HSCIC | Health & Social Care Information Centre

Accredited Safe Havens

Briefing and Update for the HSCIC Board

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Purpose of Paper

1. The purpose of this paper is to inform the Health and Social Care Information Centre Board about the current position in relation to Accredited Safe Havens and <u>seek approval for HSCIC to continue working with the IG subgroup of the ISCG to define the requirements for an ASH and controls required for accreditation</u>.

Background

2. The 2013 Caldicott Review report *To Share or not to Share* and the HSCIC's *Guide to Confidentiality* make clear that information that has been collected by health and social care services when they are providing direct care for individuals has the potential to also provide huge benefits for the community. However, to protect the individual's confidentiality, anonymised information should be used wherever possible when the information is being used for purposes other than in support of direct care.

3. The reports recognise two categories of data: *anonymised* and *identified*. The Caldicott review also recognised that data containing a single identifier (e.g. NHS Number) can be treated as anonymised as long as it is not linked Patient Confidential Information (PCD). The Caldicott report refers to this data as *de-identified for limited access*. A convenience categorisation which permits consideration of data linking whilst retaining an anonymised status.

4. De-identified for limited access data when linked to PCD becomes identified data and therefore without a clear and legal basis this linkage would be considered a data breach.

5. The Caldicott report specifies that the linkage of PCD (with a clear and legal basis) and linkage of de-identified but still potentially identifiable information from more than one organisation should be done in specialist, well-governed, independently scrutinised environments known as 'Accredited Safe Havens'.

6. The Caldicott report indicated that there were plans for at least 20 accredited safe havens. These include safe havens within Royal Colleges, National Clinical Audit contract holders, approximately 10 Data Management Integration Centres, Public Health England and the Clinical Practice Research Datalink service of the MHRA.

7. The Caldicott Report also proposed a set of criteria that could be used for the accreditation of these Accredited Safe Havens. These criteria are included as Appendix 1.

Current position

8. There is a potential for confusion with regard to ASH accreditation due to interim arrangements, but this need not be the case:

    a. A temporary arrangement has been agreed to enable data to keep flowing to a limited range of organisations for specific commissioning purpose, this interim support under section 251[1] is designed to ensure business continuity through an initial period following implementation of the Act; Commissioning organisations

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[1] National Health Service Act 2006

operating under this interim agreement are not ASH organisations as described within the Caldicott report (see Appendix 2 for more detail on this)

b. Accreditation for longer term ASH status has not yet been published and discussions with the IG subgroup of the ISCG are on-going.

9. Government response to Caldicott makes clear that the need for Accredited Safe Havens as a solution to the information sharing challenges requires further assessment.

10. If agreed as a solution, the concept of an ASH should be considered as one of the options for reducing the privacy impacts in data sharing decisions and it is important that all alternative approaches are considered including use of the HSCIC data linkage service and expanding that capacity if required.

11. HSCIC must continue to work with ISCG-IG subgroup to understand and inform the final process for agreeing and approving ASH as a solution.

a. An audit function is required to provide 'independent scrutiny' against the criteria for accrediting safe havens (see Appendix 1, extract from Caldicott), the process is yet to be determined by ISCG-IG subgroup.

b. A register of organisations meeting the ASH criteria will be held and maintained centrally. HSCIC should undertake this function subject to agreement of process through ISCG-IG subgroup.

12. Further work is also required to introduce a robust approval mechanism for data linking.

a. Organisations registered as an ASH still require an approval mechanism before linking de-identified data which carries a high risk that it could be re-identified with reasonable effort.

b. Controls for approving data linking need to be in place which would promote and protect the interests of the patient while at the same time facilitating appropriate use of de-identified patient level information for purposes beyond direct patient care.

c. These mechanisms must follow once a resolution is found to the need for ASH.

13. Regulating future ASH organisations with regard to the approved data linking will depend upon the existence of a contractual, legal basis for managing data breach with enforceable penalty.

