusts have a risk committee structure linked to Clinical Governance and Corporate Governance structures, and CNORIS requires that executive leadership on risk management issues is explicit. CNORIS Assessors have established and support a network of risk management co-ordinators throughout Scotland.

⁹ Quality Assurance in Primary Care: RCGP Practice Accreditation Progress Report, September 2002
www.clinicalstandards.org

¹⁰ The potassium chloride alert is posted on the NPSA website at
<http://www.npsa.org.uk/admin/publications/docs/riskalertpsa01.pdf>

¹¹ The SHOT reports for the last 5 years are at www.shot.demon.co.uk

¹² CNORIS standards. www.cnoris.com

6.2 Incident reporting and incident management are core CNORIS standards. The definitions used by CNORIS are similar to those used by the NPSA.

Definitions of adverse incidents, adverse events and near misses

The following definitions are currently recommended for use in Scotland by CNORIS.

- An **adverse incident** is defined as *'Any event or circumstance that could have, or did, lead to unintended or unnecessary harm, loss or damage to patient, public, staff or organisation.'*
- **Harm** is defined as *'injury (physical or psychological), disease, suffering, disability or death'*
- An **adverse event** is *'an incident which did lead to harm'*.
- A **near miss** is *'an incident which did not lead to harm, but which could have done so'*

6.3 Currently most Trusts have reached or are working towards CNORIS Level 1, which requires a system of adverse incident reporting for safety, health and environmental matters, including specifically clinical areas of activity deemed to be of high risk. Level 2 will require comprehensive incident reporting in all clinical areas.

6.4 The CNORIS draft standards, effective from 1 January 2003, include a requirement that Scottish Acute and Primary Care Trusts comply with the requirements of the NPSA including collation of minimum datasets suitable for transmission to the Agency. These standards also require the use of qualitative and quantitative information derived from local and national data to aid organisational learning through a process of robust investigation.

The NPSA approach

6.5 The Agency has piloted a system for reporting adverse incidents in Acute, Primary Care, Mental Health and Ambulance Trusts in England and Wales. A full report of the pilot is posted on the NPSA web-site at www.npsa.org.uk

6.6 The findings of the pilot have led to some changes. Updated details of the requirements for data submission will be subject to a further period of testing in early 2003. All incidents should be captured whether they were events which resulted in harm or were near misses which might have resulted in harm. There can be a great deal to learn from the incidents which were avoided and how they were avoided.

6.7 The two key datasets required will be an extended 'notification' dataset and a 'learning' dataset. For notification, a new severity rating system is being developed which can be used more consistently to identify the seriousness of incidents. For the learning data, the more serious incidents will have been analysed locally, using root cause analysis or other suitable techniques allowing the human factors which led to the incident to be reported.

- 6.8 The NPSA is developing an electronic data submission form, the 'e-form', which will be placed on a server accessible through NHS-net. It is planned to pilot the use of the new e-form in selected Trusts in England and Wales from January 2003 and the Agency aims to sign off the final version by mid-2003 subject to a business case being approved by DH.
- 6.9 In addition there are plans for an 'early warning' system to allow risk managers to share information rapidly if required.
- 6.10 In order to achieve consistency in reporting there are training implications for staff who undertake the reporting, investigation, analysis and organisational learning to achieve tangible outcomes in terms of improved safety.

What is needed in Scotland?

- 6.11 Patients in Scotland will benefit from NHSScotland collecting and contributing the same categories of data to the NPSA database as Trusts in England so that learning flows more quickly from the larger combined dataset.
- 6.12 Trusts in Scotland need to ensure that they can utilise their electronic incident reporting systems to provide data directly to the NPSA using the e-form on NHS-net. This will be piloted early in 2003 and selected Scottish Trusts may be invited to take part in the pilot. The adverse incident reporting system is then expected to be rolled out from June 2003 in England. Our target is that the system should begin to be used soon afterwards in Scotland subject to an agreement on the provision of services between NHS Quality Improvement Scotland and the NPSA. Subject to the NPSA maintaining its planned timetable for the reporting and learning system, it is expected that some Trusts in Scotland should be able to send data to the NPSA from October 2003. There would then be a rolling build up of capability.

Q1 Do you agree that Trusts in Scotland should begin to send adverse incident data to NPSA when the Agency is ready to implement its reporting and learning system?

