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

FEBRUARY 2019

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1. NEW AMENDMENTS

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Miss Katy Cassidy	Confidentiality Advisor

Study title: **Life and Bladder Cancer: The Yorkshire Cancer Research Bladder Cancer Patient Reported Outcomes Survey**

CAG reference: **17/CAG/0054**

IRAS project ID: **219200**

REC reference: **17/YH/0095**

Amendment request

The amendment form set out a request to extend the duration of support to 30 April 2020. The rationale for this amendment indicated that there had been delays in sending out the questionnaire due to unanticipated delays in getting permissions from the Office for Data Release (ODR) in Public Health England and NHS Digital.

Support was granted for one arm of the study which was the cross sectional questionnaire. The ODR and NHS Digital permissions are now in place for the cross sectional arm of the study and a pilot send out was posted to 400 participants (approximately 10% of the cohort) in November 2018. A single reminder was sent to non-responders. The completion response rate was 54%.

The study team does not believe that a 54% completion rate will provide optimal data for reliable analysis and conclusions. Other options of increasing participation rates to support the collection of interpretable and meaningful data when the remaining 90% of the questionnaires are sent out have been explored.

The study team anticipate that they will be unable to complete the cross sectional questionnaire send out before the original CAG permission end date of 30 April 2019. As such, a study extension to 30 April 2020 is requested to allow the study team to complete the questionnaire send out. Data collected will allow the study team to ascertain patients' views of their symptoms, their functional status, and their health related quality of life. It is hoped that such studies will ultimately improve patient care by assisting clinicians to provide better and more patient centred care, assessing and comparing the quality of providers and providing data for evaluating practices and policies

Amendment to REC favourable opinion

The amendment also set out information that two reminder letters were used in the separate Life after Prostate Cancer Diagnosis (LAPCD) PROMs study. This resulted in a final completion rate of 61% and the applicant indicated that no complaints were received from participants about the use of 2 reminder letters in the study. The form indicated that it would be of great benefit to the Life and Bladder Cancer study if the study team could utilise a second reminder to help enhance response rates to over 60%, thereby providing very high quality and meaningful data for accurate interpretation. It was confirmed that an ethics amendment was submitted to HRA on 22 January 2019 to request permission to send a second reminder letter.

Confidentiality Advisory Group Advice

Support extension

The request to extend the time that support is provided until 30 April 2020 was considered by the Chair who agreed that this was a reasonable extension to the timescale of the application in light of the delays set out in the amendment request form.

Amendment to the REC

The Chair noted that the sending of a second reminder letter was a change to the methodology agreed by the REC, and not a specific amendment request to the CAG as the original approach had previously been detailed in the application to the CAG. The understanding of the CAG is that such a change would require a favourable opinion by the REC in the form of a Substantial Amendment. Should the REC respond positively to the separate amendment made to them, it was noted that a copy of this favourable opinion must be provided to the CAG via HRA.CAG@nhs.net. It was advised that the applicant should double-check that the amendment to the REC has been categorised correctly, and provide the relevant documentation once available as confirmation the REC has agreed to the sending of a second reminder.

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 this activity proceeding, and therefore advised recommending support to the Health Research Authority, subject to compliance with pre-existing standard conditions, and the specific condition of support as set out below.

Specific conditions of support

1. Support to undertake a second reminder will come into place once evidence has been provided that the change to the methodology has been approved by the relevant REC.

Reviewers:

Name	Capacity
Miss Katy Cassidy	Confidentiality Advisor
Ms Natasha Dunkley	Head of Confidentiality Advice Service

Application title: Testing a diagnostic aid for hip dysplasia in primary care

CAG reference: 17/CAG/0171

REC reference: 17/LO/0631

IRAS reference: 210262

Amendment request

The amendment form set out a request to extend the duration of support to 31 July 2019. The rationale for this amendment indicated that, due to staffing problems and a lack of sufficient funding, the study team had been unable to begin the study at the planned start date in 2018. The research team plan to begin the study on 01 April 2019 and to complete recruitment by 28 June 2019. An additional four weeks are also required to undertake data analysis. The planned end date of the study is now 31 July 2019.

Confidentiality Advice Team advice

Correspondence had previously taken place with the Confidentiality Advice Team as the applicant had requested for the start date to the study to be delayed. It had been explained that once support is provided, it commences from the date of the conditional or final support letter, therefore the applicant was required to submit an amendment to extend the duration.

