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

May 2017

Application title: **Is the Current Threshold for Diagnosis of "Abnormality", including non-ST Elevation Myocardial Infarction, using Raised Highly Sensitive Troponin Appropriate for a Hospital Population? The CHARIOT Study**

CAG reference: **17/CAG/0083 (previously 17/CAG/0022)**

IRAS project ID: **215262**

REC reference: **17/SC/0042**

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Dr William Bernal	Yes	
Dr Tony Calland	Yes	
Dr Lorna Fraser	Yes	
Ms Kim Kingan	Yes	
Dr Rachel Knowles	Yes	
Dr Harvey Marcovitch	Yes	
Mr David Smallacombe (Lay)	Yes	
Dr Mark Taylor (Chair)	Yes	

Purpose of application

This application from University Hospitals Southampton specified the following. The current upper limit of normal for high sensitive troponin (Hs Trop) is derived from a healthy population aged 18-40. Any measurements above the upper limit of normal indicate the possibility of a heart attack when taken in the correct context. However, it is already known that troponin levels can be high in certain individuals as a result of other causes. Factors that can influence a patient's troponin include age, gender, infection, heart failure, high blood pressure, diabetes mellitus and inflammatory conditions. When the standard levels used from a healthy population are applied to patients presenting to hospital, patients can be incorrectly diagnosed and treated as having a heart attack inappropriately. This issue has been exacerbated by the new highly sensitive troponin blood tests being used in modern clinical practice

The CHARIOT Study aims to check the Hs Trop levels on patients who have already had blood tests undertaken as part of their routine clinical care. The study will not require any additional blood samples to be collected. A total of 20,000 consecutive patients will be recruited to the study with this number specified as required to give an accurate representation of the levels of Hs Trop in the population of patients who are admitted and cared for in the hospital.

The aim of this study is to define the upper limit of normal for a high sensitive troponin level for a hospital population.

A recommendation for class 1, 4, 5 and 6 support was requested to cover the relevant activities specified in the application.

Confidential patient information requested

Access was requested to enable access to information related to the potential cohort. In particular, this would involve access to NHS Number, Hospital Number (will be used to access the electronic hospital records of patients recruited to the study), date of birth (to confirm that the hospital number corresponds to the correct patient) and gender.

The cohort relates to all patients attending UHS and requiring biochemistry testing as part of their routine care; this includes all clinical presentations in the adult population.

Confidentiality Advisory Group advice

This outcome should be read by data controllers in conjunction with the letters dated 28 March 2017 (deferred) and 18 May 2017 (provisional approval).

Public interest

Members agreed that there appeared to be a public interest in this type of activity taking place, however, were of the view that certain aspects would need to be clarified as set out below.

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 applicant indicated that it would not be feasible to consent 20,000 patients in the proposed time frame (3-4 weeks). The study will recruit consecutive patients and the applicants stated it would jeopardise the power of the study should the consecutive recruitment process be threatened. Members had sought clarification on this aspect and were satisfied with the responses as per the provisional approval outcome.

- Use of anonymised/pseudonymised data

Identifiable data was specified to be required for subgroup analysis and to ensure that accurate information for patients recruited to the study is collected. The application also indicated that age, gender and comorbidities have a strong influence on an individual's HsTrop level and therefore the information is required to ensure strong scientific conclusions are drawn from the study.

It was stated that once all the relevant data has been collected the patients NHS Number and date of birth will be removed from the database to ensure no identifiable data is present in the database. Members had sought clarification on this aspect and were satisfied with the responses as per the provisional approval outcome.

Patient notification and objection

It is a general principle of the CAG, when recommending support under Regulation 5, 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 confirmed that if a patient's medical records report dissent in research these wishes will be respected and the data will not be included in the study. The applicant confirmed that although individual patients will not be informed of the study, steps will be taken to inform the general patient population that this study will be running through advertisement in the trust clinical research website which can be found at http://www.uhs.nhs.uk/ClinicalResearchinSouthampton/Home.aspx. This will be done prior to the commencement of the study.

