

The logo for the National Data Guardian, consisting of the letters 'NDG' in a bold, teal, sans-serif font.

**National
Data Guardian**
for health and social care

DRAFT guidance about the appointment of Caldicott Guardians, their role and responsibilities from the National Data Guardian for Health and Social Care

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National Data Guardian for Health and Social Care

Contents

About this guidance	3
Review date	3
Who is this guidance for?	3
What legislation and reports does this guidance refer to?	4
Caldicott Principles: A consultation about revising, expanding and upholding the principles	4
The Caldicott Principles	4
Executive summary	5
Guidance	6
1. Purpose and structure of this guidance	6
2. History of the Caldicott Guardian role	6
3. Should your organisation appoint a Caldicott Guardian?	7
4. Roles and responsibilities of the Caldicott Guardian	9
5. Relationship of the Caldicott Guardian to other key organisational roles	10
6. Accountability and decision making.....	11
7. The competencies and knowledge a Caldicott Guardian needs	12
8. How organisations should involve and support their Caldicott Guardian	12
9. Relationship of the Caldicott Guardian to patients, service users, the public and other staff.....	13
10. Caldicott Guardian Register	13
Annex A	14

About this guidance

This is guidance issued by the National Data Guardian for Health and Social Care in England (the NDG) under section 1(2) of the Health and Social Care (National Data Guardian) Act 2018 (the “Act”). The Act empowers the NDG to provide guidance about the processing of health and adult social care data in England. It requires that certain organisations and persons must have regard to such guidance, to the extent that it is relevant to their functions or activities.

This guidance is about the appointment of Caldicott Guardians, their role, responsibilities, competencies, knowledge, training, and continuous professional development.

It is intended for (1) public bodies exercising functions that relate to the health service, adult social care or adult carer support in England; and (2) any person or organisation (other than a public body) providing: services as part of the health service; adult social care; or adult carer support pursuant to arrangements with a public body falling within (1) above (which will require them to handle confidential information about patients or service users). These public bodies, organisations and persons must have regard to this guidance.

Other organisations which also appoint Caldicott Guardians may also find this document useful, even though these organisations have no statutory duty to have regard to this guidance.

Review date

This guidance will be kept under review and updated to reflect any changes to law and/or policy affecting the role and responsibilities of Caldicott Guardians.

Who is this guidance for?

This guidance may assist any organisation which appoints a Caldicott Guardian.

However, the guidance is directed specifically at those organisations that have a statutory duty to have regard to it, namely:

1. Public bodies exercising functions that relate to the health service, adult social care or adult carer support in England and which handle confidential information about patients and service users; and
2. Other organisations providing services as part of the publicly funded health service, adult social care, or adult carer support pursuant to arrangements with a public body falling within paragraph (1) above, and which handle confidential information about patients and service users. For the

avoidance of doubt, the duty to have regard to this guidance applies to organisations that are not public bodies only in relation to work that is publicly funded.

There is nothing within this guidance to prevent organisations or bodies which are not subject to the statutory duty to have regard to the guidance from appointing a Caldicott Guardian, for instance police forces, prisons, purely private health and/or social care providers or other organisations handling confidential information. Such organisations and bodies may well find this guidance useful.

What legislation and reports does this guidance refer to?

This guidance refers to the following legislation and reports:

- Caldicott Committee's Report on the Review Patient-Identifiable Information 1997 (also known as Caldicott 1)¹
- Health Service Circular: HSC 1999/012²
- Local Authority Circular: LAC (2002)2³
- Information Governance Review 2013 (Caldicott 2)⁴
- Health and Social Care (National Data Guardian) Act 2018⁵
- Caldicott Principles: A consultation about revising, expanding and upholding the principles⁶
- The Caldicott Principles⁷

¹https://webarchive.nationalarchives.gov.uk/20130124064947/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4068404.pdf

