Health Research Authority

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

May 2018

Present:

Name	Capacity	Items
Dr Patrick Coyle	Chair	1.a, 1.b, 1.c
Dr Malcolm Booth	CAG Member	1.a, 1.b.
Professor Jennifer Kurinczuk	CAG Member	1.b.
Ms Diana Robbins	CAG Lay Member	1.a, 1.c
Mr Marc Taylor	CAG Member	1.c

Also in attendance:

Name	Position (or reason for attending)
	Confidentiality Advisor, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 18/CAG/0078 - Prospective epidemiological surveillance of Retinal Dialysis in the United Kingdom: Incidence, demographics and clinical features

Context

Purpose of Application

The application from NHS Greater Glasgow and Clyde set out the purpose of medical research which would utilise the established BOSU methodology to investigate incidence of retinal dialysis in the UK. Reporting Ophthalmologists will report to the BOSU unit that they have seen a case within their clinic. The BOSU unit will pass details of the reporting clinician to the researcher, to enable follow-up with a data collection questionnaire.

The applicants will record incidence across England, Wales and Scotland over a one year reporting period. Follow-up will be undertaken at six months following initial incidence report. The remit of the CAG extends to the data reported from England and Wales only – the applicant has been advised to make alternative arrangements for the reporting in Scotland and Northern Ireland.

A recommendation for class 1, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

All newly reported incidence of retinal dialysis across the UK within a one year reporting period, with the CAG remit extending to cases reported within England and Wales only.

The following items of confidential patient information are requested for case identification and to prevent duplication:

- Hospital Number (England and Wales),
- Month and Year of birth – retained for analysis,
- First half postcode,
- Sex – retained for analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research aiming ascertain the incidence of retinal dialysis across a one year reporting period. It was recognised that the applicants were utilising the established BOSU methodology. Members were assured that there was public interest in the activity proceeding.

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 acknowledged the applicant's rationale that, in studying a rare condition, complete case ascertainment is desired in order to establish accurate incidence. It was also noted that patients would need to be recalled by clinicians in order to provide consent. Members accepted that consent was not feasible on this basis, as was the established protocol for studies following the BOSU methodology.

- Use of anonymised/pseudonymised data

The CAG accepted that patient identifiers were only required to enable sample validation and the removal of duplicate entries, which could not be otherwise achieved. It was acknowledged that analysis would be undertaken on a pseuodnymised dataset.

Justification of Identifiers

Members were assured that the items of confidential patient information requested had been minimised and were appropriate and proportionate to the proposed activity.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

Activity in this area had been facilitated via the Royal College of Ophthalmologists Lay Advisory Group, as was standard in applications utilising the BOSU methodology. Members agreed that the activity undertaken was appropriate and proportionate to the proposed task and raised no further queries in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The applicants explained that information around the study would be made available via participating Hospital Eye Units; however, copies of documentation had not been provided for review. The CAG agreed that sight of this documentation was required prior to any recommendation of support coming into effect. It was also explained that patients would be able to raise an objection to the use of their data for the study purposes by informing their treating clinician. It was commented that patient notification materials should make this right of objection clear to patients.

Security Assurance

It is the policy position of the Department of Health in England that all approved applications seeking support under these Regulations must evidence satisfactory security assurances through completion and satisfactory review by NHS Digital of the NHS Information Governance Toolkit (and its new format moving forwards). It was noted that relevant organisations in Scotland do not routinely complete the English Information Governance Toolkit; however, the application detail confirmed that processing of confidential patient information would take place at Scottish sites. The CAG is intending to roll out a new process for all affected applicants to accept Scottish security assurances via the Scottish Privacy and Public Benefit Panel; however, this process will not be formally implemented until the summer. Any final support cannot come into effect until satisfactory security arrangements are in place, and CAG has received the appropriate assurances from a relevant third party. As an interim measure, pending formal rollout of this process, you are advised to share this letter with the PBPP and advise them that a review of security assurances needs to be carried out, and that the PBPP should provide CAG with explicit evidence or assurance that the security arrangements specified by the applicant are satisfactory.

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 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.

