NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group
19 April 2013 at 9:30am at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Tricia Cresswell (Vice-Chair)	
Dr Charlotte Augst	
Dr Tony Calland	
Dr Robert Carr	
Mr Paul Charlton	Lay
Dr Patrick Coyle	
Professor Julia Hippisley-Cox	
Mr Anthony Kane	Lay
Professor Jennifer Kurinczuk	
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, ICO
Mr Martin Frowd	Senior Business Support Officer
Ms Rebecca Stanbrook	Director of Confidential Advice – section 251
Mr Peter Hall (items 2-3)	Deputy Director of Information and Transparency, Department of Health
Ms Ming Tang (item 3)	Director of Data and Information Systems, NHS England
Ms Karen Thomson (item 3)	Information Governance Lead, NHS England
Mr Phil Walker (item 3)	Head of Information Governance Policy, Department of Health

1. INTRODUCTION, APOLOGIES FOR ABSENCE AND DECLARATIONS OF INTEREST

Apologies were received from Dr Kambiz Boomla and Ms Madeleine Colvin.

The following interests were declared:

- Ms Clare Sanderson declared a conflicting interest in item 3 as she had helped NHS England, the applicant, prepare the application. She attended for part of this item in the capacity of an adviser to the applicant rather than that of a CAG Member, but left the room all together with the other representatives of the applicant for the remainder of the duration of the discussion.
- Professor Jennifer Kurinczuk declared a conflicting interest in item 4a (as the applicant) and item 4b (as a member of the programme board) and left the room for the duration of both discussions.
- Dr Robert Carr declared a conflicting interest in item 4b as his wife was potentially involved with the application and left the room for the duration of the discussion.
- Professor Julia Hippisley-Cox declared a conflicting interest in item 5a as she was employed by the same department as a named applicant, and left the room for the duration of the discussion.
- Dr Mark Taylor declared a competing interest in item 5b as he was employed by the same organisation as the applicant. He remained in the room but relinquished the Chair to Dr Tricia Cresswell for the duration of the discussion.

2. MANAGING NON-RESPONSE TO REQUESTS FOR CONSENT

The Chair and Mr David Evans presented an issue which had recently been identified following the consideration of a large birth cohort application. The issue posed difficulties when seeking to ensure that two requirements of the Regulations were met; demonstrating both the feasibility of consent and DPA compliance.

Historically, applications for support under the Regulations could evidence that consent was not feasible by attempting to seek consent and demonstrating a low response rate. However, the ICO position was that consent should not be requested in the first instance, if another schedule 3 condition was then to be relied on, such as a medical purpose, in the case of non-response. Therefore, in cases where consent had been sought, an application could not subsequently be made under the Regulations to access data on non-responders, as a schedule 3 condition would not be available.

It was noted that the issue was likely to affect future applications which sought to demonstrate that consent was not possible and advice given to applicants regarding seeking consent. Members were asked to consider how they would advise applicants to evidence that consent would not be feasible considering the potential conflict.

When planning a particular study or other kind of project, Members recognised that the choice of method of data collection was clearly crucial to design. It was extremely important during the design stage that the possibility of non-response to an invitation to consent to participation was considered. Members advised that this was particularly important if there was any possibility that an investigator might wish to apply for permission to access confidential patient information without consent under the Regulations. This was, in large part, because of the legal interplay between the Regulations and the Data Protection Act 1998.

A potential applicant for support should therefore be encouraged to investigate the possibility and potential impact of non-response before seeking explicit consent to participation. If there were compelling reasons to suspect that the level and nature of non-response would undermine the scientific integrity of the project, then an application for support should be considered before explicit consent was sought. However, Members agreed that it was also important that an applicant remember that support would only available if consent was demonstrated not to be a practicable alternative.

An application for support must then include reference to the evidence upon which the applicant based his or her judgement that the possibility of non-response, of a level and nature that would compromise the project, was likely. One of the ways that such evidence could be gathered would be by piloting consent.

Members agreed that consent should be piloted and planned for new activities unless there was a good reason not to do so, examples of reasons not to seek consent were discussed and included;

1. The requirement for inclusion of all cases due to a rare condition being investigated.
2. A historic cohort was engaged and current address data may not be held.
3. The cohort was particularly large.

It was agreed that evidence that consent would not be feasible from past studies that had been undertaken would also be acceptable if relevant.

If consent proved not to be feasible and the applicant relied solely on fair processing Members agreed that the following should be considered:

1. Fair processing information would need to make very clear the right and methods to opt out of processing and dissent would need to be respected.
2. Patient involvement would become particularly important and views regarding the processing of data without consent must be sought from a subset of the population.
3. Where possible pseudonymised data only should be accessed in relation to non-responders.
4. The likelihood that the information was received by the patient would need to be considered. The applicant should provide details of how they will ensure that address data is as up to date as possible.
5. A higher level of effort would be required to ensure that the cohort were as fully informed as possible and that fair processing information was received, the applicant should demonstrate how this would be achieved.
6. The nature and extent of the data being requested would need to be considered to determine whether it would be proportionate to access data without consent.