² https://static.ukcgic.uk/docs/HSC1999_012.pdf

³ [https://static.ukcgic.uk/docs/LAC2002\(2\).pdf](https://static.ukcgic.uk/docs/LAC2002(2).pdf)

⁴ <https://www.gov.uk/government/publications/the-information-governance-review>

⁵ <https://www.legislation.gov.uk/ukpga/2018/31/contents/enacted>

⁶ <https://www.gov.uk/government/consultations/caldicott-principles-a-consultation-about-revising-expanding-and-upholding-the-principles>

⁷ <https://www.gov.uk/government/publications/the-caldicott-principles>

Executive summary

- A. Caldicott Guardians are responsible for protecting the confidentiality of patient and service user information within their organisation(s). In doing so, they have particular regard to the Caldicott Principles, which they help their organisations and individuals within them to uphold.
- B. This NDG guidance means that all public bodies within the health and adult social care sector, and all organisations which contract with such public bodies to deliver health or adult social care services in England should appoint a Caldicott Guardian if they handle confidential information about patients or service users.
- C. When deciding on arrangements to appoint a Caldicott Guardian an organisation should take into account the size and type of organisation, the amount of confidential information it holds, uses and shares (“processes”), and the extent of data processing for purposes beyond the individual care of patients and service user.
- D. A key consideration in the appointment of Caldicott Guardians should be the competencies and knowledge the Caldicott Guardian needs to be effective within their organisation.
- E. Organisations should support their Caldicott Guardian in understanding and carrying out their role and responsibilities. Caldicott Guardians should be able to provide advice and guidance freely to decision makers, preferably at senior management or board level.
- F. To ensure that Caldicott Guardians continue to have the necessary competencies and knowledge to contribute to the effective upholding of the Caldicott Principles, organisations should facilitate their Caldicott Guardian receiving appropriate training and continuous professional development to address any skills gaps and keep skills up to date.
- G. Organisations should enable their Caldicott Guardians to have meaningful and effective engagement with patients and service users.

Guidance

1. Purpose and structure of this guidance

- 1.1 This is guidance on the role and responsibilities of Caldicott Guardians in respect of data processing activities undertaken within their organisation. It is issued under the NDG's power to issue guidance contained within the Health and Social Care (National Data Guardian) Act 2018.
- 1.2 The main purposes of this guidance are to: describe which organisations should appoint a Caldicott Guardian; provide guidance for those organisations in making an appointment; describe the way the role should be supported by organisations; describe the role and responsibilities of a Caldicott Guardian; and describe the competencies and knowledge that will assist a Caldicott Guardian.
- 1.3 Annex A to this guidance sets out the Caldicott Principles which the Caldicott Guardian helps to uphold.

2. History of the Caldicott Guardian role

- 2.1 The Caldicott Committee's Report on the Review of Patient-Identifiable Information, published in 1997, recommended six good practice principles to be applied to the use of confidential information in the National Health Service (NHS). It also recommended that a senior person, preferably a health professional, should be nominated in each health organisation to act as a guardian responsible for protecting the confidentiality of patient information and ensuring the principles were upheld.
- 2.2 These principles became known as the Caldicott Principles and the senior individuals responsible for ensuring the principles were upheld became known as Caldicott Guardians.
- 2.3 The United Kingdom Council of Caldicott Guardians (UKCGC) was launched in 2005. Since 2015 the Council has been supported by the NDG. The UKCGC aims to be a point of contact for all Caldicott Guardians and for health and care organisations seeking advice on the Caldicott Principles and matters regarding the Caldicott Guardian role and responsibilities. It offers a range of support including: A Manual for Caldicott Guardians, regional networks, Caldicott Guardian forum, UKCGC website and virtual workshops. Caldicott Guardians and organisations may find it helpful to explore the available support on the UKCGC website⁸

