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

Amendments October 2015

Reviewers:

Name	Capacity	Items
Tony Calland	Chair	1a, 2a, 2b
Robert Carr		1a
Mr Anthony Kane		1a

1. AMENDMENT –NON- RESEARCH

a) National Bowel Cancer Audit - ECC 1-03(d)/2012

Context

This application from the Health and Social Care Information Centre set out the purpose of collecting data in relation to bowel cancer patients in order to assess the effectiveness and appropriateness of treatment received by this patient group from NHS services. A recommendation for class 1, 4, 5 and 6 support was requested to access data in relation to all patients with bowel cancer in England and Wales.

Data sources included NHS Trusts, Hospital Episode Statistics and ONS mortality data. NHS number, date of birth, date of death and postcode were requested for linkage and analysis purposes.

Amendment request

The amendment request detailed a change to the extent of data requested, e.g. additional datasets or extension of time period covered.

The National Bowel Cancer Audit sought approval to link the Audit data to the NHS England's Cancer Patient Experience Surveys and Hospital Episode Statistics (HES) for a further three years while funding was in place.

Linkage of the available surveys from the National Cancer Patient Experience with data that was available in the Audit and HES was proposed. This would provide the opportunity to examine how representative the PREMs Survey was of all groups of patients, including those not having a major resection and those receiving palliative and supportive care. This would help the Health Service measure and improve the

quality of future services and understand how the experience has affected patients' longer term.

It was noted that the National Bowel Cancer Audit was also proposing that during the three year funding the feasibility of using information reported by patients themselves about the outcomes of their bowel cancer e.g. symptoms, functional status and quality of life was assessed. This work would be carried out as a collaborative project with NHS England's National Cancer PROMs Programme of the National Survivorship Initiative. The data was held in the National Cancer Registration Service, hosted by PHE. It was noted that the PROMs surveys were consented and previously approved as ECC 6-02(FT8)/2012 National Cancer Survivorship Initiative. The National Bowel Cancer Audit project team had discussed these proposals with NHS England's Insight team, as the data controllers, who oversee the PROMs and PREMs work and they were supportive of this project.

HQIP, as data controller of the audit data were also supportive of this request and had included this work in the deliverables for the 3 year contract.

Confidentiality Advisory Group advice

The sub-committee reviewed this amendment and recognised that it satisfied the public interest and medical purpose and that the recommended way forward was a practical way of addressing the project's objectives.

However members felt that although the researchers had provided a certain level of consent for linkage as part of participating in the cancer survey. Prospectively if they were going to carry out further linkage of patient outcomes on a routine basis it would appear that the information to participants could be updated to detail the audit and proposed linkage and that this provided a good opportunity to inform patients about the audit.

Members were happy to support for the retrospective group but felt that the applicant would need to ensure that consent was obtained for participants for any future work.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health.

b) Towards an earlier diagnosis of Neuroendocrine Tumours (NETs) - CAG 6 (PS1)/2014

Context

This application from Hampshire Hospitals NHS Foundation Trust set out the purpose of a service evaluation project which aimed to analyse and assess patients diagnosed with colorectal (and terminal illeal) NETs identified through the NHS Bowel Cancer Screening Programme (NHS BCSP). The application was defined as service evaluation by the applicants using the HRA decision tool.

A recommendation for class 5 and 6 support was requested to cover access to confidential patient information from the NHS BCSP in relation to all patients who had been identified with Colorectal carcinoid or Neuroendocrine Tumours. This information would then be used to trace patients care across NHS organisations and obtain information in relation to the care provided for CR NET to date. Information in relation to mortality was requested from the Health and Social Information Centre (HSCIC).

Confidential patient information requested

Access was requested to name, NHS number, postcode and date of birth to allow linkages to take place. Date of death would be retained for analysis purposes.

Further information

Following the advice provided by CAG summarised in the outcome letter dated 16 July 2014, the applicant contacted the HSCIC and confirmed that they would be requesting mortality data for the cohort. This would be a one-off request and the dataset would be de-identified following receipt of this information. In order to receive the additional data the following identifiers would be required:

- Patient name
- Full date of birth
- Postcode

Amendment request

An amendment was requested for an extension to the study duration for a further six months to March 2016. It was noted that without an extension to the duration the study would not be able to fulfil its aims, to assist in establishing incidence and current practice in England that will help inform the updating of national UKINETS guidelines for this patient population.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health.

2. AMENDMENT –RESEARCH

a) Case Mix Programme - PIAG 2-10(f)/2005

Context

This audit application from the Intensive Care National Audit and Research Centre (ICNARC) set out a project to develop a national resource for practising, managing and commissioning critical care in the UK, including auditing, monitoring and analysing patient treatment and outcomes. A recommendation for section 4, 5 and 6 support was requested to cover access by ICNARC to personal confidential data of all patients receiving critical care in participating units in England and Wales (it was noted that the activity also covers Northern Ireland but this is outside the remit of the Confidentiality Advisory Group). Identifiers sought were NHS number, date of birth, postcode and sex.

Amendment request

An amendment request was received on 14 August 2015 which detailed changes to the extent of data requested through access to additional datasets; the applicant wishes to link to additional, non-identifiable fields (stored locally at participating critical care units) for a subset of patients already included in the Case-Mix Programme database. The fields would be requested only for children admitted to adult critical care units in the South West region, who participate in a regional audit. The additional fields requested are;

* Booked admission
* Underlying conditions for PIM/PIM2
* Pupil response
* Base excess
* PaO2
* FiO2
* Method of O2 delivery
* Systolic blood pressure
* CPAP
* Mechanical ventilation

It was noted that the request was to support a research project funded by the Great Ormond Street Hospital Charity to evaluate alternative locations of critical care for teenagers. The researchers wish to evaluate data from critical care units in the South West Network who, as well as submitting data for the Case Mix Programme, collect (locally) the dataset for the Paediatric Intensive Care Audit Network (PICANet) on all children admitted to the adult critical care units in the region. By linking the data for children from these units the researchers hope to evaluate the comparability of data items recorded for the Case Mix Programme and for PICANet and establish an appropriate risk adjustment method that can be used in the subsequent main study, which will use anonymised, pooled data from the Case Mix Programme and PICANet.