Members discussed that non-response to a previous request for explicit consent did not automatically preclude an application if the purpose of the application was distinguishable from the purpose for which consent was previously sought. This situation would arise, for example, in the case of an existing project where there was now a possibility to pursue purposes outside the original consent. If the original consent did not cover the new purposes, and if fresh consent was not practicable, then an application under the Regulations might be appropriate to allow disclosure of additional information in relation to the original consented cohort. Whether it was appropriate to also apply to allow the disclosure of information in relation to those that did not respond originally would depend upon whether original non-response might be considered to be passive dissent to the new purposes. If the new purposes were sufficiently distinct from those originally proposed, then the effect of the Data Protection Act 1998 would not preclude an application. It was agreed

that all the usual conditions of successful applications including the fact that consent was not a practicable alternative, would continue to be in place.

Where it was demonstrably not feasible to seek consent, Members suggested that the applicant would be advised to explore a pseudonymised approach and the Health and Social Care Information Centre (HSCIC)'s Trusted Data Linkage Service could potentially be used to link datasets.

The Chair advised Members that he and the Confidentiality Advice Team would meet with the ICO in May to discuss consent the above issues further and that a draft advice paper would be circulated to Members for comment prior to that meeting

Following the meeting with the ICO, the advice paper would be finalised and circulated to Members and the ICO for comment. It was also suggested that this should be shared with the HSCIC's Data Access Advisory Group.

3. NHS ENGLAND: APPLICATION FOR TRANSFER OF DATA FROM THE HEALTH AND SOCIAL CARE INFORMATION CENTRE (HSCIC) TO COMMISSIONING ORGANISATION ACCREDITED SAFE HAVENS [CAG 2-03 (a)/2013]

The Group welcomed the attendance of Ms Ming Tang, Mr Phil Walker and Ms Karen Thomson to the meeting. Ms Clare Sanderson participated in the discussion of this application in the capacity of an adviser to the applicant, rather than as a Member of the Group, and did not participate in the consideration leading to the CAG recommendation.

Application purpose

The purpose of the application was to enable the flow of data, required to support commissioning purposes, from the HSCIC to accredited safe havens (ASHs).

Scope

It was mutually agreed at the meeting that the consideration would be restricted to the existing outbound commissioning data sets, specified in sections (i) and (m) of the application form, flowing from the HSCIC to ASHs. The rationale for this restriction was that some of the other elements involved appeared to still be in development or further detail would need to be in place, and therefore were not specific enough at this current time to meet the threshold within the Regulations.

The appendix list showing a variety of data flows was excluded from consideration on the basis they did not clearly correlate to the detail within the application form, and involved a number of broader aspects. The flow of inbound information to the HSCIC was excluded from consideration on the grounds that some of the inbound data would be legitimised via the HSCIC's own statutory powers, and there was uncertainty over the legal basis for other local data flows.

Any new data flows would be, where appropriate, the subject of a separate application to the Group.

Discussion summary

Members recommended that support should be provided for a period of six months until end October 2013, subject to a number of conditions. Due to the current uncertainty over some aspects, this should enable sufficient time for the applicants to further define and establish progress towards the 'end state'. A detailed report for consideration should be provided by

the end of this period to the October 2013 meeting of the Group to clearly identify the requirements for continuing and/or amended support, with an interim report, including a roadmap of future plans, to be provided to the June 2013 meeting.

Members welcomed the comment from the applicants that the interim 3-month approval for SUS had been critical to improving the quality of information handling practices. At this meeting, members were informed that data had not yet been transmitted to the specified Clinical Commissioning Groups (CCGs) or Commissioning Support Units (CSUs) while checks were undertaken by the applicants to ensure that the appropriate governance controls were in place. The unanimous view of the Group was that the quality of the controls would be crucial to maintaining public confidence in the development of this new commissioning system.

Previously Primary Care Trusts (PCTs) received patient identifiable information for commissioning purposes. CCGs were not direct successor bodies but were now taking forward the majority of commissioning responsibilities with some commissioning also being undertaken by NHS England Area Teams and Local Authority Public Health Teams. CSUs provide technical support to these commissioning organisations. Although it was accepted that a process of accreditation of ASHs would take some time, it was advised that data should not flow until ASHs met the agreed current minimum requirements in relation to all 'section 251' approvals. Non-NHS bodies/organisations seeking to become an ASH would not have previously received such information; therefore this would represent a new and untested data flow. The Group would expect that this category (non NHS bodies/organisations) should meet, in full, the standards for accreditation so as to minimise any potential patient concerns over data flowing to non-NHS bodies before any data flows occurred.

