



NHS Management Executive
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Dear Colleague

CALDICOTT GUARDIANS

Summary

1. The Caldicott Committee was set up to review all patient-identifiable information passing from NHS organisations in England to other NHS or non-NHS bodies for purposes other than direct patient care, medical research or where there is a statutory requirement for information.

2. One of the key recommendations of the Caldicott Report, published in December 1997, was the establishment of a network of **Caldicott Guardians** of patient information throughout the NHS. This MEL advises on the nomination of Guardians, outlines the first year work programme for improving the way the NHS handles confidential patient information and identifies the resources, training and other support for Guardians. The other recommendations made in the Caldicott Report are being addressed separately.

Action

3. Each Health Board, Special Health Board, and NHS Trust, should nominate a Caldicott Guardian by no later than 1 April 1999. The Guardian should be a senior health professional at Board level and have a degree of responsibility for the development of clinical governance.

4. Annex A to this letter should be made available to the Caldicott Guardian but should also be copied to all Board members. It outlines the action that each organisation should take during 1999/2000, as well as the Guardian's role and responsibilities. This action will include:

- a management audit of current practice and procedures
- annual plans for improvement that will be monitored through the clinical governance framework

Addressees 2nd March 1999

For action:
General Managers,
Health Boards
General Manager, CSA
General Manager, State Hospital
Chief Executives, NHS Trusts
Chief Executive, Scottish Ambulance Service

For information:
Health Board Chairmen
NHS Trust Chairmen
Directors of Public Health, Health Boards
NHS Trust Medical Directors
General Manager, Health Education Board for Scotland
Executive Director, SCPMDE
Director, Scottish Association of Health Councils
Directors of Education
Directors of Social Work
Organisations listed in Annex C

Enquiries to:

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- the development of clear protocols to govern the disclosure of patient information.

Training

5. We intend to arrange regional seminars for Guardians and supporting staff from June. Details of these seminars will be disseminated in April.

6. This MEL is available on The Scottish Office website:
<http://www.show.scot.nhs.uk/dtc>

Yours sincerely



KEVIN J WOODS
Director of Strategy and Performance Management



ANDREW FRASER
Deputy Chief Medical Officer

CALDICOTT GUARDIANS IN THE NHS

Summary

1. NHS organisations are required, on receipt of this letter and by no later than 1 April 1999, to nominate a Caldicott Guardian. The Guardian's name and address for correspondence should be sent to Andy Nichol, Health Care Policy Division, Room 277, St Andrew's House, Regent Road, Edinburgh.
2. This circular provides a broad overview of the Guardian role in the NHS. Detailed guidance on specific actions to be addressed in 1999/2000 by the NHSiS and by Guardians will be made available prior to 1 April 1999.
3. The appointment of Guardians and, in general terms, work to improve confidentiality and security, should be included in local IM&T implementation plans (MEL(1998)84).

Background

4. In its Report, published in December 1997, the Caldicott Committee made a number of recommendations aimed at improving the way the NHS handles and protects patient information. Whilst the Group's remit did not extend to Scotland it is intended to take forward a number of the Committee's recommendations here.
5. A key recommendation of the Caldicott Report was that we need to establish a network of Guardians of confidential patient information to safeguard and govern the uses made of patient identifiable information within the NHS including both clinical and non-clinical information.
6. Caldicott Guardians will be central to the development of a new framework for handling patient information in the NHSiS. Other Caldicott recommendations

identified actions which should be undertaken by the NHSiS in support of the Guardian, namely to:

- restrict access to patient information within each organisation by enforcing strict need to know principles
- develop local protocols governing the disclosure of patient information to other organisations. Paragraph 6.5 of the consultation paper on the appointment of guardians indicated that consideration is being given to producing guidance from the centre to aid this process. In the meantime Annex B to this letter provides details of a sample protocol produced by the Caldicott Committee
- regularly review and justify the uses of patient information
- improve organisational performance across a range of related areas: database design, staff induction, training, compliance with guidance etc.

7. Following the responses to the consultation on the introduction of Caldicott Guardians and the implementation of the Caldicott recommendations we recognise the need to introduce change at a pace that will not prove disruptive, whilst ensuring that we support and sustain momentum. This support and emphasis will be provided by the clinical governance initiative. The NHSiS will be held accountable, through clinical governance, to ensure that confidentiality and security procedures are being properly applied. The Caldicott Guardians will need to provide details of annual improvement plans and outcome reports to the Trust's Board. The Clinical Governance Committee will have oversight of that process as they will with all other activities delivering clinical governance.

Who should be the Guardian?

8. The Guardian should be, in order of priority:
- a senior health professional
 - an existing member of the management board of the organisation
 - an individual with responsibility for promoting clinical governance within the organisation.

