NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group
13 June 2013 at 1:00 pm at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Tricia Cresswell (Vice-Chair)	
Dr Charlotte Augst	
Dr Tony Calland	
Mr Paul Charlton	Lay
Dr Patrick Coyle	
Professor Julia Hippisley-Cox	
Professor Jennifer Kurinczuk	
Ms Clare Sanderson	
Mr C. Marc Taylor	
Ms Gillian Wells	Lay
Dr Chris Wiltsher	Lay
Mr Terence Wiseman	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager
Mr David Evans	Expert advisor, Information Commissioners Office
Mr Martin Frowd (items 1-3)	Senior Business Support Officer
Ms Christine Outram (item 3)	Director of Intelligence and Strategy, NHS England
Ms Rebecca Stanbrook	Director of Confidential Advice – section 251
Ms Ming Tang (item 3)	Director of Data and Information Systems, NHS England
Ms Karen Thomson (item 3)	Information Governance Lead, NHS England

1. INTRODUCTION, APOLOGIES FOR ABSENCE AND CONFLICTS OF INTEREST

Apologies were received from Dr Kambiz Boomla, Dr Robert Carr, Ms Madeleine Colvin, Mr Anthony Kane and Dr Murat Soncul.

Ms Clare Sanderson declared a conflicting interest in item 3 as the Health and Social Care Information Centre had been advising NHS England on the application and would be processing the information. She attended item 3 in the capacity of an adviser to the applicant but was not present for the CAG consideration of this item.

2. CALDICOTT 2 REVIEW REPORT

Ms Dunkley provided an overview of the Caldicott 2 review report for Members' discussion. Members welcomed this report, considered it to be clear and noted that the Department of Health would publish an official response in the summer and a HRA statement was being drafted to be released at the same time. A broader definition of data breaches had been established and breach reporting would be linked in to the Information Governance Toolkit. There was also a greater emphasis on the right of patients to opt out of having their information shared, in alignment with a recent government statement.

There were no key recommendations for research but the report did propose safe havens within academia although these were broadly undefined and it was not clear whether there would be a consistent governance structure underpinning these. It was noted these would not be the same type of entity as accredited safe havens (ASHs) as ASHs do not require support under the Regulations, although support is currently in place as an interim measure, and have controls in place so that there is no onward disclosure of identifiable information. A safe haven would not be following this structure and so further, consistent, work would need to take place to formally recognise these as 'safe havens', which is a term that has been accepted in principle by the British Medical Association. Members queried whether it was known how many would be established and noted that the more there are would mean a greater need for monitoring to ensure consistency.

Members noted with interest the new definitions under 'de-identified data for limited access'; a term known to the CAG in the context of Accredited Safe Havens in the NHS England application, where an administrative identifier such as the NHS number would be considered to be de-identified if suitable controls were in place. An example of controls would mean a separation of activity internally and ASHs would not have access to PDS, so it would be important to see the issue of ASHs as a whole package. Members emphasised that NHS Number was a globally unique number, and that identifiability involves associating an item with an individual, and the concept of DEID4LA sought to resolve this aspect. In the context of ASHs, it was a question of risk therefore ASHs appeared to present limited risk in this area. Members noted that the concept of DEID4LA was not accurate as it involves the holding of one strong identifier, albeit with appropriate controls in place. Members noted that there would be a role to play in monitoring the establishment of ASHs and noted this would be a government challenge to establish how this aspect can be policed to maintain public confidence in the system. Members considered the phrasing of 'monitor' to be relatively weak and noted that clear controls can only be in place if policed.

Members also noted that the right to object had been given greater prominence within the report, and following discussion with the SofS Department of Health representative, noted that in future, greater emphasis should be provided within outcome letters on the need to appropriately respect any expressed patient dissent, and on the applicant's role in proactively making information available on the activity.

Members noted that there was relatively limited time to discuss this report, therefore it was advised that should Members have further comments then they should be discussed at the meeting on the next day.