Members advised that they were unclear on how the information provided within hospital systems clarified how individuals who wish to opt out would have an accessible means of doing so, and requested further consideration as how this would practically be achieved. Members had requested information on the practical steps that would be taken to manage the process of respecting an objection that is accessible. Members had sought clarification on this aspect and were satisfied with the responses as per the provisional approval outcome.

Patient and service user involvement

It was noted that applicants had not involved service users in the design of this study due to its stated scientific nature. It was stated that if this study should lead to further investigations they intend to approach organisations such as INVOLVE for input.

Members were not initially persuaded by the information provided to justify limited engagement and felt that the patient and service user engagement should be further strengthened and a plan and detail of this should be provided back for review. Members had sought clarification on this aspect and were satisfied with the responses as per the provisional approval outcome.

Data flows

Members were unable to clearly understand the data flows, information and persons involved and requested more detailed information through provision of a clear diagram that provides all of this information. This should follow the flow of identifiable information throughout all stages and also include relevant stages at which identifiable information is removed, methods of transfer and relevant data controller bodies. Members had sought clarification on this aspect and were satisfied with the responses as per the provisional approval outcome.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, and as the specific conditions of support had been addressed, the CAG agreed that a recommendation of conditional approval would be provided.

Specific conditions of support

1. Favourable opinion from a research ethics committee. **Received.**

2. Confirmation from NHS Digital that the IG Toolkit submission has been reviewed and is considered satisfactory. **Email received 19 May 2017 confirming version 14 satisfactory from NHS Digital in relation to University Hospitals Southampton NHS Foundation Trust.**

3. Explicit right of objection to be included in information made available to the relevant population. **Provided.**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Study title: **Tracking the impact of gestational age on health, education and economic outcomes: a longitudinal record linkage study**
CAG reference: **15/CAG/0196**
IRAS Project ID: **183510**
REC number: **15/SW/0294**

Context

Purpose of application

This application from University of Oxford set out the purpose of the overall aim of the study to investigate the effect of gestational age at birth on health, educational and economic outcomes up to age 11 years.

TIGAR will use information about all children born in England during 2005/2006 (about one million). Information on the children will be obtained from: birth records; records of hospital admissions or outpatient visits up to age 10 years and primary school records (e.g. SATs results, special educational needs). The information from these sources will be linked together by independent organisations, which will make the data completely anonymous before sending it to the TIGAR team for analysis.

Support is requested to allow the disclosure of confidential patient information from:

- The HSCIC to the Office for National Statistics (ONS)
- The ONS to the Education Data Division
- The TIGAR team to access patient confidential information within the ONS VML – this is for validation purposes

A recommendation for class 1, 2, 4 and 6 support was requested.

Confidential patient information requested

Access was requested to child name, sex, date of birth and most recent postcode for the linking process.

Amendment request

The applicant was investigating health and educational outcomes associated with premature birth. They had requested identifiable information for linkage, and anonymised data for analysis.

Although initially the need to include information about deaths was not recognised, the applicant had later discovered that in order to avoid confounding survival analysis and regression models, they would need to know which children had died and approximately when the death occurred. This information would be used to create a censoring variable based on the age in months at which the child died, to enable accurate calculations to be made – for example, a child who died at 3 months old would only be at risk of hospital admission for pneumonia before 3 months.

Access would be requested to age of death in months, to be used in survival and regression analyses and to exclude these children from linkage to school data, where they died before starting school.

Confidentiality Advice Team advice

The amendment requested was considered by the CAT, who found the rationale for accessing age of death to be sound and in the public interest as it would increase the validity of the research. It was noted that the data would be coarsened, from full date of death to age in months.

Given that the full date of death would not be accessed, the additional data would not be considered identifiable and therefore no additional confidentiality concerns were raised. It was noted that access to the data had been approved in principle by ONS.

The patient notifications would not be updated, as they did not contain details of any of the specific data items to be analysed. The CAT considered this to be reasonable and justified.

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.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **V13 in place, confirmed published and reviewed as satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee.