Reporting

Due to the evolving nature of the commissioning landscape and work needed to take place to develop it, it was agreed that the Group should have an appropriate oversight and assurance role to support the relevant changes, and this would be developed via this application. It was agreed that the proposal for the Group to maintain a Register of ASHs was not appropriate for this situation as responsibility for maintaining this and the supporting activities should reside with NHS England. It was agreed that the nature of this application and currently unanswered questions required a proportionate level of scrutiny as many of the assurance controls and approaches were evolving. The six-month approval period would allow time for the medium/long-terms positions to be clearer and a more definitive report to be presented to the Group before the end of this approval period to clarify the reduced reliance on identifiers, for the 'end state' ambition to be articulated and to identify the plan to manage this. Where some aspects were more immediately pressing, in particular the accreditation processes for ASHs, it was agreed that an interim report for consideration at the 13/14 June 2013 meeting should be provided, covering final details of the approved standards and guidance on accreditation; full details on the process of accreditation (policy, procedures, templates); details of how checks would be carried out on applications for accreditation (responsibility, desk-review, on-site); clarification on whether it would be one approach for all potential ASHs, or whether it would differ for the CSUs operating under the remit of NHS England, CCGs and non-NHS organisations; and the current status of all ASH accreditations.

Members noted that a key issue in recommending time limited approval was that the commissioning landscape was in transition, with some elements yet to be confirmed due to external constraints such as potential implications from the Caldicott Report on the end state position. Members therefore requested a clear interim roadmap in June to show how the future position would be developed between now and the expiry date of the current approval,

with a clear reference to the end state position as the uncertainty that had led to this time-limited approval should have been clarified to some extent.

It was noted that a standard condition for all approved applications was that patient right of opt-out should be respected, and a requirement under the Data Protection Act 1998 that reasonable efforts should be taken to inform the relevant population of the uses of their data. Members expected that organisations operating under this support should take all reasonable measures and opportunities to ensure that patients were aware of their rights. This could be achieved using a variety of methods including accessible information being placed on websites, targeted letters, notices in waiting rooms and advertisements in local newspapers. Members requested a progress update on this aspect in both the June and October reports and in particular, the steps taken to ensure patients were made aware of their right of opt-out as this was fundamental to maintaining public confidence in this activity. The Group also expected that any expressed patient dissent at local level would be flagged so that identifiable information was not transferred to the HSCIC, or if a subsequent dissent had been recorded after data has flowed to the HSCIC, that steps were taken to manage their right of opt-out appropriately within the HSCIC.

Members requested that the interim roadmap report should provide a month by month work-off plan on activities to be covered in the period leading up to the report to be provided for the October meeting. As well as a high level description of work to be undertaken up to the end of September, it was expected that this plan would identify opportunities to share outputs of that programme or work, including interim outputs, with the Group as relevant detail emerged. Activity to be described in the road-map and reported accordingly included planned movement away from the use of identifiers, including implementation of pseudonymisation approaches for the outbound transfer of data, for each of the commissioning purposes described in part (l) of the application; improvements in fair processing and the handling of objection by patients to the disclosure of their information for purposes of indirect care; greater clarity on the end state, including highlighting any potential challenges; and an update on public engagement activities. It was appreciated that there would be a programme board and working group and Members requested that minutes from the meetings of both these bodies should be shared with the Group.

It was agreed at the meeting, and following the advice provided via the Secretary of State on 14 March 2013, that work on privacy impact assessments would need to take place as a matter of urgency as these would be critical to demonstrating compliance with the Data Protection Act 1998. The applicant was encouraged to contact the ICO to progress these, and an update on mutually agreed outcomes, milestones and progress was requested to be included in the interim road-map report in June.

It was expected that the position should have improved by the October 2013 meeting of the Group and currently developing processes would have become more embedded and greater clarity over the future direction be available. At this meeting, it was recommended that the following be provided in a report to the Group, along with any other relevant information, to aid review of the application. The report should include:

- Assurance over the accreditation process
    - Details of the final accreditation criteria
    - List of organisations that had become ASH accredited (applying/existing/ rejected/status)
    - List of organisations that were working to become ASH accredited and current status
    - Action plans/deadlines to address any information governance and assurance development required to become an ASH

    - How the right to manage any representations of patient objection to processing would be built into the accreditation process
    - Confirmation how public involvement would be incorporated into the standards
- Privacy Impact Assessment (PIA)
    - Progress report / update on milestones as agreed with the ICO
- Roadmap plan
    - Plan in October for how progression would be made over the forthcoming six months; need for continuing support and refinements to the application in light of future developments. Appropriate headers for the plan to be further defined at the June meeting of the Group.

Members queried the proposed retention period for data. It was advised that this would be in line with NHS policy.

In line with the considerations above, the Group advised recommending *partial and conditional* support to the Secretary of State for Health. The approval should be restricted to a 6 month period, as the nature of the application meant that many aspects were not yet fully in place. Support was recommended for this time as it was expected that this would enable development of the final end state position and a plan to achieve this. The scope of the approval should be restricted to existing legitimate data flows as specified in section (i) and part of section (m) as it was expected that the excluded data flows would be brought back to Group in a separate application or another legal basis obtained. The entire list of data flows in the appendix and inbound data flows to the HSCIC should be excluded as some of the data raised particular issues that should be handled separately to this application. All potential ASHs should meet the minimum standards of assurance currently in place for the approval of 'section 251' applications, and non-NHS bodies should achieve full accreditation rather than work towards accreditation before information should flow to them as an ASH. As this would constitute a new data flow, non-NHS bodies therefore should meet full NHS standards to maintain public confidence.