⁸ <https://www.ukcgc.uk/>

- 2.4 The government has recommended that NHS trusts and local authorities with social services responsibilities should appoint a Caldicott Guardian since 1999 and 2002 respectively. Many other organisations, both within the health and care sector and outside it, have chosen to appoint a Caldicott Guardian and use the Caldicott Principles to help guide safe use of information.
- 2.5 This guidance builds on these previous recommendations. By specifying a wider range of organisations that should appoint a Caldicott Guardian and issuing this guidance under her powers in the Act, this means that a wider range of organisations should appoint a Caldicott Guardian than before this guidance was issued.
- 2.6 At the time of this guidance being issued, there were over 22,000⁹ Caldicott Guardians in health and social care organisations across the UK. They are sometimes described as being the ‘conscience of the organisation’ with regards to data use. They help their organisation to protect each service user’s right to confidentiality while also protecting their welfare by ensuring that information about them is communicated safely among the professional teams caring for them, including across organisational boundaries where appropriate. Caldicott Guardians balance ethical as well as legal considerations when making judgements and providing advice to their organisations.
- 2.7 The way that Caldicott Guardians operate differs according to their organisational environment. In a large NHS hospital trust, the Caldicott Guardian may be the medical director with wide-ranging professional responsibilities and supported by teams of people expert in information management and governance. In a local authority, the Caldicott Guardian may be a director of similar seniority and with similar support, but with different scenarios of information sharing and confidentiality to consider. A Caldicott Guardian in a small or medium-sized care home might be a social care professional or registered nurse. They will likely have less infrastructure and resources to support them and may be dealing with different issues, for instance ensuring good information sharing between the health and social care sectors. There are Caldicott Guardians in hospices, clinics, prison health care teams, GP practices, pharmacies and charities. They all perform a key role in protecting patient and service user confidential information in both the largest and smallest organisations that make up the health and social care sector.

3. Should your organisation appoint a Caldicott Guardian?

- 3.1 This NDG guidance means that all of the following organisations should appoint a Caldicott Guardian:

⁹ Based on evidence provided to the Data Security and Protection Toolkit and the Caldicott Guardian Register maintained by NHS Digital: <https://digital.nhs.uk/services/organisation-data-service/services-provided-by-the-organisation-dataservice#register-and-directory-updates>

1. Public bodies exercising functions that relate to the health service, adult social care or adult carer support in England and which handle confidential information about patients and service users; and
2. Other organisations providing services as part of the publicly funded health service, adult social care, or adult carer support pursuant to arrangements with a public body falling within paragraph (1) above, and which handle confidential information about patients and service users. For the avoidance of doubt, the duty to have regard to this guidance applies to organisations that are not public bodies only in relation to work that is publicly funded.

3.2 Where an organisation appoints a Caldicott Guardian who is, or will be, a member of its staff, it will need to consider whether the individual will undertake the Caldicott Guardian role in addition to another role or duties, for example as a clinician or social care professional. While it is not an expectation that all Caldicott Guardians focus solely on the Caldicott Guardian role, the work required may be time and resource intensive.

3.3 When considering how an individual might balance other responsibilities with their Caldicott Guardian role, an organisation should take into account factors such as the amount of confidential information handled within the organisation and the extent of the organisation's data uses beyond processing for direct (individual) care. Consideration should also be given to whether the organisation uses patient or service user information which would be considered high risk processing under data protection legislation¹⁰. The more confidential information processed, the greater number of different data uses by the organisation and the higher the risk of processing, the more time and resources will likely be required for carrying out the Caldicott Guardian role. See also **section 5 (Relationship of the Caldicott Guardian to other key organisational roles)** and **section 6 (Accountability and decision making)**.

3.4 Where an organisation considers that it is not proportionate or feasible to appoint a member of its own staff to the Caldicott Guardian role, it should arrange for the function to be provided in other ways. An organisation may choose to share a Caldicott Guardian between several organisations. For example, a consortium of GP practices may arrange to share one of the consortium's Caldicott Guardians.