Action: **Increased emphasis on patient right to object and fair processing to be incorporated into approval letters on behalf of the SofS and HRA**

3. NHS England: data flows from the HSCIC to commissioning organisation accredited safe havens – June update report [CAG 2-03(a)/2013]

This application was originally considered by CAG in April 2013, and the Secretary of State for Health (SofS) provided approval for a period of 6 months. Approval was conditional upon submission of satisfactory reports to the June and October CAG meetings to respectively identify progress on achieving the specific conditions of support, and the need for continuing support.

Members welcomed the applicants and found the delivered presentation to be extremely useful in providing an overview of the current state. It was recognised that this was an emerging picture with challenging work and timescales and it was appreciated that CAG was by its nature not involved in the day to day activities so the picture of the current situation was found to be very helpful and welcome. It was also understood that much had not been finalised however members were encouraged by the approach taken and it was clear that the applicants were working hard to cohesively manage these national changes in a difficult environment. CAG welcomed the opportunity to establish an ongoing dialogue as this would enable members to be better placed to deliver its advice function. A summary of the aspects discussed are set out below:

a. ASH accreditation

Information on the draft definitions, legal framework, accreditation process, and 23 requirements for Commissioners were listed in appendix 1.

Members raised queries around the use of NHS number and the terminology within the paperwork. Appreciating that a definition had been proposed within the Caldicott 2 Review Report, Members remained of the view that NHS Number was an administrative identifier and only because of the controls in place within an ASH (such as no access to PDS) did it fall within the new definition of 'de-identified data for limited access'. However, Members emphasised that as NHS Number was still present then the ASH could only process the information for the purposes specified within the application.

Members noted that a dataset could only be considered to be fully anonymised where NHS number was not present therefore clarity was sought on whether the ASH could disclose the NHS number onwards to a third party. NHS England confirmed that NHS number could not be shared with third parties, unless it was to the relevant GP for the purposes of direct care. Members were also informed that risk stratification activity would fall outside of the purposes and NHS England would be imminently issuing guidance on this aspect. Questions were also raised on whether an ASH could outsource this activity under this support and the HSCIC confirmed that this would be restricted by contract.

Members sought clarity why pseudonymised NHS number could not be utilised as this was an established process for certain activities and would provide a clear level of additional security; it was confirmed that this would be part of the end state objectives.

Comments were made by the ICO representative that there should be a robust approach to the development of ASHs, and there should be a clear line drawn where standards were considered to be unacceptable. It was noted that preventing an ASH from operating could potentially jeopardise patient care, although details were not specified, however the general comment was that there would need to be a clear directive on the standards to be maintained by ASHs and suitable measures in place to rapidly rectify any failings within these standards, so as not to discredit the whole accreditation process.

In particular, Members were concerned that the primary use of 'section 251 support' as currently stated, was to protect the role of the HSCIC and it was unanimously agreed that this was not an appropriate use of the Regulations and other more appropriate mechanisms must be put into place to manage that specific risk. Members also reiterated that as long as disclosure is being legitimised under the basis of this support (the HSCIC to ASHs), information could only be used

in the form disclosed for the specified application purposes. Members also emphasised that there needed to be absolute clarity that disclosures from ASH's to third parties could only be for the purposes specified within the Regulations and should be anonymised. There might be instances where the received information might be transformed within the ASH so that it became no longer identifiable. If the information was genuinely anonymised then it could be used for additional purposes currently outside the scope of the approval.

b. Roadmap Plan

A summary plan with milestones was discussed; Members strongly welcomed this and appreciated the amount of work that was taking place. Clarification was sought on the 'end state' and it was confirmed this would involve the collection of information via the care.data mechanism.

Members sought clarification on whether the end state would continue to involve the disclosure of information to ASH's and whether this aspect would not require section 251 support as they would be accessing 'de-identified data for limited access'. Members noted that there should be absolute clarity on what information flows from the HSCIC and outside of ASHs while section 251 support was in place, in line with commitments to openness and transparency. Each organisation should make available a high-level list of the content of the datasets involved in data flows as a matter of course and as recommended within the Caldicott Report.

