Response to the Department of Health's consultation on the National Data Guardian for Health and Care's Review of Data Security, Consent and Opt-Outs

September 2016

Summary

- The Academy of Medical Sciences welcomes the National Data Guardian for Health and Care's Review of *'Data Security, Consent and Opt-Outs'*, which is a positive step towards establishing a robust governance model for sharing healthcare data in the UK.
- The UK has an outstanding clinical, public health and epidemiological research base, which is closely aligned with the NHS and underpinned by access to high quality data. It is therefore essential that the proposed model and data standards continue to support and enhance this research base with appropriate safeguards in place to strengthen data sharing processes.
- Building transparency and trust around data sharing and the proposed model is essential to ensuring successful implementation. This will require clear communication about the value of data sharing with the public and healthcare professionals, enabling patients to make an informed choice regarding the use of their data. It is essential that the academic research community and other key stakeholders are engaged throughout the development of this model so that we can continue to build upon our world-leading research ecosystem in the UK.
- For all communications, there should be clarity around the terminology for different data types (*'identifiable'*, *'de-identifiable'*, *'anonymised'* etc) to ensure that it is clear as to which data types the model will, and will not, cover.
- Finally, we draw attention to the importance of guidance on what use of data for 'research' might entail, and the benefits of providing examples of where data might be used in this context. Research should not be seen as an extra activity but as core to the running of the healthcare system and provision of care.

Introduction

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure that these are translated into healthcare benefits for society. Our elected Fellowship comprises some of the UK's foremost experts in medical science, drawn from a diverse range of research areas, from basic research, through clinical application, to commercialisation and healthcare delivery.

The Academy welcomes the opportunity to respond to the Department of Health's consultation on the National Data Guardian for Health and Care's Review of Data Security, Consent and Opt-Outs. This response is based on the views of the Academy's Fellows and other experts, many of whom have significant involvement in the use of healthcare data.

The UK's outstanding research base is underpinned by access to data, which is essential for a large proportion of healthcare research. It is therefore important to clearly communicate and demonstrate the significant benefits from sharing health data to support the public in making informed choices about sharing personal data. A fit-for-purpose data sharing model with appropriate safeguards will help to build this transparency and trust around access to health data.

Proposed Data Security Standards

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

1. We welcome the proposed data security standards, which are rational and appropriate, and will help to build trust in responsible handling of healthcare data. As identified in the National Data Guardian's report, we recognise there are a number of different data security frameworks, standards and guidance in use, and therefore it is important to position the proposed data security standards as best practice across the healthcare system. The standards should be aligned with the appropriate frameworks already in use such as the Information Governance (IG) Toolkit, and it would be beneficial to add further detail to these standards so that organisations can take a more informed approach to data security. Overall it is essential that a balance is maintained between supporting access and ensuring appropriate safeguards for health and social care data.
2. We highlight the significant resource implications for implementation of these standards including the costs associated with technology, skills and training. Any system for monitoring compliance should not create unnecessary burden on organisations and the use of existing systems should be encouraged – for example, the IG Toolkit that all NHS organisations and many of their partners are already working to – where possible to accommodate these standards.
3. It would be helpful to further define terms such as *'appropriate'* and *'securely'*, for example where stating that *'personal confidential data is only shared for lawful and appropriate purposes'*. *'Appropriate purposes'* could be open to misinterpretation and therefore we would welcome further guidance on these terms.
4. Although the standards are for contributing staff and organisations, it would be helpful to also provide some reassurance regarding data security at the Health and Social Care Information Centre (HSCIC) itself, which will be collating the data. It would be helpful if this also outlined the effectiveness of the anonymisation process, particularly as anonymised data is not covered by opt-outs.

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?

5. We agree that it would be helpful for the Care Quality Commission (CQC) to carry out the initial inspection of organisations against data security standards as part of its inspection framework. However, rather than significantly increasing the burden on the CQC, consideration should be given to the CQC initially carrying out a high-level routine inspection, and then alerting a competent data security body of any potential breaches or issues to carry out a more detailed investigation.

