NHS
Health Research Authority

**Minutes of the meeting of the Confidentiality Advisory Group**

**06 May at 10:00 at Barlow House, M1 3DZ**

**Present:**

| Name | Capacity |
|---|---|
| Dr Mark Taylor (Chair) | |
| Dr Patrick Coyle (Vice Chair) | |
| Ms Clare Sanderson | |
| Dr Murat Soncul | |
| Professor Barry Evans | |
| Dr Lorna Fraser | |
| Dr Miranda Wolpert | |
| Ms Sophie Brennan | |
| Ms Diana Robbins | |
| Dr Malcolm Booth | |
| Dr Martin Andrew | |

**Also in attendance:**

| Name | Position (or reason for attending) |
|---|---|
| Ms Diane Pryce | Senior Confidentiality Advisor |
| Mr Christopher Ward | Senior Confidentiality Advisor (via audio) |
| Mr Ben Redclift | Confidentiality Advisor (via audio) |

## 1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies were received from. None received

The following interests were declared:

Dr Lorna Fraser; Agenda item 4.b 16/CAG/0060: The Two Week Wait (2WW) study - an investigation of patient non-attendance at urgent referral appointments for suspected cancer.

## 2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the 6 May 2016 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the 6 May 2016 meeting applications.

## 3. NEW APPLICATIONS – Non-research

a) 16/CAG/0052: Benchmarking clinical quality healthcare measures

This application was withdrawn prior to the meeting.

## 4. NEW APPLICATIONS – Research

### a) 16/CAG/0054: Twelve month follow up of patients who have been detained under Section 136 of the Mental Health Act, 1983

Purpose of application

Section 136 of the Mental Health Act 1983 (MHA, Department of Health, 2008) allows the police to detain, in a place of safety, any person found in a public place believed to have a mental health condition resulting in a risk to themselves or others. Once within the place of safety, further assessment and care can be explored. A person can be admitted to hospital (either of their own free will or under another section of the MHA) or be discharged, with or without a referral to ongoing care.

This application from Derbyshire Healthcare NHS Foundation Trust set out the purpose of investigating the proportion of individuals (who had been detained under a section 136 in South Derbyshire), re-presenting to the Emergency Department with a self-harm or mental health related presentation, within the 12 months of their detention; and investigating how this relates to the management and outcome of their section 136 assessment. This will increase understanding around the level of risk and prognosis for this population and will help to inform clinical care.

A previous internal audit conducted by Derbyshire Healthcare NHS Foundation Trust had investigated the quality of documentation and communication for patients detained under a section 136 between 30 September 2012 and 1 October 2013. The present study will be a follow up to this piece of work. Records kept by Derbyshire Healthcare NHS Foundation Trust and Derby Hospitals NHS Foundation Trust, for patients identified within the audit, will be analysed.

A recommendation for class 1, 4, 5, and 6 support was requested to link records kept by Derbyshire Healthcare NHS Foundation Trust and Derby Hospitals NHS Foundation Trust in order to conduct a one-off patient record search for patients detained under a section 136.

Confidential patient information requested

No confidential information will be collected for this study, but the research team will, in accessing case files, have access to: name, postcode, NHS number, date of birth, & date of death.

For the linkage between the two healthcare records it is proposed that name, NHS number, & date of birth will be used.

**Confidentiality Advisory Group advice**

Public interest

Members agreed that studies of this type are potentially in the public interest.

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 group was content that it would be unfeasible to seek consent from such a difficult to reach historic cohort.

- Use of anonymised/pseudonymised data

Members were content that it was not reasonably practicable for members of the care team to extract the relevant data.

Justification of identifiers

The members concluded that the access to the identifiers requested was necessary and appropriate to achieve the purposes.

Exit strategy

The group noted that the study involves a one-off access to patient records. However they were unclear if the study ID in the application was the same as the hospital number. The applicant should clarify this and confirm that a study specific ID will be used and not the hospital number.

Patient notification and objection

The group noted that a poster had been produced to notify individuals that their records will be accessed for the study. However, given the retrospective nature of the study, the group queried whether this was the best mechanism to notify the cohort about the study.

Patient and public involvement

The members noted that some patient and public engagement had taken place, however they were of the opinion that greater engagement could have taken place (for example, with bodies representing individuals with mental health issues).

