NHS
Health Research Authority

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

10 February 2017

Present:

Name	Capacity	Items
Dr Malcolm Booth	Reviewer	1a, 2a
Mr David Smallacombe	Reviewer	2a
Dr Murat Soncul	Chair	1a, 2a
Dr Kambiz Boomla	Reviewer	1a

Also in attendance:

Name	Position (or reason for attending)
Ms Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0032 Risks and benefits of bisphosphonate use in patients with chronic kidney disease: a population-based cohort study

Context

Purpose of application

This application from NDORMS, University of Oxford set out the purpose of improving knowledge of the risks and benefits of osteoporosis treatment in patients with kidney disease.

Kidney disease is associated with a significantly increased risk of broken bones with substantial implications for patients, NHS and society. Drugs used to reduce the risk of bone fracture in osteoporosis were sometimes used for patients with kidney disease, however the mechanisms leading to bone brittleness were different in kidney disease patients, and these drugs could worsen kidney function. Further evidence was required to inform treatment for these patients.

The applicants propose to compare users of the most common treatment for osteoporosis (bisphosphonates) to non-users with similar characteristics, linking information from the Clinical Practice Research Datalink (CPRD) to the UK Renal Registry (UKRR) via NHS Digital.

Identifiable UK Renal Registry data would be provided direct to NHS Digital for data linkage using HES (Hospital Episode Statistics) IDs which would be provided by CPRD, using existing procedures approved by the Independent Scientific Advisory Committee (ISAC) at MHRA, for CPRD/HES linked data. This process is in line with previously used and ongoing similar procedures for the linkage of CPRD to external data sources including HES or the National Joint Registry.

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

Confidential patient information requested

Access was requested to data from the UK Renal Registry in relation to patients with an eGFR<45 (based on serum creatininee) aged 40 years or older at the age of biochemistry testing.

Applicant would receive:

1. CPRD (patient socio-demographics, clinical measurements as recorded by general practitioners, laboratory results, clinical events, and primary care prescriptions); and
2. UKRR relevant biochemistry measurements, renal outcomes, and acute kidney injury (where applicable).
3.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that the application defined a clear medical purpose which was in the public interest through improving knowledge of the risks and benefits of osteoporosis treatment in patients with kidney disease.

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 in this instance due to the size of the cohort, which was approximately 200,000 patients.

- Use of anonymised/pseudonymised data

The CAG was satisfied that pseudonymised data would be returned to the applicant following data linkage by NHS Digital.

Patient Involvement, Notification and Objection

Members acknowledged that the applicants had provided an overview of the approach taken in these areas by CPRD and UKRR, which were supplying the data which was considered satisfactory for this project. It was noted that patient and public involvement work had been carried out.

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.

Specific Conditions of Support

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

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 17/CAG/0030 UKSAFE

Context

Purpose of application

This application from Big Health Data Group at Oxford University set out the purpose of identifying a cost-effective strategy for follow-up after hip and knee surgery, to focus NHS resources on those patients most at need and reduce clinic visits and tests which did not add benefit.

Hip and knee replacement surgery is now part of mainstream practice. Increasing demand coupled with financial pressures has led to disinvestment in follow-up provided which could lead to complications or disease recurrence going undetected, leading to an increased need for revision surgery and costly rehabilitation.

Using data from the National Joint Registry (NJR) linked to NHS Digital Health Episode Statistics (HES)-Patient Reported Outcome Measures (PROMs) data, the applicant aimed to:

1. Determine when patient follow-up should occur and to identify any peak in the mid-late term revision risk.
2. Identify predictors of mid-late term revision to determine which patients are most likely to require intervention.

A recommendation for class 1, 4 and 6 support was requested to cover activities described in the application.

Confidential Patient Information Requested

Access was requested to data from NJR in relation to patients who have undergone joint replacement.

NHS number, date of birth, gender, postcode and unique NJR patient identifier will be provided to NHS Digital from the NJR.

HES/PROMS linked dataset to be returned to Oxford University, Big Health Data Group – pseudonymised, with unique NJR patient identifier.

Confidentiality Advisory Group advice

Public Interest

Members agreed that the application defined a medical purpose which was in the public interest through the potential improvement in patient follow-up and the identification of predictors which would identify which patients required intervention.