Proposed Consent/Opt-Out Model

Question 11: Do you have any comments or points of clarification about any of the eight elements of the model described above? If so please provide details in the space below, making it clear which of the elements you are referring to.

6. At the start of the proposed consent model, it would be helpful to clarify that opt-outs *only* apply to identifiable information and not anonymised information. Although the exclusion of

anonymised information is confirmed in statement 7, this could be made clearer by stating this upfront.

7. There is a need to clarify the terminology used for different data types such as *'anonymised'*, *'identifiable'* and *'patient confidential data'* (PCD) to ensure that all stakeholders are clear about what each of these terms mean. Otherwise, it may unclear as to what is, and is not, covered by the proposed model. Some of these definitions are discussed within the Academy's report on the *'A new pathway for the regulation and governance of health research'* and the recently established UK patient data taskforce coordinated by the Wellcome Trust will help to support the use of consistent terminology.[1]
8. We welcome the emphasis on the importance of data sharing and its benefits for healthcare, as well as the importance of public engagement in this area. The opt-out model should provide examples of the significant benefits of research and audit to support patients in making informed decisions on use of healthcare data, and we would be happy to provide examples. In addition, it would be helpful to note the importance of data *quality*, as well as quantity, and to inform the public of the compromise to data quality by incomplete datasets arising from higher numbers of opt-outs.[2]
9. Paragraph 3.3 on *'The importance of data sharing'* states that an opt-out preference *'will, in time, be shared with all health and care organisations'*. Further clarity on why this could not be carried out immediately would be welcome as well as proposed timelines for this sharing.
10. It should be noted that there is the potential for confusion by presenting a new opt-out model for using identifiable data for non-direct care, whilst we are at the same time communicating that it will be permissible to work with de-identified data for most non-direct care purposes. Therefore examples of where identifiable data may be used would be helpful.
11. It is important to acknowledge that no mechanism of anonymisation will be entirely risk-free, but that the likelihood of de-anonymisation is extremely low.

4. You have the right to opt-out.

12. There is a false dichotomy drawn between improvement of NHS services or *'running of the NHS'*, and healthcare research. This is demonstrated by the examples in statement 4 on the efficacy of a colorectal cancer screening programme and patients' expectations and experiences, which could fall within either of these purposes. Research is closely coupled to the running of the healthcare system and should be seen as integral to this running and not a separate, extra activity. Therefore in its current form, the proposed single opt-out is more appropriate than the two part opt-out.
13. In addition, it is difficult to separate direct care from *'running the NHS'* as direct care depends on the continual evaluation and assessment of NHS and social care services. Given that patients receiving direct care are benefitting from the collective use of their data for healthcare service improvement, it could be argued that this use should be considered as a general exception to the opt-outs.
14. The report concludes that an explicit consent model is not required for use of patient confidential data (PCD) for direct care, instead suggesting that a patient can elect to opt-out of sharing certain information for direct care such as with a local shared record programme (3.2.12, 3.3). Further clarity on these circumstances and how this will be implemented is

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[1] Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research.* http://www.acmedsci.ac.uk/download.php?f=file&i=13646

[2] For a case study demonstrating the importance of complete datasets, please see *Box 6.1: Bias introduced into research findings when incomplete datasets are accessed* (page 57) of the Academy of Medical Sciences' 2011 report on *'A new pathway for the regulation and governance of health research'.* http://www.acmedsci.ac.uk/download.php?f=file&i=13646http://www.acmedsci.ac.uk/download.php?f=file&i=13646

required, as this will require careful interpretation in the context of future development of electronic health records that are integrated across primary and secondary care.

15. We support the assurance that personal confidential information will not *'be used for marketing or insurance purposes'*, as this provides clarity for individuals who may opt-out based on the false perception that their data will be used to directly support these activities.