The applicant should put together a patient and public engagement plan whereby they will address the best mechanism for notifying this historic cohort together with the content of the patient notification.

A report on progress against this plan should be provided in the first annual report to the group.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

**Specific conditions of support**

1. Confirmation that a study specific ID will be used and not the hospital number.
2. Provision of a patient and public engagement plan whereby the applicant will address the best mechanism for notifying this historic cohort together with the content of the patient notification.
3. Confirmation that a report on progress against this plan will be provided in the first annual review submitted to the group.
4. Favourable opinion from a Research Ethics Committee.
5. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Once provided, the response will be reviewed by the chair.

**b) 16/CAG/0060: The Two Week Wait (2WW) study - an investigation of patient non-attendance at urgent referral appointments for suspected cancer.**

<u>Purpose of application</u>

This application from the Department of Health Sciences at the University of York set out the purpose to investigate the reasons for non-attendance at clinical appointments as part of the two week wait process of referrals for suspected cancer as well as to identify interventions to improve timely access to urgent care.

Since 2000, NHS patients with suspected cancer have been guaranteed to see a hospital specialist within two weeks of the GP requesting an urgent referral - a Two Week Wait (2WW) appointment. This policy intended to shorten time to diagnosis and treatment, and ultimately improve survival rates. However, a significant minority of patients are not seen within two weeks, largely due to patients not attending, cancelling or postponing the appointment. Despite audit data identifying the scope of the problem, reasons for patients not attending or cancelling are unknown and no current studies have been identified which are examining this issue.
This study will be completed in five phases:

Phase 1 - Categorisation of patients not seen within two weeks of referral drawing on Leeds NHS Hospital Trust data for approximately 6,000 patients in 2014 and 2015.

Phase 2 - Analyse variation in factors between patients who postpone or cancel their appointment, and those who do attend, to identify predictors of non-attendance. This will use cross-sectional analyses within the same data set as Phase 1.

Phase 3 - Compare rates of cancer diagnosis (and cancer stage at diagnosis) in attending patients with those who postpone, cancel or do not attend to assess the significance of non-attendance. Health outcome data for patients referred in 2009 will be analysed 1, 2,3,4,5 and 6 years later and 1 year later for patients referred in 2014. This data will be compared to similar data from attending patients.

Phase 4 – Explore the views of patients and GPs as to why patients do not attend 2WW appointments and interventions to improve attendance.

Phase 5 – Gain consensus from GP and patient stakeholder groups on the top 3 proposed interventions to improve attendance rates.

The quantitative research in phases 1-3 requires access to non-identifiable, routinely collected patient data via the Leeds Hospital Trusts' Patient Pathway Manager (PPM). The researcher will have access to a limited view of PPM which has been created by the PPM informatics team at the study hospital site using a previously agreed study template. Anonymised medical events and outcomes will be accessed. Consent will not be sought given that this is routinely collected and anonymised data as part of a patients care, and thus not patient identifiable. The quantitative researcher will be based at the study hospital site under the supervision of the PPM informatics team at all times whilst accessing the study data set. The quantitative researcher (Rebecca Sheridan) will then work alongside these teams to pull the relevant data to a separate research database to conduct analysis from.

Potential patient participants for Phases 4 and 5 will also be identified via the PPM system by the data teams at SJUH following a non-attendance without reason for a 2WW referral for suspected cancer. The research team are the only holders of all the information and expertise to purposively sample the potentially eligible patient participants who should then be approached by their GP to take part in the interview. In addition, data on whether the GP practice with whom the individual eligible patient is registered, has been collected by the research team potentially eligible patients for Phase 4 interviews will be identified via their routine hospital records shortly after the patient's non-attendance at their urgent 2WW appointment for suspected cancer. This will be carried out by NHS staff that have the relevant permissions to routinely access and manage this data. Confidential, minimal identifiable patient data regarding eligible patients will be transferred to the research team at the University of York on a weekly basis to capture patients who have not attended their appointment within the last 7 days. On receipt of this information, each potential patient will be checked against study eligibility criteria by the research team who will then notify participating GP practices of a newly identified eligible patient.