The amendment requested was considered by the Confidentiality Advice Team, who agreed that this was a reasonable extension to the timescale of the application in light of the delays set out in the amendment request form.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG 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. **UCL School of Life and Medical Sciences has a satisfactory score of 66% for IG Toolkit v14.1as published on website.**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **A favourable opinion from the REC for this change must be in place for this duration extension to process information without consent to come into effect**

Group Members:

Name	*Present*	*Notes*
Dr Patrick Coyle	Yes	Vice Chair
Dr. Liliane Field	Yes	
Dr Lorna Fraser	Yes	
Mr Andrew Melville	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **CAG 8-02 (a)/2014 Assuring Transformation: Data collection by Clinical Commissioning Groups to populate patient registers and reporting**

CAG 8-02 (b)/2014 Data collection by NHS England Area Teams responsible for commissioning secure mental health and child and adolescent mental health services to populate patient register and reporting.

CAG 8-02 (c)/2014 Assuring Transformation: Enhanced Quality Assurance Process Data flow (Disclosure by HSCIC to NHS England)

CAG reference: **Amendment Sub-Reference: 18/CAG/0190 – Extension to the Retention Duration**

Amendment Request

The initial application which was considered and supported for the overarching Assuring Transformation programme stated in the response provided to show compliance against principle 5 of the DPA 1998 (Section (r) of the application form):

'Data will be retained in commissioners' registers until 12 months after discharge from in-patient care for these purposes at which point the data will become be deleted, after the CCG confirms that the patient is **not** being treated as an in-patient'. The same response was also provided in response at section (aa) of the application form around data retention and destruction.

The application did not distinguish between patient information which included identifiers (confidential patient information) and pseudonymised data. NHS England had interpreted these responses to apply to the direct patient identifiers only and not the wider clinical information which was collected as part of the Assuring Transformation dataset and utilised for analysis in the management and provision of health and social care services.

Following review of the scope of support in place under the Regulations, NHS England submitted this amendment to seek specific support under the Regulations for the ongoing retention and analysis of the pseudonymised data set for five years. It is confirmed that the directly identifiable information will continue to be deleted after 12 months. The information is used by NHS England to effectively monitor commissioner management of patient care and hold commissioners to account.

Confidentiality Advisory Group advice

A Sub-Committee of the main CAG considered the applicant's response to the request for further information in correspondence.

1. **Provide further information around the de-identification process which would occur at 12 months post discharge, clarifying whether a linkage key is retained between confidential patient information and the pseudonymised dataset which would be used for analysis.**

The applicant explained that, since January 2017, the data extract provided each month from NHS Digital contains all records in the Assuring Transformation data collection, including those for episodes that have ended and the patient has been discharged. This enables retrospective changes to be accurately reported to the inpatient count and activity since March 2015 due to late reporting, late diagnosis or data correction.

Each month, the applicants pseudonymise the data by applying a pseudo identifier, and removing the identifiable fields from the dataset (NHS Number, Date of birth, and postcode fields which could contain a patient's home postcode). The use of a consistent pseudo identifier through each month's dataset enables tracking of when patients are transferred or readmitted, and to perform all necessary analyses on the pseudonymised data without reference to any of the identifiable fields. The linkage key, which matches NHS numbers to our pseudo identifier and contains no other information, is held in the secure storage area set up to hold the identifiable data and is only accessible by a small number of named analysts (currently four individuals). The pseudonymised dataset containing clinical data is stored separately and this is used for all analysis.

The applicant confirmed that they currently delete any identifiable data after 12 months. However, in reviewing processes it was confirmed that these files do not need to be retained once the data has been checked and the pseudonymised file has been created for analysis. The applicant confirmed that they would delete the monthly file containing clinical data and identifiers each month once the monthly processing has been completed. The linkage key would be retained to use where re-identification is required (e.g. for safeguarding purposes) and continue to store this securely as described above.

The Sub-Committee received the clarification and raised no further issues in this area.

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 for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS England have a satisfactory reviewed grade on V14.1, 2017/18, email assurance received 27/11/18**).

CAG reference: **Sub-Reference Amendment: 18/CAG/0191 – Duration Extension**

Amendment Request

The amendment requests an extension to support to March 2021 to allow the dual running of the Assuring Transformation programme and collation of data within the Mental Health Services Data Set (MHSDS) until such time as the applicants are confident that the data within the MHSDS of sufficient quality and completeness required by the AT programme.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence.

1. **Provide details of the compliance criteria which have been established to assess the quality of data collection via the Mental Health Minimum Dataset against the Assuring Transformation Programme.**

The compliance criteria are outlined below:

- All providers with patients currently reported in Assuring Transformation (AT) are submitting data to the Mental Health Services Data Set (MHSDS)
- All patient records in MHSDS to include a valid CCG of Origin (to allow them to be mapped to their Transforming Care Partnership (TCP)
- All inpatient and pre-admission Care and Treatment Reviews (CTRs) are reported in MHSDS
- Inpatient numbers at the end of the month to be consistent across AT and MHSDS
- NHS Digital's algorithm for identifying all in-scope activity in MHSDS, and not including any out-of-scope activity, is demonstrated to be working accurately

Note that NHS England has agreed to review these criteria with NHS Digital to set compliance percentages for some of the criteria as we recognise that with any data set data quality is not perfect and that inpatient counts in Assuring Transformation and MHSDS will never be completely consistent (e.g. due to late reporting). However, compliance is clearly currently below acceptable levels.