4. AMENDMENTS

4a. Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP) – change to anonymisation process [ECC 5-05 (f) 2012]

This amendment request sought approval for a technical change to a specific aspect of the delivery of the MNI-CORP programme for which MBRRACE-UK was now the supplier. The change would be specific to the confidential enquiries and would cover all maternal deaths from January 2009 going forward, and the rolling programme of specific serious maternal morbidities; the topic for 2013 had been confirmed as maternal sepsis. The request sought a specific change to the anonymisation requirement in that information would be sent securely to NPEU offices and the anonymisation process would be carried out by the applicant. The intent would be to revert to the usual process once the backlog had been completed.

Members agreed that confidential enquiries needed to receive full copies of clinical case notes, and it was known that these could be extensive. Previously they were sent securely to CMACE premises and then anonymised, and it had been agreed that in the interim period between the closure of CMACE and the start of this approval that the information would be sent to Healthcare Quality Improvement Partnership (HQIP) offices while Sciensus was the interim supplier for the electronic MPMN portal.

The amendment request noted that there was currently a backlog of cases to be reviewed since the CMACE closure on March 2011; some cases dated back to January 2009. The

backlog was stated to be up to 400 cases and it was indicated that some units had up to ten relevant cases falling within the inclusion criteria. It was estimated that one case could incur several hours of work to copy the notes and up to an additional ten hours to anonymise them. Information was provided showing that units had contacted the applicant to state that there was a lack of local resource to carry out this activity; it was also indicated that the standard of anonymisation varied and at times it was easy to identify the patient from the received documentation. The overarching intent in future would be to ask units to carry out the anonymisation process themselves and to send the anonymised version of the notes to the applicants, and it was indicated that moving forwards most units would not report more than one case per year.

Members noted this was a robust programme and agreed that access to the care notes for all identified cases would be critical to the success of the programme to achieve the aim of improving the care delivered to pregnant women. The Group could not identify any other practicable alternative to managing the backlog and agreed that the suggested way forward was a reasonable way to proceed. Members requested that the applicant consider how to improve the quality of anonymisation currently in place and how to manage this at the time of the next annual review.

Members agreed that the high public interest in this confidential enquiry effectively carrying out its work, and the evidence provided, supported recommending to the Secretary of State for Health that the amendment should be approved. It was advised that progress on this amendment should be reported at the time of next annual review. While not a condition of approval at this time, Members suggested that it would be helpful to approach the National Research Ethics Service to identify whether an ethical opinion should be obtained on a discretionary basis to support this activity. It was advised that this should be investigated and reported against at the time of annual review.

4b. Clinical Outcome Review Programme: Child Health Reviews-UK (CHR-UK) – follow up to triangulation process [ECC 4-03 (c)/2012]

This child health component of the confidential enquiries work programme application was originally approved in June 2012. It set out the aim to improve service provision and quality of clinical care through learning from adverse outcomes. It involved case note reviews of mortality and morbidity in children and young people (ages 1-18) with epilepsy who had received intensive or high dependency care following a prolonged seizure, or had died of any cause throughout the care pathway. Support had been provided to enable the accurate identification of eligible cases, avoid duplicate reporting and the collection of clinical information and case note assessments. It involved a change to the typical confidential enquiries methodology. However, the high public interest and strength of the protocol had persuaded the Ethics and Confidentiality Committee (ECC) that the changes were justifiable. This amendment had been raised in December 2012 and set out the view that the process should be amended by which the applicants would be notified of cases in order to increase the number of reported cases. The ECC had advised at the time that they had not recommended support for the change in process in relation to the living as this was considered to be a significant deviation from the process of confidential enquiries. A subsequent discussion took place with the applicants.

The Group were sympathetic to the position, but as a whole considered that insufficient justification had been provided to enable a recommendation of support at the current time. In reviewing the previous outcome and advice provided by the ECC, Members reiterated that greater clarity should be provided on who was intended to provide notification. The response received from the applicant provided greater clarity in that it would be someone who had a clinical relationship to the patient. However, the applicant had not provided greater evidence to demonstrate the validity of this change, as had been requested by the

ECC. Members therefore agreed to advise that there was currently insufficient information to determine whether it was in the public interest for this change to occur in relation to notification of living patients. Explicit responses were sought to clarify the evidence base behind the requested change; clarification of the current levels of ascertainment, an explanation of why the current system was not achieving the required levels of ascertainment, and evidence to confirm that the levels could be improved; justification of the approach requested in the amendment as the best method to improve ascertainment levels; and the consequences if the methodology requested in the amendment did not go ahead. Members highlighted that this change would be a significant deviation from the confidential enquiries model so the responses should take full consideration of this point.

