NHS
Health Research Authority

Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group

4 October 2013 at 9 am at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Kambiz Boomla	
Dr Tony Calland	
Mr Paul Charlton	Lay
Ms Madeleine Colvin	
Dr Tricia Cresswell (vice-chair)	
Professor Julia Hippisley-Cox	
Mr Anthony Kane	Lay
Ms Clare Sanderson	
Dr Murat Soncul	
Mr C. Marc Taylor	
Ms Gillian Wells	Lay
Dr Christopher 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 – Data protection (Information Commissioner's Office)
Ms. Rebecca Stanbrook	Director of Confidential Advice – section 251
Ms Christine Outram	Director of Intelligence and Strategy, NHS England (items 3-4)
Ms Ming Tang	Director of Data and Information Systems, NHS England (items 3-4)
Mr Hayden Thomas	Strategic Information Governance Senior Subject Matter Expert, NHS England (items 3-4)

1. INTRODUCTION, APOLOGIES FOR ABSENCE AND DECLARATIONS OF INTEREST

Apologies were received from Dr Charlotte Augst, Dr Robert Carr, Dr Patrick Coyle, and Professor Jennifer Kurinczuk.

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.

Professor Julia Hippisley-Cox declared a competing interest in item 4 as a director of ClinRisk Limited who provided one of the risk prediction software tools referred to in the application. She attended to provide expert advice to Members on the capabilities of the software, and highlight related issues, but did not participate in the advice given by the CAG for this item.

2. MEETING THE FAIR PROCESSING REQUIREMENTS OF THE DATA PROTECTION ACT

Mr David Evans gave a presentation on privacy notices and fair processing in the context of the Data Protection Act 1998. Key points included how to communicate information about processing of data effectively, for example by using a layered approach and the need to consider a variety of methods to deliver information to different audiences.

It was noted that the Health and Social Care Information Centre was planning the establishment of an online portal which would include information relating to different national uses of patient confidential data without consent, for example national audits. The Group agreed that this would be a useful resource, noting that a collaborative approach would be beneficial, and queried when this might be available. It was agreed that Ms Clare Sanderson should present at the next available CAG meeting in relation to plans for establishment.

Members discussed that for longitudinal studies it was particularly important that fair processing information was provided in relation to additional uses of data and that patients were informed where this additional data would be located.

Action: Clare Sanderson to provide presentation in relation to establishment of patient information portal at next available CAG meeting

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

This report was provided in accordance with the conditional approval provided to this activity in May 2013 and covered the areas of the predicted 'end state', ASH status and progression, the handling of fair processing and right of patient objection. A request to extend the duration of the current approval was also requested, and this request was supported by the attendance of Ms Chris Outram, Ms Ming Tang, Mr Hayden Thomas and Ms Clare Sanderson.

The CAG welcomed the opportunity to discuss the report and subsequent applications; acknowledged this was a complex, difficult and challenging activity, and appreciated the continued discussions with the applicants.

<u>Duration extension and 'end state'</u>

CAG recommendation: continuation of support for a further 12 month period until end October 2014, with a report on progress to be provided at 6 months (April 2014); the April 2014 report should set out the anticipated milestones at 3 month intervals to show intended steps towards the 'end state'.

It was anticipated that these milestones should provide accurate progression on the steps to be taken to enable support under Regulation 5 to no longer be required to a defined timescale.

Members understood this to be a complex and challenging activity and were sympathetic to the issues raised by the applicant. CAG also recognised that there had been a number of broader issues impacting on progression. It was noted that there were written discrepancies in the proposed amount of time for which extended support was requested, although verbal discussion indicated that a realistic proposition was that support would be necessary until March 2015. It was explained that the duration of the approval would enable a managed change process as experience had demonstrated that the initial timescales had been ambitious and involved a number of new bodies, emerging organisations and policy aspects that needed to be coordinated, aligned and implications managed. This context provided that the process of managed change would require more time than originally anticipated.

Members were clear that the changes involved faced in this process were significant and agreed there needed to be a realistic timescale. Members noted that the changes required could not be driven solely by the applicant, and would require support from the Department of Health and other national bodies working collaboratively in order to deliver the intended outcomes to the predicted timescale. Based upon the attendance discussion and report, it was advised that support would be recommended for a period of 12 months, with a review report to be submitted at 6 months containing a plan setting out 3 month interval milestones to enable support to no longer be required in line with the predicted timescale.