3.5 Where organisations share a Caldicott Guardian, it is up to the organisations to make these arrangements and consider factors such as the size and type of organisations involved and the amount of confidential information handled. Questions to consider include: Will the Caldicott Guardian have sufficient time and resources to take on the workload for the range of organisations involved? Will the Caldicott Guardian have sufficient access to information to look into and resolve issues? How will the Caldicott Guardian raise issues to decision

¹⁰ <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/data-protection-impact-assessments-dpias/examples-of-processing-likely-to-result-in-high-risk/>

makers in the organisations involved? The arrangements should also consider whether the Caldicott Guardian is likely to face a conflict of interests and how these will be resolved or managed. Where a Caldicott Guardian is to be shared between organisations, those organisations should consider if there should be a deputy Caldicott Guardian from another of the organisations to provide support and another perspective.

3.6 When an organisation appoints its Caldicott Guardian, it should also consider appointing a deputy Caldicott Guardian. A deputy can help ensure there is a point of call and that there is support and guidance for patients and for the organisation when the Caldicott Guardian is on leave or unavailable. Deputies may be particularly useful in large organisations where the workload of the Caldicott Guardian may need to be shared.

3.7 If an organisation with a statutory duty to have regard to this guidance chooses not to appoint a Caldicott Guardian, this decision and the reasons for it should be documented.

4. Roles and responsibilities of the Caldicott Guardian

4.1 A Caldicott Guardian makes sure that the confidential information about those who use health and social care services is used ethically, legally and appropriately, and that confidentiality is maintained. Caldicott Guardians should provide leadership and informed guidance on complex matters involving confidentiality and sharing confidential information.

4.2 It is not possible to provide a single job description for Caldicott Guardians, but this guidance explains the Caldicott Guardian's high-level responsibilities, accountability and key relationships, such as with the Data Protection Officer (DPO) and Senior Information Risk Officer (SIRO).

4.3 The Caldicott Guardian should play a key role in ensuring that their organisation(s) satisfy the highest ethical and legal standards for handling confidential information. Their main concern is confidential information relating to patients, service users and their care, but the need for confidentiality extends to other individuals, including relatives of service users, staff and others.

4.4 The Caldicott Guardian should play a key role in upholding the Caldicott Principles, using the Principles to encourage and facilitate decisions in the best interests of patients, service users and their care.

4.5 By helping their organisation uphold the Caldicott Principles, the Caldicott Guardian not only helps their organisation use information in line with the law and maintain confidentiality, but also to ensure that information sharing is effective, in line with the seventh Caldicott Principle:

The duty to share information for individual care is as important as the duty to protect patient confidentiality

Health and social care professionals should have the confidence to share confidential information in the best interests of patients and service users within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

4.6 By ensuring information is used effectively and shared appropriately, the Caldicott Guardian plays an important role in ensuring an organisation acts in the best interests of its service users while still meeting its responsibilities in protecting patient and service user confidential information.

5. Relationship of the Caldicott Guardian to other key organisational roles

5.1 The relationships between the Caldicott Guardian and other information governance (IG) professionals within an organisation and to decision makers are very important.

5.2 Most organisations within the scope of this guidance will be required by law¹¹ to appoint a DPO. The Caldicott Guardians' role and responsibilities are particularly concerned with upholding the eight Caldicott Principles and the common law duty of confidentiality, while the DPO is principally involved in providing advice on and ensuring compliance with data protection law and other relevant legislation.

5.3 Where an organisation judges that it would be appropriate, the Caldicott Guardian may also hold the DPO role.

5.4 Most large organisations that must have regard to this guidance will also be required to appoint a Senior Information Risk Owner (SIRO). The SIRO is usually an executive director or member of the senior management board of an organisation with overall responsibility and accountability for an organisation's information risk policy. The SIRO is accountable and responsible for the overall information risk across an organisation.

5.5 It would not normally be appropriate for an individual to be both SIRO and Caldicott Guardian, due to the decision-making role that the SIRO holds (see also section **6 Accountability and decision making**).