5. RESUBMITTED ITEMS FOR CONSIDERATION

5a. Investigating factors influencing the Infant Mortality Rate in Lincolnshire [CAG 2-05(a)/2013]

This application from the University of Nottingham set out details of a case control study to investigate factors affecting the infant mortality rate within premature babies in Lincolnshire. The study was commissioned in response to NHS Lincolnshire raising concerns over the infant mortality rate within the county over the last few years. Researchers from the University requested access to records of deceased babies only, born between the two gestational ages within Lincolnshire, or born outside of Lincolnshire where the mother would usually be resident in the county. Date of birth, date of death, deprivation score and ethnicity of baby would be extracted for analysis purposes.

This application was originally considered by the Ethics and Confidentiality Committee (ECC) in September 2011 (ECC 7-05(a)/2011), and it was agreed that the application could not be recommended for support at that time as the ECC were of the view that the investigation should be undertaken under the umbrella of clinical governance, with the Director of Public Health leading the investigation, and therefore could require trust compliance with the provision of anonymised data. In addition, Members were of the view that consent might be possible from those parents whose babies had survived.

The resubmission detailed that the Chief Executive of NHS Lincolnshire had requested that trusts provide anonymised records for the purposes of the study. This had resulted in only two NHS trusts providing anonymised records. Other trusts stated an inability to provide staff to assist with data extraction. The application detailed that accessing data from those two NHS trusts had uncovered a potential systematic problem with the management of intravenous fluids in babies undergoing intensive care. Therefore, in order to corroborate the findings, access was requested to the records of babies that had died at other trusts within the investigation period (2003-2009). The resubmitted application requested access to deceased babies' records only, not associated maternal obstetric records or control data.

When discussing the resubmitted application, Members agreed that the outcomes outlined in the resubmission were important and would require further investigation to determine the extent of the issue. Members agreed that, due to the potential interest that the findings of the study might receive, they would be interested to receive a report on the progress of the study within three months of final approval being issued. Members agreed that the continued expectation was that the study should be carried out under the umbrella of clinical governance and expressed their disappointment that this had not proved to be feasible. However, it was recognised that the applicant had attempted to undertake the study in line with previous ECC advice and had not been successful due to resource issues. Members therefore agreed that this option had proved not to be feasible. Members noted that the request for access to living babies' records and obstetric records had been removed from the resubmission so discussion in relation to seeking consent was not repeated as the ECC

had been sympathetic to the reasons provided for not seeking consent from parents of deceased babies.

Members noted that there was not a neonatal paediatrician within the research team and commented that they were surprised that this was the case, given the nature of the issue and records that would be reviewed. Members queried whether there was any intention to request that a paediatrician review the findings of the study and, whilst not a condition of support, recommended that this be undertaken as a minimum.

The Group 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 submission of a report in three months; time to provide an update on the progress of the study.

5b. Pandemic Influenza Triage in the Emergency Department [CAG 2-05(b)/2013]

This application from the University of Sheffield detailed a prospective observational cohort study of patients attending emergency departments with suspected pandemic influenza so as to evaluate existing triage methods, identify clinical predictors of adverse outcomes and develop new triage methods. Access was requested to a standardised assessment form completed by emergency department staff for all patients presenting to a hospital registered with the study with suspected pandemic influenza. CLRN research nurses would then track patients until 30 days after initial emergency department attendance through a hospital record review. Cross checks for completeness of the dataset would be undertaken by comparing NHS numbers with the Intensive Care National Audit and Research Centre (ICNARC) database and missing mortality data would be requested from the Office of National Statistics (ONS).

This application was originally considered by the Ethics and Confidentiality Committee (ECC) in May 2012 (ECC 3-03(g)/2013). At this time, it was agreed that the application could not be recommended for support as consent appeared to be feasible for the pilot aspect included within the application. In addition, the main study was intended to be started in autumn 2013 and the application was considered in May 2012. Members were therefore mindful that the process for lifting the common law duty of confidentiality could have significantly changed by that time, and the ECC would no longer be administering the functions. Members were also unsure whether an application for pre-emptive support, for a pandemic that was not certain to occur, could be recommended for support.

The resubmitted application detailed that the pilot phase of the study had taken place using anonymised data only and as the new processes for administering applications to lift the common law duty of confidentiality were in place, the applicant was resubmitting the application for the main study element for consideration.

When discussing the resubmitted application, Members agreed that the outcomes of the study would be of particular public benefit if a pandemic situation were to occur. Members agreed that in a pandemic situation it would not be feasible to seek explicit consent due to the emergency nature of the research. Members noted that NHS number would be required in order to allow patient follow up data to be collected and comparison with ICNARC and ONS data.
Members recognised the requirement outlined within the application to seek relevant approvals at this stage and were sympathetic to this. However, they noted that details of members of the research team could not be confirmed as the team would be disbanded until the time of the pandemic. In addition, there was no guarantee that the current legal framework under which confidential patient information was accessed would remain the same. With both the importance of the study and difficulties specified above in mind,

Members discussed that conditional support could be recommended at this stage, with the requirement for the applicant to provide details of the research team and final confirmation of the recommendation to be confirmed by the Chair at the time of the pandemic. This would mean an emergency final approval process would be in place which would take very little time.