<u>October update report</u>

CAG recommendation: the report to be considered as satisfactory, subject to provision of outstanding responses by end October 2013.

a. ASH status

Members noted that support had been provided in May 2013 to enable business critical activities to continue, and were surprised to note that information had not yet flowed under the existing support. It was clarified that the relevant organisations had taken some time to achieve stage 1 of the ASH accreditation status. It was confirmed that it was likely that the majority of CCGs would not require support and that reliance was being placed on CSUs to achieve ASH status.

It was also clear that the 'exit strategy' of ASH establishment (where one identifier was used in a controlled environment such as to render it 'de-identified') was critical to moving away from this support and that it would be essential to have this concept established and implemented as soon as possible. Members queried whether the ASH solution was a realistic approach to managing the exit strategy and emphasised how important it was for this issue to be urgently clarified as it was cited as a key reason for delays to moving away from the existing support to utilising 'weakly pseudonymised' data. Members queried whether there were clear milestones for ASH establishment to ensure that this concept would be developed to enable the existing support to no longer be necessary; clear progress on ASH status and implementation should be provided at the 6 month reporting stage.

b. Fair processing and patient objection

Members were updated that the intention was for GPs to ideally develop their own fair processing information and this was being progressed in conjunction with the Information Commissioner's Office. There was also the intent to develop a layered approach to provision of fair processing materials.

Members noted that they had previously fed back comments over fair processing in the letter dated 27 August 2013 that had not been responded to and requested, in light of the request for extended support duration, that a response be provided as it could potentially impact on the fair processing plans. CAG also offered, if thought of value, to comment on any future patient leaflets. The outstanding question was that there was currently no fair processing information provided around the

scope of this existing approval, and it was essential that suitable information be made available to interested patients.

c. Additional points

In noting the scope of the change process, Members queried whether there was sufficient resource and experience to manage and support the activity in moving towards the end state. It was noted that there had been constraints although steps had been taken to mitigate against this via further recruitment and via an IG Task Force; Members noted that much of the delivery would depend on ensuring there was sufficient resource with the appropriate expertise.

Members also sought clarity on how long information would be retained and requested that the questions set out in the letter dated 27 August 2013 be responded to as soon as possible.

In line with the comments above and applicant discussion, CAG agreed to recommend that the report be accepted as satisfactory at this current time, and recommended continuing support for CAG 2-03 (a)/2013 for a period of 12 months to enable progressive movement towards the end state.

CAG recommended that this should be subject to provision of a response to how fair processing plans would incorporate the scope of the existing approval, to be submitted by the end of October 2013; provision of a response to how retention would be managed in line with the queries previously provided, to be submitted by the end of October 2013; and provision of a report in 6 months' time (April 2014) to show progress towards the end state, including forthcoming 3 month interval milestones to enable support to no longer be required in line with predicted timescale. The applicants should engage with the Confidentiality Advice Team to identify timescales and detailed content.

4. NHS England: Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs [CAG 7-04 (a)/2013]

This non-research application from NHS England sought support for the activity of risk stratification to be used by clinical commissioners to target vulnerable patient groups and offer them appropriate services. The aim of risk stratification was to reduce hospital readmissions and target clinical interventions to high risk patients. A recommendation for class 1, 4, 5 and 6 support was requested to support the disclosure of commissioning data sets (ref CAG 2-03 (a)/2013) from the Health and Social Care Information Centre (HSCIC) and GP data from GP systems to data processors working under the instruction of GPs as data controllers; to support disclosure of patient confidential data to enable the indirect care element of risk stratification, namely for the preliminary processing to combine and process primary care and secondary care data and select target populations; and to provide protection to the HSCIC to legitimise the onward transfer. Access was requested to commissioning data sets approved under CAG 2-03(a)/2013 including NHS number, local hospital number, date of birth, postcode, gender and ethnicity, and to GP data including patient data, event data, referral data, prescriptions, conditions / diagnosis groups, health groups, interventions group, exclusions group, and practice data (practice ID and registered patient list).

