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

## March 2017

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## Reviewers:

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| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Application title:** **TargetCOPD: A randomised controlled trial of targeted case finding for COPD versus routine practice in primary care**

**CAG reference:** **16/CAG/0072**

**IRAS project ID:** **85337**

**REC reference:** **11/WM/0403**

**Context**

Purpose of application

This application from the University of Birmingham set out the purpose of a project to compare the benefits and cost-effectiveness of two alternative case-finding approaches to identify undiagnosed COPD in general practice. There is significant under-diagnosis of COPD patients and this represents a group of people who could benefit from management by their GP. There is increasing interest in finding these patients but no evidence as to which approach to case-finding would be most effective or cost-effective in the short or longer term.

Using a cluster randomised controlled trial (RCT) design in 54 West-Midlands general practices; the TargetCOPD study assessed two approaches (targeted case finding vs usual care). Using an individual patient RCT nested in the targeted arm, the effectiveness and cost-effectiveness of active case finding using a postal questionnaire, and opportunistic case finding at usual surgery consultations were also compared. Patients who reported positive respiratory symptoms were invited for further spirometric assessment to ascertain whether they had COPD or not. All data was anonymised to the investigators until patients voluntarily provided their information. The most effective and cost-effective method in identifying new patients had therefore been compared, this study aims to carry out longer term follow-up to evaluate whether the different approaches are also effective in improving long-term health of patients.

Previously, within the targeted arm of the trial, participants were randomly allocated (on a per household basis) to receive either the active case finding intervention or the opportunistic case finding intervention. As part of the previous study participants were eligible if they were aged 40-79, current or ex-smokers, and not diagnosed with COPD. Potential participants were identified through GP practice registers and anyone potentially eligible screened by the GP before being invited to take part. GPs assessed their suitability for the study; i.e. if they had conditions such as terminal illness or dementia or other reason their GP considered them unsuitable they were excluded at this stage. GPs also ensured that anyone who had died was removed from the list. In the active targeted arm, participants were offered a short questionnaire (either at the surgery during a routine visit or by post) with patient information sheet [attached] which they returned to the investigators or ignored if they so wished. They were informed of the purpose of the study which was to identify new cases of COPD. People

returning the questionnaire and reporting any of the required respiratory symptoms were invited for spirometry assessment and consent was provided. GPs were informed of any patients that met the criteria for diagnosing COPD. Patients in the opportunistic targeted arm also had their records flagged to prompt the healthcare practitioner to deliver the questionnaire as above, however, they did not receive a postal questionnaire.

In the routine arm of the trial, eligible participants did not have any individual contact with researchers. GP practices continued with their usual care and new cases of COPD were identified according to usual practice. Practices provided investigators with anonymised information on the eligible patients with basic demographic/medical characteristics at the start of the study period. Practices then notified the investigators of the new cases at the end of the one-year period with some other information including consultation rates, deaths and those who had left the practice.

In order to gather information on longer-term hospital and mortality data, the researchers now need to link GP records of all eligible patients via the HSCIC. This requires temporary access to the PID of all eligible patients whether consented or not by the researchers. As there are nearly 75,000 patients, it is proposed to seek consent for this on an opt-out basis, whereby information about the proposed linkage and associated processes will be displayed in posters in the relevant participating GP practices. These posters will link to further information on the study website and also provide contact details so that patients can opt-out.

S251 support is request cover access to patient identifiable information from GP records in relation to the NHS number, Sex, Date of Birth, Postcode. This will be transferred to the HSCIC for linkage. Hospital use data, including A&E admissions information, outpatient and inpatient data as well as mortality data, including date and cause of death will be sent back to the researchers

PID for all eligible patients whether consented or not will be accessed and stored for a maximum period of about 6 months while the information is collated and send to the HSCIC for linkage. Once linkage is successful, The PID information will be destroyed.

A recommendation for class 1, 2, 4, 5 and 6 support was requested for the process of extracting and anonymising the information, to obtain and use information about past or present geographical location, to link patient identifiable information obtained from more than one source, for auditing, monitoring and analysing patient care and treatment and for one or more of the above purposes.

<u>Confidential patient information requested</u>

Access was requested to NHS number, Sex, Date of Birth, Postcode from GP records.