Eligible patients will then be approached in the first instance by a personalised invitation letter and study recruitment pack from their GP. Due to the practical constraints to follow-up of non-responding eligible patients by their GP or GP practice, the GP invitation letter will inform the patient that a nominated, experienced researcher will contact the patient within 7-14 days to discuss the study in more detail (if a signed consent form has not already been received by the research team expressing the patient's wish to take part in the study or to not take part in the study). Eligible patients will also be made aware that, subject to their consent, the researchers would like to collect data on their cancer status toward the end of the study. Data linkage with the National Cancer Registration Service would be completed in collaboration with the informatics team at Leeds Hospital Trust to prevent unintended access to non-anonymised data.

Eligible patient participants have the option to withhold consent for collection of their cancer outcome data on the consent form whilst still taking part in the study.

A recommendation for class 3 and 6 support was requested to select and contact patients to seek their consent and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to NHS number, NI number, name, date of birth, gender, postcode at the unit level, contact telephone number, registered GP, GP practice and patient postal address

**Confidentiality Advisory Group advice**

Public interest

Members noted the public health importance of this research as a delay to cancer diagnosis can be seen as a significant contributing factor to Cancer outcomes. Historically the UK is seen as lagging behind the rest of Europe in this field so the importance in improving patient outcomes is of clear benefit.

Patient and public involvement

Members considered whether the first phases could benefit from further public engagement and whether GPs could be further consulted on the recruitment process.

Justification of identifiers

It was noted that the patient would be contacted by the researcher by telephone if no response had been received to the original letter of invitation. Members considered that this had potential to do harm as patients would be contacted by various involved parties around this time and the initial approach had been from the participants GP. It was queried whether the GP could be asked to consider the best way to approach patients based on their personal knowledge, this was not considered to be too onerous due to the relatively small numbers involved. It was not considered appropriate for researchers to make the follow up phone call.

Additional points

The consent form for participants was reviewed by members who were in agreement that there was a lack of clarity in relation to which boxes to tick to confirm agreement to participate. Members noted that question 10 requesting confirmation of agreement to participate and question 11 requesting confirmation not be contacted again regarding the study were alongside each other in the Participant Consent Form. Members considered that the separation of the consent forms into two parts would be beneficial to participants, the section to confirm agreement to participate clearly separated from the section declining to participate.

Similarly the patient participant invitation sheet should clearly state that not all boxes need to be initialled to confirm consent as the box requesting that the patient not be included would

need to be initialled in cases of withdrawal from participation. It was requested that the letter should not mention Cancer explicitly.

Members noted that it was planned for cases where dissent had been expressed by the patient that their information was to go back to the hospital rather than being excluded from the data sent to researchers; it was not clear why this was necessary. Also it was not understood whether data linkage would be undertaken by the informatics team or the researchers.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

**Specific conditions of support**

6. The consent form should be separated into two sections one to confirm consent and the other to confirm that the patient would not like to be contacted again.
7. The letter should be amended to provide clarity that not all boxes need to be initialled.
8. The letter should be amended to not mention cancer explicitly.
9. Confirmation that patient information about those who dissented would be excluded from the information passed back to the hospital and not provided to the researcher or justification as to why this was required.
10. The applicant was asked to confirm whether linkage would be undertaken by the informatics team or the researchers.
11. GPs should be asked to consider the best way to approach patients either with letter or by phone-call based on their personal knowledge. If this was not possible the applicant was asked to provide a strong justification why not.
12. The applicant was asked to consider further public engagement on the first phases of the project and whether GPs could be consulted on the recruitment process.
13. Favourable opinion from a Research Ethics Committee.
14. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-cag-application-advice/ and contact Exeter.helpdesk@nhs.net with any queries.

**c) 16/CAG/0053: Prolonged Effects of ART: a Record Linkage study (PEARL)**

Purpose of application

This application from University of Oxford set out the purpose of this project to create a linked dataset between HFEA infertility data and health data from the Clinical

Practice Research Database (CPRD) mother-baby track and to use the linked dataset to assess the effect of ART on the health of women and their children after successful fertility treatment.

In general, most children born after the use of fertility treatment (such as IVF) are healthy. However, there is a small increase in the number of children who are born early, have a low birthweight, and who have health or developmental problems. Less is known about the health of children born after fertility treatment as they grow up, as long-term follow-up studies are costly and time consuming. As a result, many studies are not big enough to detect small differences between the groups – which are important because the effects of fertility treatment on health may be subtle. More evidence is also needed about the long term wellbeing of women who have had fertility treatment.