2. **Provide a copy of the most recent compliance report which compared data collection via the Mental Health Minimum Dataset against the Assuring Transformation dataset for consideration.**

The applicant provided a detailed overview of the recent compliance report which was considered by the Learning Disabilities Programme Board on 27th September 2018.

The Sub-Committee received the response and raised no queries in this area.

3. **Provide an overview of the data collection methods for the two datasets.**

The applicant provided the below overview of the data collection methods for the two datasets:

- One of the fundamental differences in the data collections is that the Assuring Transformation data collection is a commissioner based return whereas the MHSDS data collection is submitted by providers.
- The AT collection sits on the Clinical Audit Platform (CAP) hosted on the NHS Digital website whereas the MHSDS data collection is submitted via the Open Exeter Bureau Service Portal also hosted on the NHS Digital Platform. Both collections require a registration process for submitters.
- The AT collection in CAP is specifically designed for inpatients with a learning disability, autism or both whereas the MHSDS collects data for all mental health patients. AT patients are therefore identified through a flag on MHSDS records.
- The AT collection involves data input directly into the platform (40 questions) whereas MHSDS requires a data upload type submission on the web portal which has a complex multi-table structure.
- In AT, once a patient record has been entered, it is on permanently on the system unless it is deleted. With MHSDS, patient data is unloaded onto the system every month.
- The AT collection allows retrospective updates to be submitted at any time. The MHSDS collection has primary and final submission deadline dates each month. Once final submission has been made then that month's data cannot be changed.

The Sub-Committee received the response and raised no queries in this area.

4. Explain any barriers which are known to prevent the MHMDS achieving the same level of data quality as the AT programme. This should also include details of any incentives which are in place to promote the submission of data via MHMDS over the AT programme.

The applicant provided the below overview of the barriers/incentives to the data collection mechanism:

Barriers

a) Some Independent sector providers struggle to submit to MHSDS due to HSCN connection issues. This issue will be addressed when NHS Digital move MHSDS into a new Data Services Platform in 2019.
b) The number of learning disability fields in MHSDS is similar to AT but data submission is more burdensome in MHSDS due to its complex multi-table structure amalgamated with the fact that information is required for all types of mental health patients.
c) Some of the learning disability information in MHSDS relies on SNOMED codes, e.g. for care and treatment reviews but very few providers are submitting this. All providers will be required to submit SNOMED codes from 2020.
d) AT allows retrospective updates, MHSDS just has a primary and final submission window so data quality improves over time in AT whereas there is limited opportunity for data quality improvements in MHSDS.

Incentives

e) The MHSDS data collection is the subject of Directions under section 254 of the Health and Social Care Act 2012, from NHS England to NHS Digital, similar to AT and is a mandatory data collection.
f) Commissioning for Quality and Innovation (CQUIN) national goals is being used to improve data quality in mental health in 2019/20. The CQUIN has been designed to improve data quality across the whole mental health portfolio, including MHSDS and the specification includes:
    - Monitoring of data quality
    - Improving the recording of outcome measures
    - Improving the recording of SNOMED procedure codes

CQUIN makes a proportion of healthcare providers' income conditional on demonstrating improvements in quality and innovation in specified areas of patient care. This means that a proportion of a provider's income depends on achieving quality improvement and innovation goals, agreed between the Trust and its commissioners. It is expected that this CQUIN will improve Learning Disability data in MHSDS.

The Sub-Committee received the response and raised no queries in this area.

5. Provide confirmation that NHS Digital is aware of and supportive of the proposed activity to improve the data collection via MHMDS.

The applicant provided a copy of an email from Steven Webster, Information Lead Manager, at NHS Digital which confirmed awareness of the amendment and ongoing planned activity to improve data collection via the MHSDS.

The Sub-Committee received the supporting email and raised no queries in this area.

6. Confirm whether the exit strategy is considered achievable within the scope of current duration extension (i.e. by March 2021).

The applicant acknowledged that there was still considerable work to do with MHSDS to enable the Assuring Transformation programme to be stood down by March 2021 including:

- Completion of data linkage work and other work to reconcile differences between AT and MHSDS
- Improving quality of data that are currently submitted
- Ensuring all providers submit to MHSDS
- Develop MHSDS reporting to ensure that there is comprehensive and readily accessible data available to the public and stakeholders

Delivery of this is dependent on work which is planned and commissioned from NHS Digital but NHS Digital has indicated that they expect to be able to recommend termination of the AT data collection before March 2021 providing resource commitments allow (see attached email). The NHS Digital team responsible for this package of work is currently fully staffed and NHS England is committed to funding this work going forward.