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor
Dr Murat Soncul	Alternate Vice Chair

Study title: **Hip Fracture Audit**

CAG reference: **CAG 8-03(PR11)/2013**

Context

This audit application received approval by the Secretary of State for Health on 11 April 2011. The application set out aims to use case-mix, process and outcome data together with quality standards to improve the quality of care. The audit was administered by the Royal College of Physicians (RCP) as data processor on behalf of HQIP.

A recommendation for class 1, 3, 4, 5 and 6 was requested to cover linkage with Hospital Episode Statistics (HES) data. Access was requested to NHS number, date of birth, date of death and postcode.

Amendment Request

The amendment request was for a change in data processor for the audit programme as a whole, of which the Hip Fracture Audit was a part.

The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) at Oxford University would be contracted as statistical provider for the national Falls and Fragility Fracture Audit Programme, in place of the Royal College of Surgeons Clinical Effectiveness Unit (RCS-CEU). This change would ensure scientific rigour by a credible academic unit, and this would increase public confidence in the audit.

Confidentiality Advice Team advice

It was noted that there would be no change in purposes, data sources or data items. The data would of necessity cease to flow to RCS in order to be processed by NDORMS. The change was likely to improve public confidence and ensure scientific rigour.

Patient notifications had been updated accordingly.

Confidentiality Advice Team 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.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **IG toolkit organisation code provided by the applicant, v13 confirmed published and reviewed as satisfactory.**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor
Ms Gillian Wells	Committee Member

Study title: **The EPIC-Norfolk prospective population study**

CAG reference: **CAG 9-08 (e) /2014**

REC number: **98CN01**

Context

Purpose of application

This application from the University of Cambridge detailed an existing cohort study of 25,639 patients aged between 40-79 in 1993-97 with cancer and/or chronic disease. Patients were originally recruited on a consented basis via GP practices. Support under the Regulations was requested for continued access to confidential patient information (HES data, GP data and death and cancer registration data) in order to follow up the cohort. Consent to collect follow up data was called into question following queries raised by a Caldicott Guardian who noted that the original consent materials suggested that the study would end in 2000.

Confidential patient information requested

Access was requested to name, NHS number, date of birth, postcode, gender and occupation.

Amendment request

The aim of the study was to gain a better understanding of how health could be improved and disease and disability postponed or prevented in ageing populations. With the changing demographics, having this knowledge would benefit society as whole.

Due to restructuring of medical records, and late diagnosis of some conditions, a gap in the data sources had been identified, specifically in relation to cognitive decline and dementia. The applicant would need access to this data in order to meet the aims of the study, and the data resided in the HES Mental Health Dataset.

Cognitive decline and dementia are age-related conditions that have huge implications both as a human and economic cost on society, and dementia has been described as a public health priority.

The applicant therefore requested access to all confidential patient information held on the Mental Health Data set from NHS Digital and secondary use health data sources (including those held by the Norfolk and Suffolk Foundation Trust) that would include dementia and cognitive impairment endpoints, and to relevant health information from hospital and GP medical letters, held on administrative databases located with health care service providers.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who was of the opinion that the amendment was in line with the original approval and accepted that it was in the public interest for the applicant to access the mental health record for this purpose.

Updated patient notifications materials were provided in the form of the Newsletter sent to all participants in the study. These were reviewed by the Chair, who agreed that the access to mental health data was clearly explained, however opt out was not as clear. Contact details were given for participants who wished their data to continue to be used for EPIC but not for other uses, however contact details were not explicitly given for those who wanted to opt out of EPIC altogether.

Although content to recommend support, the Chair advised the applicant to clarify this point in the Newsletter.

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.

Specific conditions of support

1. Advice only: - please clarify the opt out arrangements as in the advice above. This is a suggestion only and does not affect the recommendation of support.
2. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed via website: IG Toolkit for University of Cambridge, School of Clinical Medicine published and reviewed as Satisfactory**
3. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed**

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor
Dr Tony Calland	Vice Chair

Study title: **Prognostic factors in Prostate Cancer**

CAG reference: **ECC 3-06(m)/2009**

REC number: **99/3/040**

Context

This application was for a retrospective population based study to be carried out in patients registered on UK regional cancer registry databases who have had prostate cancer diagnosed between 1990 and 2003 inclusively. Support under section 251 was requested as patient data would be collected from hospital medical records and analysed to evaluate the prognostic value of specific factors on progression in men with clinically localised prostate cancer.