Following a sub-group meeting that had taken place on 01 September 2013, responses to queries and additional information was provided to Members. Provision of this information was welcomed, however due to the volume and noting this was received shortly before the CAG consideration of the application, Members did not have sufficient time to review this additional information.

<u>Scope</u>

The scope of the application was intended to cover all data processors working on behalf of GPs and support was requested to enable a transitional interim phase to enable those affected to work towards publicly available guidance on risk stratification. Members appreciated the importance of this activity however generally found this to be a broad-ranging application with a lack of specificity on the parties to whom data would be transferred; whereas an element of specificity was normally required to enable the Group to provide a recommendation within the framework of the Regulation.

It appeared to CAG that support was requested to cover the multiplicity of existing (current) and potential providers although the extent and justification of any gap between actual practice (reliant upon PCD) and best practice (reliant upon de-identified or pseudonymised data only) was highly variant and so refinement and articulation of this position was requested. This was considered particularly relevant as the fact that some providers could follow best practice meant by implication that there was a practicable alternative to seeking support.

The practical issues around providers were discussed and Members requested that the applicant should fully account for the lack of practical alternative in relation to specific **existing providers** and describe the tailored exit strategies. It was recognised that this information might be effectively, and perhaps efficiently, described in relation to *types* of issue currently faced by existing providers and might draw upon the information already provided under section (o) of the application form but with named providers clustered accordingly and associated with particular issues and exit strategy. In short, Members requested a specific response to the question whether the bodies that would be operating under support had an alternative practicable alternative available to them.

It was clear that the application was intended to extend to parties unknown at this time. It was unclear to Members why **new providers** should not be following best practice in line with the overall strategic direction, otherwise there would be conflict with the detail of the overarching NHS England application (CAG 2-03 (a)/2013). Following applicant discussion and in line with the managed change process and overall strategic direction, members noted that it was unlikely that support would be recommended for **new providers**; as these should commence and adhere to best practice.

Data items

Members queried the scope of the dataset in line with the issues raised in the sub-group meeting. Points were made that this involved a significantly larger dataset than the 'care.data' dataset extraction via GPES currently undergoing scrutiny.

There was detailed discussion over refinement of the dataset, the different tools in operation and feasibility of establishing a positive list of data items adequate to the requirements of existing tools; it was noted that data requirements were often due to how these tools were configured but Members considered it preferable to have a controlled list of data items that might need to be disclosed for the purposes of risk stratification rather than a list of exclusions. Members suggested that, providing there was a clearly defined dataset that could be justified relative to the purpose of risk stratification, then a recommendation of support could potentially be made on a temporary basis to enable **existing providers** to work towards the strategic aims of a pseudonymised dataset. Comments had previously been raised around excluded items and responses provided that should be reintegrated into the revised submission.

In summary, CAG concluded that due to a need for greater specificity on scope, reflection of practical issues around providers and refinement of the dataset, the application could not receive a positive recommendation for support in its current iteration. However, Members recognised the importance of the activity and advised that a resubmission should be made. Due to the urgency of the issue it was agreed that subsequent review of the application form would take place outside of the formal meeting schedule for this particular instance. Members would require a minimum of 5 working days' notice to enable arrangements to be made for further review of the documentation so a fixed written deadline for submission to the CAG office should be provided as soon as possible.

CAG resubmission advice

In terms of resubmission, Members advised the following:

a. Integration of previous queries and recent responses within the main application form

b. A clear separation of current and future activities within the application

c. Any **new providers** should be following best practice in line with the overarching existing 'section 251' approval so the application should focus on **existing providers** and remove elements now outside of the scope

d. A specific list of existing providers, the data items required overall and any obstacles to the solutions not utilising PCD

e. Detail that there was no other practicable alternative for each of the different options (e.g. full PCD / closed system/controlled environment/fully pseudonymised)

f. Any support was likely to be for a period not extending past 12 months to enable the managed change process to be implemented.

5. Public Health England – annual review of novated applications [ECC 7-04 (a) /2012]

Members discussed the paper provided by PHE and were sympathetic to the instabilities caused by the transition of disparate organisations into one. It was noted that the report provided an interim status update for the 2013/14 transition year and that PHE would provide CAG with a fuller annual update for each of the novated s251s at an agreed date.

