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

September 2017

Reviewers:

Name	Capacity
Ms Clare Sanderson	Alternate Vice Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Context

Application title: **The Role and Impact of Surgical Centralisation on Renal Cancer Survival: A Multifactorial Analysis**

CAG reference: **15/CAG/0169**

IRAS project ID: **185885**

REC reference: **15/EM/0340**

Context

Purpose of Application

This application from the University of Cambridge set out the purpose of a research study which aimed to link data from HES, ONS and Cancer Registries in order to answer five specific questions. First, how has nephrectomy practice in England evolved in the past few years in response to regionalisation? Second, what role does service reconfiguration play in changing renal cancer outcomes? Third, what is the relationship between case volume and outcome in nephrectomy, from short to long term and how does treatment in a high volume centre alter an individual's outcome compared to treatment in a lower volume centre? Fourth, what are the interactions between treatment setting, patient background and tumour characteristics in predicting renal cancer survival and mortality? Finally, how does understanding the volume outcome relationship in nephrectomy change the current paradigm on renal cancer service and risk prediction model?

A recommendation for class 1, 5 and 6 support was requested to cover access to confidential patient information from Public Health England in relation to patients undergoing a nephrectomy between 1998 and 2013 (approx. 112,000 patients)

Confidential Patient Information Requested

Access was requested to a dataset including date of death and date of birth.

Amendment Request

This amendment requested an extension to the duration of support in place for the application activity. The project had been originally approved for a two year period; however, the applicants explained that due to delay in obtaining the required data from Public Health

England, analysis of the full dataset did not commence until January 2017, which was a 1.5 year delay on the original timeframe.

The amendment requested a one-year extension to the application of support under the Regulations for the use of potentially identifiable data from Hospital Episode Statistics and the National Cancer Data Repository. It was confirmed that all required data had already been extracted and received.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Alternate Vice-Chair who acknowledged the delay the applicants had experienced in receiving the required data. The applicants had stated that the extension to support would enable them to continue processing the study data until the completion of the project. The Alternate Vice-Chair agreed that the rationale for the amendment was sound and recommended support for the one year extension.

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 Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – V14, 2016-17, 78% satisfactory reviewed grade).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Not applicable – original REC opinion stands as study duration has not been extended, acknowledged as a delay to project start).**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Context

Purpose of application

This application from NatCen Social Research set out the purpose of carrying out national social surveys focusing on the mental health of children and young people in the general population of England and Scotland. It has been commissioned by the Health and Social Care Information Centre (NHS Digital) with funding from the Department of Health and aims to estimate the prevalence of mental health conditions in children and young people aged 2-19.

The survey involves collecting information about health and wellbeing from:
- parents/carers of children and young people aged 2-19,
- young people aged 11 and over,
- teachers of children and young people aged 5-16.

All selected participants will be sent an advanced letter about the research. Following this letter, an interviewer will call at the address and leave a leaflet explaining more about the research. For those who consent to take part, information will be collected from parents, carers and young people in their own homes using a computer assisted personal interview (CAPI) administered by a trained social survey interviewer. Information will be collected from teachers using an online questionnaire.

The interview with parents, carers and young people focuses on many different aspects of health - both physical and mental - as well as subjective wellbeing, use of services, risk and protective factors (such as neighbourhood context and social support, among many other things) and standard sociodemographic factors (e.g. age, sex and employment status of parents). Interviewers are trained social survey interviewers, many of whom will have previously worked on surveys involving children and or covering sensitive issues.

The survey findings will support the planning, commissioning and improvement of services across mental health, care and education from 2018 onwards. The up to date information will allow resources to be better targeted and more responsive to the mental health and well-being needs of children and young people.

A recommendation for class 3 and 6 support was requested to cover access to: name, address, including postcode, age and sex.

Amendment Request

The amendment request was for an extension to the end date of the study. Fieldwork had been due to take place September 2016-June 2017 – however, due to delays in the receipt of the sample this would now take place January 2017-September 2017. This would in turn delay the date for destruction of the following data: names and addresses of those who do not take part and of those who do take part but do not consent to data linkage or being contacted for follow up research. This would not be possible until the end of November 2017. Data reconciliation and data processing would take longer than anticipated due to previous survey delays and as such, the applicant proposed destroying names and

addresses of those who take part but do not consent to data linkage or being contacted for follow up research by the end of January 2018.

Earlier survey delays had also had a knock-on effect on completion of the project – the proposed final end date of archiving data would now be December 2018.

Confidentiality Advice Team Advice

The amendment requested was considered by the CAT, who noted that this extension was due to delays in receipt of the sample, which had in turn delayed the date for destruction of the names and addresses of the participants. As the amendment involved no change to any other procedures and no additional time for data processing, but an extension to the beginning and end date for data processing, the CAT was content to recommend support.

Confidentiality Advice Team Conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **ONS, NatCen and NHS Digital – v14 confirmed published and reviewed as satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Study is approved. Extension does not require review by the REC.**

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor

Application title:	**Avoidable mortality from in-hospital cardiac arrest: Have interventions aimed at recognising and rescuing deteriorating patients made an impact on incidence and outcomes?**
CAG reference:	**15/CAG/0113**
IRAS project ID:	**139667**
REC reference:	**15/SW/0151**

Context

Purpose of application

This application from London School of Hygiene and Tropical Medicine set out the purpose of study which aims to determine the association between different services aimed at identification of patients at risk of deterioration and their subsequent management and ward-based cardiac arrest rates and outcomes. The applicant will investigate on the implementation and effectiveness of services and the differentiation of arrests and outcomes within hospitals as new services had been introduced. It is the objective of the study to improve outcomes for all patients and to reduce avoidable mortality. This study will also involve carrying out a staff survey with consent.

