NDG National Data Guardian
for health and social care

The National Data Guardian's response to the consultation on the Caldicott Principles and Caldicott Guardians

Published 8 December 2020

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1. Summary

1.1 The National Data Guardian for Health and Social Care (NDG) ran a public consultation from June 25 to 3 September 2020[1].

1.2 The NDG sought views on:

- proposed revisions to the seven existing Caldicott Principles
- the proposed addition of a new principle, which would make clear that patients' and service users' expectations must be considered and informed when confidential information is used
- the proposal that the NDG would use her statutory power to issue guidance about organisations appointing Caldicott Guardians to uphold the Caldicott Principles

1.3 The consultation was conducted via two principal methods: an online written survey (which had 194 respondents), and online focus groups, which involved 88 patients, social care service users and members of the public. These activities were supplemented by direct engagement with key individuals and organisations from across the health and social care system, both before and during the formal consultation period.

1.4 The consultation offered for comment a set of revised and expanded Caldicott Principles. It identified strong agreement that the existing Caldicott Principles remain a relevant and useful tool for helping to ensure that confidential information about patients and service users is used appropriately. Comments from respondents showed that the principles are particularly valued for their simplicity and the way that they work together as a set. There was very strong support for the importance of principle 7.

1.5 The consultation proposed some changes to the wording of existing principles and received further suggestions as to how the NDG and her team might further improve the wording. We are grateful for the time and care that those respondents put into this. We have used their well-considered comments to make further refinements, which are reflected in the final set of principles provided in this document.

1.6 The consultation proposed a new introduction to the principles, and an additional principle to highlight the importance of considering and informing patients' and service users' expectations when confidential information is used. It was broadly felt that the new introduction would better help users to understand how to use the principles. And we received strong support for the new principle's purpose, but many felt

[1] https://www.gov.uk/government/consultations/caldicott-principles-a-consultation-about-revising-expanding-and-upholding-the-principles

that the wording was not clear enough. We have used respondents' feedback and suggestions to provide a simpler version.

1.7 The consultation sought views on the proposal that the NDG might use her statutory power to issue guidance about the appointment of Caldicott Guardians to all public bodies within the health and adult social care sector (and organisations which contract with such public bodies to deliver health or adult social care services). We received strong support for the proposal, although we also heard clearly that the guidance should allow flexibility in how organisations implement it, depending on their size, the extent of the data they manage etc.

1.8 The consultation response confirms that the NDG will be issuing such guidance. It also explains the areas that this guidance will cover, and acknowledges that additional support for affected organisations and Caldicott Guardians will need to be provided alongside the guidance.

2 Introduction

2.1 The Caldicott Committee's Report on the Review of Patient-Identifiable Information published in 1997[2] recommended six good practice principles to be applied to the use of confidential information within the 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 safeguarding the confidentiality of patient information.

2.2 The principles became known as the Caldicott Principles. And the senior individuals responsible for ensuring that the principles were upheld within their own organisations became known as Caldicott Guardians.

2.3 Every NHS organisation has had to have a Caldicott Guardian since 1998, and each local authority with adult social care responsibilities has been required to do so since 2002. The principles and the Caldicott Guardian role are also used by other organisations within the health and social care sector, such as care homes and hospices, and by some organisations in other sectors such as prisons, police and armed forces.

2.4 The Information Governance Review[3], published in 2013, reviewed the principles and found that they had become well-established and were considered a clear and simple guide to how confidential information should be handled. It also found that Caldicott Guardians still played an important role in helping their organisations to act ethically and legally, and comply with the law.

2.5 The 2013 review also introduced a new Caldicott Principle to encourage information sharing in the best interests of patients and service users and users of social care services: *The duty to share information can be as important as the duty to protect patient confidentiality*.

2.6 The importance of applying this new principle to data sharing for individual care was later reflected in law in the Health and Social Care (Safety and Quality) Act 2015[4].

2.7 The discussions that led the NDG to conduct this consultation had their roots in work that she and her advisory panel had been progressing for several years. This work had involved a close and careful consideration of the role that the legal concept of 'reasonable expectations' should play in shaping the circumstances under which health and care data may be legitimately shared.

[2] https://webarchive.nationalarchives.gov.uk/20130124064947/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4068404.pdf
[3] https://www.gov.uk/government/publications/the-information-governance-review
[4] http://www.legislation.gov.uk/ukpga/2015/28/section/3/enacted

2.8 This had encompassed articles[5]; seminars[6] with health and care professionals, legal experts, ethicists, academics, and patient representatives; a citizens' jury[7]; discussions among the NDG panel and with stakeholders. These discussions were also informed by academic work led by two NDG panel members, Dr Mark Taylor and Professor James Wilson, which resulted in the publication of *Reasonable Expectations of Privacy and Disclosure of Health Data*[8]. This article demonstrated that since the Human Rights Act 1998 came into force, courts have developed the significance of the concept of a 'reasonable expectation of privacy' within the law of confidence. It argued that one result of this was to provide an alternative route for the lawful disclosure of confidential patient information, where there is no reasonable expectation of privacy.

2.9 As a result of the many actions and endeavours described above, the NDG concluded that she should introduce a new Caldicott Principle, which makes clear that patient and service user expectations must be considered and informed when confidential information is used. She believes that this new principle will:

- be consistent with the direction that the courts have taken in making an individual's reasonable expectations of privacy the touchstone of the duty of confidentiality
- add an explicit reference to the NDG's long-standing view that there should be 'no surprises' for the public in regard to how their confidential information is being used
- align with the General Data Protection Regulation (GDPR) emphasis on transparency and data subject rights
- align with professional guidance such as the General Medical Council's *Confidentiality: good practice in handling patient information*[9]
- reflect the welcome move in recent years away from a paternalistic 'doctor knows best' approach towards one that values partnership between health and care professionals and those in their care

2.10 The NDG made clear in the consultation documents that she did not envisage this principle would establish reasonable expectations as a legal basis in its own right to meet the duty of confidence. However, given the influence of the Caldicott Principles, she did believe that it would helpfully emphasise the perspective of patients and service users in decisions to use and share confidential information.

[5] For example https://www.gov.uk/government/speeches/reasonable-expectations and https://www.gov.uk/government/speeches/exceeding-expectations
[6] https://www.gov.uk/government/publications/sharing-data-in-line-with-patients-reasonable-expectations
[7] https://www.gov.uk/government/speeches/talking-with-citizens-about-expectations-for-data-sharing- and privacy
[8] https://academic.oup.com/medlaw/article/27/3/432/5479980
[9] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality

2.11 In addition to soliciting feedback on the new principle, we decided to use the consultation as an opportunity to review the wording of the existing principles, to ensure that they were clear and up-to-date.

2.12 We also heard from some of our key contacts across health and care that it would be helpful if the NDG expanded the scope of the consultation further to look at the role of Caldicott Guardians.

2.13 In 1997 the Caldicott Committee's Report on the Review of Patient-Identifiable Information published in 1997[10] recommended that each health organisation should nominate a senior person to act as a data guardian. Since then, the Caldicott Guardian role has developed and matured considerably. There are now more than 22,000 Caldicott Guardians in place in health, social care and beyond. Over this time, we have also seen the introduction of other important information governance roles, such as Data Protection Officers (DPOs) and Senior Information Risk Owners (SIROs).

2.14 We decided to consult about guidance that would ensure organisations and their patients and service users continue to benefit from the additional and different perspective that the Caldicott Guardian role brings and help make clear how those fulfilling a Caldicott function should relate to their organisations, other staff (in particular DPOs and SIROs) and members of the public.

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

3 Summary of Responses

3.1 The written consultation was open from 25 June to 3 September 2020[11]. It ran for an extended period so that organisations and individuals affected by COVID-19 had time to respond. The online written survey was kept open until 10 September to allow late submissions to be made.

3.2 Written consultation respondents were asked to complete an online survey of 10 questions. Four questions requested information about the respondent (such as whether they were responding as an individual or organisation). The remaining six questions elicited views on the proposals. Four questions gave respondents the opportunity to provide free text comments in addition to their multiple-choice options. The full survey is reproduced at Annex A.

3.3 The NDG also published a background summary document to provide more information for respondents, should they require it, before answering the survey[12].

3.4 The consultation survey received 194 responses. The table below breaks down respondents by the capacity in which they stated (in question 1) that they were responding.