It was noted that the expected IG toolkit was due to be submitted on the day of CAG consideration of the review; members noted the timing and agreed that the recommendation for continued support would be contingent upon satisfactory security assurance arrangements, in line with the agreed requirement set out in correspondence from December 2012.

As a whole, members generally agreed to accept the interim report and agreed that the reporting cycle should be on the May of each year to allow integration of the security assurance requirement at time of CAG review. However, when producing the annual report (cycle commencing May 2014), members advised the following:

- In line with the Transparency agenda there should be publication of datasets held by PHE so progression on this aspect would be anticipated.
- There should be suitable fair processing information to cover the various activities and this should be reported against each specific novated application, particularly in relation to what had been undertaken to improve/establish this requirement.
- Noting that CAG has no remit for the operation of Regulation 3 (aside from 3(4)) members emphasised that it may be prudent to ensure that the mechanisms being put in place to manage Regulation 2 and 5 activities should be reflected within the processes for activities carried out under Regulation 3 to ensure consistency.
- Members queried the extent of patient and public involvement in these activities, and requested details on the mechanism for opt-out and whether any complaints had been received regarding the processing of patient data under this support. This is in line with typical annual review requirements
- Members also noted that there had been no assessment of the need to continue processing PCD and that it was a requirement of the Regulations for this assessment to take place.
- Members advised that in future the expectation would be for a specific and detailed review of each application against the Regulation 7 requirements in line with all other applications. It was indicated that this requirement had already been previously raised with PHE at the pre-advice stage therefore the CAG supported this and noted that, in future, the review must provide a detailed assessment against Regulation 7.
- Members also noted that the support for activities carried out under Regulation 2 related solely to the inbound receipt of data

6. NEW APPLICATIONS – Research

6a. Investigating the accuracy of current estimates of self-harm [CAG 7-06(a)/2013]

This research application from the University of Bristol set out the purpose of a study to carry out data linkage of ALSPAC and Hospital Episode Statistics (HES) data in order to enhance understanding in relation to the accuracy of current estimates of self-reported self-harm in the community and the long term risk of hospital admission for self-harm. It was intended that the findings would have potential value for health policy by raising awareness about the importance of self-harm and would lead to greater prioritisation of preventative measures. A recommendation for class 1, 4 and 6 support was requested in order to access HES data in relation to self-harm episodes of non-responders. Access was requested to NHS number, date of birth and district level postcode.

Public interest

Members agreed that the application had demonstrated a significant public benefit and that self-harm was an important and under recognised issue and were of the view that further information in relation to this issue would help define policy decisions.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members noted that the request was to access data in relation to the whole enrolled ALSPAC cohort in order to avoid bias caused by high levels of non-response within certain demographics and misreporting of incidences by patients themselves which might cause prevalence estimates to be affected.

- Use of anonymised/pseudonymised data

Identifiable data was requested in order to carry out data linkages only and anonymised data would be provided to researchers.

Retention of study data

Members advised that data for this particular study should only be retained for the duration of the study and requested confirmation that the data would be removed from the main ALSPAC dataset once the study was complete.

Requirements of the Data Protection Act 1998

It was a requirement of the Regulations that an application could not be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA required that reasonable efforts should be made to inform data subjects of the use of their data. Members advised that further information in relation to this specific study should be made available to the cohort and requested confirmation of how this would be achieved.

Patient involvement

It was noted that consultation with the Teenage Advisory Panel had suggested that there were no concerns regarding the proposed use of data.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending conditional support to the Health Research Authority, subject to confirmation that data would be retained for the purposes of this study only and not for the entire duration of the ALSPAC project, and that fair processing information would be provided including details of the processing of data in relation to self-harm, in line with the requirements of the DPA.