7 DEVELOPING AN OPEN AND FAIR CULTURE IN THE NHS AND SKILLS FOR ANALYSING INCIDENTS

What is in place in Scotland

- 7.1 Risk Managers / Co-ordinators are already actively engaged in educational initiatives in their Trusts. Trusts aim to meet CNORIS standards which require capacity in risk management. Training is being provided locally and also bought in from UK suppliers who are working with the NPSA. The CNORIS Assessors have set up a network of risk managers / co-ordinators to actively support these key staff. CNORIS and CSBS ensure that the standards are assessed and the results for the whole of Scotland are published.
- 7.2 NHS Education for Scotland acknowledges that facilitating the development of patient safety modules and Healthcare Acquired Infection training for induction courses for all staff is core business which it will progress over the next few

years. NHS Education for Scotland is already working with key stakeholders on the generic elements of training such as basic patient safety and risk management, communication skills and team working.

The NPSA approach

7.3 The Agency is developing a range of educational and support initiatives to build capacity for local staff to be able to collect and analyse data on incidents. Recognising that staff must feel able to report incidents, the Agency aims to provide support to create a culture in each organisation which is 'open and fair' and that supports learning from adverse events to improve services. The following initiatives are underway in England and Wales:-

7.3.1 Induction

A flexible training package is being developed to ensure that every new permanent or temporary member of staff has certified training in patient safety before they begin work in a new setting. This training package will include web-based training, but since computer-based learning may not be accessible to all, there will also be a paper-based version. In time, completion of this induction module may become mandatory. In the meantime, it will be accredited under CPD.

7.3.2 Pre-registration and post-registration training

The NPSA is working with the Deaneries in England and Wales and the English Workforce Development Confederations to ensure that medical and other clinician training must include patient safety as a compulsory appraised component.

7.3.3 Continuing Professional Development (CPD)

Training modules in Patient Safety are being developed for inclusion in existing CPD provision.

7.3.4 Non-executive development

Patient safety is to be included in induction programmes for Non-executive Directors in England and Wales.

7.3.5 Accreditation and credentialing for Patient Safety / Risk Managers

Skills in 'root cause analysis' (RCA) need to be consistently applied for reporting of incidents to the NPSA. The NPSA is developing a tool kit for training on two levels. Level 1 will be for members of staff who take part in RCA but will not be the lead or expert within their Trust. Level 2 will be for Risk / Patient Safety Managers who will train other staff.

7.3.6 Management development

Research in the airline industry has shown that the most common causes of errors are failures in communication, teamwork and decision making. These management development competencies should, in time, be included in the appraisal system for all staff.

7.3.7 Involvement of Royal Colleges and regulatory bodies.

NPSA have approached the UK Royal Colleges and regulatory bodies to include patient safety in curriculum design. The response has been supportive.

7.3.8 Involvement of Trade Unions and staff side organisations

To support a change of culture from one of blame to one of open and fair treatment of staff, the NPSA ensures that incident reporting is entirely anonymised with regard to the patient and the member of staff involved.

7.3.9 Disciplinary Procedures

The existing procedures lead to a focus on *the individual* rather than *the individual working within the system* that can lead to error. The NPSA are working with the National Clinical Assessment Authority (NCAA) and other staff organisations to develop and pilot a 'decision support tool' based on James Reason's 'culpability tree'¹³ to enable managers to look at alternatives to suspension.

7.3.10 Bank and Agency staff

It is known that the number of incidents increases where there are more temporary staff. The NPSA aims to make the patient safety induction module form part of induction for temporary staff and in time to make it part of the mandatory staff induction system.

Developing capacity to report and learn from adverse incidents and implementing an open and fair culture in NHS Scotland

7.4 NHSScotland staff require the same training and support as those in England to enable them to collect and analyse incident data for the NPSA database. They also need training and support to build an open and fair culture to encourage reporting and safety conscious working.

7.5 Representatives of NHS Education for Scotland and the Human Resources Directorate of Scottish Executive Health Department (SEHD) have met with the NPSA and are keen to take forward the ideas identified above in a way which meets Scotland's needs. The educational tools will be welcomed. The involvement of the Scottish Partnership Forum and the Scottish Royal Colleges will be needed to take this agenda forward.

Q2 Do you have any comments on these approaches to implementing educational support on patient safety in Scotland?

