The Academy of Medical Sciences

The Academy of Medical Sciences' response to the Department of Health's 'Protecting Health and Care Data' consultation

August 2014

Summary

- Greater access to data, and appropriate data sharing, provides the opportunity to improve patient care, enhance public health and benefit scientific progress through research. In order to realise these benefits it is important that mechanisms are provided to enable such access and linkage whilst upholding the duty of confidentiality and protecting the data subjects' right to privacy.
- The Academy therefore welcomes the Department of Health's intention to clarify how information relating to health and social care will be used, by whom, and the safeguards around the information.
- We are, however, concerned that the proposed Regulations relating to the establishment of 'accredited safe havens' (ASHs), data access, use, and dissemination by ASHs and the Health and Social Care Information Centre do not encompass research to a clear or satisfactory degree.
- We note that a number of different initiatives relating to the sharing of confidential data are currently underway, including - although not limited to - care.data. We would like further clarity on how the proposed Regulations in this consultation relate to, and will influence, these separate initiatives and existing and planned databases for research and other purposes. In addition, how will ASHs fit into this wider environment?
- We consider that current proposals will be enhanced by greater details about how ASHs will be accredited and monitored, which should be conducted by an independent body with adequate resources.
- Researchers can provide invaluable input into policy developments on the framework and criteria for accrediting data safe havens, reflecting on existing best practice and ensuring their utility for the full range of data use. We would welcome ongoing dialogue with the Department of Health as the Regulations are developed.

Introduction

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. Our Fellows are the UK's leading medical scientists from hospitals and general practice, academia, industry and the public service. We are pleased to respond to the Department of Health's consultation on '*Protecting Health and Care Information: proposals to introduce new regulations*'.

The Academy welcomes the value that the Department of Health has placed on appropriate data sharing to improve health services, and the acknowledgement that there is a need for proper safeguards, greater openness and transparency.

Our 'Vision for medical science'[1], published in 2010, highlighted the importance of allowing researchers access to electronic health records in improving patients' health and healthcare. This was reinforced in our review of the regulation and governance of medical research in the UK[2]. We are therefore concerned that the current consultation does not make clear the extent to which research activities will be covered by the proposed Regulations. Our response to this consultation has been informed in part by the 'Data in Safe Havens' workshop held by the Academy, with support from the Medical Research Council (MRC) and the Wellcome Trust, in March 2014[3].

Scope of the proposed Regulations

Greater access to data, and appropriate data sharing, provides the opportunity to improve patient care, enhance public health and benefit scientific progress through research. We are therefore concerned that the proposed Regulations relating to the establishment of 'accredited safe havens' (ASHs), data access, use, and dissemination do not encompass research to a clear or satisfactory degree.

Whilst some of the proposed purposes for which data could be disclosed and used within an ASH could relate to research activities (e.g. analysing differences between population groups), they do not cover the full spectrum of biomedical research. If research is indeed within the scope of the Regulation, we consider that this should be made explicit.

The consultation document does imply that data held by the Health and Social Care Information Centre (HSCIC) or ASHs will be available for research purposes, subject to controls to prevent misuse (section 4). The Academy is pleased to see research acknowledged in this way. However, as highlighted above, given that the purposes for which data could be disclosed to and used by an ASH do not explicitly include research, we would welcome a more confirmatory explanation of who may request such information and the permissible uses of disseminated data.

The data to be held by ASHs and the HSCIC are likely to be invaluable resources for researchers to improve the safety of medicines, to better understand the causes of disease, to identify research participants and to locate patients who would benefit most from targeted health interventions. The consultation document highlights how researchers currently have access to data via the Clinical Practice Research Datalink (CPRD) and under certain circumstances though section 251 of the National Health Services Act 2006. Whilst we would continue to support data access to researchers through these means, it is unclear whether all data held by ASHs and the HSCICs will be available through these mechanisms both in the short and long term. Will there be any harmonisation between ASHs and CPRD? To what degree will data collected by ASHs and the HSCIC be concordant with that available via CPRD?

