Understanding Patient Data response to National Data Guardian consultation on revising the Caldicott Principles

About the consultation

This consultation was open between 25 June 2020 to 3 September 2020, in the format of an online form. Our responses are best read alongside the proposed changes to the Caldicott Principles which are outlined in in this document, which also gives more information about the consultation.

Q. Do you agree that the NDG should introduce the new proposed principle?

We agree with the proposal to expand the Caldicott principles to include a new principle on informing the public and setting people's expectations.

This is because:

- we know that public awareness of how health and care data is collected and used remains low; and,
- conversations about data use beyond individual care are best when they are held at local level and in the context of someone's care. National-level programmes or campaigns can feel abstract and be too far removed from people's lives to resonate with them.

We know this because:

- our most recent survey found that 63% of the public are unaware that NHS organisations permit third parties to access NHS-held data (see *Foundations of Fairness* report: https://understandingpatientdata.org.uk/sites/default/files/2020-03/Foundations%20of%20Fairness%20-%20Summary%20and%20Analysis.pdf); and,
- successful engagement about data use should happen in the context of people's interactions with the health system, and therefore more closely connect to what matters to people. (See our recent project: https://understandingpatientdata.org.uk/news/what-we-learned-not-talking-about-data).

Areas for improvement

Whilst we support the intent behind Principle 8, it is unclear what achieving it would look like in practice and exactly what is expected of those bound by the Caldicott Principles.

Firstly, the current wording of the Principle is difficult to understand. This is because it combines two elements: merging informing the public about health data use and setting their expectations. A clearer way of expressing 'what good looks like' in the principle would focus on informing the public, which is commonly understood, more easily measured and can be linked to outcomes that can be tracked over time.

However, if both informing and setting expectations need to be included, Principle 8 could be re-worded in several ways to make the actions required by professionals more easily understandable.

Option 1: Split the principle into two, one focused on informing the public; the second on setting expectations.

First part: ‘Inform patients and service users about how their confidential information is used’

Second part: ‘Set patient and service users’ expectations about how their confidential information is used’

Option 2: reword to show how expectations should follow from being informed.

‘Help set the expectations of trustworthy data use with patients and service users by informing them about how confidential information is used'

Option 3: reword to show how informing people contributes to creating expectations.

‘Inform people about how confidential patient information is used so that they have clear expectations about what happens to data about them, why, and what choices about its use are available.’

Secondly, Principle 8 may place significant demands on health and social care professionals. As previously stated, most members of the public do not have initial expectations about data use beyond individual care, so there is a substantial learning and education requirement to inform people to the extent that they have their own expectations. We believe a more feasible expectation would be to aim to ensure that people can access meaningful, quality information about data use. This way, if uses do not match initial expectations, the public can be better equipped to scrutinise, know where and how to ask questions, and understand and exercise their choices.

Thirdly, the reference to ‘no surprises’ in Principle 8 suggests that there is a ‘common-sense’ view around data use. In reality, research has uncovered a multitude of publics and attitudes (See the summary on our website: https://understandingpatientdata.org.uk/how-do-people-feel-about-use-data), often informed by diverse life experiences and varied health care interactions. Practically then, it does not seem realistic to create ‘blanket’ expectations for patients and service users, both because there is enormous diversity in different people’s starting points, perspectives and understanding, and because the specifics of data use are constantly evolving. Data-driven technologies and their application in healthcare are advancing quickly and the pandemic has changed the landscape of data use in the health and care system. The Caldicott Principles need to be mindful of what is feasible for health and care organisations to achieve in this shifting context.

Principle 8 should be reinforced by further guidance on what ‘steps’ are available for health and social care professionals to take, 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.

Q. 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?

We agree that the Caldicott Principles are a useful tool, however they should form part of a broader vision for responsible, patient-centred data use across health and social care, with a clear plan for resourcing, implementation and sustainability.

