

medConfidential response to the DH consultation on Protecting Personal Health and Care Data

Throughout this response, we make references to the attached briefing paper on a comprehensive way forwards. In this paper, we address DH's questions and question some of the (missing) assumptions behind it. Our preferred way forward starting from the current confusion is in the paper "ASH response -- A substantive proposal based on a designed process incorporating safe settings".

In short, this consultation only considers the possibilities visible from the current starting point, which could charitably be described as "somewhat in a hole", and uncharitably as "still digging". From an external perspective, it is considerably easier to see how to get to a long term sustainable from here, even if the initial steps are not intuitively obvious to DH in its current position.

This is an incredibly complex consultation topic. In discussions with other organisations, it has proved clear that there has been insufficient time and pre-discussions for those writing submissions from various expert groups with whom we have had contact, to come to a shared coherent understanding of the words and concepts the Department was attempting to convey, if indeed, it had such an understanding itself.

This consultation does not explicitly take account of various issues:

- That all data extracted from GP practice systems under care.data will only be processed in the 'data lab' at HSCIC;
- That if fair processing is required for extraction for commissioning uses of GP-held data under care.data then it is required for all such flows and uses elsewhere.
- There appears to be (the potential for) confusion between a lawful data processor, an Accredited Safe Haven and a safe setting in a safe host for access to data in HRRDL.
- The separation of governance and operational responsibilities inherent in the health research remote data laboratory design, which is derived from other safe setting models.
- ASHs should only be data processors, with controllers using the processing facility of the ASH for specific purposes using custom data to serve only those purposes.

Section-by-section commentary:

1) Introduction

We welcome the adoption of the principle of data minimisation: appropriate and not excessive collection (DPA), identifiable only when absolutely necessary for the specified purpose. However this requires the de-conflation of purposes, which is the opposite approach to that taken so far in this consultation.

Much is made of “failure to share information” in tragic cases when in fact information sufficient to identify a problem was available, yet it was simply not acted upon. In other cases, absence of information was not acted upon when this absence should clearly have raised alarm bells. Data is not ‘truth’, and to presume that ‘data sharing’ will fix process failure and systemic abuse is both naive and dangerous. Of course, people need information - but they also need the resources to act and investigate when they have concerns.

2) Accredited Safe Havens

Primary Care Trusts were abolished in April 2013. In August 2014, there is a rushed, unclear consultation on replacing their data flows. In response to the overlapping NHS England consultation, on which this consultation nominally builds, we said:

“We feel that this process should be paused, and reconducted based on lessons from care.data, IGAR, and other NHS England, HSCIC and DH reforms.”

This is the first step in that process, however, it could be approached in a manner that doesn’t try to finish the process in 6 months. This new model has been clear since 2012 when the Health and Social Care Act received Royal Assent. It is not a new “urgency”

The list of purposes (para 16) has been expanded from just “population based research and statistical analysis” (Thomas/Walport) to “population based research, statistical analysis, audit, surveillance and service improvement” (s6.5, Caldicott2). These require radically different data products, in different forms, for different purposes. It is unlikely to be the case that conflating purposes and process will suffice to an adequate level of transparency and governance.

The defining characteristic of this data is its linkability. Even if human identifiers (name, address) are removed, and common data identifiers could be removed (NHS number, postcode, Date of Birth), the pretense that the remaining data is not inherently identifiable is pure administrative fiction which is unlikely to result in clear, safe and transparent regulations.

Paragraph 20 is quite clear, **“These local flows will also contain person-level data that is capable of being used to re-identify individuals”**.

Regulations must not allow an organisation to set itself up as a “safe haven” and transfer data at will. It is not a “safe haven” if it is not fully auditable and audited as to what was done, on what data, on what basis, by whom, and why. To have credibility, an external party must be involved, and the only party with suitable standing is HSCIC. A safe setting does not prevent, nor necessarily limit, what data can be matched, but it does require that process to be auditable, and not based on files on a USB stick.

We see no reason that an ASH would wish to run it’s own longitudinal studies. That suggestion is emblematic of the confused governance and failure of transparency of these current proposals. If a longitudinal study is to be created, it should follow good practice, and not be a collection of data items in a safe setting left lying around. If the data products to be used for particular purposes in a haven were to have been clearly stated at any point, the lunacy of paragraph 22 would be self-evident. This strongly suggests that they have not even been considered prior to going out to consultation. In short, data should not be retained purely because it may be useful in the future for some other purpose. The Data Protection Act is rather clear on this point, and it would seem unusual for an ASH to have such a hole in it’s founding documents, which should attempt to raise public confidence rather than highlight why the approach is flawed. This suggests that each ASH, whatever those may be, can start creating their own mini-silo-focussed subset of care.data without oversight, discussion or consent. Was this intentional?

Similarly, paragraph 23 presumes an ASH is an independent entity, when public confidence requires a facility run and used by entities with differing Governance lines. Paragraph 23 and 32 contradict each other regarding Governance, and oversight. In a properly constituted safe setting, the concerns around processing and governance are impossible or audited. In potential outcomes from this consultation, they are significant and potentially catastrophic. Audit must apply to each additional function.

