

The Caldicott Guardian Manual 2006



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October 2006

DH INFORMATION READER BOX

Policy HR/Workforce Management Planning Clinical	Estates Performance IM & T Finance Partnership Working
Document purpose	Best Practice Guidance
Gateway reference	7019
Title	The Caldicott Guardian Manual 2006
Author	DH/Digital Information Policy
Publication date	October 2006
Target audience	Caldicott Guardians
Circulation list	PCT CEs, NHS Trust CEs, SHA CEs, Care Trust CEs, NHS Foundation Trust CEs, Directors of Adult SSs, Directors of Children's SSs
Description	The manual, which is a DH publication, is guidance that takes account of developments in information management in the NHS and in Councils with Social Services responsibilities since the publication of the Caldicott report. It sets out the role of the Caldicott Guardian within an organisational Caldicott/confidentiality function as a part of broader Information Governance.
Cross reference	NA
Superseded documents	Caldicott Guardian Manual 1999
Action required	N/A
Timing	N/A
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1. Introduction

- 1.1 The 1997 report of the Review of Patient-Identifiable Information, chaired by Dame Fiona Caldicott (the Caldicott Report), made a number of recommendations for regulating the use and transfer of patient-identifiable information between NHS organisations in England and to non-NHS bodies. The Caldicott Committee's remit included all patient-identifiable information passing between organisations for purposes other than direct care, medical research, or where there was a statutory requirement for information. The aim was to ensure that patient-identifiable information was shared only for justified purposes and that only the minimum necessary information was shared in each case. The Committee also advised on where action to minimise risks of confidentiality would be desirable.
- 1.2 The recommendations of the Caldicott Committee defined the confidentiality agenda for NHS organisations for a number of years. Central to the recommendations was the appointment in each NHS organisation of a "Guardian" of person-based clinical information to oversee the arrangements for the use and sharing of clinical information. Subsequent work extended the requirement to appoint Caldicott Guardians into Councils with Social Services Responsibilities [CSSRs].
- 1.3 A key recommendation of the Caldicott Committee was that every use or flow of patient-identifiable information should be regularly justified and routinely tested against the principles developed in the Caldicott Report.

Principle 1 – Justify the purpose(s) for using confidential information

Principle 2 – Only use it when absolutely necessary

Principle 3 – Use the minimum that is required

Principle 4 – Access should be on a strict need-to-know basis

Principle 5 – Everyone must understand his or her responsibilities

Principle 6 – Understand and comply with the law

- 1.4 Since then developments in information management in the NHS and CSSRs have added further dimension to the Caldicott Guardian role. These include:
- the Data Protection Act 1998
 - the Human Rights Act 1998

- the Freedom of Information Act 2000
- the Health and Social Care Act 2001 (Section 60)
- the establishment of the Patient Information Advisory Group 2001
- the NHS Code of Practice on Confidentiality 2003
- the inception of NHS Information Governance 2003
- ICT strategic developments (such as the NHS Care Records Service, Electronic Social Care Records, and the Secondary Uses Service) 2005 onwards
- the election of the UK Caldicott Guardian Council 2005
- the Cayton review of NHS Information Governance 2006

1.5 This guidance takes account of these developments and, importantly, sets the role of the Caldicott Guardian within an organisational Caldicott/confidentiality function which is itself a part of broader Information Governance. The guidance does not aim to reproduce or codify all the guidance available, but it updates existing materials where necessary and otherwise provides pointers to other current sources of guidance and standards. It replaces the Caldicott Guardian Manual published in 1999. The intention is that this new Caldicott Guardian guidance will be reviewed annually and updated as required.

2. Who should be a Caldicott Guardian?

2.1 The Guardian should be, in order of priority:

- an existing member of the management board or senior management team of the organisation
- a senior health or social care professional
- the person with responsibility for promoting clinical governance or equivalent functions within the organisation

2.2 Where it is not practicable to satisfy the criteria listed above, assignment of Guardian responsibility should be kept under review. The individual performing the role should also have a close relationship with the senior health professional responsible for promoting clinical governance or their social care equivalent.