6. Explicit consent will continue to be possible

16. We are highly supportive of the opportunity to provide specific consent for selected activities, such as certain research studies, which enables patients to still participate in important scientific research. Further clarity is needed on how patients that have opted out will find out about these research opportunities, and the challenges around this were considered in the Academy's 2011 report.[3]

7. The opt-out will not apply to anonymised information

17. Although the model does not require an opt-out arrangement for the use of de-identified data in planning and research, organisations should be encouraged to continue their engagement with the public around the benefit and uses of both de-identified and anonymised data. It would be helpful to provide some specific examples in the model of where anonymised information may be used.

8. The opt-out will not apply in exceptional circumstances

18. It is important that the opt-out does not apply in certain circumstances, such as those of overriding public interest including monitoring and control of diseases and other public health risks.
19. The example that the HSCIC *'has powers to collect information when directed by the Secretary of State or NHS England'* may cause concern and so there needs to be further clarification on what this might entail, and the circumstances under which this might be exercised.

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

20. We support the recommendation for stronger sanctions which will promote accountability and best practice in use of data.[4] These sanctions should be aligned to other data protection legislation. Further to this, it has been suggested that sanctions could also consider barring individuals or organisations from further using health data for a given timeframe if a breach of a certain nature occurs.
21. The sanctions should be proportionate to the breach and therefore differentiate between deliberate and careless conduct, particularly where the latter does not qualify as 'gross-negligence', to prevent disincentivising appropriate activities using data. In general, it would be helpful to further define *'negligence'*. Stronger sanctions for *all* data and misuses, for example, 'selling' of identifiable data and other such activities, should also be considered.

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?

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[3] Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research.* http://www.acmedsci.ac.uk/download.php?f=file&i=13646

[4] The importance of establishing clear penalties for breaches in data use was discussed at a 2014 workshop held by the Academy of Medical Sciences on *'Data in safe havens'.* http://www.acmedsci.ac.uk/download.php?f=file&i=29879

22. Clarity around the implementation and interpretation of the opt-outs is essential, and how these will interact with the current safeguards in place for the use of personal confidential information, such as Section 251 support which requires substantial scrutiny and processes to allow data use where signed informed consent is not possible.[5] From the report, it appears that even with Section 251 approval, individuals now opting out will not have identifiable data made available for this purpose. This will cause a particular problem in areas such as mortality data studies which are critical for studying health outcomes, and are carried out by the HSCIC through data linkage using identifiable data. This would not only result in incomplete data – as the HSCIC will not be able to identify who has opted out – but studies will not be able to ascertain whether data missing for individuals is through an absence of events or an elected opt-out. Therefore the opt-out exemptions should be reconsidered, and careful attention given to how these are implemented.
23. It is not yet clear how opting out will be implemented, and therefore it is important that there are appropriate timelines in place for the introduction of this model, allowing sufficient time for developing and refining the model as well as for creating a robust implementation plan. The opt-out questions need to be carefully considered to ensure that an informed choice can be made based on an understanding of where, and why, data may be used. The involvement of the academic research community in the development and implementation of this model, as well as other stakeholders, is critical to ensure that the UK retains its world-leading research ecosystem.
24. During the time to implementation, it is also important to clearly establish and communicate what will happen to existing opt-outs and how these will be managed.
25. As outlined above, to support informed choice by patients it is important to communicate the value of data sharing. Engagement with the public, healthcare professionals and other key stakeholders is critical to ensuring that the model is successfully adopted by the healthcare system through building understanding and trust in the model. Many academic researchers have experience of public engagement and contribution of patient data to major research projects such as the UK Biobank and the Million Women Study, and it would be helpful to draw on learnings from these initiatives to ensure effective communication with the public in the future. The UK patient data taskforce will again play a key role in this engagement.

This response was prepared by Liberty Dixon (Policy Officer) and was informed by the Academy's Fellows. For further information, please contact Liberty Dixon (Liberty.Dixon@acmedsci.ac.uk; +44(0)20 3141 3222).

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[5] Section 251 as part of the NHS Act 2006 c.41