Request for Further Information

1. Provide copies of the study patient information materials will be used to promote the project in participating Hospital Eye Units.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 26 March 2018**).
2. Confirmation from the Privacy and Public Benefit Panel of suitable security arrangements (**Pending**).

b) 18/CAG/0082 - Breast Cancer (BC) Predict - Providing breast cancer risk as part of the national breast cancer screening programme: building an evidence base on benefits and harms to inform a decision to implement

Context

Purpose of Application

This application from the University of Manchester set out the purpose of medical research which aimed to automate the breast cancer risk estimation process to assess feasibility of rolling this out more widely as part of the NHS Breast Screening Programme.

The National Institute for Health and Care Excellence (NICE) states that women at high-risk of breast cancer should have more frequent breast mammography (x-ray) screening and be offered risk-reducing treatment with the medicines tamoxifen, raloxifene or anastrozole. However, women at increased risk of breast cancer in the NHS Breast Screening Programme (NHSBSP) cannot be offered prevention drugs or extra screening as the screening programme does not currently estimate or inform women of their risk.

A proportion of women attending breast screening will be invited to join the study. Those opting to participate will join via online consent, following which they will complete the online breast cancer risk estimation tool. Women may also opt to have a mammogram, though this is not compulsory. Those who have a mammogram will have breast density assessed from the mammogram and this will be combined with the information they provide in the online questionnaire to estimate their breast cancer risk. Risk information will be sent to participants via letter after confirmation of a normal mammogram result (approximately 6-weeks after consent).

There are three elements to the study which required support under the Regulations which include Phase 1 of the proof of principle – in which women attending on the day for a mammogram will be invited to participate in order to test the systems. Phase 2 of the proof of principle will be initiated once the initial phase has tested that the study processes work and will test whether these work optimally and confirm that there is no requirement for a control group. Following this, the main study will be initiated across the three areas.

Women will be recruited from three NHS Breast screening programmes: Greater Manchester (Withington Community Hospital, Oldham lntegrated Care Centre and the Trafford mobile screening van only), East Cheshire (Macclesfield District General Hospital and Stockport mobile breast screening van locations) and East Lancashire (Burnley General Hospital and East Lancashire mobile breast screening van locations). Recruitment is over a 16-month period and sites will each be open to recruitment to BC-Predict for a period of 8 months.

A recommendation for class 3, 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

The following inclusion criteria have been established for the various study phases:

Proof of Principle Study - Phase 1 inclusion criteria

- Attending for breast screening at relevant site.
- Mammogram to be performed at relevant site on day of consent to the study.
- Able to complete the BC-Predict risk assessment questionnaire at their screening visit.
- Willing to receive their breast cancer risk information.
- Born biologically female.
- Approximately 20 participants across three sites.

Proof of Principle Study - Phase 2 inclusion criteria

- Invited for breast screening at active site.
- Able to complete the BC-Predict risk assessment questionnaire
- Willing to receive breast cancer risk information.
- Born biologically female.
- Approximately 180-360 participants across three sites.

Main study inclusion criteria

- Born biologically female
- Invited for first breast screening with the Greater Manchester, East Cheshire, or East Lancashire breast screening programmes or invited for a mammogram at East Cheshire or East Lancashire and aged between 57 and 63 years.
- 8,000 who join the study, but 18,700 who are invited.
- Main study controls - approximately 18,700 but these women will not be recruited to the study.

Support is requested for three elements of the application activity. In Phase 1 of the proof of principle study, support under the Regulations is requested to enable the research assistant access to confidential patient information from the NHS Breast Screening Service (NBSS) system in order to invite patient to the study. Support is requested to allow the applicants remote access to confidential patient information held within the NBSS database at the three NHS Trusts in order to extract information in relation to relevant patients in order to invite them to participate in the study, together with the control cohorts.

The following items of confidential patient information are required for the purposes as set out below:

- Name – to allow invitation and risk letters,
- NHS Number – validation and linkage,
- Date of birth – sample validation,
- Date of death – sample validation and analysis,
- Full Address and postcode – send invitation and risk letters,
- GP Name and address – to enable outcomes to be shared,
- Breast Screening number – to enable outcomes to be shared.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the study defined an appropriate medical purpose, which was medical research, which aimed to assess the feasibility of rolling out the automated breast cancer risk estimation process as part of the NHS Breast Screening Programme. Members agreed that there was a public interest in the proposal proceeding.

Scope of Support

The Group considered the inclusion of the control cohort. The applicants had confirmed in response to queries that, for the control cohort 'Confidential information will be extracted because the reports used to extract data will include patient identifiers, but this information will not be retained'. Members were in agreement that support under the Regulations was required to support this element of the overall proposal, as the applicants would be in receipt of confidential patient information in relation to the control cohort.