Q3 How else should the education and training initiatives to build capacity and change the culture be taken forward in Scotland?

8 DEVELOPING SOLUTIONS

What is in place in Scotland

8.1 Local solutions to identified risks are developed through risk management structures in Trusts. Advice on patient safety is issued from time-to-time by SEHD. The challenge for the future is to take a co-ordinated, Scotland-wide approach to implementing solutions to problems of patient safety.

¹³ Reason JT (1997) *Managing the Risks of Organisational Accidents*. Aldershot: Ashgate

The NPSA approach

- 8.2 The Agency has begun work on developing practical solutions for the NHS where patient safety issues amenable to change are identified. There are currently over 20 such solutions under development.
- 8.3 The Agency has issued its first Patient Safety Alert on restricting the availability of concentrated potassium chloride solutions on wards and is working with manufacturers to ensure that products are available in suitable forms.

Scottish involvement in developing solutions

- 8.4 Scottish expertise should be utilised to contribute to the development of 'solutions' by the Agency and the benefits of 'solutions' should be initiated in NHSScotland at the same time as they are in England and Wales.
- 8.5 Multi-disciplinary groups set up by the NPSA to devise solutions may involve Scottish experts, and Scottish groups may lead some of this work where appropriate.
- 8.6 NHS Quality Improvement Scotland will, where necessary, issue interim advice on patient safety to NHSScotland and will ensure that, in implementation of any solutions to problems recorded by the NPSA, proper account is taken of the geographical and service organisation and delivery context in Scotland.

Q4 Do you have any comments on this approach to the development of solutions to problems of patient safety in Scotland?

Q5 Are there other ways that Scottish interests should be involved in the development of 'solutions'?

9 PATIENT SAFETY ALERTS

What is in place in Scotland

- 9.1 The Pharmaceutical Division of the SEHD is responsible for disseminating information from the Medicines Control Agency about defective medicinal products to NHSScotland. They are also the point of contact for the notification of defects in medicinal products from NHSScotland.
- 9.2 Scottish Healthcare Supplies run the Incident Reporting and Investigation Centre (IRIC) to investigate issues related to Medical Devices and manage the link with the Medical Devices Agency. They issue Hazard Notices, Safety Notices and Device Alerts and they are the point of contact for NHSScotland to report adverse incidents and defective equipment.

The NPSA Approach

- 9.3 The Agency is developing Patient Safety Alerts. The need to issue an Alert may arise on the basis of errors reported to the NPSA, when the NPSA is notified by another agency, from research evidence or from experience of other health services.
- 9.4 The NPSA aims to ensure that the Alert is issued with the same content to all parts of the UK and will ensure the devolved administrations are fully involved.

Alerts will be published on the NPSA web-site and through the electronic bulletins used by DH in England.

Disseminating Patient Safety Alerts in Scotland

- 9.5 Patient Safety Alerts developed by the NPSA should be distributed to NHSScotland at the same time as they are issued to the NHS in England and Wales. Where there are differences in the nature of service arrangements in Scotland these should be taken into account.
- 9.6 It is proposed that NHS Quality Improvement Scotland will be responsible for arrangements to ensure the dissemination of Alerts to NHSScotland and to independent sector healthcare providers in Scotland.
- 9.7 NHSScotland Trusts must understand the importance of Alerts and have systems to disseminate them to appropriate staff and be ready to act on them where they involve immediate risk to patients. NHS Quality Improvement Scotland will monitor NHSScotland to ensure that change is embedded in local systems in response to Alerts. The Clinical Governance Committees of NHS Boards and Trusts are expected to ensure that this work is undertaken locally.

Q6 Do you have any comments on the principles for disseminating Patient Safety Alerts in Scotland and monitoring whether action has been taken by NHSScotland to change ways of working?

10 INVESTIGATING ISSUES OF SERIOUS CONCERN

Current practice

- 10.1 When something goes wrong in Scotland there are already systems in place to notify relevant agencies such as the Health and Safety Executive, Medicines Control Agency, Medical Devices Agency, Procurator Fiscal or one of the national Confidential Enquiries. There is also a responsibility to investigate a patient's or their relatives' concerns through the NHS Complaints Procedure. In addition, the most serious adverse events are reported to the Director of Public Health of the relevant NHS Board.
- 10.2 In England, the Department of Health has set up an Investigations and Inquiries Unit to act as a source of expertise in the management and follow up of independent inquiries in consultation with the Commission for Health Improvement.