The Sub-Committee received the assurance in this area and recognised the established plans which had been put in place to progress the exit strategy from support under the Regulations. No further issues were raised in this area.

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 this activity, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS England have a satisfactory reviewed grade on V14.1, 2017/18, email assurance received 27/11/18**).

2. APPLICATIONS

Group Members:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Dr William Bernal	Yes	
Dr Patrick Coyle	Yes	Vice Chair
Mrs Diana Robbins	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Use and impact of the pre-hospital 12-lead electrocardiogram in the primary PCI era. Mixed method study (PHECG-2).**

CAG reference: **18/CAG/0164**

IRAS project ID: **248748**

REC reference: **18/LO/1679**

Context

Purpose of application

This application from Kingston University and St George's, University of London set out the purpose of medical research which aims to assess the association Pre-Hospital 12-lead electrocardiogram (PHECG) with patient outcomes, and research patient, practitioner and contextual factors contributing to the decision to record (or not) a PHECG. The Pre-Hospital 12-lead electrocardiogram (PHECG) is a simple test that helps ambulance clinicians assess patients with suspected acute coronary syndrome (heart attack), and helps to inform ongoing care, such as direct transfer to a specialist heart attack centre. All NHS emergency ambulances carry this equipment. This project builds on previous work by this team, which found that one in three eligible patients did not receive a PHECG, but those that did had a lowered risk of short-term death. Women, the elderly and people with more complex health status were less likely to receive PHECG. The dominant treatment for heart attack at the time of the earlier analysis was 'clot buster' drug therapy (fibrinolysis). This study will update that work, in the context of the shift in recent years to a more interventional strategy for treatment of heart attack (angioplasty and stents), and explore reasons for variations in practice-highlighting opportunities to improve care and outcomes.

The study will involve the use of data collected within the Myocardial Infarction National Audit Project (MINAP) dataset, collected with support as part of the National Institute for Cardiovascular Outcomes Research NICOR programme (17/CAG/0071), which is managed by Bart's Health NHS Trust, linked with ONS mortality information held by NHS Digital for the purposes of analysis.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover activities as described within the application.

Confidential patient information requested

Cohort

- Work Package One: Patients aged 18 years or older when admitted with heart attack between 01/01/2010 and 31/12/2017 to one of 228 participating hospitals in England, Wales and Northern Ireland. For patients with multiple admissions, only the earliest record of their ACS event will be included. Approximately 420,000 patients to be included.
- Work Package Two: Patients with confirmed diagnosis of heart attack (STEMI and nSTEMI) on MINAP database and taken to hospital by one of the three participating ambulance services (Welsh, West Midlands and South West). Approximately 1,800 patients to be included identified from patients in WP1.

The following items of confidential patient information will be released from the MINAP audit held by NICOR to NHS Digital for the purposes described:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Date of birth – sample validation,
- Date of death – sample validation and analysis,
- Postcode (northing and easting references) – analysis,
- Ambulance Job Number – sample validation and linkage,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's written response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Clarify whether the statistical team would have access to confidential patient information during the initial access to the MINAP dataset prior to linkage with ONS.**

The applicant confirmed that the statistical team at Swansea University would not have access to confidential patient information prior to the linkage with ONS**,** with the exception of ambulance job number, to enable a sample of patients/records for data abstraction from Work Package 2 to be generated.

The Sub-Committee received the clarification from the applicant. It was recognised that, outside of the specific Trust environment, the ambulance job number would not be considered to be an identifiable data item. No further issues were raised in this area.

2. **The status of research paramedics at the Welsh Ambulance Services NHS Trust as members of the patient's direct care team should be reconsidered. If determined not to be part of the direct care team, response should formally request an extension of the scope of support to extend to the data processing to be undertaken at this site.**

The applicant explained that this point had been discussed with the Welsh Ambulance Service, which had agreed that the research paramedic employed for the purpose of the project would not be a member of the direct care team. The applicant confirmed that support under Regulations was requested to extend

to the research paramedic's access to confidential patient information at the Welsh Ambulance Services NHS Trust.

The Sub-Committee received the clarification around the scope of the support required under the Regulations and raised no issues in this area. A copy of the associated Caldicott Principles into Practice Report to evidence that the appropriate security assurances were in place at the site was provided. NHS Wales Informatics Service provided confirmation that the document had been approved via email.

3. **Provide assurance that research paramedics would be provided with appropriate training in free text extraction to ensure that confidential patient information is not incidentally disclosed.**

The applicant confirmed that both the study training manual and training for Work Package 2 (WP2) would reinforce that confidential patient information abstracted from free text of ambulance records must not identify patients or clinical staff. In addition, the applicant explained that the REDCap data collection tool for WP2 would contain a warning message regarding confidential information each time free text was entered, and before the record was saved and/or submitted to the study server at Swansea University.