There must continue to be a clear statutory and legitimate basis for data collection, processing and use, and passing between the various parts of the systems. The use of any form of safety measures such as settings or havens does not mean that the actions may not be necessary, appropriate or lawful. For the use of individual level medical records, there must always be a clearly defined need with confidence and audit in the system to ensure patient confidence. Such rules should be no more lax than those applied to researchers using the same data. Section 251 does not cease to be necessary because the data is processed in a safe haven. Correcting the historical negligent governance, introduced in a bit of a panic, does not mean lowering the bar for process and criteria, it should mean meeting it.

Whether CAG, DAAG or some other body is the approval body (and this is far from clear), single strike must continue to apply. Some of this relates to segregation of data uses and facilities. A commitment must be given that any controls will be as strong as those on HSCIC, this should not be a soft option for handling of identifiable patient data as was previously done with HES prior to February’s debacle.

Given the changes in guidance since this consultation was written, we would expect the new HSCIC Governance models, Codes of Practice, Transparency and Consent mechanisms to be fully integrated into these systems. It can not be the case that because DH was considering something in March, that a consultation closing in August can ignore everything in the interim.

Given the evidential failure of the post-April-2013 NHS Information Governance model over the last few months, a long term solution should be considered, rather than another patch on a breaking patchwork.

We consider that further in the document “Accredited Safe Settings -- getting there from here”

DH questions:

Q1. Are these purposes the right ones? Are there any other purposes that it is acceptable for an ASH to use data for? Please set out what you think the purposes should be.

Purposes should be limited and defined, and solely be accepted commissioning purposes relating to direct care.

Q2. Are there any other regulatory controls that you think should be imposed?

Yes. They should be no weaker than those agreed for the research community under the Care Act and related changes. See Parts B and C of our “ASH world view” paper.

Q3. What are your views on the maximum amount of the civil penalty that we should set for breach of the controls proposed above in relation to ASHs?

They should be no weaker than those agreed for the research community under the Care Act and related changes. See Parts B and C of our “ASH world view” paper.

Q4. Should there be any restrictions as to the type of body which might become (in whole or in part) an ASH, for example, a social enterprise, a private sector body or a commercial provider (working under a data processor contract)? Please let us know what you think.

There are a range of governance questions ignored by this consultation.

Types of body that may **use** the data products in a remote virtual safe setting, (as economists do in the ONS Virtual Microdata Laboratory which is used for access to detailed business data).

That is wholly different to the type of body that may **run** a safe setting and have any form of governance role over it - but nothing other than an NHS body should ever qualify to receive linkable copies of identifiable or pseudonymised data.

“*In part*” raises serious questions about governance, legal form and accountability which are covered further in our paper “Accredited Safe Settings -- getting there from here”.

Q5. Is there a maximum number of accredited safe havens that you would consider to be acceptable? Please give your reasons

HSCIC, although that may be multiple “havens” which each serve an individual purpose, without allowing cross linking of data between havens except in well defined circumstances.

The smaller the number, the more closely audited they can be, the greater public confidence. Confidence loss in one requires work by all, and that is required to be managed.

There may be a case for NHS England providing some functions to Commissioning Support Units, however, as detailed in our world view paper, this can be achieved very differently.

CCGs, Local Authorities/Councils do not.

It may be that the ONS, given it’s statistical function, may also be designed for statistical purposes if deemed necessary. This may be resolved as lines of responsibility between HSCIC and UKSA become clearer over time.

The rules must be robust to judicial review and legal action from commercial parties who otherwise believe they meet the criteria

Q6. What are your views on the level of the civil penalty that we should set for providers who do not comply with this duty?

See Parts B and C of our “ASH world view” paper.

Q7. Do you agree with the circumstances in which commissioners (case managers) should be able to obtain confidential patient information of an individual for whom they commission care?

Not entirely. This must be consent based, however, there should be an expert discussion over precisely what non-clinical aggregated data is needed to support commissioning, and how small numbers are handled for those cases

Commissioners should not be able to access a medical history, but may need to handle aggregated data with small number counts. Here, there is a prima facie case against small count suppression, if suitable handling is agreed. As with other areas of finance which request access to medical data (insurers for example), there are standards agreed between the BMA and the insurance industry for what is necessary, proportionate and appropriate. We have seen no reason that commissioning is any different.

Q8. What controls do you think should be in place in respect of such access? Please provide details.

They should not have access to individual level records.

An properly defined and appropriate aggregate data product without small number suppression is not an individual level record.

Q9. What are your views of the controls set out above?

See above

Q10. What are your views on the level of the civil penalty that we should set for any breach of these controls?

Insufficient. See Parts B and C of our “ASH world view” paper.

Any penalties must be possible at both an individual, organisational and organisational-parent level, to ensure appropriate responses are possible.

Any penalties lower than those imposed on HSCIC data users must be clearly and adequately justified, and subject to external scrutiny prior to Regulations being laid.

Q11. Are there any other controls that you think should be imposed? If so, please set out what you think these should be.

See Q10

Q12. 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?

Inadequate handling of patient data is likely to cause risk to the most vulnerable in society, who are those most at risk if the trusted confidential relationship with their doctor is undermined by the external system.

Q13. 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.

See the research section of our worldview paper