6b. Understanding decision making for children with high risk brain tumours: A prospective, longitudinal study of parents, children and clinicians to provide guidance for clinical consultations [CAG 7-06(b)/2013]

This research application from University College London set out the purpose of a project to explore decision making amongst clinicians, parents and children regarding care and treatment for children with high risk brain tumours. The study aimed to allow the production of guidance to be used by health care professionals, parents and children. A recommendation for class 1, 3 and 6 support was requested in order for a researcher to attend a multidisciplinary neuro-oncology meeting held weekly at the study site and identify eligible participants. The researcher would record name, gender, age diagnosis, planned investigations and their results. The researcher would then be present for the first clinical consultation with the family in order to seek consent. Access was requested to name and date of birth.

Public interest

Members agreed that they were supportive of the application in principle and agreed that there was a significant public benefit in the study outcomes.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

Attendance at multi-disciplinary team meetings

Members noted the intention to obtain consent for the majority of the study. However, in order to identify the cohort it would be necessary for a researcher to attend multi-disciplinary team meetings and record information about patients who would be eligible for the study. The researcher would then attend the first clinical consultation where diagnoses would be discussed. Members agreed that the attendance at multi-disciplinary team meetings would be necessary in order to identify patients and were supportive of this aspect.

Attendance at first clinician appointment

Members raised some concerns about the on-going disclosure following attendance at the multi-disciplinary team meeting and in particular the proposed attendance at the first clinical consultation. It was agreed that the applicant should carry out additional steps to ensure that parents (and where appropriate patients) were aware that there may be a researcher in attendance prior to attending the appointment. This would ensure that there was sufficient time to register an objection if preferred. It was agreed that if parents were sufficiently informed, support under the Regulations would not be required for this stage of the process.

Members suggested that awareness could be raised via a carefully worded information sheet about the research project being included with the details of the appointment when the latter were given to the patient, and an information sheet being displayed at reception when the parent and child attended for their first appointment to meet the clinician, discuss symptoms and arrange tests.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met in relation to attendance at multi-disciplinary team meetings, and therefore advised recommending support to the Health Research Authority, subject to making efforts to raise awareness of the study prior to attendance at the first clinical consultation to ensure that objections could be registered. It was reiterated that as long as this was undertaken, support would not be required with respect to the researcher attending the first clinical consultation.

6d. Reasons for Non-Participation in Physical Activity Interventions [CAG 7-06(d)/2013]

This research application from the University of Cambridge detailed a study to determine the reasons that non-responders to a preceding trial gave for turning down the opportunity to take part. A 'profiling' study would be conducted alongside these interviews and would involve analysis of non-responders data from GP practices. A recommendation for class 1, 2 and 6 support was requested to cover access to data relating to non-responders, including unit-level postcode. Access was requested to postcode.

Retention of identifiable data

Members queried whether the applicant could carry out the conversion of postcode to SES within the GP practice and there would then be no requirement to extract identifiable data from GP practice sites. Members asked that the applicant explore this option in detail. If this option was not feasible, Members advised that the postcode data should be deleted as soon as possible following conversion and that the retention period should be agreed with the GP practices and confirmation of deletion should be provided to the GP.

Patient information materials

It was a requirement of the Regulations that an application could not be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA required that reasonable efforts were made to inform data subjects of the use of their data.

Members commented that the patient information materials should be clear that researchers would have access to basic data in relation to the cohort if no response was received to the invitation to interview. The Information Commissioner's Office representative provided further advice and recommended that the applicant ensure that the materials were explicit in terms of detailing the processing of data, outlining what consent was being sought for and what researchers would have access to in relation to those who did not respond. This would allow patients to make an informed choice regarding whether they would need to object to the processing. The ICO representative, Mr David Evans, advised that the applicant contact him directly to discuss the fair processing aspects of the application.

In addition, Members noted that the entire eligible cohort would not be written to with information about the study and therefore advised that the applicant should make patient information available within GP practices so that people were made aware of the processing of data.

Registering objections

Members advised that it should be ensured that opting out was as easy as opting in to the study and therefore a cost free alternative to allow opt out should be provided to patients.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Health Research Authority, subject to clarification whether it would be possible to access data on GP surgery sites in order to carry out

conversion to SES, and confirmation that revised patient information materials would be provided at GP surgeries in line with the fair processing requirements of the Data Protection Act 1998.