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 impracticable due to the cohort size, which was identified as approximately 1,500, 000 patients.

- Use of Anonymised/Pseudonymised Data

Data would be linked and pseudonymised by NHS Digital.

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 Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support

3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Context

Purpose of application

This application from the University of Manchester set out the purpose of monitoring the long-term safety of new drugs prescribed for rheumatoid arthritis in the NHS clinical setting. The BSRBR-RA study (a national observational study led by the British Society for Rheumatology) was set up in 2001 for this purpose.

Each patient has consented to flagging with the national registers, access to full medical records for the completion of study questionnaires and for their name to be registered on the study database. However, the level of information within the consent form is not sufficient to fully explain the extent that participant's data will be used to link their data with NHS Digital/HES/other national organisations such as MINAP.

The consent form was updated in October 2016 to include linkage with HES data via NHS Digital, therefore consent is prospectively valid. As the previous consent did not include this linkage (which was not available at the time) this application is for support to carry out this linkage for patients consented into the study prior to October 2016 (previous consent form included with application).

Section 251 support was requested for the disclosure of confidential patient information from BSRBR-RA to NHS Digital, for patients recruited prior to October 2016.

A recommendation for class 4 and 6 support was requested to link patient identifiable information obtained from more than one source and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to NHS number/CHI/ HCN, date of birth and study ID – to be transferred to NHS Digital for linkage.

Confidentiality Advisory Group advice

Public interest

The CAG agreed that the application demonstrated a medical purpose and 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 CAG was convinced that consent was not practicable, as the patients would mostly be lost to follow-up, and also that it could confound the study results.

- Use of anonymised/pseudonymised data

Identifiable data had previously been collected without consent. The proposed linkage with HES data would be done via NHS Digital using the minimum dataset for linkage.

Justification of identifiers

As above – no concerns were raised with the use of additional identifiers.

Additional points

Members agreed that the patient and public involvement for the application was adequate, and the approach to patient notification and opt out was appropriate.

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. Favourable opinion from a Research Ethics Committee. **Confirmation provided with application.**

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmation provided with application.**
3. **Applicant was advised that approval from CAG applies only to England and Wales – applications should be made to the appropriate bodies in Scotland and Northern Ireland for the processing of data in these countries.**

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

24 February 2017

Present:

Name	Capacity	Items
Dr Tony Calland	Chair	1a, 1b
Dr Harvey Marcovitch	Reviewer	1a, 1b
Ms Gillian Wells	Reviewer	1a, 1b

Also in attendance:

Name	Position (or reason for attending)
Ms Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0031 REmLap

Context

Purpose of application

This application from The Dudley group NHSFT set out the purpose of examining recovery in patients, following emergency Laparotomy, using questionnaires to capture the patient's experience of recovery.

This high risk operation was often carried out on elderly and very unwell patients; it was known that an average of 15% would die within 30 days of surgery. Less was known about recovery, particularly after discharge. This small pilot study aimed to investigate the feasibility of a larger trial, to discover how many patients made a full recovery to the quality of life they had before the illness preceding the emergency laparotomy, and to find out about the experiences of those who did not. This research would help to inform patients about the long-term prospects of recovery, and to inform treatment during recovery.

Section 251 support was requested in order to screen records to identify and contact a cohort of patients who had undergone the operation.

A recommendation for class 3 and 6 support was requested in order to select and contact patients to seek their consent and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to operation details and age in order to check eligibility. For eligible patients the name, hospital number, ward location and names of operating surgeons, anaesthetists and the patient's normal medical/surgical team would be retained for the purpose of approaching first the clinician, then the patient, in relation to participation in the study.

Confidentiality Advisory Group advice

Public interest

The CAG agreed that there was a strong public interest in the study, and that it was important to investigate the high mortality rate following emergency Laporotomy.

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

It was noted that the application was made to enable the research team to screen records in order to identify and contact eligible patients to gain consent, therefore consent would be sought at the earliest opportunity.

- Use of anonymised/pseudonymised data

It was accepted that anonymised or pseudonymised data could not be used for this purpose.