PEARL is a record-linkage study of women and children in England. The study aims to:

1. Find out the effect of fertility problems and fertility treatment on the health and development of ART children to adolescence.

2. Look at the impact of successful fertility treatment on the health and wellbeing of women who underwent treatment.

3. Estimate the additional costs to the NHS (if any) of caring for women and their children after successful fertility treatment.

4. Explore how changes in the number of patients agreeing to allow information about their fertility treatment to be used in research affects the results of studies that use this information.

PEARL will include about 270,000 mothers and their children, around 4000 of who will have had fertility treatment.

The information to be used comes from over 20 years of existing health records: details of fertility treatments held by the Human Fertilisation and Embryology Authority; Health records from GP practices in England held by the Clinical Practice Research Datalink, and records of hospital care, from Hospital Episode Statistics already linked to CPRD data and held by the HSCIC.

A recommendation for class 1, 2, 4 and 6 support was requested to achieve the specified purpose.

Confidential patient information requested

Access was requested to process; name, postcode, NHS number, date of birth/date of death and link to mother baby data already held by HSCIC, in relation to pre 2010 data only, i.e. 1999 – 2009 inclusive.

Linked data to be provided to the researcher was in relation to pre 2010 data for English patients only.

**Confidentiality Advisory Group advice**

Public interest

Members were of the opinion that this application demonstrated clear public interest and was for a medical purpose.

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 agreed that consent was not practicable for the data which pre dated 2010.

Justification of identifiers

Members were in agreement that the identifiable information requested was justified to enable the linkage process.

Patient and public involvement

Members felt that the patient and public engagement should be improved and were of the opinion that the poor consent rate from patients, 50%, which had been achieved since 2010 may be due to a lack of clear information available to patients. They were of the opinion the consent rate may improve if the patient information clearly outlined the public benefits of the use of patient data for research opposed to a possible perception of the use of embryos in research.

Patient notifications

Members noted that the applicant was relying on the HSCIC objections process to manage patient opt out and that there was no direct route for patients to opt out of the further processing of their information for this project during the trial phase e.g. via either the university or the HFEA. Members requested that an opt-out process was introduced and clearly signposted to patients.

Members questioned whether the decision of patients not to give consent since 2010 had been retrospectively applied to the 1999 – 2009 data covered by the HFEA regulations in cases where patients had undergone treatment previously.

Members also requested sight of the draft patient information which it is planned to make available on the www.npeu.ox.ac.uk/pearl web pages and that this information was signposted from other places, e.g. the web pages of other organisations involved. Members similarly requested that the applicant ask the PPI group their opinion as to where and how this information should be made available.

Additional points

Members confirmed that the scope of support was to cover the processing of confidential patient information (CPI) within the HSCIC.

The disclosure of HFEA data to the HSCIC was permissible under the HFEA regulations and as such was outside the scope of s251 support. The data to be disclosed to the HSCIC would only contain cases related to English patients; data relating to patients from other Home Nations was to be removed by the HFEA prior to disclosing the cases to the HSCIC.

Members wished to clarify that the HFEA regulations support the disclosure of data from the HFEA to the HSCIC for data collected between 1999 to 2009 only.

The disclosure of any data from 2010 onwards was for HFEA, as the Data Controller, to determine as this was understood to be done under another legal basis, in this case the consent of the patients concerned.

Members also questioned the applicants response to question 53 of the application form, where it states data will be kept for 100 years and asked if this was in error.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

**Request for further information**

1. Provide an opt out process during the trial phase and advise how this will be managed and sign posted to patients.
2. Confirm with the HFEA whether any objections received post 2010 are applied to the data for the same patients which are already held related to treatments between 1991 – 2009.
3. Provide the draft web content which is planned to be published on the NPEU web site.
4. Confirmation of the data retention period, if 100 years is correct please provide the rational for this and advise how the security of the data will be assured.

**d) 16/CAG/0063 aTTom-Extended Version 1.0, 15th March 2016**

Purpose of application

This application from the University of Birmingham set out the purpose of the aTTom: adjuvant Tamoxifen Treatment offer more? Trial (MREC (1) 97/34, ISRCTN17222211) to determine if taking tamoxifen for 10 years compared with the standard of 5 years improved overall survival and disease free survival. The preliminary analysis of the primary outcome measure was performed in 2013 and presented at the American Society for Clinical Oncology

(ASCO (http://meetinglibrary.asco.org/content/112995132).