**Amendment Request**

This amendment concerned revisions to two documents which had previously been considered by the CAG and the corresponding REC. The two documents, which were a patient poster and website information, had previously been approved; however, NHS Digital had requested minor alterations to wording in the documents to improve clarity, before releasing the research data required.

**Confidentiality Advice Team Advice**

The CAT considered the amendment together with the revised documentation and it was noted that the revisions had been mandated by NHS Digital in order to allow the approved flow of data to begin. It was noted that the revisions did not reflect any changes to the

established protocol and represented NHS Digital's request for improved clarity. It was agreed that the revised text was in line with that which had previously been considered and support was recommended.

**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. **(Confirmed – Version 13, 2015-16, reviewed grade of satisfactory at 72%).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – 10/02/17)**

## Reviewers:

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|---|---|
| Dr Patrick Coyle | Vice Chair |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Application title:** **Understanding the Nature and Frequency of Avoidable Significant Harm in Primary Care (Phase 2)**
**CAG reference:** **15/CAG/0182**
**IRAS project ID:** **180854/836881/4/573**
**REC reference:** **15/EM/0411**

### Context

This application from the University of Nottingham set out the purpose of a retrospective cohort study (over the course of 12 months) involving case note review of primary care patients to identify instances of significant harm that are judged to be avoidable. Significant harms will include any serious adverse health events occurring during the 12 month data collection period.

It will involve 16 general practices in England in the retrospective cohort study. The total population of patients covered will be around 100,000; 2,500 patients in total across all of the practices. This sample will receive detailed retrospective case note review to identify the extent to which failures in primary health care contribute to any of these significant health problems.

The findings will be published in a report to the Department of Health, and in professional academic journals. Information will also be made available to the public and organisations/charities concerned with patient safety (using presentations/focus groups, social media, and liaison with the media).

The stated aims were:

1. To estimate the incidence of avoidable significant harm in primary care in England.
2. To quantify, describe and classify the different types of avoidable significant harm, and their severity.
3. To identify factors that, if addressed, could help reduce the incidence of avoidable significant harm in primary care in England in the future.

A recommendation for class 1, 5 and 6 support was requested to achieve the above activity and aims.

<u>Confidential patient information requested</u>

Access was requested to name, date of birth and NHS Number, gender, age and participating practice name.

### Amendment Request

The final approval for the application, which was issued in February 2016, attached a condition to the support which stated that support to process confidential patient information was only in place until 31/12/2016, as by this time it was anticipated that pseudonymised data only will be processed. An amendment was subsequently submitted to extend the duration of support to provide cover up to 31 March 2017. The current amendment requested a further extension to the duration of support to provide cover up to 31 December 2017, which is the projected study end date. It was recommended in the original outcome

that should the applicants require an extension to the duration of the support, this request should be submitted four weeks in advance of the proposed end date.

The applicants explained that the amendment was required as, whilst GPs have been recruited, they are unable to devote as much time as expected to data collection and so will take longer than expected to provide data. The amendment was submitted in line with the previously advised timeframe ahead of the expiration of the existing support.

**Confidentiality Advisory Group Advice**

The amendment requested was forwarded to the Chair who considered the rationale provided by the applicants and recommended support to the duration extension included within the amendment.

**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 – Reviewed grade was confirmed satisfactory at 91% on version 13 (2015/16).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed – REC will not issue formal letter to confirm extension (16 February 2017)**

## Reviewers:

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| Dr Mark Taylor | Chair |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Application title:** **National Prostate Cancer Audit – PROMS/PREMS**

**CAG reference:** **15/CAG/0143**

**Context**

This application from Royal College of Surgeons, sponsored by the Healthcare Quality Improvement Partnership, set out the purpose of collecting Patient Reported Outcomes Measures (PROMS) and Patient Reported Experience Measures (PREMS) data in response to patients who underwent radical treatment between 1 April and 31 March 2016 and 1 April 2016 and 31 March 2017 who are candidates for radical treatment for whom the National Prostate Cancer Audit (NPCA) has complete data for.

A recommendation for class 4 and 6 support was requested to cover access by Quality Health to patient name and address from the National Cancer Registration Service (NCRS) in order to send out surveys and NHS number and date of birth are requested to ensure that patient sample and survey response data are accurately matched.