6e. EpiHealth Outcomes Project – The effect of maternal age, embryo cryopreservation and culture on perinatal outcomes and child health: Scottish Data Linkage Study [CAG 7-06(e)/2013]

This research application was processed in line with a memorandum of understanding developed between the Human Fertilisation and Embryology Authority (HFEA) and the Health Research Authority's Confidentiality Advisory Group. It had been agreed that the HFEA would delegate the assessment of all applications with a medical purpose under the Human Fertilisation and Embryology Act 1990 to the Confidentiality Advisory Group (CAG). Under this delegated authority, CAG would consider and recommend to the HFEA whether to grant or refuse permission to use identifiable register information (or to impose conditions upon its use). As data controller of the register, the HFEA would take a final decision based upon this recommendation, and then if disclosure was permitted would work with the applicant to enable use of the dataset.

This research application from Central Manchester University Hospitals NHS Foundation Trust set out the purpose of a study aiming to assess the role of parental ages, IVF treatment method, in-vitro culture and embryo freezing on neonatal health and subsequent growth in IVF-conceived babies, adjusting for known confounders. A recommendation for support was requested to cover access to the Human Fertility and Embryology Authority (HFEA) Research Register by Informatics Services Division in Scotland who would undertake linkage to health information routinely held by NHS Scotland and provide a de-identified extract to the applicant. Access was requested to name, NHS number, hospital number, date of birth and sector level postcode from the HFEA register.

Members agreed that the application demonstrated a significant public benefit and were supportive of the study in principle.

Data Protection Act requirements

It was a requirement of the Data Protection Act 1998 that reasonable efforts should be made to inform individuals of the processing of their personal data. With this in mind, Members advised that the applicant make information in relation to the specific study available on the HFEA and/or applicant website.

Security of data flows

As the applicant was not seeking to link research register data to any data sources that fell within the remit of the Health Services (Control of Patient Information) Regulations 2002, there had not been a review of the security aspects. However, it was noted that the requested data was very sensitive and Members recommended that the HFEA take steps to ensure appropriate security measures to manage the data flows that were in place prior to disclosure.

Patient involvement

Members agreed that further patient involvement should be undertaken as part of the study and requested that the applicant consider additional ways to engage with the patient population.

CAG advice conclusion

Members agreed to advise the HFEA that permission to access the research register for the stated medical purposes should be granted, subject to provision of fair processing information in relation to the specific study on relevant websites and further patient involvement being undertaken.

6f. Small area geodemographic profiling of health needs [CAG 7-06(f)/2013]

This research application from University College London set out the purpose of an application for a PhD project which aimed to build on a previous study that used extracts from Hospital Episode Statistics (HES) data to assess health needs based on small area information in relation to the location of service providers. The current study aimed to assess local health needs more comprehensively by means of population profiling. A recommendation for class 1, 4 and 6 support was requested to cover access to patient surnames to apply a classification tool. The Health and Social Care Information Centre (HSCIC) would link HES data to Personal Demographics Service (PDS) data and provide surname data only to the applicant. The applicant would then apply the classification tool on the dataset and provide the resultant lookup table including a unique ID and classification to the HSCIC, to enable the HSCIC to provide the applicant with an HES data extract linked to the classification data. Access was requested to name and postcode.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The large number of patients included within the requested dataset was noted and it was agreed that consent would not be feasible in this instance.

- Use of anonymised/pseudonymised data

Members noted that the gridlink, rather than postcode, would be sufficient but would only be available from 2002/2003. Full name would be required to apply the ONOMAP software.

- HSCIC carrying out analysis

Members noted that the size of the dataset requested was particularly extensive and that the applicant had been in correspondence with the HSCIC regarding reducing the identifiability and extent of the requested data. Members queried whether the applicant had explored whether it would be feasible for a member of HSCIC staff to apply the ONOMAP software and the costs involved in this. Members were of the view that the researcher could then supervise the analysis without accessing identifiable data. If this proved not to be feasible, Members queried whether the applicant had considered if it would be possible to undertake analysis at the HSCIC. This was viewed as a positive alternative to extracting a large and identifiable version of the HES dataset.

CAG advice conclusion

Members agreed that if the above alternatives to extracting a copy of the HES dataset proved not to be feasible, any further submission should include confirmation that the HSCIC were content to allow a copy of the HES dataset to be provided.