5.6 Some organisations will also have other roles related to the handling of patient and service user data, for instance a chief clinical information officer or a chief information officer.

¹¹ <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/data-protection-officers/#ib1>

5.7 With all of these roles, it is important to stress however that there is some overlap, and they should be seen as complementary; close working and partnership between those with various responsibilities for managing information and data is essential.

5.8 The Caldicott Guardian may have other tasks and duties to fulfil outside their role as the Caldicott Guardian such as when they have an additional role/s within an organisation or as noted at paragraph 3.2 above. The organisation(s) and Caldicott Guardian should ensure that any such tasks and duties do not result in a conflict of interests and that there are procedures in place for managing any conflicts that arise.

5.9 The Caldicott Guardian should have direct access to the organisation's most senior management or board level (see also section **6 Accountability and decision making**).

6. Accountability and decision making

6.1 The role of the Caldicott Guardian is advisory in nature and they must have the freedom to act in the best interests of patients and service users to ensure their confidential information is used ethically, legally and appropriately.

6.2 In order to demonstrate accountability for their advice, the Caldicott Guardian should document their advice and reasoning for it.

6.3 The relationship between the Caldicott Guardian and decision makers in the organisation(s) is of critical importance. The Caldicott Guardian should be able to freely provide advice to and raise concerns with decision makers. The Caldicott Guardian should have direct access to the organisation's most senior management or board level. It may be appropriate and helpful for the Caldicott Guardian to attend senior management or board meetings in an advisory capacity.

6.4 Some Caldicott Guardians, due to other roles they hold, will also be decision makers, for example as a member of an organisation's board, but this is not necessary. If they are, it is important that the Caldicott Guardian has the freedom to give advice to the board which prioritises the best interests of patients and service users and that any conflicts of interest are managed appropriately. It will also be important that they can dedicate sufficient time to their Caldicott Guardian duties, alongside the demands of being a board member/senior decision maker.

7. The competencies and knowledge a Caldicott Guardian needs

- 7.1 All appointed Caldicott Guardians should have the skills required to advise decision makers on how to uphold the Caldicott Principles.
- 7.2 It is essential that the Caldicott Guardian should be a person with the ability to apply the Caldicott Principles wisely using common sense, an understanding of the law, and the freedom and courage to speak freely with authority to the highest level of decision maker in the organisation. They should act with compassion, integrity, objectivity, honesty and in the best interests of the organisation's patients and / or service users; recognising their advice will affect people. All Caldicott Guardians need a strong commitment to the role, the inquisitiveness to question, analyse and challenge and to apply wise judgment to the precise circumstances of each case. They need good inter-personal and communication skills.
- 7.3 It is helpful for Caldicott Guardians to have experience and / or knowledge of interacting with patients and / or service users served by an organisation e.g. as a clinician, social worker, care worker.
- 7.4 Organisations may make their own judgment on which of these competencies and knowledge is required by their Caldicott Guardian with reference to their organisational needs and needs of their patients and service users. These may include skills, personal attributes, qualities and capabilities, such as the ability and willingness to learn and develop new skills.

8. How organisations should involve and support their Caldicott Guardian

- 8.1 Organisations should ensure that the Caldicott Guardian is involved appropriately in issues which relate to the use of confidential information to ensure it is used legally, ethically and appropriately, and that confidentiality is maintained.
- 8.2 Organisations should support the Caldicott Guardian to perform their role by providing the resources necessary to carry out the role and responsibilities, such as allowing appropriate access to confidential information to resolve issues, providing opportunities to maintain his or her expert knowledge.
- 8.3 The Caldicott Guardian should not be dismissed or penalised by the organisation for performing their role and responsibilities.
- 8.4 Organisations should enable their Caldicott Guardians to have meaningful and effective engagement with patients and service users in issues which relate to the use of confidential information about those who use services to ensure it

is used ethically, legally and appropriately, and that confidentiality is maintained. This is covered more in section **9 Relationship of the Caldicott Guardian to patients, service users, the public and other staff**

8.5 The organisation should provide or facilitate access for the Caldicott Guardian to training and continuous professional development that is appropriate to the individual and the organisation, based on their current skills and experience. The organisation should, where necessary, set aside time and resource for this purpose.