Quality Health would send out postal questionnaires to patients and carry out mortality checks using DBS.

Confidential patient information requested

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

**Amendment request**

The change requested was to substitute access via Quality Health to the PDS/DBS service with NHS Digital's list-cleaning service.

This update to the dataflow reflects NHS Digital's updated processes that have been recently implemented in response to the instruction from the Secretary of State in April 2016 to remove the records of patients who had requested a type 2 opt-out.

The list-cleaning service would provide the required demographic data only for those patients who had NOT raised a type 2 opt-out.

**Confidentiality Advisory Group advice**

The amendment request was forwarded to the CAG Chair, who agreed that the change in data flows was appropriate.

**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.

**Specific conditions of support**

1. Confirmation of suitable security arrangements via IG Toolkit submission.

**Reviewers**

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| Professor Jennifer Kurinczuk | |
| Dr Mark Taylor | Chair |
| Ms Clare Sanderson | |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Study title:** **Global surveillance of cancer survival (CONCORD programme)**

**CAG reference:** **ECC 3-04(i)/2011**

**REC number:** **11/LO/0331**

**Context**

This application from the London School of Hygiene and Tropical Medicine set out details of the UK arm of a global surveillance of cancer survival systematic comparison of international differences and trends in cancer survival.

**Amendment Request**

This amendment requested a change to the title of the programme from 'Cancer survival in five continents: a worldwide population based study (CONCORD-2)' to the more generic title of 'Global surveillance of cancer survival (CONCORD programme)', to reflect the change from a large single study to a world-wide public health surveillance programme.

The amendment further requested specific changes to this research programme to reflect an extension of the calendar period covered by the programme from 2009 to 2014, and the addition of data for five more common malignancies - oesophagus, pancreas, melanoma of the skin, lymphomas and brain tumours.

There is no substantive change in the design, quality control, analytic methods or publication policy, and especially no change in the tightness of the procedures for physical, electronic and administrative procedures to maintain the security and confidentiality of the data.

**Confidentiality Advisory Group Advice**

The amendment requested was forwarded to a Sub-Committee of the CAG for consideration.

Members requested further information from the applicants to provide clarification that it was the intention to retain and add to the data collected as part of the original study, which had a previously cited an end date of 31 December 2016.

The applicants clarified that they intended to retain the CONCORD-2 data, but also to acquire additional data for the wider CONCORD programme. It was explained that amendment to the original approval which was requested was to change the title to reflect the change from a specific study (CONCORD-x) to a surveillance programme (CONCORD programme), and to extend the calendar period from 2009 to 2014, as well as to include more countries and five additional cancers.

The applicants advised that within section three of the amendment form, they had referred to an official government request to update the results of CONCORD-2 for the UK, which was supplied as an example to support the justification for seeking this amendment and stated:

*'It is in the public interest for the surveillance of cancer survival in the UK to continue, including comparison of cancer survival trends in the UK nations with those in other countries. This was recognised by the Independent Cancer Taskforce that prepared the most recent strategy for cancer control in England in 2015. The Taskforce asked us to update the results of CONCORD-2 with respect to the most recent cancer survival trends in England as part of the basis for its reflections.*

*The amendment will enable us to provide up-to-date figures on cancer survival trends in each of the UK nations for 15 major cancers that collectively represent 75% of all cancers.'*

The applicants clarified that the request for the amendment itself was made in relation to the wider CONCORD programme within section two of the amendment form and required the amendment to be considered for approval until 31 December 2020.

The applicants explained that under the CONCORD programme, new and updated data would be analysed for the period 2000 to 2014, as set out in section two of the amendment form. It was further explained that the request for an amendment was thus separate from the need to retain the original data for 1995-2009, acquired for CONCORD-2, for ongoing analyses and publications beyond the original date of 31 December 2016.

The Sub-Committee received the response and agreed that this clarified the scope of the amendment request and support was recommended in line with these clarifications.

