

Response to the National Data Guardian's Caldicott Principles: a consultation about revising, expanding and upholding the principles

September 2020

5. Do you agree that the NDG should introduce the new proposed principle (number 8 in the list above)?

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

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.

- Our responses to Questions 5 and 6 were largely informed by the Academy's 2018 report on 'Our data driven future in healthcare'. This report discusses data-driven technologies in healthcare, which often involve the use of patients' and service users' confidential information and have the potential to support individual care, improve NHS services and public health, and advance medical research and innovation.¹ The principles outlined in the report were informed by dialogues with patients, the public and healthcare professionals and so it is particularly suited to advise on the new proposed Caldicott Principle to "*Inform the expectations of patients and service users about how their confidential information is to be used*".
- Overall, **we strongly support the addition of the new proposed Principle**. It is clear from dialogues with patients and the public that there are strong expectations for transparency around the intended use of data-driven technologies and the data that drives them, and that patients and the public retain a strong interest in how data about them are used and want data to be used with respect to and in line with their expectations.^{2,3} It is important to make patients meaningful partners in the development and deployment of data-driven technologies, including how these technologies use confidential patient data, in order to fully realise their potential benefits in health and social care and to mitigate their potential risks.
- It is vital to understand what these expectations are, and public and patient involvement is an essential component of this. Previous dialogues with patients and the public have attempted to address this question, but ongoing dialogue and engagement is needed as expectations may change over time.
- In our report, we suggest five key pieces of information that are required to fulfil these expectations, based on evidence from multiple public dialogues:^{2,3}
 - When and where data are being collected and data-driven technologies are being used, especially when continuous observations or pervasive monitoring are involved.

¹ The Academy of Medical Sciences (2018). *Our data-driven future in healthcare*. <https://acmedsci.ac.uk/file-download/74634438>

² Ipsos MORI (2018). *Future data-driven technologies and the implications for use of patient data*. <http://www.acmedsci.ac.uk/datadialogue>

³ Ipsos MORI (2016). *The One-Way Mirror: Public attitudes to commercial access to health data*. <https://wellcome.ac.uk/sites/default/files/public-attitudes-to-commercial-access-to-health-data-wellcome-mar16.pdf>

- What data the technologies are collecting and whether these are in a personally identifiable or depersonalised form.
 - Who will curate, have access to, or use the data.
 - Why data-driven technologies are being used and the value of doing so.
 - How data are collected and how they are used for decision-making, and when this is with the knowledge of the patient and when it is not.
- **We recommend that the new Principle explicitly lists the information that should be provided to the patient or service user** to inform their expectations, perhaps basing the criteria on the five points above. Clear and transparent answers to these criteria would enable patients to understand and contribute to decisions made on the use of data-driven technologies. **This list should be regularly reviewed based on consultations with patients and service users**, as expectations may change over time.

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
- Don't know

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.

- **We agree that the revisions to the Principles helps to improve clarity of message**, and the introductory statement provides useful context by defining 'confidential information' and setting out where the Principles apply. However, we would like to address two specific changes to the Principles:
 - The change from 'personal confidential data' to 'confidential information' in all cases. 'Information' is often defined as data that has been processed and organised to make it more useful. Therefore, 'information' may be interpreted as not including raw data, and so **'data' might be a better term to encompass both raw data and the interpretations of that data.**
 - Principle 7 has changed in emphasis. Previously it read "the duty to share information **can be** as important as the duty to protect patient confidentiality", it now reads "the duty to share information **for direct care is** as important as the duty to protect patient confidentiality". **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
- 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.
- In light of this, **we recommend that the Principles explicitly refer to patients and service users as active partners** in decision-making processes that involve their confidential information, either through modifying the language used throughout all the Principles, incorporation into proposed Principle 8, or by including a new separate Principle devoted to this concept.
- In order for patients to serve as 'active partners', they should feel able to make informed decisions on when and how their data is used. An evidence-based evaluation of the security and privacy of data-driven technologies deployed in

⁴ CurvedThinking (2019). *Understanding public expectations of the use of health and care data.* <https://understandingpatientdata.org.uk/sites/default/files/2019-07/Understanding%20public%20expectations%20of%20the%20use%20of%20health%20and%20care%20data.pdf>

real-world settings (as well as the effectiveness and safety of the technology itself) should be provided to the patient to inform their decision-making.

- **We recommend that the Principles explicitly state the importance of providing patients and service users access to evidence of data-driven technologies and evaluations of how these technologies use confidential information,** to help inform their decision-making. This could be incorporated into proposed Principle 8, or included as a new separate Principle.

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*

(No free text box)

8. 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)*

Free text box

- We are appreciative of the work of the Caldicott Guardians and their role in ensuring that health and social care organisations follow the Caldicott Principles, and we are glad that NDG will produce guidance to further support their work.
- The NDG recognises the concern that a statutory recommendation to appoint a Caldicott Guardian might prove challenging for smaller organisations such as general practices and care homes. As responsible persons within these organisations may have multiple roles, a requirement that an additional role be allocated to one of the few people in these organisations might detract from their main business in delivering care, and risk them becoming alienated and overburdened.
- Therefore, **NDG guidance should support organisations where incorporating a Guardian function may be challenging**. This support might involve delegation of responsibilities upwards to higher-level structures or assistance with the coordination of smaller organisations to share a Guardian.

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

- *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)*

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

- The Academy would like to take this opportunity to discuss NDG's role in safeguarding confidential patient and public data during the COVID-19 crisis. We would be happy to expand on the points below, or meet with the NDG to discuss further if it would be helpful.
- As emphasised in our report on 'Our data driven future in healthcare', involvement of patients and the public in the co-creation of technologies that use patient data is necessary to build trust and ensure the product better meets patients' needs.¹
- We have heard concerns that the NHS COVID-19 app currently under development to support the NHS Test and Trace service does not appear to include co-creation in its development and deployment. In addition, there are concerns that during the trial phase of the app there has been little transparency in how personal data is being used or linked with NHS data, and little detail on who is responsible in informing the user how their data is being used.
- **We would therefore encourage the NDG to continue to work to ensure the NHS COVID-19 app is developed and deployed in a way that builds public trust.**
- Similarly, much COVID-19 research is being carried out at pace. Research such as the RECOVERY trial, to identify treatments for people hospitalised with COVID-19, are rightly lauded for their benefits. However, it is vital that public trust in research is retained despite the urgency of COVID-19 research. It is therefore important that **NDG work to ensure that, privacy and transparency are maintained as far as possible** in COVID-19 research to prevent a loss of trust in the research by the public.

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