9. Relationship of the Caldicott Guardian to patients, service users, the public and other staff

9.1 Caldicott Guardians should be available and accessible for patients and service users to engage meaningfully and effectively about the use of their confidential information.

9.2 Caldicott Guardians can play an important role in helping patients and service users understand how information is used, why and the choices they have. The experience or knowledge that many Caldicott Guardians have of interacting with patients or service users served by an organisation e.g. as a clinician, social worker, care worker, can be particularly helpful in this regard.

9.3 Contact details for the Caldicott Guardian should be publicly accessible to patients and service users, for instance on websites, notice boards and other information provided to the public.

9.4 It is also helpful for other members of staff to be aware of the Caldicott Guardian, their role and responsibilities and how they can be contacted, so that the guardian can be appropriately involved where a novel and/or difficult judgment or decision about the use of confidential information is required.

10. Caldicott Guardian Register

10.1 Organisations are responsible for including contact details of their Caldicott Guardian on the Caldicott Guardian register which is maintained by NHS Digital.¹²

¹² <https://digital.nhs.uk/services/organisation-data-service/services-provided-by-the-organisation-data-service>

Annex A

The Caldicott Principles

Good information sharing is essential for providing safe and effective care. There are also important uses of information for purposes other than individual care, which contribute to the overall delivery of health and social care or serve wider public interests.

These principles apply to the use of confidential information within health and social care organisations and when such information is shared with other organisations and between individuals, both for individual care and for other purposes.

The principles are intended to apply to all data collected for the provision of health and social care services where patients and service users can be identified and would expect that it will be kept private. This may include for instance, details about symptoms, diagnosis, treatment, names and addresses. In some instances, the principles should also be applied to the processing of staff information.

They are primarily intended to guide organisations and their staff, but it should be remembered that patients, service users and/or their representatives should be included as active partners in the use of confidential information.

Where a novel and/or difficult judgment or decision is required, it is advisable to involve a Caldicott Guardian.

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

Every proposed use or transfer of confidential information should be clearly defined, scrutinised and documented, with continuing uses regularly reviewed by an appropriate guardian.

Principle 2: Use confidential information only when it is necessary

Confidential information should not be included unless it is necessary for the specified purpose(s) for which the information is used or accessed. The need to identify individuals should be considered at each stage of satisfying the purpose(s) and alternatives used where possible.

Principle 3: Use the minimum necessary confidential information

Where use of confidential information is considered to be necessary, each item of information must be justified so that only the minimum amount of confidential information is included as necessary for a given function.

Principle 4: Access to confidential information should be on a strict need-to-know basis

Only those who need access to confidential information should have access to it, and then only to the items that they need to see. This may mean introducing access controls or splitting information flows where one flow is used for several purposes.

Principle 5: Everyone with access to confidential information should be aware of their responsibilities

Action should be taken to ensure that all those handling confidential information understand their responsibilities and obligations to respect the confidentiality of patient and service users.

Principle 6: Comply with the law

Every use of confidential information must be lawful. All those handling confidential information are responsible for ensuring that their use of and access to that information complies with legal requirements set out in statute and under the common law.

Principle 7: The duty to share information for individual care is as important as the duty to protect patient confidentiality

Health and social care professionals should have the confidence to share confidential information in the best interests of patients and service users within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

Principle 8: Inform patients and service users about how their confidential information is used

A range of steps should be taken to ensure no surprises for patients and service users, so they can have clear expectations about how and why their confidential information is used, and what choices they have about this. These steps will vary depending on the use: as a minimum, this should include providing accessible, relevant and appropriate information - in some cases, greater engagement will be required.