Justification of identifiers

The identifiers to be accessed were appropriate for the purpose of the application; no concerns were raised by the CAG.

Additional points

Public involvement

The CAG was satisfied that the requirement to carry out patient and public involvement work had been met.

Patient notification and opt out

Members discussed the issue of patient notification and opt out in relation to this activity. It was noted that the patient notification materials only enabled the patient to opt out of being approached by the researcher, rather than opting out of the screening of their medical record.

It was acknowledged that implementing a process to enable patients to opt out of the screening of their records would be difficult in this situation, given that patients would be undergoing emergency surgery and could be too unwell to register dissent. It was also agreed that the public benefit for the study was significant and this went some way to counter-balancing the risk that of bypassing the requirement to provide a method of opt out.

The CAG agreed, however, that efforts should be made to allow opt-out from screening. It was suggested that the poster could be altered to give details of how to opt out from this part of the study, together with a phone number and email address in addition to the option of directly contacting the care team. This would mean that the research team would need to wait for a reasonable period (a week was suggested), to give time for the patient to register dissent.

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. The applicant was asked to provide details of how objections to the screening of patient medical records would be respected.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

b) 17/CAG/0034 The Nuclear Community Charity Fund Chromosomal Study

Context

Purpose of application

This application from the London School of Hygiene and Tropical Medicine set out the purpose of recruiting veterans exposed to ionising radiation, in order to research potential genetic damage and the possibility of transmitted genetic alterations in their children.

The British Government undertook a series of nuclear tests at sites through the South Pacific and Australia during the 1950-60's in which over 22,000 British troops took part. Approximately 3000 veterans of this programme remain alive today. The question of whether these service personnel were exposed to ionising radiation as a consequence of their participation and, whether their health and that of their children has been unduly affected was raised in the decades following this testing programme and continues to be debated to this day.

This project aimed to carry out chromosomal analysis of cells from nuclear test veterans and their children. A control group of veterans would be matched on age, service, rank, and would have served at the same time in tropical regions but would be verified as not being present at test sites.

The applicant stated that the work would help to improve understanding in this area, and would inform health and social care providers in their provision of care to this community of veterans and their families.

Participants would be identified from the UK nuclear test veterans cohort study. Details of the cohort including updated vital status and cancer incidence was maintained by Public Health England, who

would provide details to NHS Digital, in order for NHS Digital to provide patient GP details to the applicant.

The applicant would use the details supplied to write to each potential participant's GP explaining the purpose of the study and asking for confirmation that the subject had a surviving spouse/partner who was also registered at the same GP practice. If so, and if the GP did not feel it was inappropriate for any reason, the GP practice would be asked to pass on a letter, participant information sheet & consent form and reply slip with pre-paid addressed envelopes outlining the study.

A recommendation for class 3 and 6 support was requested to select and contact participants 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, date of birth and GP contact details.

Confidentiality Advisory Group advice

Public interest

The CAG agreed that the application demonstrated a medical purpose and benefit to the patients. There was a public interest in the activity.

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 application was made in order to obtain patient details for the purpose of contacting them to obtain consent, via the GP. Members agreed that this was appropriate.

- Use of anonymised/pseudonymised data.

It was noted that efforts had been made to minimise the flow of identifiable data.

Justification of identifiers

As above, members were satisfied that the identifiers to be used were appropriate and justified.

Additional points

Members agreed that the applicant had satisfied the requirement to carry out patient and public involvement work.

The CAG discussed the approach to patient notification and opt out, which had been addressed in relation to the nuclear veterans groups who would be able to access information on the nuclear veterans' website. The CAG was satisfied with the information provided, although it was suggested that clear headings and a review by a member of the patient group could help to make the information clearer.

There was no information relating to the control group, who would not access the nuclear veterans' website. The CAG agreed that this should be addressed, suggesting that efforts could be made to notify this group via army or Navy websites or groups.

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. The CAG suggested that the patient notification was reviewed by a member of the cohort to ensure clarity (they were advised that this was a suggestion only, approval was not conditional upon this point).
2. The applicant was asked to provide details of how the control group could be notified of the intention to access identifiable information for the purpose of seeking consent.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.