Members queried whether ASHs would be carrying out other types of activities as the Caldicott 2 review report talked about other organisations becoming 'safe havens', however, there was no information on the standards that would be met by these other organisations. It was confirmed that, at present, accredited ASHs were being developed to support commissioning purposes and the 'safe havens' referred to within the Caldicott report did not reflect the current definitions of ASHs.

Members discussed the role of section 251 and noted that the intent was for new Regulations that would regulate the use of information, not permit the flow of information as was the current state. It was noted that responsibility for advising the SofS on new Regulations fell to the Care Quality Commission (CQC) via its National Information Governance Committee, and the HRA were seeking to make contact with the CQC.

c. Progress on developing fair processing mechanisms and right of opt-out

A brief update was provided and it was confirmed that the provision of fair processing information would be utilising the approach taken via 'care.data' as the vehicle for dissemination of information and patient right of opt-out to aid in consistency.

It was understood that the applicants were seeking to utilise the mechanism of care.data as the vehicle to publish information about the activity. However, Members were clear that care.data involved an inbound flow of data to the HSCIC that was mandated under the Health and Social Care Act 2012. This application considered by CAG related to the stage after this, and to the flow of information from the HSCIC to Accredited Safe Havens for commissioning purposes. The pragmatic approach being taken was understood, however Members emphasised that the patient information on fair processing should therefore make clear what is covered. The ICO representative noted that if utilising the care.data publicity as the mechanism, it would be essential that such information must be completely accurate and transparent; it was strongly advised that advice should be sought from the ICO on this aspect.

Members discussed how patient objections would be managed and asked for consideration on the following aspects: should an objection be raised, what was the nature of the objection that would be recorded and what implications would this have for those operating under the support of these Regulations, therefore the terms of the fair processing would become particularly important? How would the situation be handled if the patient dissented, but only in relation to a specific purpose? Members requested responses to this at the same time an update was provided on the privacy impact assessment.

d. Update on Privacy Impact Assessment (PIA)

The importance of carrying out an impact assessment in line with guidance issued by the ICO had originally been indicated in the outcome arising from the 14 March 2013 meeting and in the previous SofS approval letter dated 16 May 2013. Members, while sympathetic to the undeniable time pressures, were disappointed and concerned to note that this had not progressed as expected and therefore requested that urgent liaison take place with the Information Commissioner's Office. It was advised that this PIA should be completed by end July 2013 at the very latest, therefore Members requested that an agreed position should be in place in liaison with the ICO and this must be completed to enable it to be reported against at the August CAG meeting. It was reminded that this was a fundamental aspect of the conditions of support and considering the time passed since the requirement was highlighted, should be progressed to ensure this timescale was achieved.

e. Toolkit improvement plans

The CAG thanked the applicants for provision of these documents.

In conclusion, the CAG was grateful to receive this update and welcomed further opportunities to work with the applicants. The report was generally considered to be satisfactory, noting that there was a clear need to quickly manage the data protection aspects and to clarify how the right of patient opt-out will be managed. CAG also reiterated its enthusiasm for receiving the outputs from the Programme Board and would welcome a copy of these at the October CAG meeting. Finally, CAG reiterated its appreciation for the applicant attendance and looked forward to a continuing positive working relationship in future.

3a. NHS England – potential request: risk stratification

Members were informed that the applicants had contacted the advice team prior to issue of the papers to inform them that this potential request had been withdrawn as the intent was for NHS England to produce guidance on how risk stratification could be carried out without resorting to support under the Regulations.

4. HEALTH AND SOCIAL CARE INFORMATION CENTRE CODE OF PRACTICE

Ms Clare Sanderson delivered a presentation to update the Group on the Health and Social Care Information Centre's Code of Practice for Confidential Information. It was indicated that the first part of the Code would be published shortly once approvals had been received from the SofS and NHS England, and part 2 covering the principles in practice would be published at a later date.

5. HRA INDUCTION

This item was considered on 14 June 2013.

6. ANY OTHER BUSINESS

There was no other business to transact and the meeting came to a close.