The Sub-Committee received the applicant's assurance and raised no further queries in this area.

4. **Clarify whether the northing and easting postcode references which would be retained for analysis are identifiable.**

The applicant clarified that the eastings and northings postcode references would be rounded to factor 10 which would reduce the risk of re-identification. Supporting email correspondence was provided from NICOR providing confirmation of this.

The Sub-Committee received the confirmation and raised no further queries in this area.

5. **Provide a clear overview of the data flows required to facilitate work package one. This should confirm what information is disclosed between each organisation and in what format (i.e. identifiable, pseudonymised), to ensure that the elements of this data flow which require a recommendation of support under the Regulations can be clearly identified.**

The applicant provided a revised data flow chart which addressed the queries raised by the CAG.

The document was received and no further queries were raised in this area.

6. **Provide details of the project-specific notification and dissenting mechanism which has been devised with NICOR – copies of any text which will be used to facilitate this mechanism should be provided for review. This information should be easily accessible from the NICOR homepage, and a link to this detail provided.**

The applicant provided a copy of the notification text for information, together with supporting correspondence with the NICOR team for information purposes.

The Sub-Committee received the documentation and raised no further queries in this area.

<u>Additional Change Request</u>

The applicant informed as part of the response to the provisionally supported outcome, that patient information was now available in the Myocardial Infarction National Audit Project (MINAP) dataset up to the end of 2017. It was requested that the scope of the cohort for inclusion in the study be extended to include this additional calendar year of data to ensure the study analysis is based on the most contemporary data available. It was confirmed that the REC had provided a favourable ethical opinion to this request and revisions had been made in the documentation.

The CAG was assured by the rationale provided to support the cohort extension and recognised that the REC had issued a favourable ethical opinion to this requested and no further issues were raised in this area.

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 (Final)

3. Planned patient and public involvement and engagement activity should be progressed, with feedback on the actual activity undertaken provided at the time of first annual review. If the responses given were negative, this would be taken into account by the CAG when considering whether support can continue, or whether further action is required.
4. Favourable opinion from a Research Ethics Committee (**Confirmed**).
5. Confirmation from appropriate security assurance for organisations processing confidential patient information with support under the Regulations (**Confirmed:**
    - **NHS Digital, South Western Ambulance Services NHS Foundation Trust and West Midlands Ambulance Services NHS Foundation Trust all have satisfactory reviewed grades on V14.1, 2017/18,**
    - **Welsh Ambulance Services NHS Trust – Caldicott Principles into Practice report received with an assessment score of 92.3% NHS Wales Informatics Service confirmed approval via email on 15/02/2019).**

Group Members:

Name	*Present*	*Notes*
Dr. Liliane Field	Yes	
Dr Murat Soncul	Yes	Alternate Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Using National Congenital Heart Diseases Audit data to explore the impact of non-medical risk factors on late post-operative outcomes for children with complex congenital heart defects.**

CAG reference: **18/CAG/0184**

IRAS project ID: **252035**

REC reference: **18/LO/1688**

Context

Purpose of application

This application from Great Ormond Street Hospital for Children NHS Foundation Trust set out the purpose of medical research which aims to undertake follow-up of children who underwent surgery for complex heart defect since 2000 to assess longer term health outcomes in this patient group.

The patient cohort will be identified from the National Congenital Heart Diseases Audit, which is commissioned by the Healthcare Quality Improvement Partnership (HQIP) and carried out as part of the NICOR (National Institute for Cardiovascular Outcomes Research) programme by Barts Health NHS Trust. The NICOR audit programme operates with support under the Regulations via reference 17/CAG/0071 (non-research activity) and 17/CAG/0078 (extended uses of audit data for research purposes). Confidential patient information will be disclosed to NHS Digital to facilitate linkage with ONS mortality information. The applicants will undertake analysis on a pseudonymised dataset.

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

Confidential patient information requested

Cohort

Patients recorded within the National Congenital Heart Diseases Audit between 01 April 2000 and 31 March 2018 as having procedures (both surgery and catheter) for complex heart defects. The audit contains an estimated 120,000 patients.

Confidential patient information will be identified from the National Congenital Heart Diseases Audit held by Barts Health NHS Trust to be released to NHS Digital for linkage. The following items of confidential patient information are required for the purposes stated:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Hospital ID – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Postcode – sample validation and linkage,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information, detailed in the provisionally supported outcome, in correspondence.

1. **Clarify the sample size to be included in the project from the overarching audit cohort.**

The applicant confirmed that the entire sample of English patients undergoing paediatric cardiac surgery within the study period would be included from the overarching study cohort. This was estimated to be around 120,000 children. Supplementary information was provided to justify the patient sample.

