

Data Regulations Consultation
c/o Jennifer Byrom
Room 2N12
Quarry House
Quarry Hill
Leeds
West Yorkshire
LS2 7UE

By email: phacd@dh.gsi.gov.uk

Department of Health: Protecting Health and Care Information

Response by the Wellcome Trust

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Key Points

- There is a pressing need for clarity on the controls governing the sharing and use of personal information relating to health and social care. It is imperative that the proposed Regulations strike the right balance between ensuring patient confidentiality and enabling information sharing where it is needed.
- While we support the intent of the proposals, we are extremely concerned that in their current form they may impact on research uses of health and social care information:
 - If research uses do not fall within the scope of the Regulations, it is unclear whether and how valuable research activities that require information from ASHs, not available from CRPD or through s.251 approval, could be permitted.
 - If research uses do fall within the scope of the Regulations, the 'accredited safe haven' (ASH) requirements are disproportionate and would prevent much research from being conducted.

Both of these outcomes would be highly detrimental to biomedical and health research and we would strongly oppose any Regulations that precluded information sharing for research purposes.

- The basis for establishing ASHs does not cross refer with any of the HSCIC's work on developing standards and processes for the handling of confidential information. This would create a damaging confusion for data controllers and users over the information processing standards they are required to adhere to.
- We consider the civil penalties proposed do not reflect the severity of the breach of trust that would occur if data are misused, nor can they ensure that breaches do not recur.
- Building a trustworthy system will be essential to gaining public confidence in the way this information is used. The proposals would substantially benefit from setting out how the accreditation and auditing of ASHs would be independently overseen – by a body that is not itself an ASH.
- There remains a worrying lack of clarity over the circumstances under which patients are able to opt-out of their information being processed and used by an ASH for the purposes listed.

Introduction

1. The Wellcome Trust is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We provide significant funding for clinical and biomedical research in the UK, much of which makes use of health and social care information. We believe that the responsible use and sharing of data is vitally important for research and the development of an evidence based healthcare system. We are pleased to have an opportunity to contribute to the consultation on *Protecting Health and Care Information: proposals to introduce new regulations*.

Comments on the proposals

2. We welcome the Department of Health's recognition of the benefits of data sharing, not only for direct care but also for wider health purposes. We strongly support the intention that the Regulations should clearly limit the purposes for which data can be used and impose statutory controls on ASHs. As highlighted in the Information Governance Review, it is very important that there are "no surprises" in how people's information is being used. However, there are a number of issues in the proposals that raise significant concerns, both for our research communities and for the potential to ensure public confidence in the planned governance arrangements.

Scope and purposes: creating ASHs

3. The proposals appear to indicate that research uses of data are not included in the scope of the Regulations, with their primary purpose being to set out governance for information sharing for care and commissioning purposes. Although paragraphs 11 and 12 indicate the exclusion of certain research purposes from their scope (access via CPRD and s.251 approvals) there is a far wider range of research uses than these two provisions alone allow, and some of the purposes for which ASHs may be formed do appear to be research uses (for example, paragraph 16, "*population based research*"; paragraph 26, "*analysing differences between population groups*"). Patient records are invaluable for health and biomedical research and it is essential that there is no ambiguity around how research uses of such data will be regulated. The Information Governance review was clear that all purposes – care, commissioning and research – need to be covered by proposals for ASHs.
4. If research studies and uses are intended to be included in the Regulations, the requirements for ASH accreditation would, in our view, be disproportionate, particularly as many studies are relatively small scale, of limited duration and their use of patient information poses minimal risks to privacy. Additionally, numerous research studies would not have the resources to seek accreditation and their research would be rendered impossible to conduct by the ASH requirements.
5. If, on the other hand, research studies and uses are not intended to be included in the scope of these Regulations, and these would continue to be governed under the existing regime of the 2002 Regulations, it needs to be unambiguous that the requirements to create an ASH in order to process confidential data do not apply to research. There is a risk that if research purposes are not set out within the Regulations, they will be excluded in practice as ASH requirements may be seen to overrule them. For example, where a research participant has given consent for access to their medical records as part of a research study, the blanket restrictions on disclosure of identifying information from an ASH (paragraph 57) may overrule this consent and prevent the data from being accessed by the researchers (see also paragraph 19 in this response). We urge the Department of Health to consider the ways in which the relationship between ASHs and

research studies and uses of information can be clarified within the scope of the Regulations.

6. If ASHs are to be championed as the 'safe' way to hold and process confidential and potentially identifiable information, it will undermine public confidence if the governance of the uses of this information is fragmented, with research being dealt with by a different regime. We strongly advocate well-defined, robust and proportionate controls for research uses as well as commissioning and care purposes.

Scope and purposes: processing of information

7. The proposals aim to establish "*clear rules around the use of data that might potentially identify individuals disseminated by ASHs and the Health and Social Care Information Centre (HSCIC)*" (Foreword). We would welcome clarification on whether it is the intent of the Regulations to specify that *only* accredited ASHs are permitted to process and link confidential information relating to health and social care (see **Box 1**). This would appear to undermine the HSCIC's draft code of practice¹ for organisations processing confidential information, which does not restrict the types of organisations that could perform such processing or set restrictive limits on the purposes for which the information could be used. This disparity is likely to generate confusion among data controllers and users over their legal obligations with regard to processing information, and uncertainty among the public over how their data may be used.

Box 1: UK Biobank

UK Biobank is a large scale national health resource that aims to contribute substantially to the understanding, prevention, diagnosis and treatment of a range of serious health conditions. It has recruited 500,000 participants in the UK aged 40-69 and collected extensive personal health data and samples, with their consent. Participants will be followed up over many years, and it is essential to the research purposes of UK Biobank that the data collected are able to be linked to particular participants. Scientists undertaking health-related research are able to apply to access data from the resource. Under the terms of these proposals, should UK Biobank be required to obtain ASH status?