**Confidentiality Advisory Group Conclusion**

In line with the considerations above, the Sub-Committee 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 13, 2015-16, reviewed grade of satisfactory at 66%).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – Ethical Opinion issued 21/2/17)**

**Reviewers**

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| Miss Rachel Heron | Confidentiality Advisor |

**Study title:** **Sentinel Stroke National Audit Programme (SSNAP)**
**CAG reference:** **ECC 6-02 (FT3)/2012**

**Context**

The Sentinel Stroke National Audit Programme (SSNAP) was commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of the Department of Health.
The audit was run by the Stroke Programme at the Royal College of Physicians (the RCP). The RCP were responsible for the clinical input, determing the dataset, reporting on the results and making recommendations based on findings.

The audit measured how the processes of care for stroke patients, from onset of symptoms up to 6 months post discharge from hospital, compared when reviewed against nationally agreed, evidence based standards. It also set out to assess outcomes for all stroke patients, including mortality at various intervals, change in modified Rankin score and institutionalisation rates.
Analyses are produced (in patient-anonymised form) to allow stakeholders (commissioners, stroke clinicians, managers and patient advocates) to compare performance and practice. The audit provided a unique and timely, comprehensive data source enabling a range of analyses to be completed and reported to highlight locations where units have good or poor results and indications of where potential improvements can be introduced, in comparison to the nationally agreed standards.

**Amendment request**

The data collection for this audit had been extended by HSIP up to 31 March 2018. An updated contract with HQIP was included with the amendment request.

**Confidentiality Advice Team advice**

The Confidentiality Advice Team noted that this was a continuous, long-running audit which served to drive improvements to the service provided to stroke patients. There would be no changes to the audit other than the extension of the end date.

**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.

**Specific conditions of support**

1. Confirmation of suitable security arrangements via IG Toolkit submission. **V13 of the IG Toolkit confirmed published and reviewed as Satisfactory.**

**Reviewers**

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| Dr Patrick Coyle | Vice Chair |
| Mr Anthony Kane | |
| Dr Rachel Knowles | |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Study title:** **National Bowel Cancer Audit**
**CAG reference:** **ECC 1-03 (d)/2012**

**Amendment Request**

The amendment submitted requested a change to the data flow and source and asked for permission to link the National Bowel Cancer Audit dataset with the Intensive Care National Audit and Research Centre (ICNARC) dataset, to enable audit data to be linked to critical care data in order to understand the full patient care pathway and treatments received as a result of their bowel cancer.

The data linkage will be undertaken by NHS Digital by using the audit tumour ID, which will be the only identifier disclosed outside of NHS Digital.

**Confidentiality Advisory Group Advice**

The Sub-Committee considered the applicants rationale that whilst the national audit was able to report its findings without approval of this amendment, the results would not identify all data about certain patient groups.

The CAG supported the rationale provided by the applicants that this additional data linkage would enhance the outputs of the audit, through the creation of a fuller, more accurate picture of the patient care pathway. Members agreed that this strengthened the public interest in the application.

It was acknowledged that amendment had also been supported by HQIP (Data Controller) in an attached letter.

Patient Notification

The Sub-Committee noted that the patient information leaflet which was referenced within the amendment form required revision as it still referenced HSCIC; however, it was noted that these administrative updates were part of an ongoing work programme for NHS Digital and as such, this revision would be undertaken in due course.

**Confidentiality Advisory Group Conclusion**

The Sub-Committee 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. Patient Notifications – ensure that references to HSCIC are updated to NHS Digital within the referenced patient information leaflet. Confirmation should be provided at next annual review.

2. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – for Royal College of Surgeons and NHS Digital as Data Processors – 24/04/2017).**

**Reviewers**

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| Ms Clare Sanderson | Alternate Vice Chair |
| Dr Paul Mill | CAT Support |

**Study title: Evaluation of linked antenatal and newborn NHS Sickle Cell and Thalassaemia Screening Programme**

**CAG reference: ECC 6-06 (f)/2009**

**Context**

The "Evaluation of linked antenatal and newborn NHS Sickle Cell and Thalassaemia Screening Programme" set out the assessment of newborns' overall outcome and timely early entry into care of all babies identified with sickle cell disease. Information would be retained until the child was 5 years old to allow follow up. Section 251 support was requested in order to collate patient identifiable data from newborn screening laboratories and clinical networks programme for linkage purposes.