The result demonstrated that taking tamoxifen for 10 years was superior to 5 years in reducing breast cancer recurrence and, probably, mortality.

However, as the reductions in breast cancer mortality only emerge after 10 years, even longer follow-up is needed to assess how large the benefits are and to monitor safety (incidence of new primary tumours, in particular endometrial cancer and non-cancer mortality.

It is entirely possible that the incremental improvements will continue longer term. Therefore, it is important that follow-up continues for these patients to ensure the full impact on overall survival was understood.

This application seeks to extend the aTTom study, and to continue the follow up of the participants enrolled into the aTTom clinical trial (MREC (01)97/34) by obtaining mortality data from the Office of National Statistics. Additionally approval was sought to conduct a translational sub study to validate diagnostic tests using tissue blocks from the patients previous randomised into the aTTom clinical trial (Trans aTTom - Sub study of aTTom Extended).

A recommendation for class 4 and 6 support was requested to achieve the specified purposes.

Confidential patient information requested

Access was requested to; participants' name, Date of Birth, address and NHS Number for linkage purposes and to; date of birth, date of death and post code at sector level for analysis purposes.

The following data was to be requested from the Office for National Statistics via HSCIC:

- Date of death

- Cause of death

- Date of Cancer diagnosis

- Site of Cancer

**Confidentiality Advisory Group advice**

Public interest

Members were of the opinion that this application demonstrated clear public benefit and was for a medical purpose.

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 agreed that consent was not practicable and would be disproportionate when balanced with the patient and public benefit and public interest.

Justification of identifiers

Members were of the opinion that the use of identifiers was justified for the linkage purposes but questioned if this could be achieved using fewer fields. The applicant should consider how the data fields could be reduced for linkage purposes e.g. use of NHS number and date of birth or post code only.

Patient notification

Members were of the view that the patient notification approach needed improving and materials/information should be made available via various mediums and not solely the trials unit website. The applicant should consult with representative and patient groups in the local area to discuss the best approach about how the study population could be reached. They should also refer to the Information Commissioners Office (ICO) Privacy Notice Code of Practice.

https://ico.org.uk/media/for-organisations/documents/1610/privacy_notices_cop.pdf

Members noted that the applicant was intending to provide information via the trials website but have not had sight of the proposed text. The applicant should provide the draft copy text.

Patient and public involvement

Members agreed that the patient and public involvement was not representative of the cohort. The applicant should consult with local representative and patient groups to inform them about the study and provide an opportunity for them to provide feedback.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

**Request for further information**

1. Provide a plan about how local representative and patient groups will be approached in order to provide input into the study patient notification approach and input into the patient and public involvement

2. Provide the draft copy text for the trials unit website
3. Confirm that fewer fields will be used in the linkage process or provide justification why the fields listed are required

**5. MINUTES OF THE MEETING HELD ON 11 April 2016**

The minutes were agreed as an accurate record.

**6. ANY OTHER BUSINESS**

**Training log**

The Chair advised members that going forward it was intended to have a standing item on the agenda to cover CAG member training requirements and any subject it was considered should be included as an education item for future meetings and away days.

Items put forward;

- Age of consent and considerations for applications involving children in research
- GP Practice databases

The Chair also asked members for their thoughts as to what medium would be the most suitable to use to disseminate and ensure all members could access material if they were unable to attend training events and away days, or for reference following a meeting or away day.

The CAT was tasked with exploring the possibility of utilising a web cam with the HRA training team.

It was also suggested that CAT approach existing applicants who are involved with projects or research involving children in order to share their experiences and approach.

ACTION:

- Christopher Ward – follow up with training team
- CAT – follow up with applicants

**EU General Data Protection Regulations**

The EU GDPR has been published and will come into effect May 2018.

**HRA Decision making procedure**

The HRA has published its decision making procedure on the website, this is signed off at board level. http://www.hra.nhs.uk/news/2013/05/10/new-decision-tools-for-researchers/

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| Signed – Chair | Date |
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| Signed – Confidential Advice Team | Date |