At present, many health and care professionals are reluctant to enable use of confidential patient information because they are unclear on the rules and are legitimately concerned about the consequences of falling foul of the guidance. Iterating the wording of the principles alone will not help professionals navigate the complex landscape of guidance, rules and frameworks that exist around patient data use.

As such, Caldicott Principles should be understood within a wider context of changes in the data policy landscape; including Laura Wade-Gery's NHS Tech Review; the development of NHSX's Centre of Expertise; The Good Practice Guide to Digital and Data-Driven Technologies; and the National Data Strategy. Health and social care professionals should be able to see how these principles support a wider health and social care system and contribute to improved health outcomes.

Reflections on precise wording of Principles

Positives

- We agree with changing the language in Principle 4 to include a 'need-to-know' basis, as this resulted from engagement with citizens in the OneLondon programme
- Principle 6 wording is clear, but it should refer to specific law i.e. Data Protection Act; Equalities Act; Common Law on Confidentiality so that the link between legal obligations and Caldicott Principles is unambiguous.

Areas for improvement

- Principle 1 should provide more information about what 'scrutiny' means. Health and social care providers will need guidance around what a good review process looks like; how and when to involve patients; what scrutiny is required; and what it means in different use cases. Understanding Patient Data has reflected on what this could mean in a July 2020 blog outlining 'new approaches to decisions about data'. URL here: https://understandingpatientdata.org.uk/news/new-approach-decisions-about-data]
- Principle 8 should outline 1 or 2 short examples of the types of "range of steps" necessary to ensure there are 'no surprises'. These examples should be placed within the wording of the Principle or in more detailed guidance.
- Wording in Principle 8 could be changed from 'accessible way to opt-out' to 'Patients and service users should be provided a way to opt-out that caters to different accessibility needs' to clarify the technical meaning of accessibility that is inferred in the current wording.

Q. 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?

We agree because:

- consistency across the sector is necessary to avoid confusion;
- Caldicott Principles should be relevant and responsive to both health and social care organisations; and,
- COVID-19 highlights the urgency of talking to patients about data use, particularly in light of the Control of Patient Information notices.

The General Data Protection Regulation has increased the visibility of Data Protection Officers within health and care organisations. The revised guidance should include advice and information about how DPOs and Caldicott Guardians should support one another.

Q. What issues should NDG guidance about Caldicott Guardians cover?

Please select all that apply

- Role and responsibilities
- Competencies and knowledge required
- Training and continuous professional development
- Relationships to other key roles e.g. 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)

- All of the above
- Caldicott Guardians should develop relationships with other organisations that support health and social care professionals, to learn from and complement their work. These include but are not limited to: Health Education England (NHS Digital Academy); Academic Health Sciences Networks; HDR-UK Hubs.
- Issues surrounding diversity and inclusion in health datasets should be included in guidance to health and social care organisations. This should include guidance covering data accuracy, completeness and representativeness.

Q. What additional support would be necessary to help implementation of the guidance?

- Training, renumeration and credit for Caldicott Guardians
- Information/training for senior staff/boards on the role of Caldicott Guardians
- Resourcing for peer-to-peer support for Caldicott Guardians

Other (please use text box below to tell us)

Additional support

- There should be efforts to professionalise Caldicott Guardians and the Caldicott Guardian Council to better equip them to: uphold the principles; share learning and best practice; act as an on-the-ground network picking up emerging issues or themes in the uses of data that could be channelled back to the National Data Guardian.
- The National Data Guardian Panel as it is currently constituted is unrepresentative of the sector and the wider population in England and Wales. Steps should be taken to better reflect the health and care sector and the diversity of society at large in the National Data Guardian's own guidance making processes.

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

- We are very happy to discuss this response further with the National Data Guardian, Panel members and NDG office staff. Specifically, we would be keen to talk further about how the revised principles can complement existing activities at a national and local level to build public trust in data use, as well as what worked examples could be used to ensure widespread take up amongst health and social care professionals