The Group 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 of the details of the research team in the event of a pandemic, so that final support could be confirmed within five working days following Chair's advice.

6. NEW APPLICATIONS (NON-RESEARCH)

6a. Maternity Information System Data Linkage Pilot [CAG 2-06(a)/2013]

This service evaluation application from the Royal College of Obstetricians and Gynaecologists (RCOG) detailed a pilot project to collect patient information from electronic maternity information systems (MIS) and Hospital Episode Statistics (HES) data in order to create a database to enable the development of robust and clinically meaningful performance indicators for maternity care. The database would be used to develop new indicators for evaluating maternity services, including maternal and neonatal outcome. Support was requested to allow access to identifiable data from 15 maternity services over a 12 month period and link to HES inpatient and maternity data already held by the Royal College of Surgeons (RCS). In order to link to HES data identifiable data would be submitted from MIS and provided to the HSCIC. A look up table with identifiable data and HESID would be sent to the applicant. The HESID would then be used to link MIS and HES datasets. It was confirmed RCS would process the data on behalf of the RCOG.

Members agreed that the project outcomes would have significant benefits for users of maternity services. Members noted that due to the large number of patients involved and the retrospective nature of the data collection it would not be feasible to contact each patient in order to request their consent. Members queried whether the applicant had considered requesting separated demographic and treatment datasets from MIS, attaching a record identifier for each patient to both datasets. This would allow demographic data to be sent to the HSCIC to allow them to provide the corresponding HESID and record identifier for linkage purposes, but would mean that minimal identifiable treatment data from MIS would only be processed by RCS. Members advised that this pseudonymised approach should be explored to determine whether the transfer of identifiable treatment data could be kept to a minimum.

Members noted that baby date and time of birth would be required for calculating several measures such as length of stay after delivery and that dates would be destroyed once measures were calculated. In addition, postcode was requested to calculate Index of Multiple Deprivation and for linkage purposes, but would be destroyed at the earliest opportunity.
It was noted that the pilot would be undertaken using retrospective data; however, Members advised that reasonable efforts should be made to inform data subjects about the processing of their data, in line with the fair processing requirements of the first principle of the Data Protection Act 1998. Members advised that, as part of the pilot, the applicant should consider methods to ensure that the processing was as transparent as possible if collection of data was to be carried out on a prospective basis. It was suggested that, in order to raise awareness and carry out additional patient involvement, Maternity Services Liaison

Committees could be informed about the activity and provided with an opportunity to comment.

Members commented that access to HES data appeared to be limited to England and queried whether corresponding hospital data would be requested from other countries such as Wales. With this in mind, Members asked the applicant to confirm the added value of using HES data.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Secretary of State for Health, subject to reasonable efforts to inform the cohort of the processing in line with fair processing expectations; clarification whether it would be feasible to separate demographic data required only for linkage from treatment data; clarification whether MIS data would be linked with HES-equivalent data from other countries; and justification of the additional benefits of linking to HES data in England.

7. NEW APPLICATIONS (RESEARCH)

7a. Developing effective strategies to reduce unscheduled care in chronic disease: Validation of a "red flag" system that identifies patients who are at risk of becoming frequent users of unscheduled care [CAG 2-07(a)/2013]

This research application from the University of Surrey aimed to understand the need for urgent or unscheduled healthcare and assess whether the need may be reduced if more comprehensive routine care was developed. The application detailed carrying out data linkage only in order to test the validity of a "red-flag" system which was developed as part of a wider research programme. Support was requested to allow a researcher access to data on GP practice sites in order to extract pseudonymised data to link to SUS data. Access was requested to demographic data in all adult patients' records within participating GP practices. The processing of demographic data including NHS number, name and date of birth was required in order to pseudonymise patient information at GP practice sites.

Members noted that the purpose specified within the application was to try and reduce the use of unscheduled care for patients with chronic disease. Whilst Members recognised that the outcome would be of benefit to the population as a whole as it would reduce the burden on NHS services, they queried how much patient involvement had taken place in relation to ensuring that the benefits were realised to the patients with chronic diseases, as well as NHS services. Members were pleased to note that consultation had taken place with a number of user organisations. However, in order to ensure that patients continued to be represented the Group recommended that at least two patients were invited to sit on the project advisory group.

Members noted that an application had been received previously in relation to the investigation of genetic and environmental factors underlying cardiovascular disease – the London Life Sciences Population (LOLIPOP) study, which had used similar pseudonymisation methods to those specified within the current application. At the time of considering the LOLIPOP application, a teleconference had taken place with the applicant to ensure that the pseudonymisation process was fully understood. Members who had attended the teleconference confirmed to the Group that the extraction process detailed was undertaken completely within GP practices and only pseudonymised data would be taken off site.