The Sub-Committee received the clarification and raised no further issues in this area.

2. **Provide a copy of the patient notification text for consideration. This should include telephone, email and postal contacts to facilitate objection, a lead-in time to enable dissent to be raised and also account for the potential for patients within the cohort to now be adults.**

A copy of an information leaflet was provided for review.

Members reviewed the document and commented that the text was quite complex in places and did not clearly describe the data flows and organisations involved in the study. The Group recognised that ongoing patient and public involvement and engagement activities were planned, with a specific focus on patient information. It was agreed that the patient-facing information materials should be reviewed as part of this future activity. Support would be recommended on conditional basis that revised documentation was provided within three months of support coming into effect.

3. **An approach should be made to the charities with which links were already established to explore the potential of including information around the study on their websites in order to widen the communications strategy for the project. Feedback should be provided around these discussions, together with copies of any text which would be displayed on the websites.**

The applicant confirmed that future engagement was planned with the patient user group 'Little Hearts Matter' (LHM), which would held at UCL between members of the research team and LHM Chief Executive and User Information Lead. The applicant explained that the purpose of this activity was to discuss patient information about long term outcomes of congenital heart diseases, which was a central theme of the research team's work. It was explained that LHM had an established network of patients of a wide range of ages, some of them growing up.

The applicant also confirmed that discussions would be held with the charity around display of information on its website. The applicant explained that the intention was for the package of information

to be displayed on the website to go beyond the information leaflet provided to the CAG, which would be discussed at the planned engagement session, noting that the User Information Lead had responsibility for the charity's website.

The applicant confirmed that wider updates would be provided in this area in the annual reports, as it was also intended to extend the scope of this activity to other user groups as the project evolved, including the Somerville Foundation which represents grownups with congenital heart disease.

The Sub-Committee received the response and recognised that the ongoing review and improvement of patient-facing material was an integral part of the applicant's agenda. It was recognised that the condition of support to revise the current patient-facing information sheet was in line with this planned activity.

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 (Final)

1. The existing patient-facing information leaflet should be revised to make the language more accessible and to ensure that the description of the data flows and organisations involved in the study was easily understood. The review of the text should form part of the patient and public involvement and engagement activity which is already planned. A revised document should be provided for consideration within three months of this outcome letter.
2. Consider ways to include young persons and adults who underwent surgery for complex heart defect when they were young within the patient and public involvement and engagement activities for the study. Feedback should be provided at the time of annual review around the progress which has been made here, together with an overview of any activity carried out.
3. Favourable opinion from a Research Ethics Committee (**Confirmed**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed: Barts Health NHS Trust (covering NICOR), and NHS Digital – published satisfactory reviewed grade on v14.1, 2017/18**).

Reviewers:

Name	*Present*	*Notes*
Dr Tony Calland MBE	Yes	Chair
Mr. David Evans	Yes	
Dr Rachel L Knowles	Yes	
Mr Andrew Melville	Yes	Lay Member
Ms Clare Sanderson	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Dose Reductions in Palliative Lung Cancer following an episode of Neutropenia**

CAG reference: **18/CAG/0206**

IRAS project ID: **242100**

REC reference: **18/YH/0478**

Context

Purpose of application

This application from the University of Bradford set out the purpose of medical research which aims to evaluate the factors responsible for increasing the risk of neutropenia in palliative lung cancer patients and if dose reducing appropriately, will lower further incidences of neutropenia. This will reduce neutropenia related hospital admissions and also improve patient outcome by reducing chemotherapy delays.

The study will involve a retrospective case note analysis of patients on palliative lung cancer treatment who have undergone a dose reduction for neutropenia. The project aims to understand whether a predictive model can be designed to recommend a dose reduction based on patient factors such as kidney/ liver impairment or co-morbidities. Eligible patients will be identified from the Chemocare database, the electronic prescribing software for all chemotherapy treatment, by the database manager. Confidential patient information relating to the eligible patient cohort will be transferred to the main applicant, to enable wider patient records to be accessed to extract relevant information for analysis.

A recommendation for class 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

The cohort would consist of palliative lung cancer patients who received chemotherapy in the 2017 calendar year at any hospital in South Yorkshire. 385 patients in total will be included in the study (360 phase one and 15 phase 2).

The main applicant, who is not considered part of the direct care team, will use NHS number to access complete patient records in order to extract the relevant information required for analysis. The following items of confidential patient information are required for analysis:

- Date of birth – converted to age,
- Sex,
- Ethnicity.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Clarify how patients would be identified as eligible for inclusion in the study and who would be undertaking this process.**

The applicant confirmed that that chemocare data manager would only be able to identify which patients have had palliative chemotherapy for lung cancer in South Yorkshire & Bassetlaw. This individual would not be able to identify which patients would meet the inclusion criteria as they do not have access to all the relevant records and are not clinically trained to identify chemotherapy induced neutropenia. This activity would be undertaken by the chief investigator, who would screen the relevant patients on the chemocare database to see if they meet the inclusion criteria.