The CAG requested that the applicant carry out further exploration into the options outlined above.

7. ANY OTHER BUSINESS

7a. Invoice Validation supporting the provision of healthcare to supplement data used within application CAG 2-03(a)/2013 "Application for transfer of data from the Health and Social Care Information Centre (HSCIC) to commissioning organisation Accredited Safe Havens (ASH) [CAG 7-07(a)/2013]

This item was considered at the same time as the other NHS England applications, however due to legal advice it had been unclear at time of submission whether the CAG had remit to review the application. It had also been noted that the application did not clearly reflect the agreements and discussions that had subsequently taken place following submission, therefore members discussed the anticipated content with the attendees in order to aid the accurate revision of documentation.

This non-research application from NHS England sought support to enable the correct commissioner to be identified to enable payment for treatment. This was requested as an interim measure and would form a part of NHS England's managed change process.

Legal advice

Members noted that they had sought legal advice from the Department of Health Legal Services on whether the activity of invoice validation could fall within the scope of Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002. Advice was received on 12 September 2013 that indicated there was potentially another legal basis under which the activity could take place which meant that the application should be withdrawn from consideration as there appeared to be a reasonably practicable alternative to seeking support. Subsequent communications indicated this position required further clarification so CAG agreed with the applicants to provisionally retain the application on its agenda. Further legal advice was received on 3 October 2013 via Mr Phil Walker that indicated that Regulation 5 could support invoice checking.

Members indicated that it was unfortunate that the legal advice had not been as comprehensive as hoped and that this impacted on the considerations of the Group. In summary the issues were:

1. Could Regulation 5 support the activity of invoice checking? (Affirmative answer received)

2. Whether there was an alternative legal basis to support this activity rather than reliance upon Regulation 5 ('practicable alternative') as indicated in the original legal advice provided to CAG (clarification still awaited)

3. Whether the intended data flows were permissible under the Data Protection Act 1998. The legal advice received on 3 October 2013 indicated that Legal Services would address this separately however CAG had not yet received advice on this question, which was fundamental to CAG recommendations. (clarification still awaited)

These unaddressed questions, particularly the second and third, led the CAG to conclude that they could not provide a clear recommendation to the approving body. It was agreed that these questions would be escalated to the approving body in order to obtain clarification.

Application detail

Members were mindful that the legal advice and implications had generated a number of discussions with various parties, and this position was evolving at the time the application was considered. It was acknowledged that the application detail did not reflect all of the intended parties to whom data would flow and required further clarity over the precise scope for which support was sought. Members also queried for how long the information was intended to be retained to achieve the stated purpose and requested clear detail on how those processing the data would be expected to handle and remove the information. Members also requested further detail around the exit strategy from the proposed support.

As the details were not fully articulated Members were unable to carry out a detailed review, although the verbal discussion helped provide clarity. Members were sympathetic to this situation following discussion with the applicants, were supportive of commissioners being enabled to deliver their core functions and appreciated the urgency of this situation being quickly and appropriately resolved.

CAG advice conclusion

CAG agreed that while they were supportive in principle, the application form and outstanding legal advice meant that CAG was unable to advise whether the minimum criteria under the Regulations had been met. It was agreed that the CAG would recommend deferral while two key actions took place to allow a recommendation to be provided to the approving body:

1. Complete revision of the application form to explicitly cover the bodies for whom data was intended to flow and the data flows; explicit refinement of the overall scope, retention period/arrangements and exit strategy with timescales.

2. Resolution of all of the legal advice aspects raised as indicated above.

Due to the urgency of the issue it was agreed that subsequent review of the application would take place outside of the formal meeting schedule for this particular instance. Members would require a minimum of 5 working days' notice to enable arrangements to be made for further review of the documentation so a fixed written deadline for submission to the CAG office should be provided as soon as possible.

CAG were mindful that further external guidance on invoice validation was imminently expected by NHS England, however emphasised that due to the timing the applicants must mitigate against any risk of issuing guidance if the application had not received approval, and to avoid any issues of inaccurate guidance being provided. It was also noted that as this application was linked to CAG 2-03 (a)/2013, all those receiving data under this support should ensure they were operating to the agreed level of security assurance.

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