



Department of Health

National Data Guardian for Health and Care's Review of Data Security, Consent and Opt-Outs

Response Form

Question 1: Please tell us which group you belong to? (Required)

UK Clinical Research Collaboration registered clinical trials unit network

Question 2: If you are a member of an organisation or profession, please tell us if you are responding in a personal or private capacity

NA

Question 3: If the Department of Health or other organisations were to create further opportunities to engage on data security and the consent/opt-out model, would you be interested in attending? If so where would you find it helpful an event to be held?

Yes No

Event location

Through a series of regional meetings and webinars to ensure maximum engagement

Question 4: The Review proposes ten data security standards relating to Leadership, People, Processes and Technology. Please provide your views about these standards.

Which standard do you wish to comment on?

1 2 3 4 5 6 7 8 9 10

Comments

The standards are a good attempt at outlining several key issues that need to be addressed in order to protect patient confidential information and assure data security. There are some aspects which would benefit from further detail. In particular, the standards claim to focus on people, process and technology but there is little mention of 'process' and no mention of systems/technological methods for controlling access and allowing data to flow between users. In the clinical trials community we generally favour a controlled access system for sharing consented anonymised patient data for research purposes, with data sharing agreements in place between data user and data controller to ensure a robust environment for data sharing.

Specific comments on standards:

1. "All staff ensure that personal confidential data is handled, stored and transmitted securely, whether in electronic or paper form. Personal confidential data is only shared for lawful and appropriate purposes"
 - To increase public trust it might be worth adding to the phrase 'appropriate'. Is it the interest of the patient that would always prevail when decisions to share personal confidential are made?
2. It would be useful to understand how this would be carried out. If this is part of the mandatory training for staff in part 3 then this should be stated and possibly merged with 3 or if it is a contractual responsibility then this should be mentioned.
4. "Personal confidential data is only accessible to staff who need it for their current role and access is removed as soon as it is no longer required. All access to personal confidential data on IT systems can be attributed to individuals. "
 - This is key information to communicate to the public using easy to understand examples showing that their data can only be accessed by particular staff rather than anyone working in the NHS. If there will be checks on compliance to these standards via an audit program then it would be useful to state this.
7. Would be useful to provide best practice for testing for data breaches.
8. Not sure what this means 'no-unsupported operating systems' does it mean that as long as you have IT staff then it is supported? For example, when Microsoft stated they were no longer 'supporting' XP does that mean that data could not be shared with an organisation that had an XP machine?

Question 5: If applicable, how far does your organisation already meet the requirements of the ten standards?

Where 0 = Not at all and 10 = Fully compliant

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Please provide examples which might be shared as best practice

Question 6: By reference to each of the proposed standards, please can you identify any specific or general barriers to implementation of the proposed standards?

Which standard do you wish to comment on?

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1. Accountability - who decides whether data are being shared for lawful and appropriate purposes?

5. Unclear what the processes being referred to are and who should review these at least annually? Important to consider the standardisation of processes to avoid fragmentation of approaches. Who will be responsible for identifying and improving processes which have caused breaches or near misses? How will information about such breaches be recorded and monitored centrally to inform future developments. Would be useful to have a definition of 'near miss'.

Question 7: Please describe any particular challenges that organisations which provide social care or other services might face in implementing the ten standards.

Lack of resources and lack of guidance on how to implement the standards. Risk of organisations interpreting standards in different ways.

If a high proportion of the public select to opt out there is a danger that the utility of the data will be reduced particularly if reason for opt-out is related to patient factors such as socio-economic status. It is crucial that the public are provided with sufficient information about the potential benefits of secure data sharing so that informed, rather than risk averse decisions are made. Information to help the public make such decisions should be presented using easy to digest and concise methods, perhaps communicated via short video clips and leaflets. Patients need to be made aware of how valuable their data could be for the benefit of other patients and for improving NHS services, acknowledging of course the small risk of a data breach but also the measures that have been put in place to mitigate risks and protect data.