The Sub-Committee received the response and raised no further issues.

2. **Provide a data flow chart for the study, which captures the flow of confidential patient information, identifies who is accessing at each stage and what the extraction and disclosure procedures.**

The applicant provided an overview of the data flows involved in the study which addressed the points raised by the CAG.

The Sub-Committee received the response and raised no further issues.

3. **Provide justification to support the ongoing retention of the linkage key. Confirm who would retain the key and for what duration.**

In response to follow-up queries, the applicant confirmed that the linkage key would be retained for a period of three months, which would be sufficient for data collection, analysis and to allow time for any patients/representatives to raise an objection to the use of data.

The Sub-Committee received the response and raised no further issues.

4. **Provide copies of the website text which will be used to facilitate the study communications strategy. An overview of how patient objection would be operated is also required.**

The applicant provided draft website text which addressed the points raised by the CAG. It was explained that patients, or their representatives, could contact the main applicant directly in order to raise an objection to the use of their data within the study. Any dissent raised would be respected by excluding patients from the master database and subsequent deletion from the analysis dataset as necessary.

The Sub-Committee received the website text and overview of the dissenting mechanism and raised no further queries in this area.

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 (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 19/12/2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Sheffield Teaching Hospitals NHS Foundation Trust has a published satisfactory reviewed grade on V14.1, 2017/18. The Rotherham NHS Foundation Trust has a satisfactory score on V14.1 2017/17 – confirmed by NHS Digital email 15/02/2019**).

Group Members:

Name	*Present*	*Notes*
Ms Sophie Brannan	Yes	Lay Member
Dr Tony Calland MBE	Yes	Chair
Dr. Liliane Field	Yes	
Mr. Myer Glickman	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **How have electronic prescribing and medication administration systems transformed pharmacists' communication in an inpatient setting? A multi-site observational study**

CAG reference: **19/CAG/0006**

IRAS project ID: **249203**

REC reference: **18/WS/0239**

Context

Purpose of application

This application from University College London set out the purpose of medical research which aims to explore how pharmacists communicate with each other and wider healthcare professionals in an inpatient setting and how electronic prescribing and medication systems may affect this.

During the study, the Student Investigator will observe pharmacists on general medical and surgical wards in three NHS hospital Trusts. Two of the participating Trusts will use differing electronic prescribing and medication administration systems and the third site will operate a paper-based prescribing system. The Student Investigator will follow pharmacists during the course of their daily duties, including prepping for wards rounds, time on the ward and any follow-up activities. Observations will be recorded on a paper data collection form. The observer will follow-up any queries identified around the observation with the pharmacists to gain a greater understanding. During the course of the observations, patient bed number will be recorded to enable the communications relating to the same patient to be clustered for follow-up and analysis.

Up to 20 pharmacists will be observed at each participating Trusts in order to collect information on the required number of communication events, which has been calculated as 1,089 events per Trust. It estimated that the observations will last up to four hours per day, across 20 working days per site.

Confidential patient information is not required for the purposes of the project analysis and will not be recorded during the observation field work. However, as the observer will be shadowing pharmacists during the course of their daily activities, there is a risk that the observer may be exposed to confidential patient information for which there is no established lawful basis, under the common law duty of confidentiality, for the individual to receive.

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

Confidential patient information requested

Cohort

The pharmacist observations will be undertaken on general medical and surgical wards within the three participating Trusts: Imperial College Healthcare NHS Trust, London North West University Healthcare NHS Trust and Whittington Hospital NHS Hospital NHS Trust. The patient cohort would involve all inpatients resident within the participating wards during the course of the staff observations.

No direct patient identifiers would be recorded as the focus of the study is the pharmacists; however, it is stated that patient bed number would be retained to enable communications relating to the same patient to be clustered.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. Explain what wider patient benefit could be achieved from the study's findings.

The applicant explained that poor communication among health care professionals is well known to affect the quality and safety of patient care, with a recent systematic review they had undertaken, which has been submitted for publication, concluding that electronic systems can have a significant effect on the nature and quality of such communication.

The importance of this issue was also highlighted in a recent priority setting partnership led by the NIHR Imperial Patient Safety Translational Research Centre in partnership with the James Lind Alliance. This set out to identify the most pressing questions for research which, if addressed, could improve the safety of care of adults with complex health needs. Patients, carers and health and social care professionals were involved at all stages of this process. The applicant explained that, of the many hundreds of research questions which were put forward to the group, one of the most important research questions identified was "how can communication be improved among the healthcare professionals within a single organisations who are all involved in a patient's care?".