Option selected	Total number	Percentage of responses
As a member of the public	19	9.95
On behalf of an organisation	77	38.74
In a professional capacity	90	47.12
Other interested party	7	3.66
Not answered	1	0.52

3.5 Question 2 asked respondents to state the name of their organisation, if applicable. We received 126 responses to this question.

3.6 Question 3 asked respondents to indicate what type of organisation they worked for, if applicable, choosing from a list of options. They were able to select multiple options, as some organisations could fall into more than one category. The table below breaks down respondents by organisation type(s).

[11] https://www.gov.uk/government/consultations/caldicott-principles-a-consultation-about-revising-expanding-and-upholding-the-principles

[12] This is available on the consultation page on gov.uk: https://www.gov.uk/government/consultations/caldicott-principles-a-consultation-about-revising-expanding-and-upholding-the-principles

Option selected	Total number	Percentage of responses
NHS provider	80	41.88
Other NHS body	14	7.33
Social care provider	10	5.24
Other social care body	2	1.05
Arm's length body	9	4.71
Local authority	11	5.76
Independent sector healthcare provider	14	7.33
Professional body representing clinicians	8	4.19
University	10	5.24
Other	41	21.47
Not answered	15	7.85

3.7 Question 4 asked respondents to select their role from a list of options, if applicable. They were able to choose multiple options, as some roles could fall into more than one category. The table below breaks down respondents by role(s).

Option selected	Total number	Percentage of responses
Clinical	53	27.75
Administrative	17	8.90
Managerial	87	45.55
Other	66	34.55
Not answered	17	8.90

3.8 In addition to the online written survey, the NDG commissioned YouGov to run virtual focus groups with members of the public. The sessions explored participants' perception of the relevance and appropriateness of the principles, whether they supported the introduction of the proposed new principle, and asked them whether they thought the wording of the principles was clear. They explored what they, as members of the public and service users, would expect of Caldicott Guardians.

3.9 Groups were split primarily by participants' type or pattern of use of health and social care services, as indicated below. Within this, groups also contained a mix of demographics including age, gender, social grade

classification, region, work status, and ethnicity. Groups included some parents, and participants were recruited to have a mix of views on data sharing.

3.10 In total, 88 people took part in two-hour focus groups. The table below sets out the groups. A face to face approach had been planned, but was moved to an online, text-based platform in response to coronavirus.

Monday 10th August 6:30-8.30pm	Tuesday 11th August 6:30-8.30pm	Wednesday 12th August 5:00-7:00pm	Wednesday 12 August 7:00-9:00pm
18-54 year-olds who have not accessed services in past six months and did not have existing conditions.	All had used secondary care services in past year (18-54 years old).	All had used secondary care services in past year (55 years old+). All had long term health conditions.	All had used primary care services in last six months (18-54 years old).
Thursday 13th August 5:00-7:00pm	**Thursday 13th August 7:00-9:00pm**	**Monday 17th August 6:30-8.30pm**	**Wednesday 19th August 6:30-8.30pm**
All had accessed primary care in last six months 55 plus all had long term health condition.	All had used social care services or were carers for someone accessing social care services currently.	All had accessed primary or secondary care in last six months and all had mental health issues.	All had accessed primary or secondary care in last six months. All self-identify as from Black, Asian, Minority Ethnic background.

3.11 YouGov recruited participants from its UK online panel, which contains over one million individuals. A recruitment screening questionnaire assessed eligibility, and potential participants were asked to opt-in. In line with Market Research Society guidelines, participants were offered an online retail voucher on completion of the focus groups.

3.12 Participants explored topics in stages: patient information and data sharing in the health and social care context; the seven existing Caldicott principles (with updated wording); an eighth principle; the role of Caldicott Guardians.

4 What we heard about the Caldicott Principles

What we heard about our proposal for a new Caldicott Principle in the written survey

4.1 Respondents were provided with the proposed wording for the eighth principle alongside revised wording for the set of seven existing Caldicott Principles. The full set published for consultation was:

Caldicott Principles as presented for consultation

These principles apply to the use of and access to confidential information within health and social care organisations, from health and social care organisations to other organisations and between individuals.

Where a novel and/or difficult judgment or decision is required, you should involve your Caldicott Guardian.

Where the term 'confidential information' is used in these principles, this means all information collected for the provision of health and social care services where patients and service users would expect that it will be kept private. In some instances the principles should also be applied to the processing of staff information. This may include for instance, details about symptoms, diagnosis, treatment, names and addresses.

Principle 1 - Justify the purpose(s) for using confidential information
Every proposed use or transfer of confidential information must be clearly defined, scrutinised and documented, with continuing uses regularly reviewed, and decided upon 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) of the use and access to that information. The need for patients and service users to be identified should be considered at each stage of satisfying the purpose(s).

Principle 3 - Use the minimum necessary confidential information
Where use of confidential information is considered to be necessary, each individual item of information must be considered and justified so that only the minimum amount of confidential information is included as is necessary for a given function to be carried out.

Principle 4 - Access to confidential information should be on a strict need-to-know basis
Only those individuals who need access to confidential information should have access to it, and they should only have access to the information items that they need to see. This may mean introducing access controls or splitting information flows where one information flow is used for several purposes.

Caldicott Principles as presented for consultation

Principle 5 - Everyone with access to confidential information should be aware of their responsibilities
Action should be taken by organisations and individuals to ensure that all those handling confidential information are aware of their responsibilities and obligations to respect the confidentiality of patients 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 the 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 direct care is as important as the duty to protect patient confidentiality
Health and social care professionals should have the confidence to share 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 the expectations of patients and service users about how their confidential information is to be used
A range of steps should be taken to ensure 'no surprises' for patients and service users about how their confidential information is to be used - these steps will vary depending on the use. As a minimum, this should include providing relevant and appropriate information - in some cases, greater engagement will be required to promote understanding and acceptance of uses of information. Patients and service users should be given an accessible way to opt out.

4.2 Question 5 of our written consultation asked whether respondents agreed that the NDG should introduce a new principle. Respondents indicated their degree of agreement by selecting a multi-choice box.

4.3 We received strong support for the new principle, with 84% of respondents agreeing that it should be introduced. Of those agreeing, 73(38.22%) strongly agreed, and 87 (45.55%) agreed. The following table provides the full breakdown.

Question 5: Do you agree that the NDG should introduce a new proposed principle?

Option	Total	Percentage
Strongly agree	73	38.22
Agree	87	45.55

Neither agree nor disagree	8	4.19
Disagree	11	5.76
Strongly disagree	9	4.71
Don't know	1	0.52
Not answered	2	1.05

4.4 The survey also provided a free text box where respondents could share their views on the new principle. In the main there was a lot of support for the new principle, as reflected by the table above. Comments included:

"I think that this is an important addition - I think that the principle of "NO SURPRISES" is a key principle."

"We support the introduction of the proposed eighth principle and the way it is worded."

"If adopted into practice, the eighth Caldicott Principle would help patients and the public understand how their data is used and expect it to be used in situations where they are not asked to give consent to that use.

"The inclusion of this principle would demonstrate how important it is for those processing health data to be open and transparent with patients and the public about how their data is used. It reflects the long held NDG principle, which we support, that there should be no surprises for patients and the public about how their data is used."

4.5 Among the smaller group of respondents who disagreed with the introduction of an eighth principle, a key objection was that statutory data protection law already requires transparency.

"It is my view that transparency is covered by current legislation and additional Caldicott Principles are not required."

4.6 Conversely, alignment with data protection law was a reason *for* support from other respondents:

"Gives colleagues a clear direction, also aligns to data protection laws."

4.7 Looking at the phrasing of the principle, many of the responses commented that the drafting was too wordy. We received some excellent suggestions for rewording to make it clearer.

4.8 Some respondents were also worried that the reference to 'acceptance' in the original draft might wrongly give the impression that the principle was saying confidential information may only be used with consent.

"Regarding the wording of the principle, we wonder whether the reference to "acceptance" in this sentence: "to promote understanding and acceptance of uses of information" may be slightly misleading. It could be taken to imply that agreement is required. However, there are many circumstances where agreement or consent is not required. We would therefore suggest that further consideration is given to whether it may be more appropriate to delete "acceptance" here".