Members advised that the applicant should ensure that patients were fully informed in relation to the activity in line with the requirements of the fair processing aspect of the Data Protection Act 1998. Members queried how long the poster would be displayed within GP

practices and whether the applicant had considered undertaking further fair processing activities, such as including information in relation to the project on GP websites or informing patients in routine letters or emails from their GP.

Members also queried what provisions had been made to allow dissent and agreed that reassurances in relation to how this would be managed should be provided. In particular, it was noted that the poster included no information in relation to how a patient could opt out of the study and Members requested that this be amended.

It was noted that data in relation to the entire population of the GP practices would be pseudonymised and linked to SUS data in order to identify controls. Members queried when data would be deleted in relation to those patients who would not be included within the study. Whilst it was noted that the data would be pseudonymised, Members recommended that this patient level data should be destroyed when no longer required.

The Group 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 confirmation that at least two patient representatives would be included in the project advisory group; confirmation of provision to enable patients to opt out of inclusion in the study, including amending the patient information poster; confirmation of how long data in relation to those who were not identified as either cases or controls would be retained; and submission of a plan for provision of further fair processing information to patients. Support would not include access to SUS or equivalent datasets in identifiable format as it was understood that these would be fully pseudonymised prior to disclosure to a researcher.

7b. The assessment of institutional violence and aggression: an evaluation of the predictive accuracy of five risk assessment tools [CAG 2-07(b)/2013]

This research application from Ashworth High Secure Hospital detailed a study to follow up 111 patients who were engaged in a baseline study carried out between 2000-2002 in order to determine the validity of a risk assessment tool developed within the baseline study.
Access was requested to records in relation to admissions over the 10 year period since the baseline study took place. Records would be accessed using the Patient Administration and Clinical Information System (PACIS). Support was requested in relation to those patients who had left the Ashworth Hospital. Where patients were still in treatment at Ashworth, they would be approached for consent where it was considered to be appropriate by the responsible clinician.

Members agreed that the outcomes specified within the application would be important and of public benefit. Members noted that consent would be obtained, where appropriate, for those that remained within the hospital. However, where the patients had left the hospital, Members agreed that it would not be appropriate to contact the cohort, noting that the Research Ethics Committee opinion had concurred. Members noted that the consent form issued to the responsible clinician referred to whether a patient would be capable to consent. Members wished to highlight that if a patient lacked capacity to consent then the requirements of the Mental Capacity Act must be considered and met. It was noted that this consideration would not be relevant to the application if access to data in relation to those patients who were still in hospital and not approached for consent would not have their data included.

Members queried whether the applicant intended to use data in relation to those patients who were still in treatment but where the clinician had advised not approaching for consent and requested clarification on this aspect.

Members noted the intention to anonymise data once linked. However, concerns were raised that some events would be easily re-identifiable even if all personal demographic data was removed from the dataset, for example those that related to high profile events. It was therefore advised that the applicant should ensure that if disclosing data from the hospital for any reason, the information should be fully anonymised and access to the linked dataset on site kept to a minimum.

The Group 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 the caveat that support was for those patients who had left Ashworth Hospital only and did not relate to patients still in care at the hospital.

7c. The Pesticide Users' Health Study: Nervous system, eye, respiratory and skin disease among certified pesticide users [CAG 2-07(c)/2013]

This research application from the Health and Safety Laboratory (HSL) detailed a large cohort study of pesticide users comprising of more than 60,000 individuals with the aim to determine whether exposure to pesticides could be associated with an increased risk of neurological disease. Access was requested to patient level HES data in relation to inpatient episodes from the HSCIC. This would then be linked to study data retained by the HSL using a unique reference number. Access was also requested to patient level data in relation to the entire population to use as control data.

Members agreed that the application detailed clear benefits to patients and that they were supportive of the application in principle. Members noted that obtaining consent for data linkage from all 60,000 cohort members would not be feasible due to the size and retrospective nature of the cohort. In particular, the 14% response rate quoted from previous requests was noted. However, Members queried whether there would be opportunities to carry out further efforts to inform the cohort about the data linkage activity, and to provide them with an opportunity to opt out, in line with the requirements of the Data Protection Act 1998. If it was not feasible to inform patients individually, Members suggested other methods might include updating a study website, and requested that the applicant provide further information in relation to this.

Members raised concerns that accessing patient level HES data in relation to control patients appeared to be disproportionate in order to meet the purposes. It was noted that the applicant had contacted the HSCIC to determine whether aggregated anonymised data could be provided; however Members felt that it was still unclear what data would be accessed in relation to controls. It was agreed that this should be in aggregated form, unless further justification for accessing patient level data for the control cohort could be provided.