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 acknowledged that support under the Regulations was sought in order to establish the patient cohort to be invited to participate in the project. Consent would be sought from participating patients; however, the invitation process could not be achieved without initial access to confidential patient information. The Group was content to provide a recommendation of support to the activity.

- Use of anonymised/pseudonymised data

The CAG recognised that the invitation process could not be achieved without access to confidential patient information.

Justification of Identifiers

Members agreed that the patient identifiers were appropriate and proportionate to enable the research invitation process to be achieved.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Whilst Members acknowledged that the applicants had established an exit strategy from support via patient consent, further clarification was required around the overall duration of support which was required under the Regulations to facilitate the invitation process. Confirmation would be requested from the applicants around this point.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The Group acknowledged that a patient and public involvement panel had been established to support the project, which included a diverse population. It was explained that the group had been convened twice since August 2017 and it was planned that meetings would continue to be held two to four times per year as the project progressed. Members were satisfied with the proposed activity in this area and no further issues were raised.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The CAG recognised that those patients who were invited to participate in the study would receive appropriate information materials and be provided with the opportunity to object to their involvement in the study.

Members commented that there did not appear to be generic communications strategy established for the study which would inform the wider population about the project. As the study would include a control cohort of women who would not receive any direct correspondence around their participation in the study, the Group agreed that further work would be required in this area to establish a patient notification mechanism for the wider elements of the study. The purpose of this was to raise the profile of the project in the public domain to enable the wider population of women eligible for breast screening, who were not formally invited to participate in the study, to be informed of the study and to facilitate a mechanism of objection to those women who would be included as controls. The CAG agreed that an overview of the wider communications strategy would be required, together with copies of any documentation, prior to any recommendation to support coming into effect. An overview of how dissent would be managed for women within the control cohort was also required.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score for Manchester University NHS Foundation Trust had been published in respect of version 14.1 (2017/18) of the toolkit; however, this self-assessment had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. Confirmation of NHS Digital's satisfactory review of the toolkit would be required prior to any recommendation of support coming into effect.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Confirmation of the favourable ethical opinion would be required prior to any recommendation of support coming into effect.

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 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.

Request for Further Information

1. Clarify the overall duration of support which is required under the Regulations for the project.
2. A wider communications strategy should be established in order to raise the profile of the project in the public domain. The purpose of this is to inform women eligible for breast screening who may

be included in the control cohort about the project and provide an opportunity for these individuals to raise an objection to the use of their data. An overview of how and where information will be displayed should be provided, together with a copy of any information materials which will used to facilitate this. An explanation of how the dissenting mechanism would be operated should also be provided.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending**).

c) 18/CAG/0087 - A critical evaluation of community based integrated care policy

Context

Purpose of Application

This application from the University of Essex set out the purpose of medical research which aims to determine how national policy discourses underpinning community based integrated care have been enacted as programme resources designed to create behaviour change in health professionals and service users. Secondly, the study will aim to evaluate to what extent these programme resources have been successful at meeting both policy maker's aims and creating changes to wider structures. The aim of the research is to conduct a critical evaluation of community based integrated care policy by first of all determining the way in which the local implementers (CCG, County Council, Lead Provider) have re-contextualised and enacted national policy discourses in the form of discursive and material programme resources. The applicant will be undertaking interviews with patients and various members of staff delivering care, as well as undertaking observations of the multidisciplinary teams who deliver community-based care.

The project has a number of elements which are out of scope for the CAG review. The two elements which the CAG is being asked to consider are the day-to-day office observations and the recordings of multi-disciplinary meetings. The research aims and outcomes do not require confidential patient information; however, it is acknowledged that the applicant may be incidentally exposed to information of this type when observing health care professionals delivering their work.

The applicant will undertake 140 hours of participant observation within the multidisciplinary team offices. This will be split across the four integrated care teams and will involve 35 hours of observation in each office. The main applicant will hot desk in the office, in order to blend into the office environment. No confidential patient information would be recorded by the Chief Investigator, as part of her field notes.