4.9 There was also concern that the reference to opt-out was not clear. Some respondents were not sure whether this referred to National Data Opt-out or to opt-outs and objections to information sharing for individual care or both.

"I do not believe that there should be a right to opt out of information being shared for direct care. This has to be balanced against the right of clinicians and care providers also having the right to make decisions based on all relevant information. So I would modify the last sentence of Principle 8 to read "Patients and service users should be given an accessible way to register a request to opt out. There are many scenarios where health and social care providers might choose to override these requests, e.g. child protection, mental health sectioning decisions, where other considerations may be paramount."

4.10 Several respondents thought that organisations and professionals would benefit from advice on what range of actions could be taken to appropriately inform expectations about data use.

"Principle 8 should be reinforced by further guidance on what 'steps' are available for health and social care professionals to make, using examples. This guidance should be responsive to different health contexts: e.g. a GP may only need advice on when to share an information leaflet with patients, whereas a researcher attached to an NHS Trust may need advice on what constitutes 'minimum' confidential patient information in order to undertake a service evaluation. Well-structured worked examples will help organisations understand their obligations better."

What we heard about our proposal for a new Caldicott Principle in our focus groups

4.11 Participants in the YouGov focus groups were presented with the principles one-by-one to discuss and consider. Having been presented with the first seven, participants were then asked to consider whether there was anything missing – what else should the principles cover?

4.12 Many commented that the application of the principles should be adequately supported, for example through training and administrative processes, if they are to succeed. A minority also called for clarity on what actions could be taken should these principles be breached.

4.13 The most common suggestion for an additional principle was to ensure service user involvement. To participants, this seemed missing from, or at least not explicit in, the existing seven principles.

"There's nothing much about the user in there. The patient - where do they fit in."

"They need a lot more work and the patient needs to be at the centre of permission, treated with respect so that they can trust those caring for them to do the right thing."

4.14 Respondents were supportive across all groups when presented with the new, eighth principle. Some had spontaneously suggested the need for a principle focusing on the service user and were pleased to see its inclusion. Some expressed surprise that it was not in the original seven.

"That's a good one and it ensures patient involvement in all this info stuff!"

"This seems to be an improvement and should be included immediately."

4.15 Many saw the principle as a way to increase transparency in data sharing in health and social care, allowing patients and service users greater control over what happens to their data and showing genuine consideration for the needs and wishes of the individual.

"I think this is very important for patients to feel involved in their care... it's important to feel in control of your information and understand how it's used."

4.16 While there was broad support for the principle, many commented that the language could be simplified to improve its accessibility. A majority felt that it was too wordy.

"Agree with comments about the language used with these...If you can't explain something in simple terms, then you need to think again about what you are trying to say."

4.17 Many were also supportive of the fact that the option to opt out was being presented clearly as part of this principle. It was something that many had been unaware of previously.

"Seems to be a good and great addition. This would protect the patient to opt out if they wanted to. Always a good idea as it's their information to either agree or not to."

4.18 However, many respondents were worried that the reference to opt-out could endanger patients or service users. They felt that it may lead them to opting out of data sharing for their own individual care.

"There should be a clear distinction between data exchange for patient health and treatment and data for other purposes."

4.19 The focus groups were asked what sort of information should be provided to patients and service users to inform their expectations about data use – what were the 'range of steps' that might be necessary?

4.20 Information provision was supported by a majority of respondents; however, some raised the issue of capacity, and accessibility of information. Given the wide reach of health and social care services, and the high likelihood that some patients and service users may struggle to process complex information, many were keen to see commitment to making such information truly accessible.

"I'd hope the NHS accessibility standards would apply to this too!"

"How will this information be provided? My brother would need it in written form as his Autism means he forgets information easily and has to refer to things."

4.21 In this context, the information that was most frequently requested to support informed decision making about sharing data was: how data would be used, and what exactly would be shared.

"I want to know what data is being shared with said third party company, generic info like gender and age or personal."

"How would they use this information and to what purpose?"

"Length of time they would keep the data; whom, if anyone, they might pass it on to, who in their organisation would have access to it."

4.22 Some respondents also expressed concern about what the introduction of the eighth principle would mean in reality for the workload of health and social care professionals. While a majority were supportive of the principle in theory, they were keen to ensure that it was managed properly to avoid overburdening workers.

"More work for organisations in providing the info in a format good for a wide range of users."

4.23 While respondents across groups were generally satisfied with their data being shared to facilitate their own individual care, many raised concerns over their data being shared with private companies.

4.24 Some acknowledged that there are potential benefits to sharing data with private companies, however there was a consensus that further information would be required in this instance in order to give reassurance.

"They're [private companies] essentially making money using our information…I don't know if the company can be trusted…I'd want to be able to look them up online and see what their reputation was like."

4.25 Across groups, respondents were clear that the additional principle is about informing the patient and service user about the sharing and use of their data, and offering a level of control over this that is not present in the existing eight principles. This could provide reassurance and is in line with expectations that health and social care professions operate in a patient-centred way.

What we heard about our proposed revisions to the existing Caldicott Principles in our written survey

4.26 As well as proposing a new Caldicott Principle, the consultation presented suggested a revision to the wording of the existing seven principles (see above point 4.1 for the full set that was presented) and new introduction.

4.27 Question 6 of our written consultation asked views on the usefulness of the principles to ensure appropriate use of confidential information. Respondents indicated their degree of agreement by selecting from a list of options. The following table provides a breakdown of responses.

Question 6: Do you agree that the revised Caldicott Principles are a useful tool to help ensure that confidential information about patients and service users is used appropriately?		
Option	**Total**	**Percentage**
Strongly agree	82	42.93
Agree	81	42.41
Neither agree nor disagree	12	6.28
Disagree	7	3.66
Strongly disagree	8	4.19
Don't know	0	0.00
Not answered	1	0.52

4.28 The survey also provided a free text box where respondents could tell us more, including what they thought about the revised Caldicott Principles.

Comments on the new introduction

4.29 The revised set of Caldicott Principles included an introduction, the purpose of which was to provide some context about how the principles should be used.

4.30 The introduction describes the scope of information to which the principles should apply. The previous version of the Caldicott Principles had used the term 'personal confidential data'. In reviewing the previous version of the principles before issuing the consultation, the NDG decided that the term 'personal confidential data' was no longer well-used and the simpler term 'confidential information' should be used in the revised principles for consultation. The term 'confidential information' is generally well understood by frontline professionals and frequently used in professional and regulatory guidance.

4.31 This was welcomed by many respondents:

General comment – I think the phrase 'confidential information' is a lot easier to read and understand than 'personal confidential data'.

"The definition of 'confidential information' as information collected 'where patients and service users expect that it will be kept private' as a reflection of the approach that has been taken by the courts.

"The removal of references to personal information, personal data and 'data' are a helpful way of distinguishing this guidance from potentially different considerations that are relevant to processing 'personal data' under the GDPR and DPA 2018."

"The use of the terminology 'confidential information' as opposed to 'personal data' is welcomed for the following reasons:

- *It prompts consideration of whether the information under consideration was provided in the expectation that it will be kept private.*
- *If it was provided in the expectation that it will be kept private it serves as a reminder that it was provided under a duty of confidence and prompts consideration of the importance and meaning of that.*
- *It draws a distinction between the statutory data protection provisions and the distinct consideration to be given to common law duties of confidence.*
- *It serves as a reminder that the Caldicott Principles apply to the confidential information of deceased patients and service users."*

4.32 The previous version of the Caldicott Principles referred to 'patients' whereas the revised set, and introduction, refers to 'patients and service users'. This was welcomed by several respondents:

"…the expansion to 'service users' provides a welcome acknowledgement of the application of the Caldicott Principles outside frontline/direct healthcare settings."

"[name of respondent organisation] especially supports the amendments throughout the principles to include service users, as well as patients,

among the beneficiaries. Healthcare information can sometimes be known by those who are not healthcare professionals, such as staff in social care facilities or prisons, who may not identify individuals as patients. Further, the Caldicott Principles can be applied outside of healthcare settings. Extending the principles to service users avoids doubt concerning who is protected, and who holds responsibilities under the principles.

4.33 We also received several requests for amendments to make clear in the introduction that the principles only apply to information where individuals are identifiable (i.e. not to anonymous data).