**Amendment request**

The NHS Sickle Cell and Thalassaemia (SCT) Screening Programme plans to move the registry part of the project from King's College London (KCL) to Public Health England (PHE) National Congenital Anomaly and Rare Diseases (NCARDs) register from 1 April 2017. NCARDs (CAG 10-02(d)/2015) has also been given section 251 support, and has submitted an amendment in parallel to this one.

Obtaining this data will further progress the integration of rare disease datasets into NCARDRS in line with the UK Rare Disease Strategy. It will specifically help to improve case ascertainment and completion for cases of sickle cell and thalassemia, thus facilitating the effective evaluation of this screening programme and meeting the data protection principle 4 of keeping up to date, accurate records. Taking on the SCT dataset into NCARDRS will negate the need for frontline clinical staff to submit this data in two separate streams to PHE and they can continue to use the established systems and process for data submission.

**Confidentiality Advisory Group advice**

This request was considered via Chair's action where it was agreed that the request appeared reasonable. Being able to receive disease-specific data sources such as SCT will speed the expansion of the service into rare diseases. Having national sources will negate the need for these data transfers taking place at a regional level, thus reducing the risk which is inherent in transferring identifiable data. It will reduce the duplication in data flows from clinical staff to PHE and be the most effective use of staff resources in PHE and frontline clinical settings.

It was noted that both KCL (managing the SCT programme) and PHE (managing the NCARDRs register) have up to date Information Governance Toolkits.

It is noted that all clinics where SCT patients are screened for and treated will be sent the NCARDRS patient leaflet and poster. This will ensure that individuals are informed that their data may be shared with NCARDRS for the purposes of congenital anomaly and rare disease registration and their right to opt out. A link to the NCARDRS website will be added to the SCT pages on NHS choices and there will be reference made to data sharing with

NCARDRS in the ‘Screening for you and your baby’ leaflet given to all pregnant women. All opt out request made to NCARDRS will be upheld.

Upon clarification it was also discussed whether ongoing support will be needed once the transfer has been made. The applicant should confirm to the CAG when they believe support is no longer required.

**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**.

**Reviewers**

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|---|---|
| Ms Clare Sanderson | Alternate Vice Chair |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Study title:** **The Trauma and Audit Research Network (TARN)**
**CAG reference:** **ECC 7-05(g)/2011**

**Context**

Purpose of application

This application from the University of Manchester set out details of an activity which would allow PCTs to link SUS activity data to TARN data. TARN data provides an assessment of injury severity of patient injuries, seniority of clinicians treating the patient, time to transfer for non-emergency referrals for specialist care and presence of a prescription for rehabilitation. It was noted that the collection of confidential patient information for these purposes was included within a separate application, PIAG 3-04(e)/2006. The datasets would be linked at PCT level in order to support the implementation of the Best Practice tariff for trusts receiving major trauma and continue monitoring standard of care across the country.

A recommendation for classes 4, 5 and 6 support was requested to provide a legitimate basis for TARN to access confidential patient information for the purposes of providing PCTs with a method to link TARN data to SUS activity data.

In 2012 an amendment was approved to allow access to HES data from the Health and Social Care Information Centre for all patients who met the TARN inclusion criteria, including NHS number, ICD10 code, and NHS trust. This allows TARN to feedback NHS numbers to trusts and PCTs for patients who had not been included in their submission, allowing them to identify patients who should form part of the audit.

A further amendment was received in 2012 to access ONS mortality data via HSCIC as part of assessment of long term outcomes.

Confidential patient information requested

Access to NHS number and date of birth by TARN was requested to facilitate linkage at PCT level.

**Amendment Request**

The existing approval supports the flow of patient identifiable information to PCT (NHS Number and Date of Birth). This provides PCTs with a method to link TARN data to SUS activity data which in turn supports the allocation of Best Practice Tariff for Major Trauma.

However, SUS is being replaced by a new in-house NHS Digital system which will handle Commissioning Data Set (CDS) data. This will be under the current programme title 'SUS+'. Key fields will be uploaded by TARN to a new secure Data Landing Portal at NHS Digital. The amendment requested support for this change of data flow.