Non-participant observation of eight complex case review multidisciplinary team meeting (two meetings per integrated care team), which include members of external agencies, such as GPs, social workers, and mental health professionals will be carried out. The meeting would be video-recorded without the main applicant being present. The reason for this approach is to capture highly valid data that can be subject to detailed sociolinguistic analysis that accounts for body language, as well as verbal communication. The main applicant would be there at the beginning and end of the meeting to set the video recorder up. The Chair of the meeting will briefed on how to pause and restart the recording if sensitive information was being discussed that they did not want to be recorded. These observations will take place in the Multidisciplinary Team offices where the meetings are held. The main applicant will transcribe the video recording on site, so no confidential patient information would be transferred offsite. The applicant would not transcribe any confidential patient information from the recordings.

A recommendation for class 1 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

The applicant will be observing:

- Health Professionals contained with multidisciplinary teams, internal to the community based integrated care provider (nurses, physios, OTs).
- Professionals belonging to external partners who are involved in multidisciplinary team meetings (GPs, social workers, mental health professionals)

The applicant is not seeking access to any confidential patient information; however, it has been identified that this may be disclosed incidentally during the course of the observations with staff.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research, which had an overarching aim to evaluate community-based integrated care services in the Essex locality.

Scope of the Application

Members considered a wider element of the application activity, which would involve the extraction of patient PROMS information collated by Sky Blue. It was unclear from the information included within the application whether this data would relate to the patients of the care professionals who were being observed, or those patients which would be discussed at the recorded MDT meetings. The Group agreed that clarification around this point was required, as should the data relate to patients within these categories, further information would be required to explain how the linkage would be achieved. Clarification of this point would be required prior to any recommendation of support coming into effect.

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 acknowledged that the focus of the project was to observe the practices of health care professionals, rather than any direct involvement with patients. Any disclosure of confidential patient information would be incidental in the observation of the care providers. The applicant had explained that it was not possible to seek patient consent, as it would not be known in advance of the observations being undertaken, which patients may be discussed. Members were assured by the rationale provided that consent was not feasible for the proposal.

- Use of anonymised/pseudonymised data

It was recognised that the applicant did not require access to any confidential patient information for the purposes of the project; however, this may be incidentally disclosed. The Group acknowledged that the applicant had established steps to reduce the disclosure of confidential patient information during the

course of the staff observations being undertaken in the study. It was also confirmed that the applicant would not transcribe any patient identifiers should they be disclosed.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The applicant had confirmed that the Service User Engagement Lead, at the School of Health and Social Care, University of Essex, had been approached to arrange a focus group with representatives from the Shaping Our Lives network, which appeared to be an appropriate group to consult around the project. Members agreed the planned activity should proceed and feedback on the outcomes of the focus group would be required as part of an interim six-month report. It was noted that if the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

It was acknowledged that no formal communications strategy had been established for the project. Members recognised that the implementation of a patient notification mechanism may be difficult when the impacted patients were unknown from the outset; however, due to sensitive nature of the personal information which the multi-disciplinary teams would be discussing, the requirement for transparency around the research which was being undertaken was important.

The Group agreed that a generic notification system, which will raise the profile of the project within the public domain, should be developed which would offer patients the opportunity to object and withdraw if they were not satisfied by the proposed measures to protect their identity. Members advised that this requirement should be explored as part of the patient and public engagement activity to inform the most appropriate mechanism of drawing these patients' attention to the study and meaningful opt-out system. An overview of the communications strategy would be required, together with any documentation which would facilitate this, for consideration by the CAG as part of the interim six-month report.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score for Anglian Community Enterprise had been published in respect of version 14.1 (2017/18) of the toolkit; however, this self-assessment had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. Confirmation of NHS Digital's satisfactory reviewed grade would be required prior to any recommendation of support coming into effect.

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 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.

Request for Further Information

1. Confirm whether the patient PROMS information which will be provided from Sky Blue will relate to the patients under the care of the health care providers being observed and/or discussed at the MDT meetings. If so, clarify how this relevant linkage will be performed.

Specific Conditions of Support (Provisional)

1. The planned patient and public engagement activity should proceed, which should include discussion around the communications strategy and patient dissenting mechanism for the study. Feedback on the outcomes of this activity should be provided within six months of final support coming into effect. If the responses given are negative, the CAG would take this into when considering whether support can continue, or if further action is required.
2. Patient Notifications and Dissent – a communications strategy should be developed for the study, including a meaningful dissenting mechanism. An overview of how and where information would be displayed, together with copies of any documentation, would be required as part of the six month interim report.
3. Favourable opinion from a Research Ethics Committee (**Confirmed – 26 March 2018**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending**).