Members noted that the cohort had previously been asked for consent and had provided this at the beginning of the study. However, it was also noted that since this consent had been provided other approaches had been made to the cohort. The Group wanted to ensure that none of these approaches had included a request to access further information in relation to their health records, as this would mean that an attempt had been made to rely on explicit consent to process sensitive personal data under the Data Protection Act 1998. Guidance from the ICO indicated that, where a data controller had previously relied on explicit consent as a schedule 3 condition to process sensitive personal data, they could not then rely on another condition, such as a medical purpose. Therefore, if any attempt at consent for data linkage had been made since the original consent and no response had been received, processing data as specified within the application would not be compliant with the Act.

Members noted that question 15-2 on the IRAS form had not been answered with details of how patients had been consulted in relation to the current activity. Members highlighted that where patient information was to be used without explicit consent for purposes that were in the public interest, it was of particular importance to consult with patients to determine the acceptability of the activity and demonstrate that interest.

The Group agreed that further information would be required prior to making a final recommendation. The Group requested clarification on any previous requests for consent from the cohort; confirmation of what attempts would be made to inform the cohort of the intended processing of their data and confirmation of any patient involvement planned or already carried out. The Group also requested that the applicant continue to liaise with the HSCIC to determine whether aggregate data could be provided in relation to the control population, in order to ensure that excessive patient level data was not requested.

d) Service Evaluation on the missed opportunities for the diagnosis of HIV infection in North West London area [CAG 2-07(d)/2013]

This research application from NHS England (London Regional Office) detailed a study which aimed to analyse which healthcare settings patients accessed prior to a diagnosis of HIV to evaluate where testing may take place and also where opportunities for testing may have been missed. Access was requested to data from four London HIV clinics in order to link with retrospective Secondary Uses Services (SUS) data (2005-2012). Identifiable data items including name, NHS number, GP registration, date of birth and district level postcode were requested to allow data linkages to take place.

Members agreed that the specified outcomes were particularly important and agreed that they were supportive of the study in principle. Members were mindful of the sensitive nature of the information requested and agreed that, where possible, data in relation to treatment of patients with HIV should not be disclosed in identifiable format. With this in mind, Members noted that partially pseudonymised (name Soundex coded) data was already collected by the HIV/STI Department of Public Health England (previously the Health Protection Agency) from NHS organisations in relation to the treatment of HIV patients, and queried whether Public Health England (PHE), together with the HSCIC, could undertake linkage between this currently collected HIV data (the HARS dataset) and SUS data. Members emphasised that evidence would need to be provided that this alternative would not be feasible (for example that sufficient identifiers for matching were not available in HARS) prior to the Group being able to recommend support for the processing of confidential patient information by the applicant. It was noted that the applicant now had support from colleagues within the HIV/STI Department at PHE and it was advised that discussions be undertaken to determine whether the requested data was already available.

If the suggested linkage alternative was feasible, the Group were of the opinion that support under the Regulations might still be required, depending on the process and identifiers used for linkage to SUS, as this would be a research use of HARS data collected under Regulation 3/Sexual Health Directions. However an additional flow of highly sensitive data from the London HIV clinics would be avoided.

It was noted that the application specified transferring SUS data to NHS England or the North West London CCG. However, it was not clear from where the SUS dataset would be disclosed to NHS England or the CCG, noting that the North West London CCG would only have access to SUS data relating to the previous financial year for business continuity purposes. Members therefore suggested that, if the alternative linkage proposal proved not to be feasible, the applicant contact the HSCIC to request historical SUS data. If access to data from the HSCIC was to be pursued, Members also queried whether the applicant could be provided with pseudonymised data only.

Members noted that the application form had originally been completed when Primary Care Trusts were still in existence and that the intention had been to submit the application prior to their abolition. The applicant had been unable to amend the original IRAS form and therefore had submitted a covering note indicating where the application would have changed following transition to NHS England. Whilst Members were sympathetic that transitional changes outside the applicant's control had resulted in the application form being out of date, they commented that this had led to a number of discrepancies between the additional information provided by the applicant and the application form, including provisions for dissent and clarification over Data Controller responsibilities. The Group indicated that if an application continued to be required, then the application form would need to be amended to ensure that accurate details were reflected throughout.

The Group noted that it appeared that limited patient involvement had taken place in relation to the activity and advised that where patient information was to be obtained without consent, particularly in relation to a sensitive condition such as HIV, greater efforts should be made to engage with the public. It was noted that the applicant intended to submit further information in relation to public involvement and Members requested that if a further submission was made, this should be included.

The Group agreed that there appeared to be an alternative to the use of confidential patient information without consent which required further exploration and therefore a recommendation was deferred at this time pending exploration of the alternatives and provision of further information.

8. ANY OTHER BUSINESS

Ms Rebecca Stanbrook clarified for Members following a question at the meeting on 18 April 2013 that Members could download attachments received via their NHSMail accounts to mobile or personal devices, on the basis that the devices were password protected and that documents would be deleted when no longer required.

Ms Stanbrook presented the HRA's Freedom of Information Act policy, highlighting that the HRA was required to inform the source of information (e.g. an applicant for section 251 support) of any request under the Act and seek the source's views on publication, thus giving the originator of the information the opportunity to cite any applicable exemptions from publication under the Act.