8. The distinction between data processing and data linking is an important one: linking between different datasets may increase the risk of individuals being re-identified, and it may therefore be appropriate that linking only takes place in an ASH in order to mitigate this risk. However, the proposals are unclear as to whether accreditation will be required for *all* processing of personal or potentially identifiable information: this would be severely detrimental to research studies that use and process such information but do not necessarily link it with other sources. We are concerned that under the proposals, many legitimate research purposes using confidential data would be ruled out.
9. The proposals to develop ASHs also appear to undermine the suggestions mooted over the past few months that the HSCIC could develop a 'secure data lab' to act as a single point of entry for health and social care information into a secure environment. We urge collaboration between the Department of Health and HSCIC on these fundamental issues.

¹ Available at <http://systems.hscic.gov.uk/infogov/codes/cop>

10. ASHs need to take an appropriate, proportionate approach to processing confidential information for particular purposes and this should be the primary consideration in deciding under what circumstances setting up an ASH is necessary.
11. The proposals fall under s.251(9) of the NHS Act (2006). However, given that they are intended to apply to HSCIC it would be beneficial to clarify how the purposes listed in the consultation are supposed to cohere with the restrictions on dissemination of information from the HSCIC stipulated in s.122(3) of the Care Act (2014), and the decisions made on access to data by the Confidentiality Advisory Group. In the interests of parsimony and clarity for potential data users these purposes need to be consistent across legislation relevant to the control and processing of personal or potentially identifiable information.

Civil penalties

12. We consider that the civil penalties proposed (a £5000 fine) are inadequate both as a deterrent against misuse and as a means of ensuring data breaches do not recur. Fines of this order will do little to bolster public trust in the governance and use of personal or potentially identifiable information.
13. Civil penalties need also to be proportionate and sensitive to the cause of the breach: different sanctions should be available against individuals deliberately misusing data, and organisations whose poor data security and governance lead to data breaches.
14. Potentially identifiable information is not covered under the sanctions available through the Data Protection Act (1998). Much potentially identifiable data may be rendered identifying if linked in novel ways: we believe that there should be a strong deterrent against attempts to re-identify, or reckless use of de-identified data in such a way that it could yield identities.² We suggest that criminal sanctions could be imposed for deliberate attempts to re-identify individuals from potentially identifiable data.
15. With regard to penalties, there is no mention of implementing any mechanisms for redress in the case of data being misused. This disregards an explicit recommendation in the Information Governance Review (Recommendation 24) and overlooks an important mechanism for ensuring accountability. We strongly urge the Department of Health to reconsider this oversight and to include measures for redress in draft Regulations.

Audit and oversight

16. The proposals indicate that accreditation of ASHs will require approval from the Secretary of State on the advice of the HSCIC. The HSCIC would itself, under the terms of these Regulations, be an ASH, which would generate a conflict of interest for the HSCIC. This does not demonstrate accountability or transparency in decision-making. It would also have significant resource implications for the HSCIC and for all ASHs, particularly if annual renewals of accreditation are required. We suggest that the Health Research Authority would be better placed to undertake accreditations, if it could be adequately resourced to do so.
17. It is vital for building public confidence in the governance of health and social care information that the systems and oversight mechanisms developed are trustworthy. Clear, independent oversight of ASHs – not merely the processes required to establish

² Several major research funders have recently looked into this issue and are taking a proactive stance towards ensuring the risks of re-identification in research studies can be mitigated as far as possible:
http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wt_p055971.pdf

an ASH (paragraph 35) – is essential. Regular audit of their functions, data flows, the organisations to whom they permit access and the reasons for sharing, all need to be available and subject to public scrutiny.

Objections from patients

18. If patients are to feel confident in allowing their confidential medical records to be shared for purposes beyond direct care, it is imperative that these are handled securely and respectfully. There must be absolute clarity about the legal standing of a patient's decision to object to their data being shared. Patient objections appear to be given strong legal standing (paragraph 19), but it is then unclear whether such an objection would be overruled by a s.251 approval to use confidential data (paragraph 21: *"the Regulations would enable information to be passed, despite any obligation of confidence owed in respect of it"*). This suggests there will be circumstances in which individuals' objections will not prevent information sharing. Although these proposals explicitly exclude care.data there is a need for joined-up thinking with this programme on the status of opt-outs. Whilst we support s.251 as extremely important for research, we believe that patients should be given unambiguous, accurate information about the circumstances under which an objection will or will not be respected.
19. The proposals would substantially benefit from clarifying the status of consent in the Regulations. For some research studies participants have consented to their confidential medical information being accessed by researchers, and it is the identifiability of that information that renders it valuable for those research purposes. The blanket restrictions presented in paragraph 57 imply that there is no scope for the disclosure of identifying information even if explicit consent has been given by the individuals concerned for the purposes of research. Again, this indicates that these proposals may impact valuable research uses for health and social care information even if research is excluded from the Regulations, and we strongly urge the Department of Health to take these into account as the Regulations are drafted.

Final comments

20. We encourage the Department of Health to work with the HSCIC on its vision for the purposes, scope and criteria for ASHs, and with the research community to ensure that appropriate research uses of health and social care information are not impeded by the Regulations. It is crucial for building a system that can gain the trust of the public that there is clarity over different types of data use, for what purposes, and what rights individuals do and do not have to object to their information being processed.
21. We would be happy to work with the Department of Health as the Regulations are developed further to shape a regulatory environment that supports valuable health and biomedical research and healthcare services, whilst fully protecting and respecting patients' confidentiality.

The Wellcome Trust is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.