The applicant explained that the proposed study aimed to shed light on this issue through identifying the differences in communication strategies between different electronic systems and a paper based system. The study would identify any potential consequences of any difference in communication strategies on patient safety, and make recommendations as needed to improve patient care.

The Sub-Committee received the additional information and raised no further queries in this area.

2. Provide further detail around what information would be read out loud by the pharmacists when operating computers or reviewing paper drug charts.

The applicant explained that the original application form stated that, 'The observer may ask the pharmacist to talk out loud when using the computer or drug chart so that the observer can record the pharmacist's communication accurately on the data collection form'. It was further explained that this related only to, for example, where the pharmacist switches between patient records on the computer and it may not be clear to the observer that the pharmacist has switched to documenting their communications for a different patient. In this situation, the observer may ask the pharmacist what the relevant bed number is. Or in a paper system, the pharmacist may write an instruction on the paper drug chart regarding administration advice, and the observer may want to clarify who the communication is targeted at. It was clarified that observer would request that the observed pharmacists do not read out any confidential information such as patients' names.

The Sub-Committee received the clarification and raised no further issues in this area.

3. Clarify what protocol has been put in place to reduce the risk of wider disclosures of confidential patient information during the observations.

It was confirmed that the observer would only need to observe the pharmacist during the study and would not need access to any additional documents. The applicant reiterated that the pharmacist would be asked not to read out any confidential information such as patients' names. The observer would work to place themselves out of direct view of the computer screens or paper drug charts when undertaking an observation, to reduce the risk of wider disclosure.

The Sub-Committee received the response and raised no further issues in this area.

4. Provide an estimate of the number of patients that may form the basis of the staff observations.

The applicant confirmed that the patients were not the subject of interest in the study as the focus was to observe the pharmacists' interactions with other healthcare professionals. The number of patients that may form the basis of staff observations would be dependent on the size and complexity of the ward. However, from pilot work (2 pharmacists' observations), the applicants had found that 24 patients were physically present on each ward and the pharmacist reviewed all 24 electronic drug charts while conducting their clinical duties. In both pilot observations, one patient was seen face-to-face by the pharmacist on each ward and the observer stood outside the bay when the pharmacist spoke to these patients.

On the basis of this information, the applicant estimated that the observed pharmacist would talk to between 1-5 patients at each hospital during the course of the proposed study. The observer would stand outside the patient's bed or bay during this discussion in the line with the methodology employed in the pilot study.

The Sub-Committee received the response and raised no further queries in this area.

5. Assurance is required that patient bed number was a sufficient data item to link information related to an individual patient collected during the various staff observations for analysis.

The applicant confirmed that during the pilot observations, collecting the patient's bed number sufficed. Observations on each ward would last only around 2-4 hours and it was unlikely that a significant number of patients would move beds during that time. It was further explained that a statistician was also consulted at UCL who confirmed that this would be the only piece of information needed to carry out the planned statistical analyses.

The Sub-Committee received the assurance from the applicant and raised no further issues in this area.

6. **Some patient and public engagement activity should be undertaken to seek views around the proposed study and the potential disclosure of confidential patient information during the staff observations. Provide feedback on the activity undertaken and the views provided. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.**

The applicant explained that eight members of a patient and public advisory group relating to the Centre for Medication Safety and Service Quality at Imperial College Healthcare NHS Trust were invited to feed back their views on the proposed study. The session was held in early February.

At the session, researchers introduced themselves, summarised the research question, methodology, the issue of potential incidental disclosure of patient information during staff observations, and the proposed opt-out approach, and invited views on our proposed approach, a draft ward poster and a draft patient information leaflet from attendees.

An overview of the outputs from the session was provided for review, which were all supportive of the proposal and the methodology.

The Sub-Committee received the information and raised no further issues in this area.

7. **Patient notification and dissent – the following points should be addressed:**
   a. **The ward poster should be revised to provide a clearer overview of the full scope of the staff observations which would be carried out,**

An updated document was provided which addressed the points raised.

The Sub-Committee received the document and raised no further issues.

   b. **A brief information leaflet should be produced to support the information included within the poster. If it is determined that this cannot be produced, a strong justification should be provided to support this decision,**

A brief information leaflet was provided.

The Sub-Committee received the document and raised no further issues.

   c. **It is recommended that the documents are reviewed as part of the patient engagement activity to ensure these are deemed appropriate.**

The applicant confirmed that both the ward poster and patient information leaflet were reviewed by the patient and public advisory group and their feedback was incorporated.

The Sub-Committee received the assurance and raised no further issues in this area.

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 (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 14 December 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Imperial College Healthcare NHS Trust, London North West University Healthcare NHS Trust and Whittington Hospital NHS Hospital NHS Trust all have published satisfactory reviewed grades on V14.1, 2017/18**).