If research is not within the scope of the proposed Regulations, we call on the Department of Health to review how data could be disclosed to and used within an ASH and disseminated from ASHs and the HSCIC for research purposes. The Academy's review of the regulation and governance of medical research highlighted how the legal

[1] Academy of Medical Sciences (2010). *Reaping the rewards: a vision for UK medical science*. http://www.acmedsci.ac.uk/viewFile/51b9ca237ecdf.pdf
[2] Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research.* http://www.acmedsci.ac.uk/viewFile/publicationDownloads/newpathw.pdf
[3] Academy of Medical Sciences (2014). '*Data in Safe Havens'.* http://www.acmedsci.ac.uk/viewFile/53c7d8a7567db.pdf

framework around access to patient data is highly complex, involving UK legislation, case decisions, and an EU Directive. There are also a wide range of bodies involved in producing advice, each of which differs slightly in their focus, context and jurisdiction[4]. This has resulted in conflicting interpretations of the regulation among stakeholders and a lack of clarity for patients and the public. We consider that separation of research from the scope of the proposed Regulations is likely to exacerbate this situation.

Adding to this complexity are the different initiatives relating to the sharing of confidential data that are currently underway, including, although not limited to: care.data; the HSCIC's consultation on the 'Code of practice on confidential information'; the HSCIC's proposed development of a new 'data lab' service; and the Care Act 2014 and new Regulation on the Confidentiality Advisory Group providing advice to the HSCIC in respect of data disclosure. We would like further clarity on how the proposed Regulations in this current consultation relate to, and will influence, these separate initiatives and existing and planned databases for research and other purposes. How will ASHs fit into this wider environment? For instance, how will the controls put in place to protect the data held by an ASH align with the HSCIC's 'data lab' service?

We are pleased to find that the HSCIC is in discussion with the MRC and the Chief Medical Officer in the development of the 'data lab' service[5]. Research is generally seen as a bastion of good practice for data stewardship. The Information Governance Review, chaired by Dame Fiona Caldicott, notes how researchers have devised robust solutions to enable access to detailed patient information, while ensuring confidentiality is protected.[6] We consider that researchers can provide invaluable input in policy developments on the framework and criteria for data safe havens, to reflect existing best practice and ensure their utility for the full range of data use.

Accreditation and governance

We note that bodies seeking to become an ASH will have to be sponsored by the Department of Health and their status approved by the Secretary of State on the advice of the HSCIC. We would like to seek clarification on whether the HSCIC would be considered an ASH under the Regulations. If this is the case, we would consider that provision of advice by the HSCIC could constitute a conflict of interest. It has been suggested that another independent body, such as the Health Research Authority, should be considered to provide that function instead. We would also like to seek clarification on whether it is possible for research organisations to become an ASH.

The Academy welcomes the development of clear regulatory controls on ASHs and the proposed provisions for regulating the disclosure of information from ASHs and the HSCICs. However, we seek further explanation on the governance involved. It is unclear who will monitor adherence to the provisions, and the mechanisms by which it will be achieved. We also have concerns over the resource implications for the organisations assigned to accredit and/or monitor the potentially large number of bodies that will become ASHs. They must be properly resourced.

[4] Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research.* http://www.acmedsci.ac.uk/viewFile/publicationDownloads/newpathw.pdf
[5] Health Committee (2014). *Oral Evidence: Handling NHS Patient Data, HC 484.* http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-committee/handling-of-nhs-patient-data/oral/11192.pdf
[6] Caldicott F (2013). *Information: To share or not to share? The Information Governance Review*. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

Sanctions

The Academy is supportive of penalties in cases where the proposed controls are breached. Delegates at the Academy's 'Data in Safe Havens' workshop emphasised the importance of penalties against data misuse, which may also act as reassurance to the public that such issues are taken seriously[7]. Delegates felt that sanctions should be at the individual level rather than the institutional level, which are neither practical nor proportionate.

All penalties need to be severe enough to act as a proper deterrent to data misuse, and ensure good practice. However, we feel it is also necessary to look at the nature of the breach, and adjust the penalty in accordance with the motivation behind the breach and its severity. For example, accidental breaches – possibly arising from poor organisational control mechanisms in place - may benefit from a systems review and root cause analysis with a requirement to implement remedial action.

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The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. Our Fellows are the UK's leading medical scientists from hospitals and general practice, academia, industry and the public service.

The Academy seeks to play a pivotal role in determining the future of medical science in the UK, and the benefits that society will enjoy in years to come. We champion the UK's strengths in medical science, promote careers and capacity building, encourage the implementation of new ideas and solutions – often through novel partnerships – and help to remove barriers to progress.

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[7] Academy of Medical Sciences (2014). '*Data in Safe Havens'.* http://www.acmedsci.ac.uk/viewFile/53c7d8a7567db.pdf