2.3 It is particularly important that the Guardian has the seniority and clear authority from the Board/senior management team and Chief Executive or Director of Social Services to influence policy development and strategic planning, and carry the confidence of his or her colleagues. Obvious candidates for the role include:

Table 1: Caldicott Guardians by organisation type

Organisation	Possible Caldicott Guardian
Strategic Health Authority	Director of Public Health
NHS Provider Trust	Board-level clinician
Primary Care Trust	Board member with clinical governance responsibilities
Special Health Authorities (using/sharing patient data)	Board-level clinician or other senior officer
Cancer Registries	Senior officer – clinically qualified if possible
Clinical Research Bodies	Clinically qualified board member with ethics responsibilities
Non-NHS Clinical Contractor	Senior clinical manager
Social Services	Senior social care professional manager

- 2.4 Individual general medical and dental practices, pharmacists and opticians do not need to appoint a Caldicott Guardian, but do need to have an Information Governance lead who, if they are not a clinician, will need support from a clinically qualified individual. Primary Care Trusts should ensure that within every practice there is an Information Governance lead and provide support and guidance as required.
- 2.5 Quantifying the time that should be allocated to Caldicott duties is difficult to do without a clear understanding of the context and available support for the Guardian. Examples of what has been found to work well or otherwise will be posted on the UK Caldicott Guardian web-site: <http://www.connectingforhealth.nhs.uk/infogov>

3. The Role of the Caldicott Guardian

- 3.1 The Caldicott Guardian should play a key role in ensuring that NHS, CSSRs and partner organisations satisfy the highest practical standards for handling patient-identifiable information. Acting as the ‘conscience’ of an organisation, the Guardian should actively support work to facilitate and enable information sharing and advise on options for lawful and ethical processing of information as required. Local issues will inevitably arise for Caldicott Guardians to resolve. Many of these will relate to the legal and ethical decisions required to ensure appropriate information sharing. It is essential in these circumstances for Guardians to know when, and where, to seek advice.
- 3.2 In all but the smallest organisations the Caldicott Guardian should work as part of a broader Information Governance function; with support staff, Caldicott or Information Governance leads etc, contributing to the work required.
- 3.3 The Caldicott Guardian also has a strategic role, however, that is less appropriate to delegate. This involves representing and championing Information Governance requirements and issues at Board/management team level and, where appropriate, at a range of levels within the organisation’s overall governance framework. This role is particularly important in relation to the implementation of the National Programme for IT and the development of Electronic Social Care Records (ESCRs) and Common Assessment Frameworks.
- 3.4 Sample job descriptions and specifications can be accessed through the web pages provided in the guidance section of this document.

Table 2: Key Caldicott Guardian Responsibilities

Strategy & Governance: the Caldicott Guardian should champion confidentiality issues at Board/management team level, should sit on an organisation's Information Governance Board/Group and act as both the 'conscience' of the organisation and as an enabler for appropriate information sharing.

Confidentiality & Data Protection expertise: the Caldicott Guardian should develop a knowledge of confidentiality and data protection matters, drawing upon support staff working within an organisation's Caldicott function but also on external sources of advice and guidance where available.

Internal Information Processing: the Caldicott Guardian should ensure that confidentiality issues are appropriately reflected in organisational strategies, policies and working procedures for staff. The key areas of work that need to be addressed by the organisation's Caldicott function are detailed in the Information Governance Toolkit.

Information Sharing: the Caldicott Guardian should oversee all arrangements, protocols and procedures where confidential patient information may be shared with external bodies both within, and outside, the NHS and CSSRs. This includes flows of information to and from partner agencies, sharing through the NHS Care Records Service (NHS CRS) and related IT systems, disclosure to research interests and disclosure to the police.

4. Information Governance

- 4.1 NHS Information Governance¹ is one element of the Integrated Governance framework promoted by the Department of Health in its Integrated Governance Handbook 2006². Information Governance has four main components:
- Information Governance Management
 - Confidentiality and Data Protection Assurance
 - Information Security Assurance
 - Information Quality Assurance
- 4.2 Staff, skills and resources assigned to each of these assurance areas can be thought of as organisational functions. Caldicott Guardians are central to the Confidentiality and Data Protection Assurance function, so much so that this is often referred to as the Caldicott function. Examples of how a range of organisations have supported their Caldicott function can be accessed through the links provided in the guidance section of this document.
- 4.3 In addition to the key area of Confidentiality and Data Protection Assurance, the Caldicott Guardian needs to provide input into the other areas of Information Governance. The reverse is also likely to be the case, with staff working on other aspects of Information Governance being well placed to contribute to confidentiality and data protection work. It is important that organisations put in place effective governance arrangements to ensure that the organisation's approach to Information Governance is coordinated and inclusive.
- 4.4 A review of NHS Information Governance in England,³ carried out at the end of 2005 and subsequently approved by Ministers, has called for a strengthening of existing requirements for organisations to have Information Governance steering groups or boards as outlined in the Information Governance Toolkit. The Caldicott Guardian role needs to be strongly represented on this steering group and it is recommended that Caldicott Guardians attend in person.