Where it is not possible to identify a Guardian in line with the criteria listed above, an indication of the reasons for this should be provided to the NHS Management Executive.

9. It is particularly important that the Guardian has the seniority and authority to exercise the necessary influence on policy and strategic planning and carry the confidence of his or her colleagues. Obvious candidates include:

Health Boards
NHS Trust

Director of Public Health
Medical or Nursing Director or Board
level Clinician

10. Other organisations who share NHS patient information, such as the divisions of the CSA who hold patient identifiable information, the Scottish Centre for Infection and Environmental Health (SCIEH), Universities and Research Bodies, Mental Welfare Commission etc should also nominate a senior officer to fulfil the Guardian's role.
11. It is recognised that a degree of flexibility is required to accommodate the organisational structure and complexity of Local Health Care Co-Operatives. There should be a single Guardian (with clinical governance responsibilities) appointed by each Primary Care Trust, but within each practice there should be a nominated lead for confidentiality issues.

Resources and Support for Guardians

12. Preserving the confidentiality of patient information, specifically through implementation of the Caldicott recommendations should be seen as a cornerstone of the NHS information strategy. Action in this area, including the appointment of Guardians, should be noted within each organisation's local information strategy implementation plan.
13. The requirement for a senior member of the organisation to act as the Caldicott Guardian raises concerns about workload and priorities. Nevertheless, this is an extremely important role and Guardian responsibilities must only be delegated within a clear framework. Guidance for Guardians will identify key Guardian responsibilities which should not be delegated, and which aspects might be actioned by other staff under the Guardian's direction. Wherever possible, tasks will build on existing procedures and requirements. This clarity of focus should minimise the additional workload resulting from Guardian responsibilities.
14. It is not intended or even desirable that the Guardian should have responsibility for all aspects of confidentiality, data protection or IM&T security, though this may be the pragmatic solution in small organisations. However, the Guardian should liaise closely with IM&T Security Managers, Data Protection Officers and others charged with similar responsibilities, to ensure that there is no duplication/omission of duties.
15. Local networks of Guardians may find it advantageous to discuss issues, share best practice and identify training needs. Health Boards may wish to facilitate this local networking, and offer a lead in protecting the use of population and patient indices.
16. Training seminars for Guardians and supporting staff will be organised on a Regional basis during June and July. Further details about the venue and timing of these will issue shortly. The seminars will cover the actions required in the first year, the wider responsibilities of Guardians, and the sources of advice that are available to

Guardians. Detailed guidance will also be available by March 1999 on the specific tasks that will need to be addressed by the NHSiS and their Guardians in the first year. Additional material will draw together, from existing sources, relevant guidance on a wide spectrum of confidentiality and security related issues.

The Guardian Role

17. The creation of a network of Caldicott Guardians in the NHS is a key component of work to establish the highest practical standards for handling patient information in the NHS. NHS performance in this area will be monitored through clinical governance and year on year improvements sought.
18. This emphasis on year on year improvement, at a pace that the NHS is able to sustain, is of paramount importance. Pressure for improvement must be balanced by a realistic appraisal of what is practicable each year. The specific tasks for the NHSiS and Guardians outlined later in this paper take account of this balance and the NHSiS should be able to complete this work to a satisfactory standard. This intentionally limited approach in the first year should in no way constrain those able to achieve more.
19. Guardians will be responsible for agreeing and reviewing internal protocols governing the protection and use of patient-identifiable information by the staff of their own organisation or those shared with other NHSiS organisations. Guardians will need to be satisfied that these protocols address the requirements of national guidance/policy and law and that their operation is monitored.
20. Guardians will also be responsible for agreeing and reviewing protocols governing the disclosure of patient information across organisational boundaries, eg with social work services and other partner organisations contributing to the local provision of care. These protocols should underpin and facilitate the development of cross boundary working, health improvement programmes and other changes heralded in the White Paper '*Designed to Care - Reviewing the National Health Service in*

Scotland' and *'Modernising Community Care – An Action Plan'*. The need for national guidance on sharing of information between health and other agencies is also being addressed by the NHS Management Executive.

21. Guardians will have a strategic role, developing confidentiality and security policy, representing confidentiality requirements and issues at Board level, advising on annual improvement plans, and agreeing and presenting annual outcome reports.
22. Local issues will inevitably arise and be referred to the Guardian for resolution. It will be important in these circumstances for the Guardian to know when and where to seek advice. This may be either on the particular issue or on the alternative and perhaps more appropriate ways of handling the issue eg referral on to the NHS complaints procedures, to the Multi-Centre Research Ethics Committee, Local Research Ethics Committee or to the Data Protection Commissioner.