Question 8: Is there an appropriate focus on data security, including at senior levels, within your organisation?

Yes No

Please provide comments to support your answer and/or suggest areas for improvement

Working within a University that handles data from external organisations, including the NHS, and also collects primary research data from patients within the NHS with potential for this data to be shared with other external researchers and organisations, data security is a priority and systems have been developed to protect this valuable data. However, I would like to see greater visibility and engagement with Caldicott Guardians eg posters to display in departments and communal areas, drop-in sessions, and examples of how the Caldicott Guardian can provide support to staff.

Question 9: What support from the Department of Health, the Health & Social Care Information Centre, or NHS England would you find helpful in implementing the ten standards?

Short videos with examples to explain the standards which could be interpreted in different ways. Clear guidance and training. Patient relevant information with easy to digest summaries that inform patients about the value of sharing data and how this will be undertaken using responsible and secure measures that safeguard their interests.

Question 10: Do you agree with the approaches to objective assurance that we have outlined in paragraphs 2.8 and 2.9 of this document?

Yes No

Please comment on your answer

Question 11: Do you have any comments or points of clarification about any of the eight elements of the model described above?

Which standard do you wish to comment on?

1 2 3 4 5 6 7 8

Please provide details

The model does not highlight the potential benefits of sharing data, both for the direct care of the patient and for the benefit of others. This should be the first point.

The eight point model does not provide sufficient information or reassurance to a patient about what will happen to their data nor what is meant by consent/opt-out. Is consent being requested or does the model assume that all data will be shared (as deemed appropriate) unless a patient has opted out? This isn't clear from the current 8-point model. The model also does not clearly distinguish between sharing for direct care purposes (no opt-out?) and sharing for other purposes (opt-out). Some re-structuring, re-ordering and re-wording may help. A flow diagram showing different points where patient confidential information may be shared and for what purpose may help with communicating the model to patients. Otherwise there is a danger of misinterpretation.

The distinction between confidential information being used both in running the health and social care system and to support research and improve treatment and care may cause confusion and increase the chance of ill-informed opt-outs. It is difficult to think of examples where a patient would be happy to share data for one but not the other purpose. It may therefore be preferable to provide patients with the opportunity of a single opt-out covering personal confidential information being used both in running the health and social care system and to support research and improve treatment and care.

Clarity is required on the infrastructure, procedures and the basis upon which information is shared, emphasising the measures put in place to ensure that data are stored and shared securely with the aim of protecting patient confidentiality, but secondly that data would always be shared within a controlled access system with accountability extended to data users i.e. the public need to be reassured that their data would be shared for legitimate research purposes only.

Is there a need to ask the public for different levels of 'opt-out'? For example, would some be happy that their aggregate data is shared or is it a given that their records would be included in any aggregate? If so, this should be clearer if they are only opting out of individual record sharing. In

clinical trials, clinicians often access their local systems to assess if they have the patients to participate in trials. If this still continued as a practice then would their feasibility queries on local hospital systems potentially include patients that opt-out?

Question 12: Do you support the recommendation that the Government should introduce stronger sanctions, including criminal penalties in the case of deliberate re-identification, to protect an individual's anonymised data?

Yes, this is a key part of building public trust

Question 13: If you are working within health or social care, what support might your organisation require to implement this model, if applicable?

Guidance and exemplars to help establish when it would be appropriate to share data. Education to those working within health or social care around the differences between consented and unconsented data sharing for research purposes would be helpful.

Question 14: If you are a patient or service user, where would you look for advice before making a choice?

internet

Question 15: What are your views about what needs to be done to move from the current opt-out system to a new consent/opt-out model?

Yes No

Please comment on your answer

Question 16: Do you think any of the proposals set out in this consultation document could have equality impacts for affected persons who share a protected characteristic, as described above?

Question 17: Do you have any views on the proposals in relation to the Secretary of State for Health's duty in relation to reducing health inequalities? If so, please tell us about them.

Send your responses to:

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