The research study received a favourable opinion from the NRES Committee South West – Central Bristol (REC reference 14/SW/1131)

Confidentiality Advisory Group advice

It was noted that the extra fields requested do not compromise confidentiality and the purpose to include children admitted to adult intensive care units seemed to be an appropriate addition to the study.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

b) Understanding age inequalities and inequities in cancer diagnosis, treatment and outcomes in brain, colorectal and ovarian tumours, sarcoma and Hodgkin's lymphoma - CAG 2-03(PR1)/2014

Context

This application from the University of Leeds set out the purpose of a study which aimed to use routine health data to quantify and understand the influence of age on the incidence, tumour characteristics, diagnosis, treatment, survival and outcomes of a number of cancers at a population level.

The application detailed linking a number of datasets; cancer registry, HES and pathology and treatment information, at the NCRS Northern and Yorkshire offices. It was confirmed that any datasets taken off site would be fully anonymised.

A recommendation for class 2, 4, 5 and 6 support was requested to cover access to date of birth, date of death, postcode and NHS number. All identifiers would be removed once all linkages had taken place.

Amendment request

An amendment was requested for a change to the extent of data requested. It was noted that the original approval specified that information would be sought for those with an ICD10 code of C56 (malignant neoplasm of ovary) but after discussion with the clinical collaborators it became clear that additional ICD10 codes would be required to capture all the patients necessary as the coding of ovarian tumours varies across the country. Both C48 (malignant neoplasm of retroperitoneum and peritoneum) and C57 (malignant neoplasm of other and unspecified female genital organs) are now required to ensure that all ovarian tumours are recorded. It is similarly requested that sarcoma cases are identified using morphology codes (Appendix 1) as well as the ICD10 site codes.

Confidentiality Advisory Group

The amendment requested was forwarded to the Chair who agreed that access to the additional data codes could be supported.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

c) Survival of children born with congenital heart disease - CAG 5-08(b)/2013

Context

This research application from Newcastle University set out a study to determine survival for all children with congenital heart disease and examine predictors of survival using demographic data.

A recommendation for class 1, 4 and 6 support was requested to provide BINOCAR data to the Health and Social Care Information Centre (HSCIC) and a linked BINOCAR and ONS dataset to the Regional Maternity Survey Office (RMSO) at Newcastle upon Tyne Hospitals Trust. The aim was for the RMSO to carry out survival analysis and provide a pseudonymised dataset to Newcastle University.

Confidential patient information requested

Access was requested to name, date of birth and postcode in order for the HSCIC to link BINOCAR data to mortality data

Amendment request

The amendment request specified that linked anonymised data would now be sent from the HSCIC to Public Health England Regional Maternity Survey Office (RMSO), rather than Newcastle University.

Confidentiality Advice Team advice

The amendment requested was considered by CAT who noted that there was no additional disclosure of identifiable data and therefore the amendment could be recommended for support.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

1. Updates to previous applications

15/CAG/0114 – Yorkshire Health Study

This was considered at the September 2015 CAG meeting and was the culmination of a number of previous discussions and engagement with the Information Commissioner's Office. The applicant has specifically asked for their thanks to be passed to CAG members, stating "*they have been impressed with the CAG process and efforts made by CAG to work with ICO to bring a sensible resolution*".

15/CAG/0179 West Midland Regional National Children's Registry

Support was recommended for a period of six months to enable a number of actions to take place, however it is noted that the REC has subsequently provided an unfavourable ethical opinion.

Due to potential links with Regulation 2, Members had previously queried Public Health England's approach in relation to onward identifiable disclosure. PHE has confirmed for clinical audit purposes it would not release identifiable cancer registration data under regulation 2. Where identifiable data is released for the purposes of clinical audit this would only be done so if the requester was a medical professional with a direct care and legitimate relationship with the patient through implied consent. The release of patient identifiable data for research purposes would only be permissible if there was a clear legal basis such as consent or another legal basis

15/CAG/0005 Research to identify measures of quality & safety of healthcare

The final CAG outcome letter, dated 30th July 2015, required the applicant to report on the following two items for the 22nd October 2015 CAG meeting.

1. Appropriate contractual arrangements should be established with trusts who are not customers of DFI; progress towards this should be reported within 6 months.

The applicant confirmed that a contractual agreement for non-DFI customers was sent CAG on 20 March 2015. The applicant also sent a copy to the Health and Social Care Information Centre on 28th August 2015 for comments, but although HSCIC have confirmed receipt of the draft agreement no comments had been received to date. The proposed contractual arrangements will be reviewed by the Independent Group Advising on the Release of Data (IGARD/DAAG) to HSCIC within the application for identifiers for the remaining non-DFI hospital trusts.

2. Further information in relation to the discussions with HSCIC around the filtering of datasets and feasibility of them offering the re-identification service for DFI customers.

It was noted on page 3 of the final outcome letter, dated 30 July 2015, that further information was provided from HSCIC on 16th July 2015. The information was forwarded to a sub-committee of members who noted and agreed that HSCIC's response meant that there was evidence that there was no alternative of providing a re-identification service at this time. CAG members have agreed that an update in relation to this should be provided at an annual review stage to which the applicant will respond accordingly.