Specific Tasks in the First Year

23. The following section briefly outlines the action that each NHS organisation is required to undertake during 1999-2000. Caldicott Guardians will have an important role in developing policy and "signing off" many of these actions as having been satisfactorily completed. However, safeguarding confidentiality should be seen as an organisational responsibility - the Guardian's role is essentially advisory even though in some organisational settings he/she may be closely involved in implementation work.
24. The initial task for each organisation will be to conduct a management audit of existing procedures for protecting and using patient-identifiable information. This management audit will inform an initial stock-take report for the Guardian to present to the organisation's senior management team. Detailed guidance on conducting the management audit and the required content of the stock-take report will be made available shortly, but it will cover the following core areas:

- an overall "health-check" assessment of the organisation, including existing codes of conduct, induction procedures, training needs, risk assessment, IT physical security, quality of information supplied to the public etc
 - a review of existing flows of patient-identifiable information
 - a review of database construction and management where patient-identifiable information is stored
 - a review of procedures for handling patient-identifiable information collected by or transferred to the organisation, and of procedures for disclosing information to other organisations
25. This stock-take will itself inform the development of an improvement plan that will begin to address any identified deficiencies. Again, detailed guidance on the content of improvement plans and the standards that all NHS organisations are expected to achieve in 1999/2000 will be available shortly, but key requirements will include the need for protocols governing the receipt, collection and disclosure of patient-identifiable information to be locally agreed and complied with.

Further Information

26. Any enquiries about the content of this circular or further information on related subjects should be addressed to:

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Appendix 11 - Sample protocol

SAMPLE FRAMEWORK FOR THE SHARING OF PERSONAL INFORMATION BETWEEN NHS AND NON-NHS BODIES THROUGH ORAL REPORTS, WRITTEN RECORDS AND COMPUTER SYSTEMS

1. Outline

1.1 This framework document contains six sections:

- Objectives of a locally agreed protocol
- General Principles governing the sharing of personal information
- Setting Parameters for sharing personal information
- Defining Purposes for which personal information is required
- Holding personal information, access and security
- Ownership of information and the rights of individuals

2. Objectives

- 2.1 To set parameters for the sharing of information between agencies which contribute to the health or social care of an individual.
- 2.2 To define the purposes for holding personal information within each agency.
- 2.3 To define how personal information should be held within each agency and who should have access to this information.
- 2.4 To define which information is designated as health services information and which is designated as social services information and to specify the rights of access to each for individuals as required by legislation.

3. General Principles

- 3.1 Whilst it is vital for the proper care of individuals that those concerned with that care have ready access to the information that they need, it is also important that service users and their carers can trust that personal information will be kept confidential and that their privacy is respected.

- 3.2 All staff have an obligation to safeguard the confidentiality of personal information. This is governed by law, their contracts of employment, and in many cases by professional codes of conduct. All staff should be made aware that breach of confidentiality could be a matter for disciplinary action and provides grounds for complaint against them.
- 3.3 Although it is neither practicable nor necessary to seek an individual's specific consent each time that information needs to be passed on for a particular purpose **that has been defined within this protocol**, this is contingent on individuals having been fully informed of the uses to which information about them may be put. All agencies concerned with the care of individuals should satisfy themselves that this requirement is met.
- 3.4 Clarity about the purposes to which personal information is to be put is essential, and only the minimum identifiable information necessary to satisfy that purpose should be made available. Access to personal information should be on a strict **need to know** basis.
- 3.5 If an individual wants information about themselves to be withheld from someone, or some agency, which might otherwise have received it, the individual's wishes should be respected unless there are exceptional circumstances. Every effort should be made to explain to the individual the consequences for care and planning, but the final decision should rest with the individual.
- 3.6 The exceptional circumstances which override an individual's wishes arise when the information is required by statute or court order, where there is a serious public health risk or risk of harm to other individuals, or for the prevention, detection or prosecution of *serious* crime. The decision to release information in these circumstances, where judgement is required, should be made by a nominated senior professional within the agency, and it may be necessary to take legal or other specialist advice.
- 3.7 There are also some statutory restrictions on the disclosure of information relating to HIV and AIDS, other sexually transmitted diseases, assisted conception and abortion.
- 3.8 Where information on individuals has been aggregated or anonymised, it should still only be used for justified purposes, but is not governed by this protocol. Care should be taken to ensure that individuals cannot be identified from this type of information, as it is frequently possible to identify individuals from limited data e.g. age and post code may be sufficient.

4. **Setting Parameters**

- 4.1 There should be a nominated senior professional, within each agency covered by this protocol, responsible for agreeing amendments to the protocol, monitoring its operation, and ensuring compliance.
- 4.2 Personal information should be transferred freely between the agencies who have agreed and are complying with this protocol, for the purposes it defines. A regularly updated register of individuals who need access to

personal information, and the defined purpose for which they need this access, shall be made available to each agency concerned.