4.34 Some people suggested that we needed to better emphasise that patients and service users should be seen as active partners in the use of their information. We believe that the new principle 8 does this to some extent, and we have also made amendments to the introduction to reinforce the point.

"As they stand, the Principles place the patient or service user in a passive role, being informed of how their data will be used as and when it is collected. However, patients should be seen as 'active partners', involved at all stages of the decision-making process from the development of data-driven technologies through to their governance and implementation in healthcare organisations. This approach will help to build trust in data-driven technologies as well as ensure their utility and subsequent adoption."

4.35 We received one suggestion to change the name of the principles in order to make explicit that they are not just for Caldicott Guardians:

"...rather than calling them Caldicott Principles it would be helpful to call them Health and Care Information Principles to be followed by Caldicott Guardians and Data Protection Officers."

4.36 Whilst an interesting suggestion, we believe that the potential advantage of doing this is outweighed by the advantage of maintaining the current name, which is very well recognised by frontline health and care professionals.

4.37 We have also added some sentences at the beginning of the introduction to outline the importance of using information both for direct (individual) care and other purposes. The feedback that led us to do this is covered in points 4.49 to 4.52 below.

Comments on the existing Caldicott Principles

4.38 The new phrasing for principle 1 had inserted wording to say that continuing uses of information should be reviewed **and decided upon** by an appropriate guardian. Some queried this change:

"Through use of the new words 'and decided upon by an appropriate guardian', the revised principle also appears to elevate the role of the Caldicott Guardian from (in many cases) an advisor to the organisation (and see paragraphs 11-13 of the Caldicott Guardian manual) to the ultimate decision maker and risk owner for all of the activities described in the revised principle. If this is not what is intended, this should be reworded (i.e. delete '...and decided upon...')"

4.39 We agreed and have amended principle 1.

4.40 In relation to principle 2, we received a suggestion that it should acknowledge and encourage the importance of using data from which individuals cannot be identified (e.g. anonymised). We also received suggestions for simplifying the language further, which we have used to amend principle 2.

4.41 In relation to principle 3, we received suggestions for simplifying the language further, which we have used to amend principle 3.

4.42 We received some comments that principles 1 and 2 and principles 2 and 3 overlap or duplicate each other. It was suggested that they could be merged. We took the view that while they do deal with the broad area of ensuring that as little confidential information should be used as necessary and appropriate, the principles do cover different actions that should be taken to ensure this. We have therefore retained them as separate principles.

4.43 In relation to principle 4, we received suggestions for simplifying the language further, which we have used to amend principle 4.

4.44 In relation to principle 5, respondents noted that the previous version of this principle did not refer to 'organisations and individuals' taking action to ensure that all those handling information were aware of their responsibilities. The previous version simply said 'Action should be taken'. Some supported this change, while some did not. Having evaluated the advantages of both approaches, we decided to revert to the previous formulation. This was to reflect that there will be different responsibilities on individuals and organisation, and this could not be differentiated within the principle simply and concisely.

4.45 We also received some suggestions for simplifying the language further, which we have used to amend principle 5.

4.46 In relation to principle 6, we received a suggestion on how we might clarify the wording about responsibilities:

"We believe that it may be helpful to clarify the scope of the revised wording in the second sentence. For instance, does the wording suggest that individuals are responsible for ensuring that their own use of and access to confidential information complies with legal requirements, as

set out in statute and under the common law? Alternatively, could the sentence be understood as suggesting that individuals are responsible for ensuring that the use of and access to confidential information by others in their organisation complies with legal requirements?"

4.47 We agreed that this would help clarity and have made an amendment.

4.48 We also received some suggestions that the principle should be amended to specify which role within the organisation should provide guidance on this, and to name the relevant statutes. We thought that the provision of too much specific detail could prove inflexible for organisations and would date the principles.

4.49 In the version of principle 7 that we put to consultation, we had introduced the words 'for direct care' into the headline principle, so that it read: *The duty to share information for **direct care** is as important as the duty to protect patient confidentiality*. The amendment was intended to reinforce the main reason behind the introduction of the 7th principle, as outlined in the 2013 Information Governance Review[13] – to address anxiety among health and care professionals that information governance rules were preventing sharing information to support individuals' care.

4.50 There were differing views on this. Many supported:

"We agree to this change especially when made in combination with the addition of new Principle 8, because the public has an expectation that health information will be shared for the purposes of individual direct care, with the caveat that clarity and transparency are necessary to allay any concerns that data is being used for secondary purposes that the public might find less acceptable."

4.51 However, several respondents were concerned that this change could be misinterpreted, and taken to imply that the Caldicott Principles would not support appropriate other uses of data beyond direct care, such as for research and planning:

"...we agree that it is important that doctors share information for direct care. However, in focusing the revised principle on direct care specifically it may raise questions in doctor's minds about the importance of disclosures for other purposes, relative to the duty to protect patient confidentiality.

"However, we are concerned that by explicitly including the words 'for direct care', other uses such as research to improve healthcare may be

[13] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

implicitly excluded and hence the change could add a barrier to the use of data for other purposes not specifically mentioned in the text…"

4.52 We understood these concerns. In response, we have placed new wording to at the very beginning of the new introduction to the principles, which makes clear that good information sharing is essential for individual care and that there are also other important reasons to use confidential information for other purposes. The introduction also makes clear that the principles apply to uses both for individual care and for other purposes.

4.53 Some respondents commented on the change in the wording from "*The duty to share information **can be** as important as the duty to protect patient confidentiality"* to "*The duty to share information for direct care **is** as important as the duty to protect patient confidentiality*." Respondents noted that this further emphasised the importance of sharing information. Several respondents supported this:

"We agree to this change especially when made in combination with the addition of new Principle 8, because the public has an expectation that health information will be shared for the purposes of individual direct care, with the caveat that clarity and transparency are necessary to allay any concerns that data is being used for secondary purposes that the public might find less acceptable."

4.54 A few respondents did not support this:

"This could be interpreted as making the principle more absolute and suggesting that sharing information for direct care is always as important as protecting patient confidentiality….Emphasising that sharing information for direct care is as important as protecting patient confidentiality may undermine the fact that, sometimes, sharing information for direct care may not be as important because the patient may exercise their right to object."

4.55 We considered this carefully and decided to retain the new wording "is as important". We do not believe that this creates an absolute duty to share information for individual care, even where there are reasons not to do so, such as a patient objection. The statutory reflection of this principle in the Health and Social Care (Safety and Quality) Act[14] also reflects that the duty to share does not apply where an individual objects, or would be likely to object, to the disclosure of the information. We think that our wording strikes the appropriate balance between sharing for and protecting confidentiality in the context of individual care.

[14] https://www.legislation.gov.uk/ukpga/2015/28/section/3/enacted

4.56 We have also changed the wording of principle 7 to use the term 'individual care' rather than direct care, acknowledging the evidence that this term is better understood by the public[15].

What we heard about the set of Caldicott Principles in our focus groups

4.57 Before participants were presented with the principles, they were asked to consider what sort of restrictions and safeguards should apply. Many mentioned that information should be shared on a 'need to know' basis only, with use of the information justified; for many, this meant information sharing only for the direct benefit of the service user. Some also mentioned that this 'need' should be assessed on a case-by-case basis.

4.58 Across groups, there was low awareness of the Caldicott Principles; while some had assumed that restrictions or guidelines would be in place, few were familiar with what these were in reality. While some were familiar with the name, particularly if they'd had experience of working within health and social care, few were aware of what these principles entailed. Having said this, once the principles were introduced, agreement was high. Many responded positively to the principles being in place, felt 'reassured' and saw the reasoning behind them.

4.59 Throughout the discussions, participants saw that a balance needed to be struck between the ability for practitioners to do their job without too much bureaucratic encumbrance, and the rights of patients to have their data protected.

"I think it is OK in principle, but it depends on how it operates in practice. I don't want an A&E doctor to have to fill out a load of paperwork before he can get hold of my medical records".

4.60 Some also drew a distinction between the type of information that is necessary for medical care, versus information which should not directly impact patient care and acknowledged that some may prefer for all such information to be kept private.