Outstanding concerns

14. The IG subgroup of the Informatics Services Commissioning Group has considered a DH policy paper on Accredited Safe Havens. This set out the need for new regulations under Section 251 to control the way in which Accredited Safe Havens are established and operate, primarily because many will be NHS organisations that cannot be controlled through contractual terms and conditions with other NHS bodies.

15. There were concerns expressed by members of the group about the way in which the concept might be implemented in particular the widespread use of the NHS number as the weak pseudonym. The group understood that this would allow data linkage within the Accredited Safe Haven but felt that the widespread availability of access to the Personal

Demographic Services required a more detailed risk assessment and consideration about the risks relative to benefits.

16. A further meeting of a working group of the IG subgroup discussed:

    a. The need for regulations under s251
    b. Alternative options to an Accredited Safe Haven such as increased capacity and capability of the HSCIC and its DSCROs to undertake the data linkage
    c. Consideration of Data Quality issues and whether data quality is sufficient to support linkage on NHS number alone

17. No firm conclusions were reached and it is clear that there are significant differences of opinion on where an Accredited Safe Haven should be considered as the solution for a data sharing requirement.

Next steps

18. HSCIC to continue working with the IG subgroup of the ISCG to define the requirements for an ASH and controls required for accreditation

Appendix 1 - Criteria for Accrediting Safe Havens

19. The Caldicott Review identified the need for a consistent national minimum standard of data stewardship, with the leadership (Boards or equivalent body) of organisations with accredited safe havens held accountable for any failings. This was to be supported by a system of external independent audit, which is published, and an accreditation process for all organisations that act as an accredited safe haven. These were:

- Attributing explicit responsibility for authorising and overseeing the anonymisation process e.g. through a Senior Information Risk Officer.

- Appropriate techniques for de-identification of data, the use of 'privacy enhancing technologies' and re-identification risk management.

- The use of 'fair processing notices'.

- A published register of data flowing into or out of the safe haven including a register of all data sets held.

- Robust governance arrangements that include, but are not limited to, policies on ethics, technical competence, publication, limited disclosure/access, regular review process and a business continuity plan including disaster recovery.

- Clear conditions for hosting researchers and other investigators who wish to use the safe haven.

- Clear operational control including human resources procedures for information governance, use of role-based access controls, confidentiality clauses in job descriptions, effective education and training and contracts.

- Achieving a standard for information security commensurate with ISO27001[61] and the Information Governance Toolkit

- Clear policies for the proportionate use of data including competency at undertaking privacy impact assessments and risk and benefit analysis.

- Standards that are auditable.

- A standard template for data sharing agreements and other contracts that conforms to legal and statutory processes.

- Appropriate knowledge management including awareness of any changes in the law and a joined up approach with others working in the same domain.

- Explicit standard timescales for keeping data sets including those that have been linked, which should be able to support both cohort studies and simple 'one-off' requests for linkage

Appendix 2 - Interim Arrangements to support Commissioning

20. Confusion has been introduced by the use of the term Accredited Safe Havens within the interim arrangements being established to support the new commissioning environment.

21. NHS England has been granted S251 support by the Secretary of State for confidential information to flow from the HSCIC to support commissioning. The initial support was provided until the end of October (an application for extension to this application was made to the October meeting of the Confidentiality Advisory Group) to enable Commissioning Support Units and Clinical Commissioning Groups to realign business processes that currently use confidential information to use instead 'de-identified data for limited access'. In order that this realignment can progress the concept of Interim Accredited Safe Havens has been introduced.

22. Under the S251 support, each organisation that requires access to confidential information for commissioning purposes is required to demonstrate that they have achieved a level 2 satisfactory IG Toolkit Score, to sign an overarching data sharing contract and specific data sharing agreement for individual flows from the HSCIC and to commit to undertake an independent audit of their procedures and processes.

23. It has been made clear to all concerned that these are interim arrangements put in place to support business continuity and are not to be assumed to be the on-going standards for accreditation. However, it should be noted that there are 69 CSU and CCG organisations that are currently seeking this interim ASH accreditation.