- 4.3 If appropriate, service level agreements can be used to establish standards for sharing information, e.g. speed of response.
- 4.4 Specific consent is required prior to personal information being transferred for purposes other than those defined in this protocol, unless there are exceptional circumstances as outlined above.
- 4.5 Where individuals are unable to give consent, the decision should be made on the individual's behalf by those responsible for providing care, taking into account the views of patients and carers, with the individual's best interests being paramount. Where practicable, advice should be sought from the nominated senior professional and the reasons for the final decision should be clearly recorded.

5. **Defining Purposes**

5.1 There will be a range of justifiable purposes to be locally agreed. The following list is not exhaustive and covers internal NHS purposes only:

- delivering personal care and treatment
- assuring and improving the quality of care and treatment
- monitoring and protecting public health
- managing and planning services
- contracting for NHS services
- auditing NHS accounts and accounting for NHS performance
- risk management
- investigating complaints and notified or potential legal claims
- teaching
- statistical analysis
- medical or health services research

6. **Holding information, access and security**

6.1 Staff should only have access to personal information on a need-to-know basis, in order to perform their duties in connection with one or more of the purposes defined above. Clinical and professional details should be available to all those, but only those, involved in the care of the individual.

- 6.2 Each agency will ensure that they have mechanisms in place to enable them to address the issues of physical security, security awareness and training, security management, systems development, site specific information systems security policies, and systems specific security policies.
- 6.3 Each agency will take all reasonable care and safeguards to protect both the physical security of information technology and the data contained within it.
- 6.4 All information systems will be effectively password protected and users will not divulge their password nor leave systems active whilst absent.
- 6.5 All personal files and confidential information must be kept in secure, environmentally controlled locations when unattended, e.g. in locked storage cabinets, security protected computer systems etc.
- 6.6 Keys to lockable storage cabinets should be held only by staff who require regular access to the information they contain. Keys must be held in a secure place.

7. Ownership of information and the rights of individuals

- 7.1 Whilst written and computerised records will be regarded as shared between the agencies, an individual's right of access to the information contained in the records differs when it has been provided by a health professional from when it has been provided by Social Services staff.
- 7.2 Any health professional contribution to records maintained by Social Services staff, whether a letter, a case record or a report, must be clearly marked as such, and where practicable, kept in a closed part of the file. Social Services staff cannot grant access to this information without written authorization.
- 7.3 The reverse also applies. NHS staff cannot grant access to Social Services information without written authorization.

Accounts Commission
Association of Optometrists
Audit Commission
British Dental Association
British Medical Association
BUPA
Chartered Society of Physiotherapy
Chief Executives, NHS Trusts
College of Optometrists
Conference of Colleges and Faculties in Scotland
COSLA
Deans of Dental Schools
Deans of Postgraduate Medical Education
Deans of the Faculties of Medicine
Director, Cancer Registration
Directors of Public Health Group
Dr Spaul, Director, Chief Scientist Office
General Manager, Common Services Agency
General Manager, State Hospital
General Managers, Health Boards
Health Board Directors of Nursing (Scotland) Group
Health Education Board for Scotland
Health Service Commissioner (Scotland)
Joint Committee for Postgraduate Training of GPs
Marie Curie Hospices
Mental Welfare Commission for Scotland
National Board for Nursing, Midwifery and Health Visiting in Scotland
National Dental Advisory Committee
National Health Service Central Register (Scotland)
National Nursing, Midwifery and Health Visiting Advisory Committee
National Paramedic Advisory Committee
National Pharmaceutical Advisory Committee
Practice Managers Association
Practice Nurse Association
Royal College of General Practitioners, Scottish Council
Royal College of Nursing
Royal College of Physicians
Royal College of Psychiatrists
Royal Pharmaceutical Society for Great Britain (Scottish Department)
SAC Faculty of Public Health Medicine
Scotland Patients Association
Scottish Ambulance Service
Scottish Association of Fundholding Practices
Scottish Association of GP Community Hospitals
Scottish Association of Health Councils
Scottish Centre for Infection and Environmental Health

Scottish Chief Administrative Pharmaceutical Group
Scottish Consumer Council
Scottish Council for Postgraduate Medical and Dental Education
Scottish Courts Administration
Scottish Dental Practice Board
Scottish General Medical Services Committee
Scottish Health Visitors Association
Scottish Independent Acute Sector Management Group
Scottish Joint Consultative Committee
Scottish Medical and Dental Defence Union
Scottish Medical and Scientific Advisory Committee
Scottish National Blood Transfusion Service
Scottish Prison Service
The Law Commission
Trust Directors of Nursing
UNISON