4.61 Participants particularly acknowledged the importance of the 'need to know' point in principle 4 – the idea that confidential information should not be distributed widely, and without restriction, across the health and care sector. For many, this was a return to a theme that had been touched on and explored in other principles, that of separating access between administrative and medical staff, with much more support for

[15] https://understandingpatientdata.org.uk/what-are-best-words-use-when-talking-about-data

the idea of medical staff having controlled, but 'full picture' access to their data, particularly when it is of a medical nature.

"If they need to know for medical purposes then I'm happy for them to know the full picture. I am under several health professionals from different departments, I would like to think they all had a full picture of what was going on with my medical condition, especially where prescription of medications is concerned."

4.62 Many participants made the point that staff should be supported with training and education to apply the principles. Some wanted the principles to go further and outline the possible punishments should they not comply with their responsibilities or breach data protection. This was particularly important amongst those who were concerned about patient data being used by commercial organisations.

"Encourage them during the training with the responsibilities they have but make sure that there are severe penalties based on the extent of inappropriate access and the intent."

4.63 Many brought existing concerns to the discussion that there is too much caution about sharing data within the NHS, where it is unlikely to be shared for nefarious reasons. Some had concerns that the principles further encouraged this caution. These concerns may have been exacerbated in the focus groups because of the way that participants were presented with the principles one-by-one to allow detailed discussion and consideration of each. This meant that it was not until the 7th principle that participants saw that the principles as a whole *do* acknowledge the need to balance confidentiality and the duty to share information.

4.64 Participants were particularly positive about the seventh principle, noting that it adopted a different tone to the others, emphasising the carrot rather than the stick. They noted that this principle was slightly different to the other principles in that it felt like less of a warning, or a reminder of rules and restrictions, and rather, struck a more positive, affirmatory tone, stressing that data sharing was often in the best interest of patients.

"The regulations should be clear and simple enough that medical professionals have the confidence to perform their jobs whilst easily remaining within the boundaries of sharing data."

5 What we will do: the Caldicott Principles

5.1 We have concluded that there is strong support for the continued use of the Caldicott Principles, and for the creation of an additional principle to emphasise the importance of there being no surprises for patients and service users with regard to how their confidential information is used. We have amended the wording of the new and existing principles in accordance with feedback we have received.

5.2 Next year, in partnership with other organisations, we will consider what advice and practical resources would help organisations and professionals to take a range of steps to appropriately inform expectations about data use.

5.3 The finalised set of eight Caldicott Principles is:

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.

6 What we heard about the proposal for the NDG to issue guidance about Caldicott Guardians

6.1 Our consultation noted that NHS organisations have been required to have a Caldicott Guardian since 1998, and local authorities with responsibilities for social services in England since 2002. We observed that many other organisations, both within health and care and more broadly, have recognised the role's value and chosen to appoint a Guardian, or have a Caldicott Guardian function. For example: private healthcare providers, residential care homes, hospices, organisations delivering domiciliary care, police forces and prisons.

6.2 We wanted to hear views on our proposal that the NDG use her statutory power to issue guidance which would specify 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 have a Caldicott Guardian.

6.3 Question 7 of our written consultation asked whether respondents agreed that the NDG should issue such guidance. Respondents indicated their degree of agreement by selecting from a list of options. The following table provides a breakdown of responses.

Question 7: Do you agree with the NDG's proposal to issue guidance that all public bodies within the health and adult social care sector in England, and all organisations which contract with such public bodies to deliver health or adult social care services, should have a Caldicott Guardian?

Option	Total	Percentage
Strongly agree	93	48.69
Agree	67	35.08
Neither agree nor disagree	17	8.90
Disagree	4	2.09
Strongly disagree	8	4.19
Don't know	1	0.52
Not answered	1	0.52

6.4 As the table above shows, most of the respondents agreed with our proposal to issue guidance. This quote sums up the support:

"Since GDPR and the requirement to appoint a Data Protection Officer (DPO) came into effect there has understandably been increased focus within organisations on their legal obligations. This development may have

led to a reduced emphasis on the requirements of the common law duty of confidentiality and the ethical dimensions which must accompany all decisions about use of and access to confidential information. The proposal will help to address this imbalance where it exists"

6.5 But a small number of respondents disagreed:

"This assumes I think the role of Caldicott Guardian should be perpetuated ... I don't see any value in it at all."

Scope of NDG guidance

6.6 We had indicated that we wanted to hear whether people agreed with the organisational scope we were proposing for the guidance – namely 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 have a Caldicott Guardian. Given the scope and remit of the NDG as set out in law, this would be the maximum organisational scope she could stipulate within the guidance.

6.7 No respondents offered alternative proposals for organisational scope. Among the small number who disagreed that guidance should be issued at all, objections tended to be on the grounds of additional burden, or duplication with existing roles. There were many more who agreed that the guidance should be issued, but wanted to see flexibility in how organisations may apply it.

6.8 In the consultation survey, the NDG also sought views on what matters should be covered in any guidance about the Caldicott Guardian role. Respondents were given a list from which they could select multiple options. Both options and responses are detailed in the table below.

Question 8: What issues should NDG guidance about Caldicott Guardians cover?		
Option	**Total**	**Percentage**
Role and responsibilities	93	90.58
Competencies and knowledge required	67	84.82
Training and continuous professional development	17	79.58
Relationships to other key roles e.g. Data Protection Officer	4	83.25
Accountability	8	81.68
How small organisations could arrange a Caldicott function where it's not proportionate to have their own Caldicott Guardian	1	76.96

The types of organisations that should be appointing dedicated Caldicott Guardians	1	73.30
Other	40	20.94
Not answered	6	3.14

6.9 Respondents were also provided with a free text box to tell us more.

Role and responsibilities

6.10 From the options presented, 91 per cent of respondents wanted 'role and responsibilities' to be covered in the guidance.

"As a GP, and CG at our practice, clarity about my roles & responsibilities will be helpful. And ability to delegate to another!"

"It is important that the Caldicott Guardian focuses on the 'should you' and related ethical questions; it is not appropriate for these role holders to act as if they are line managing other subject matter experts - each SME should work in partnership with the other."

"Clearer guidance for Local Authorities (not in healthcare provision) on the delivery of the role"

"It could be made clear that Caldicott Guardians should use the principles in a positive way which can encourage and facilitate decisions to be made in the best interest of the people (often patients) involved."

Competencies and knowledge required

6.11 85 per cent of respondents wanted the guidance to cover the competencies and knowledge required to do the role. We received some useful suggestions on what this should look like. Many reflected that Caldicott Guardians work across a wide range of organisations, and so a 'one size fits all' approach would not work:

"Not sure a CG needs knowledge upfront. They can learn this as they start the role. This is useful not for a job advert for a CG but for what should be linked to their learning objectives as part of the role."

"Diversity in qualification for the role should be recognised, and it does not necessarily need to be a clinician."

6.12 Participants in our YouGov focus groups received an explanation of the role of the Caldicott Guardian. When asked what skills and competencies they would need, participants tended to focus instead on the *qualities* they thought a Caldicott Guardian should have. For example, the ability and integrity to challenge, commitment to patient care, and an understanding of diversity.

"They should also be tough enough to fight within their organisation to ensure the highest standards are being followed... Need to have the support of the organisation when it comes to challenge."

"I think diversity here is really important because it's such a nuanced job that can be quite complex...different experiences will make sure that all angles/viewpoints are taken into account when making the difficult decisions."

Training and continuous professional development

6.13 80 per cent of respondents wanted the guidance to cover this subject. Many made the point that the guidance should make clear to organisations that they should provide Caldicott Guardians with the time and resources to undertake training and continuous professional development (appropriate to demands of the role in that organisation).

6.14 Not only did we hear that the guidance should cover this subject, we also heard that such training should be more readily available to support the implementation of the new guidance. We cover this in **What we heard about the support needed to implement the guidance**, in section 8.

Relationships to other key roles e.g. Data Protection Officer

6.15 83 per cent of respondents called for the guidance to outline how Caldicott Guardians should relate to Data Protection Officers and other roles, in particular the Senior Information Risk Owner, where this is applicable.

"In addition to the relationship with the DPO the other key role to consider is the SIRO and I think this should also be stressed in the guidance."

"The relationship between DPO and CG is really important, clarity where one stops and the other starts would be useful, particularly in light of the new guidance. This should cover DPIA involvement etc."

"Team working of multiple disciplines should be recognised in the guidance - for example: Information Governance, legal, security and management are all important contributors to Caldicott functions."