Amendment Request

The amendment requests an extension to the data collection dates to allow access to data on patients who have had a prostate cancer diagnosis up to 2006 (current approval extends only to 2003), with continued follow-up to 2030.

The amendment also requested a change to contact details for the application, due to the departure of staff from Centre for Cancer Prevention.

Confidentiality Advisory Group Advice

The amendment request was forwarded to the Vice-Chair who agreed that the amendment request was in line with the terms of the original approval. It was acknowledged that the extension of the cohort would provide a larger sample size for inclusion in the study which would enable validation of the CPC (Cell Cycle Progression) Score and the identification of new biomarkers for distinguishing cancer.

The Confidentiality Advice Team had queried the time lapse between the REC approval and submission to CAG for consideration of the amendment. The applicants advised that the staffing changes came shortly after REC approval was granted and the delay in submission to CAG was down to the delay appointment of new staff. Changes to contact details were noted and no further issues were raised. Support was recommended for the amendment.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Vice 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.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – 08/05/2017 – Barts Cancer Centre, V13 2015/16 published reviewed grade of satisfactory at 100%).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – issued 28 August 2014).**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Study title: **A case-control evaluation of the NHS Breast Screening Programme**

CAG reference: **ECC 6-05(e)/2012**

IRAS Project ID: **91136/332725/1/761**

REC number: **12/LO/1041**

Context

Purpose of application

This research application from Queen Mary University of London (QMUL) detailed a case control study to evaluate the impact of the National Breast Screening Programme. The study would incorporate the following four case control comparisons:

- Breast cancer deaths with living controls to assess impact on mortality;
- All breast cancer cases with disease-free controls to assess the effect on breast cancer incidence;
- Late stage breast cancer cases with controls to assess the effect on incidence of late stage disease;
- Breast cancer deaths with surviving breast cancer cases to assess the interplay of early detection, tumour attributes and treatment on mortality from breast cancer

A recommendation for class 1, 4 and 5 support was requested to cover disclosure of MRIS and cancer registry data to NHS Connecting for Health. NHS Connecting for Health would then link MRIS, cancer registry and NHAIS screening data and identify controls. A linked dataset including NHS number, date of birth and date of death would be transferred to QMUL for analysis purposes.

It was noted that in the period since the initial application, NHS Connecting for Health had been subsumed into the Health and Social Care Information Centre.

Confidential patient information requested

Access was requested to NHS number, date of birth and date of death.

Amendment request

The amendment request was for an extension to the timeframe of the study until December 2018.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team (CAT) who noted that there would be no extension to the time taken to process data; the amendment was requested to allow for delays in data collection. No additional confidentiality concerns were raised by the time extension.

The variation to contract was provided and reviewed.

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.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **V13 confirmed published and reviewed as Satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee.

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **Extension to existing approval PIAG 1-05(e)/2006 HTA 04/33 Frequency of follow-up for patients with intermediate risk adenomas**

CAG reference: **PIAG 1-05(e)/2006**

IRAS Project ID: **55943**

REC number: **06/Q0501/45**

Amendment Request

This amendment was submitted to request changes to the data sources, an extension to the original follow-up period, together with a request for an additional analysis on the existing data set.

The additional analysis data source will be Public Health England Office for Data Release to enable information around costs of different surveillance strategies to be gathered to allow economic analysis to be undertaken.

The extension request is to gather follow-up data up through to 2016.

The additional analysis which is proposed on the existing data source would be to review the frequency of follow-up for patients within the low and high-risk adenoma groups, in addition to the analysis which has already been undertaken on the intermediate group.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Chair who agreed that the rationale for the amendment appeared sound and it was acknowledged that support in principle had been provided by NHS Digital for the additional data linkage. Support for the amendment was recommended.

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.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. (**Confirmed – Version 14, 2016/17 at a reviewed reported grade of 94% satisfactory**).
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – 10/04/2017)**