Looking to the future

- 10.3 **Serious service failures.** From time-to-time it becomes apparent that groups of patients have experienced adverse outcomes of care, been harmed or died because of significant weaknesses in the way the service has operated. Sometimes it becomes evident that a service is dysfunctional even though there has as yet been no harm to patients. In both these circumstances it may be appropriate to establish an independent inquiry, in addition to any of the actions outlined above.

10.4 Scottish Ministers will be able to ask NHS Quality Improvement Scotland to investigate serious failures in clinical service delivery. NHS Quality Improvement Scotland will also be able to undertake inquiries on its own initiative or in response to public concerns. Its reports will be fully independent.

10.5 **Poor clinical practice.** There are also provisions to address issues of poor clinical practice by individual health practitioners. These aim to support practitioners and to strengthen and assure quality of care. The approaches differ across the United Kingdom. We intend to review the arrangements in Scotland to ensure that staff in all clinical professions have the skills and capabilities to fulfil their clinical roles effectively within any particular setting at all times in their career.

Q7 Do you have any comments on this approach to investigating issues of serious concern in Scotland?

OTHER MATTERS IN THE NPSA WORK PLAN

11 PATIENT AND PUBLIC INVOLVEMENT

The NPSA Approach

11.1 The Agency is committed to involving patients and the public in the reporting system and in the design of solutions.

Involving People in Scotland

11.2 The Involving People strategy and the current work in Scotland confirms that patient and public involvement will be integral to the work of NHS Quality Improvement Scotland and we welcome the commitment that has been made by the NPSA.

12 RESEARCH

The NPSA Approach

12.1 The NPSA is developing a strategy to promote research and development in patient safety. The DH has set up a Patient Safety Research Programme headed by Professor Richard Lilford at Birmingham University.¹⁴

Scottish involvement in UK patient safety research

12.2 Scottish academic institutions and researchers have a track record in this field and are free to apply for support under this programme.

13 WORKING WITH OTHER AGENCIES

The NPSA Approach

13.1 The NPSA is developing Memoranda of Agreement with other organisations that have an interest in patient safety. These include the Medical Devices Agency and Medicines Control Agency (to be merged in April 2003), the

¹⁴ www.publichealth.bham.ac.uk/psrp.

Commission for Health Improvement (to become Commission for Healthcare Audit and Inspection), the National Institute for Clinical Excellence, and the National Clinical Assessment Authority. Some Agencies such as the Information and Statistics Division and Central Legal Office of the Common Services Agency are exclusive to Scotland. The Agency has already signed a service level agreement with the National Assembly of Wales.

Including Scottish Agencies.

13.2 Arrangements should be made for relevant data from Scottish Agencies and organisations to be collected by the Agency along with the information from UK agencies and English organisations.

14 RESPONSIBILITY OF NHS QUALITY IMPROVEMENT SCOTLAND (ONCE ESTABLISHED)

14.1 Responsibility for patient safety in Scotland rests with Scottish Ministers. We therefore propose to designate NHS Quality Improvement Scotland as the lead agency for patient safety issues in Scotland. It will be responsible for assuring patient safety systems in NHSScotland and managing the overall relationship with NPSA.

14.2 We propose that NHS Quality Improvement Scotland should be the lead agency for patient safety issues and develop an agreement with the NPSA on behalf of NHSScotland

15 THE PROPOSED WAY FORWARD

15.1 Consultation responses should be sent to Mrs Liz Neil, Ground East Rear, St Andrew's House, Regent Road Edinburgh, EH1 3DG or by e-mail to liz.neil2@scotland.gsi.gov.uk by 28th February 2003.

15.2 Discussions will take place immediately with NHS Education for Scotland concerning the education and training requirements for staff and the relationship with initiatives developed by the NPSA.

15.3 Negotiation of a Memorandum of Agreement between NHS Quality Improvement Scotland and NPSA will take place during 2003.

15.4 A business case for the funding required for the Agreement will be made at the same time.

15.5 Sites for implementing pilots of the NPSA reporting and learning system in Scotland will be selected and work will begin from March 2003.

15.6 We aim for the Agreement to begin from October 2003 with a phased roll-out of sites for the incident reporting system.