Accountability

6.16 82 per cent of respondents wanted the guidance to cover accountability. Some thought it was important to make clear that the Caldicott Guardian role is to advise. The Caldicott Guardian's freedom to act was also raised, as was the need for organisational leadership to understand the role and accountability:

"The position of the Caldicott Guardian with regards to the rest of the organisation (e.g. accountability and decision making)" is often confused. The need for Caldicott Guardian engagement and advice may be interpreted as Caldicott Guardian approval, which then creates pressure on Caldicott Guardians to 'sign off' on a particular initiative, effectively owning the associated risks. Guidance to reinforce the concept that Caldicott Guardians are accountable for the advice they give, but not for decisions taken by their organisation (as to whether to use or share information in a given scenario) would be valuable."

"I think that guidance for Trust Boards / Executives related to the CG and Caldicott functions would be helpful - perhaps with some guidance and proposals on how the CG could and should interact with and report to Trust/organisational Boards."

"Specifically, the Caldicott Guardian must have time and resources to perform their role, as well as the freedom to act with respect to giving advice. This includes appropriate protections to ensure that the Caldicott Guardian should not be penalised for carrying out their role."

How small organisations could arrange a Caldicott function where it may not be proportionate to have their own Caldicott Guardian

6.17 We indicated in our consultation that it may not be proportionate for some smaller organisations to appoint a dedicated Caldicott Guardian. We suggested that our guidance could make clear that while all organisations in scope should have a Caldicott function, in some organisations this may be delivered as part of another role, or one Caldicott Guardian might serve several organisations (e.g. a consortium of GPs).

6.18 73 per cent of respondents wanted the guidance to explain how small organisations, for whom it is not proportionate to have their own Caldicott Guardian, might establish a Caldicott function.

6.19 Responses to the written consultation indicated strong support for the guidance providing this flexibility.

"At the moment all small GP practices have Caldicott Guardian usually a clinician and this is a role that could be fulfilled centrally/ jointly as it is not a good use of clinician time. There is no reimbursement for this role."

[please provide guidance on] *"Any particular roles which smaller organisations could be encouraged to merge, e.g. DPO & Caldicott Guardian"*

"The issue of small organisations is particularly important and needs careful consideration as there are many very small local charities who provide services on behalf of both NHS and Local Authorities, particularly

related to social care. Some of these may not be obvious, for example community transport providers."

[please provide guidance on] *"Providing (and receiving) a Caldicott function as an outsourced service (eg a health informatics service providing the function to a group of GPs, etc)."*

"As a small organisation it would not be practical to have a dedicated Guardian. I am concerned that as small charitable organisation this will present a cost pressure"

6.20 In our YouGov focus groups, some participants thought that where an organisation did not have a dedicated Caldicott Guardian, there should still be one available to the public to consult with if required.

"I was going to say maybe the Domiciliary care organisation might not need one but again this has made me sceptical...maybe they [service users] would want someone they can go to if they feel their data is being shared."

"I think they all should have it... or at least have access to one even if the organisation itself doesn't have one."

The types of organisations that should be appointing dedicated Caldicott Guardians

6.21 While 73 per cent of respondents agreed that the guidance should state which kinds of organisations should have a dedicated Caldicott Guardian, we did not receive any comments specifying the types of organisation that should fall into this category.

6.22 Participants in our focus groups received an explanation of the role of the Caldicott Guardian. They were presented with a list of different types of organisation and asked if they would expect them to have a Caldicott Guardian. The list included NHS trusts, local authorities with adult social care and public health functions, GP practices, pharmacies, care homes, charities providing health and social care services e.g. hospices, domiciliary care providers, organisations producing medical devices and equipment.

6.23 Across groups, there was consensus that, ideally, all of the organisations listed should have a Caldicott Guardian, given that all would have access to patient or service user data. However, a minority distinguished between organisations which they assumed to have more restricted access to information (e.g. organisations producing medical devices, opticians), in comparison to organisations providing direct care.

"Well I guess maybe the one producing accredited medical devices. If they are only making the device and not dealing with patients than maybe it isn't necessary?"

6.24 A minority also suggested that, where an organisation is not required to have a Caldicott Guardian, there should still be one available to them externally to consult with if required.

"I was going to say maybe the Domiciliary care organisation might not need one but again this has made me sceptical...maybe they would want someone they can go to if they feel their data is being shared."

"I think they all should have it... or at least have access to one even if the organisation itself doesn't have one."

Other suggestions we received about the guidance

Attention to the needs of social care organisations

6.25 Several respondents made the point that the guidance must be suitably tailored to both the health and social care sectors:

"The social care sector is incredibly diverse. It is essential that the guidance recognises the wide range of organisations and roles that contribute to providing care and support and provides clarity on how the principles might be applied both in sharing and receiving personal and confidential information about the people they care for. For instance, there are a large number of small organisations and providers who are not currently CQC registered such as personal assistances and day services. It is not clear how far reaching this requirement for a Caldicott Guardian would be and how smaller providers would be supported to meet any new requirements and the impact this may have on smaller providers."

Public-facing role of Caldicott Guardians

6.26 The participants in the YouGov focus groups wanted Caldicott Guardians to be available to patients and service users. In particular they wanted this in cases where there has been a breach in data sharing practices. While some saw the role fitting into the complaints process, others felt that dealing with issues in this capacity should focus more on understanding and then explaining why decisions were taken.

"If there is a misuse or a situation where you don't agree but want to find out the reasoning."

"If you felt there had been a breach of confidence in your information and wanted to trace it back. How it happened? What could be learned from it?"

6.27 Many YouGov focus group participants also said they would speak to a Caldicott Guardian to find out more about how their data may be used in health and social care settings, to gain clarity and help to inform their choice around opting out.

6.28 Visibility was seen as vital in supporting the public to access Caldicott Guardians; many respondents highlighted that they were unaware of the role prior to taking part in the discussion and felt that this would be the case for the wider public too. Raising the profile of Caldicott Guardians in the public sphere, as well as of the Caldicott Principles themselves, is needed in order to ensure patients and service users are properly informed.

6.29 YouGov focus group participants wanted a number of avenues to be available to the public to contact a Caldicott Guardian. Suggested methods of contact included online access, telephone appointments and in some cases face-to-face meetings. Face-to-face meetings may be particularly appropriate if dealing with sensitive issues, or where an individual has additional needs in terms of accessibility.

"Be visible and let the patient know who they are."

"If I wanted to find out more about the Caldicott principles and how they're applied...able to have a discussion to voice your concerns."

"Face to face meeting to discuss how my information is being shared, particularly for research."

6.30 We also received other suggestions for subjects that the guidance should cover. However not all of these suggestions would be suitable for the scope of the guidance, which is to advise organisations about the appointment of Caldicott Guardians and how organisations should support the role.

6.31 Some of these additional suggestions related to the support that will be necessary to help organisations to implement the guidance and to support Caldicott Guardians in their role. This is covered in section 8: **What we heard about the support needed to implement the guidance.**

6.32 Other suggestions were about important topics such as digital identity authentication standards or accuracy and adequacy of datasets used for purposes beyond direct care. Whilst important, these are beyond the scope of guidance to organisations about the appointment of Caldicott Guardians.

7 What we will do: Caldicott Guardian guidance

7.1 The NDG will use her statutory powers to issue guidance about the appointment of Caldicott Guardians for all public bodies within the health and adult social care sector in England, and all organisations which contract with such public bodies to deliver health or adult social care services.

7.2 The guidance will provide flexibility for organisations for which it is not proportionate to appoint a dedicated Caldicott Guardian and will suggest options/models to ensure those organisations can still have a Caldicott function.

7.3 The guidance will cover the role and responsibilities of Caldicott Guardians, with particular attention given to what Caldicott Guardians provide in addition to other roles; their role in helping to uphold the Caldicott Principles; and the role in social care settings.

7.4 The guidance will cover the competencies and knowledge required by Caldicott Guardians. It will emphasise the qualities required, and acknowledge that given the diversity of organisations across health and social care, a 'one size fits all' approach is not appropriate.

7.5 The guidance will cover the requirement for organisations to provide Caldicott Guardians with appropriate training and time for development. The NDG will work with the UK Caldicott Guardian Council[16] and others to ensure e-learning is available for all Caldicott Guardians - see next section **What we heard about the support needed to implement the guidance**.