The following key fields were required by NHS Digital to enable the data linkage:

1. NHS Number
2. Date of Admission
3. Time of Admission

4. Site Code
5. Injury Severity Score
6. Best Practice Tariff (BPT) indicator

It is the change to the flow of data that was proposed as there was no requirement for additional identifiable data to support this change. The implementation of the proposed amendment would also make NHS Digital Data Processors for the project.

**Confidentiality Advisory Group Advice**

The amendment requested was forwarded to the Alternate Vice-Chair who was satisfied with the proposed changes to data flow following the introduction of NHS Digital's SUS+ system. Support for the amendment was recommended.

**Confidentiality Advisory Group Conclusion**

In line with the considerations above, the Alternate 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 Secretary of State for Health.

**Standard Conditions of Support**

1. Confirmation from the Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed – TARN Version 14, 2016/17 reported reviewed grade at satisfactory at 66%. NHS Digital Version 13, 2015-16 reported reviewed grade at satisfactory at 91%.**

**Reviewers**

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|---|---|
| Dr Patrick Coyle | Vice Chair |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Study title: National Confidential Inquiry into Suicide and Homicide by People with Mental Illness**
**CAG reference: PIAG 4-08(d)/2003**

**Context**

The original application considered by PIAG in 2003 detailed a national study of adverse incidents within the NHS psychiatric services which aimed to improve the clinical care provided.

**Amendment Request**

The applicants currently obtained data from the Office for National Statistics (ONS) on all deaths in England and Wales that have received a suicide or undetermined (open) conclusion. These data form the basis of the communication with the records departments of mental health trusts to ascertain whether individuals who lived or died in their area were known to be in receipt of services at the time of death.

This amendment requested permission to be notified by the Department of Health (DH, on behalf of NHS England) when a young person under the age of 18 dies whilst an in-patient of a CAMHS specialist services, and the death was suspected to be self-inflicted. This would be an additional data flow to support the existing approvals. Through this request, the applicants were not seeking permission to obtain any additional data items above those they are already approved to receive. The amendment request concerns an alternative process for obtaining notification of in-patient deaths to be put into place alongside usual procedure. The applicants will continue to receive quarterly data from ONS and process it using the approved methods as set out in the current protocol.

**Confidentiality Advisory Group Advice**

The amendment requested was forwarded to the Chair who agreed that the proposed amendment was fully justified as this ongoing confidential enquiry was in the public interest as suicide prevention remains a high priority. The Chair agreed that the proposed amendment would assist the applicants in ensuring they had complete data.

**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)**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – Favourable Opinion issued 13/02/17.**

**Reviewers**

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|---|---|
| Miss Clare Sanderson | Alternate Vice Chair |
| Miss Rachel Heron | Confidentiality Advisor |
| Dr Paul Mills | CAT Support |

**Study title: National Congenital Anomaly and Rare Disease Registration Service**

**CAG reference: CAG 10-02(d)/2015**

**Context**

Purpose of application

This application from Public Health England set out the purpose of the establishment of a national registry to provide continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies and rare diseases for the population of England.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to confidential patient information.

**Amendment request**

As part of the ongoing development of the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS), and the expansion into rare diseases, additional national data sources have been identified to help with the core registration functions of case ascertainment and completion.

These new data sources were:
- Sickle Cell and Thalassaemia (SCT) legacy data
- Hospital Episode Statistics (HES)
- ONS births and deaths data

Whilst the applicant believed that the SCT data items were covered under the existing approval, the applicant listed these data items in the amendment for clarity. These data items were:

- Blood transfusion
- Mother's Hb carrier state
- Father's Hb carrier state
- PND offered
- Date of first prevenar (immunisation)
- Details of any failures in the screening process.

**Confidentiality Advisory Group advice**

This request was considered via Chair's action where it was agreed that the request appeared reasonable.

The applicant provided further information regarding the security measures in place to allow secure transfer of data from HES and ONS to Public Health England (PHE). This will be undertaken using NHS Digital Secure Electronic File Transfer.

The applicant also further confirmed (as well as providing updated documentation) that mothers undergoing screening are made aware of data sharing with the NCARDRS service should their baby have a suspected or confirmed congenital anomaly or rare disease and that the NCARDRS website has more information about this.

**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**.