1 An introductory booklet describing NHS Information Governance can be found at www.connectingforhealth.nhs.uk/infogov/publications

2 <http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/Governance>

3 http://www.connectingforhealth.nhs.uk/crdb/information_governance_review.pdf

4.5 The Information Governance Toolkit (IGT) for health sets out a range of standards or controls that encompass the entire Information Governance agenda and form the basis for NHS work programmes to provide the required assurance that an organisation is performing at the required level. Since its introduction in 2003/4 the IGT has served to reduce the burden on NHS organisations by eliminating duplication of effort and reducing central reporting requirements whilst providing:

- a 'one-stop' shop for guidance and resource materials
- a clear framework for assurance and controls
- an on-line tool for efficient performance assessment and reporting

An equivalent toolkit for CSSRs has been developed for (currently) voluntary use in CSSRs and work to refine this is planned.

5. Guidance

General advice and support

The UK Caldicott Guardian Council

<http://www.connectingforhealth.nhs.uk/infogov/caldicott>

This web-site contains the minutes of Council meetings, back issues of the Caldicott Guardian newsletter, Frequently Asked Questions, example job descriptions and specifications and other useful information.

caldicott.guardian@cfh.nhs.uk

An e-mail help line that is supported by Magi Nwolie, part of the Council secretariat. Magi will endeavour to find answers to questions and will collate responses as part of the Council's FAQ resource.

DH/NHS Connecting for Health – Digital Information and Health Policy

diginfo@dh.gsi.gov.uk

The Digital Information and Health Policy Branch provides policy advice and guidance on Information Governance issues.

The Information Governance Toolkit

www.igt.connectingforhealth.nhs.uk or nww.igt.connectingforhealth.nhs.uk

The IGT provides guidance on how organisations should satisfy confidentiality, data protection, information security, FOI, records management and information quality requirements. It also contains an extensive knowledgebase of exemplar documents, guidance materials and useful links.

helpdesk@cfh.nhs.uk

An e-mail help line for assistance with the Information Governance Toolkit – content, technical advice and administration issues.

The Department of Health

<http://www.dh.gov.uk/>

The DH web-site contains a range of materials relevant to Caldicott Guardians and those working within an organisation's Caldicott function.

The Patient Information Advisory Group (PIAG)

<http://www.advisorybodies.doh.gov.uk/piag>

Provides the minutes of PIAG meetings and guidance on the use of powers provided under section 60 of the Health & Social Care Act 2001 which allow confidentiality requirements to be set aside in limited circumstances for purposes such as research and public health work. PIAG also provides guidance on issues of major significance that are brought to its attention and its guidance is published here.

Guidance on Information Sharing and legal aspects

The NHS Confidentiality Code of Practice

<http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf>

Guidance on how confidentiality, data protection and human rights legislation impact on the use and sharing of patient information.

Public Sector Data Sharing

www.dca.gov.uk/foi/sharing/

Guidance on administrative law, regulatory 'gateways'; perhaps the clearest description of the legal framework available.

Working Together to Safeguard Vulnerable Children

www.everychildmatters.gov.uk

Guidance produced by the Department for Education and Skills that concentrates on the issues around sharing information to support the care of children, with a multi-agency focus. Resource materials can also be obtained from these web pages.

Data Protection Act 1998: Legal Guidance

<http://www.ico.gov.uk/>

Guidance produced by the Information Commissioner to explain how this fairly complex piece of legislation should be interpreted.

Other Useful Guidance and/or Links

Guidance on good practice in information security

<http://nww.connectingforhealth.nhs.uk/igsecurity/gpg/>

NHS Connecting for Health produces good practice guidelines on technical information security as well as the new controls that are being introduced in support of the NHS Care Records Service.

NHS Records Management Code of Practice & Roadmap

<http://www.dh.gov.uk?PolicyAndGuidance/OrganisationPolicy/RecordsManagement>

2006 guidance that replaces the previous records management circular, including records management principles, retention schedules and a legal compendium. The Road Map that accompanies the Code of Practice is an evolving body of guidance and best practice materials on specific aspects of records management and information quality.

Good Practice Guidelines for General Practice Electronic Records v3.1 (2005)

[http://www.dh.gov.uk/PublicationsAndStatisticsPublications/
PublicationsPolicyAndGuidance](http://www.dh.gov.uk/PublicationsAndStatisticsPublications/PublicationsPolicyAndGuidance)

Useful compendium of materials associated with paperless practice.



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277311 1P 2k Oct 06

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