7.6 The guidance will cover the relationship of the Caldicott Guardian to other key information governance roles, and in particular the DPO and SIRO.

7.7 The guidance will specify that Caldicott Guardians should have the freedom to act; cover issues around accountability – distinguishing between accountability for advice and decision making; and emphasise the importance of appropriate relationships to boards/executive decision making in relevant organisations.

7.8 We expect to develop our draft guidance for consultation in the new year and hope to publish the final guidance before the end of the financial year 2020-21.

7.9 We anticipate that there will be an implementation period between our publishing the guidance during the financial year 2020-21 and it coming into force during 2021-22. We will consult on the appropriate timings and ensure that this takes account of the need to develop appropriate support

[16] https://www.gov.uk/government/groups/uk-caldicott-guardian-council

for its implementation - see next section **What we heard about the support needed to implement the guidance**.

8 What we heard about the support needed to implement the guidance

8.1 Every NHS organisation has had to have a Caldicott Guardian since 1998, and each local authority with adult social care responsibilities has been required to do so since 2002. The principles and the Caldicott Guardian role are also used by other organisations within the health and social care sector, such as care homes and hospices, and by some organisations in other sectors such as prisons, police and armed forces. There are now more than 22,000[17] Caldicott Guardians in the UK.

8.2 Therefore, for many organisations, the issuing of guidance about appointing a Caldicott Guardian will not represent a significant change. Nonetheless, we anticipate that more organisations will, as a result, need to consider whether to appoint a Caldicott Guardian or ensure that they can fulfil the Caldicott function.

8.3 We were therefore keen to hear what additional support would be necessary to help implementation of the guidance.

8.4 Question 9 of our consultation survey asked about support would be needed to help implement the guidance. Respondents were able to select multiple options from the list in the table below, provided alongside the responses.

Question 9: What additional support would be necessary to help implementation of the guidance?		
Option	**Total**	**Percentage**
Training for Caldicott Guardians	169	88.48%
Information/ training for senior staff/ boards on the role of Caldicott Guardians	146	76.44%
Peer-to-peer support for Caldicott Guardians	135	70.68%
Other	37	19.37%
Not answered	7	3.66%

8.5 Respondents were also provided with a free text box to tell us more.

Training for Caldicott Guardians

[17] 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-data-service#register-and-directory-updates

8.6 We heard a clear demand for training to be more accessible and available, with 89 per cent of respondents wanting this. In comments, we heard that the cost of training was a concern in particular for smaller organisations. Many respondents suggested online training and workshops would be appreciated.

"...I would also add we are extremely frustrated as a provider of care to nearly two million patients both in and out of hours, we are a not for profit social enterprise, and yet, we are unable to access basic training offered by NHSE, I & X as we are 'not a Trust'. This includes SIRO training."

Information/ training for senior staff/ boards on the role of Caldicott Guardians

8.7 There was also strong agreement that senior staff and boards should be supported to understand the role of the Caldicott Guardian.

"I think that guidance for Trust Boards / Executives related to the CG and Caldicott functions would be helpful - perhaps with some guidance and proposals on how the CG could and should interact with and report to Trust/organisational Boards"

Peer-to-peer support for Caldicott Guardians

8.8 Many respondents emphasised how important peer support is for Caldicott Guardians to operate effectively – we heard this particularly in responses from Caldicott Guardians.

"It can feel lonely being a Caldicott Guardian! It's often a job that no-one else really wants to do, but better, appropriately contextualised training, clear accountability and channels to local DPOs could make it a more secure and less worrisome role."

"Something about the UKCGC, and where to turn to get support and advice if needed for specific challenging questions."

Other suggestions for support to implement the guidance

Manual for Caldicott Guardians

8.9 Several respondents commented on the usefulness of the content in A Manual for Caldicott Guardians[18], and named it as an important support tool for those carrying out the role or function of Caldicott Guardians.

"Protection and Use of Patient Information and the Caldicott Guardian manual were good sources of guidance about the role and responsibilities and could be updated."

[18] https://www.ukcgc.uk/manual/contents

"It is also important to ensure that all organisations are aware and have access to the Manual for Caldicott Guardians, which provides relevant information."

Tools such as FAQs, case studies, checklists

8.10 Caldicott Guardians also suggested other tools they would like to support them in their roles.

"...The intelligence we gather from fielding questions on confidentiality from registrants indicates that registrants appreciate being able to consult FAQs and case studies which cover complicated scenarios."

"If we could sign up for updates and have these plus training and case studies sent to us on a regular basis then this keeps it at the forefront of your mind. Regular bulletins and reminders as well as Webinars and online training - even just short bursts of 30 minute sessions on very targeted issues would be helpful - it doesn't have to be huge training sessions. As I have already said case studies are hugely powerful to help us understand the right way to handle something. Myth busters are also great as the differences in views between people can cause real problems which unfortunately tend to result in no one doing anything because they dare not!"

"Provision of checklists to support decision making."

"Agree to all being ticked, additional items to raise are: FAQs, information network and templates (implementation framework)."

"Tools for practitioners. Easy read handouts."

Materials to help raise the visibility of the role

8.11 We also heard a demand for materials that can be used to help raise the visibility of the role within organisations and more widely outside them.

"How to raise the visibility of Caldicott guardians and how to inform the rest of the organisations about the importance of them."

"National organisational slide set (e.g. for use in staff induction)."

"... as the new guidance is largely consistent with [what] has been good practice and is similar to the existing position, an information campaign ... to confirm and improve awareness would be additionally important."

9 What we will do: support to implement the guidance

9.1 To meet the demand heard in the consultation, the NDG will support the UKCGC to develop an e-learning module. We will ensure that it is made available online, free of charge, to all registered Caldicott Guardians in organisations.

9.2 To supplement the e-learning module, the NDG will support the UKCGC to continue its work with training providers who develop and deliver training for Caldicott Guardians. Whilst the UKCGC does not formally endorse or accredit training providers, it does work with them to review the content and quality of the training they are delivering.

9.3 The NDG will work with the UKCGC and others to consider how information and training about the Caldicott Guardian role can be extended to the senior leadership of organisations.

9.4 The NDG will support the UKCGC to further develop the range of support mechanisms it offers to facilitate peer-to-peer networking between Caldicott Guardians. These include:

Digital Health Caldicott Guardian Forum: The online forum provides an opportunity to ask questions, discuss topics, and provide feedback on any national guidance affecting Guardians.

Caldicott Guardian Newsletter: There have been three Issues of this since it started to be distributed in April 2020. With a mailing list of 22,000 existing Caldicott Guardians, this will be a key channel for communication about the new guidance.

Virtual workshops: The UKCGC has previously organised virtual workshops to examine some of the complex scenarios faced by Caldicott Guardians on the frontline of health and care today. We would anticipate the demand for these to continue.

9.5 The NDG will support the UKCGC to work with NHS Digital to improve the registration process for Caldicott Guardians (which is currently done on a system it provides).

9.6 The NDG will provide the UKCGC with communications support to help it raise awareness of the new guidance and the resources available to organisations and Caldicott Guardians:

Development of UKCGC website: The UKCGC website will be refreshed and appended to support the implementation of the new guidance. The new site will continue to act as a central hub of resources and information for Caldicott Guardians.

Communications package: The UKCGC will develop a range of communications materials to inform organisations of: the changes to the

Caldicott Guardian role and the Caldicott Principles; how they impact their organisation; what they need to do; and where they can find help.

10 Annex A: Online written survey text and questions

Page 1 of 5: Overview

Caldicott Principles: a consultation about revising, expanding and upholding the principles

Consultation runs June 25 to September 3

Overview

The Caldicott Committee's Report on the Review of Patient-Identifiable Information published in 1997[19] recommended six good practice principles to be applied to the use of confidential information in the 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 safeguarding the confidentiality of patient information.

The principles became known as the Caldicott Principles and the senior individuals responsible for ensuring the principles were upheld in their organisations became known as Caldicott Guardians. Every NHS organisation has had to have a Caldicott Guardian since 1998, and every local authority with adult social care responsibilities has been required to do so since 2002.

The *Information Governance Review*[20], published in 2013, reviewed the principles and introduced a new principle to encourage good information sharing in the best interests of patients and between the health and social care sectors, this being: Caldicott Principle 7: *The duty to share information can be as important as the duty to protect patient confidentiality*.

Why we are consulting

The National Data Guardian for Health and Social Care (NDG) is now seeking views on:

1. Proposed revisions to the seven existing Caldicott Principles.
2. Proposed extension of the Caldicott Principles through the introduction of an additional principle which makes clear that patient and service user expectations must be considered and informed when confidential information is used.
3. The proposal that the NDG uses her statutory power to issue guidance about organisations appointing Caldicott Guardians to uphold the Caldicott Principles.
4. The proposal that the NDG uses her statutory power to issue guidance about organisations appointing Caldicott Guardians to uphold the Caldicott Principles.

These proposed changes are based on discussions the NDG has had with a range of stakeholders. Wider insight is now sought from the public, patients and service users, health and social care providers, clinicians, care professionals, other health and care staff and other

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

[20] https://www.gov.uk/government/publications/the-information-governance-review

key stakeholders to ensure that we address any significant issues and concerns. For more detail, see our consultation background document.

The work that has led to this consultation has been taking place over more than two years. These proposals are not a response to the current pandemic or the data sharing arrangements that it has prompted. However, we hope that by conducting our consultation now we can develop our new set of Caldicott Principles and guidance in time to inform decisions and discussions about data sharing after the pandemic is resolved.

Note: This survey is branded NHS Digital as NHS Digital has kindly offered us the use of its survey tool. However, the survey is being run for NDG purposes and all analysis of responses will be undertaken by members of the NDG team.

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Page 2 of 5: About you

1. **In what capacity are you responding to this consultation?**

- As a member of the public
- On behalf of an organisation
- In a professional capacity
- Other interested party – please specify below

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2. **If applicable, please provide the name of your organisation:**

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3. **If applicable, please tell us what type of organisation you work for - please tick all that apply:**

- NHS provider
- Other NHS body
- Social care provider
- Other social care body
- Arm's-length body
- Local authority
- Independent sector healthcare provider
- Professional body representing clinicians
- University
- Other – please specify below

4. **If applicable, please tell us what your role is - please tick all that apply:**

- Clinical
- Administrative

- Managerial
- Other – please specify below

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Page 3 of 5: Revising and expanding the Caldicott Principles

Based on preliminary engagement undertaken by the NDG prior to issuing this consultation, she believes that the existing Caldicott Principles still remain useful and relevant but may benefit from some amendments to ensure they are clear and accessible. The NDG is also proposing to introduce a new principle, which emphasises the importance of there being no surprises for patients and service users with regard to the use of their confidential information. The new proposed principle is listed below as principle 8.[21]

For more on the history of the Caldicott Principles and the detail and reasoning behind our proposed revisions, please see our consultation background document here.

5. **Do you agree that the NDG should introduce the new proposed principle (number 8 in the list above)? If you think it would be useful for us to know why, or if you have specific amendments to suggest, please use the free text box to tell us.**
   - Strongly agree
   - Agree
   - Neither agree nor disagree
   - Disagree
   - Strongly disagree
   - Don't know

Free text box for Q5

6. **Do you agree that the revised Caldicott Principles are a useful tool to help ensure that confidential information about patients and service users is used appropriately?**
   - Strongly agree
   - Agree
   - Neither agree nor disagree
   - Disagree
   - Strongly disagree

[21] The survey presented the set of principles as shown at point 4.1 in the main body of this document. We have not reproduced these again in this annex.

- Don't know

Free text box for Q6

Next page

Page 4 of 5: Upholding the Caldicott Principles: the role of the Caldicott Guardian and NDG statutory power to issue guidance

The role of the Caldicott Guardian

It has been a requirement to have a Caldicott Guardian since 1998 for NHS organisations and since 2002 for local authorities with responsibilities for social services in England.

Although organisations in both the NHS and social care sectors were instructed to appoint Caldicott Guardians, it was left to individual organisations to determine how they would operate. Many other organisations, both within the health sector and more broadly, have recognised the value of the role and also chosen to appoint Caldicott Guardians, or have a Caldicott Guardian function (such as private healthcare providers, residential care homes, hospices, organisations delivering domiciliary care, police forces and prisons).

The UK Caldicott Guardian Council (UKCGC)[22] works to be a point of contact for over 18,000[23] Caldicott Guardians in the UK, and to encourage consistent standards and training, for example through its 2017 *Manual for Caldicott Guardians*[24]. The manual outlines that Caldicott Guardians act as *"the conscience of the organisation" as a "senior person within a health or social care organisation who makes sure that the personal information about those who use its services is used legally, ethically and appropriately, and that confidentiality is maintained."* The UKCGC is a sub-group of the NDG's advisory panel and not a professional or regulatory body.

NDG statutory power to issue guidance

The National Data Guardian is seeking views on the proposal that she uses her statutory power[25] to issue guidance that all public bodies within the health and adult social care

[22] https://www.gov.uk/government/groups/uk-caldicott-guardian-council
[23] Evidence from the Data Security and Protection Toolkit returns, August 2019 and the Caldicott Guardian Register maintained by NHS Digital: https://digital.nhs.uk/services/organisation-data-service/services-provided-by-the-organisation-data-service#CG (Note: since the survey ended this figure has since been updated to over 22,000.)
[24] https://www.ukcgc.uk/manual/contents
[25] http://www.legislation.gov.uk/ukpga/2018/31/contents/enacted

sector, and all organisations which contract with such public bodies to deliver health or adult social care services in England, should have a Caldicott Guardian.

We are aware that it may not be appropriate for some smaller organisations to appoint a dedicated Caldicott Guardian. We would propose that the NDG guidance makes clear that while all such organisations should have a Caldicott function, in some organisations this may be part of another role or one Caldicott Guardian might serve several organisations (eg a consortium of GPs). Likewise, the guidance could specify the types of organisation that should have a dedicated Caldicott Guardian.

The NDG could also take the opportunity to provide other guidance in relation to the Caldicott Guardian role, for instance: about how the role should be carried out, the position of the Caldicott Guardian with regards to the rest of the organisation (e.g. accountability and decision making), and the relationship of the Caldicott Guardian to other key roles such Data Protection Officers and Senior Information Risk Officers (SIROs).

For more detail on the role of the Caldicott Guardians, the UKCGC, and the reasoning behind the proposed scope of the guidance, please see our consultation background document here.

7. **Do you agree with the NDG's proposal to issue guidance that all public bodies within the health and adult social care sector in England, and all organisations which contract with such public bodies to deliver health or adult social care services, should have a Caldicott Guardian?**

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

8. **What issues should NDG guidance about Caldicott Guardians cover? Please select all that apply. Use the text box to tell us anything else it should cover.**

- Role and responsibilities
- Competencies and knowledge required
- Training and continuous professional development
- Relationships to other key roles eg Data Protection Officer
- Accountability
- The types of organisations that should be appointing dedicated Caldicott Guardians
- How small organisations could arrange a Caldicott function where it's not proportionate to have their own Caldicott Guardian
- Other (please use text box below to tell us)

Free text box for Q8

9. What additional support would be necessary to help implementation of the guidance? Select all that apply and use the free text box if you need to tell us more.

- Training for Caldicott Guardians
- Information/training for senior staff/boards on the role of Caldicott Guardians
- Peer-to-peer support for Caldicott Guardians
- Other (please use text box below to tell us)

Free text box for Q9

10. Is there anything else you want to tell us about the proposals in this consultation?

Free text box for Q10

☐ If you are happy for us to contact you to clarify your comments, please tick here and provide your email address below.

Email _____

We will publish a consultation response document, summarising what we have heard and what we will do. Wherever we provide quotes, these will not be attributable to an individual or organisation.

You have now reached the end of our questions.

Please press Next page to move to the submit page.

Next page

Page 5 of 5: Almost done…

You are about to submit your response.

- If you want to review your answers before doing this, click **First**.
- If you are happy with your answers, click **Submit**.

You can register to receive a copy of your response by providing your email address in the field below.

*Please note that if no field appears below to provide your email address it means that you have already provided this information and you will automatically receive a copy of your response after you click **Submit**.*

Thank you.

If you provide an email address you will be sent a receipt and a link to a PDF copy of your response.

Email address _____

☐ Please tick this box if you would like to be alerted when the results of this consultation are published.

Submit