The application of support was requested to permit the disclosure of confidential personal information from Intensive Care National Audit and Research Centre (ICNARC) to the Health and Social Care Information Centre (HSCIC) in order to carry out linkage with Hospital Episode Statistics (HES) and Office for National Statistics (ONS) Mortality and outcome data.

A recommendation for class 4 and 6 support was requested to cover access to allow access to an authorised user for the purpose of linking patient identifiable information obtained from one or more source.

Confidential patient information requested

Access was requested to link NHS number, date of death and postcode in order to carry out the linkages specified above.

Amendment Request

The amendment requested an extension to the end date of the study, which was now identified as 30 September 2018. The request was not an extension to the required duration of support.

Confidentiality Advice Team Advice

The Confidentiality Advice Team considered the amendment to be in line with the principles of the original approval, and noted that it concerned the extension of the end date of the

project, which appeared to be justified. The applicants confirmed that the extension to the end date was required due to a delay in receipt of data from NHS Digital.

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 – reviewed reported grade of 83% satisfactory on Version 14, 2016-17).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Amendment Type considered minor by REC – no longer requires review).**

Reviewers:

Name	Capacity
Dr Mark Taylor	Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **Congenital Anomaly Register and Information Service for Wales (CARIS)**

CAG reference: **CAG 6-06(b)/2014**

Context

Purpose of Application

This application from Public Health Wales set out the purpose of a systematic collection, registration and publication of population level data of congenital anomalies in Wales. The data would be used to assess patterns of anomalies, possible clusters of anomalies and their causes, antenatal screening and other healthcare interventions and health service provision for affected babies and children.

A recommendation for class 3, 4, 5 and 6 support was requested to allow the disclosure of confidential patient information from a number of different sources to Public Health Wales.

Confidential Patient Information Requested

Confidential patient information from a range of sources was requested in relation to any foetus or baby who had or was suspected of having a congenital anomaly and whose mother was normally resident in Wales at time of birth.

Data items including mother and baby name, postcode, NHS number, date of birth and date of death and father name were requested.

Confidentiality Advisory Group Advice

Background

This application was originally considered by the CAG at a meeting held on 28 August 2014, following which a conditionally supported outcome was issued to the applicants on 18 September 2014. A response to this outcome was received on 14 November 2014; however, it was acknowledged within this correspondence that the MoU between DH and NWIS around security assurance remained outstanding. Final support was not issued at this stage due to this outstanding condition of support.

In the interim, two amendments and two annual review submissions were made in connection to the application activity and there appears to have been some correspondence in relation to the outstanding final support between the Confidentiality Advice Team and Public Health Wales, as applicants, within this time period.

NWIS submitted a CPiP assurance report in relation to the application on 13 March 2017. Following receipt of this outstanding assurance report, a letter was issued to the applicants

on 04 April 2017 by the Confidentiality Advice Team, requesting a status update on the application, as it appeared from the correspondence which had been received in the interim, that activity had been undertaken in relation to the application when final support was not yet in place.

Application Status

An interim response was received from the applicants on 18 April 2017, with a final response submitted on 10 August 2017. Public Health Wales confirmed that activity had proceeded for the programme in the intervening period since the conditional support recommendation was issued. The applicants clarified that the processing which had been undertaken in connection to this long-term health intelligence programme was essential in the public interest of the people of Wales. As such, the applicants did not believe that this processing was in breach of the Common Law of Confidentiality.

Following receipt of the above clarifications, an acknowledgement was sent to applicants on 21 August 2017 and it was queried, in light of all outstanding points of the original conditional support having now been addressed, whether it was intended for the application for support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to be progressed. Confirmation was received on 24 August 2017 from Public Health Wales that the application for support under the Regulations should proceed to full support, to enable the legal basis for the application activity to be established under the Regulations.

Specific Conditions of Support

As part of the initial outcome which recommended conditional support to the project, issued to the applicants on 18 September 2014, the following points required response, in addition to the security assurance issue.

3. Confirmation of the nature of data flows to the EUROCAT register.

The applicants confirmed that data is disclosed to EUROCAT. This included the bare minimum of patient identifiable information for the infant (date of birth, sex, birthweight, and anomaly details) and no identifiable information on mother or father (see EUROCAT guide 1.3).

Data is transmitted twice yearly on 15th February and 15th October using the BINOCAR gateway (a secure file transfer system), which links the CARIS register to both EUROCAT and BINOCAR, so that files can be transferred securely between all three registers.

The purpose of sending data to EUROCAT is for surveillance and bench-marking. Surveillance can be conducted at both a register level and at a pan-European level by EUROCAT. A UK subset of processed data is also transferred back to BINOCAR so that an annual report at a UK level can be published. As data is processed in a standard way with strict rules, data within EUROCAT can be used to compare numbers and rates between registers across Europe.

4. Further information in relation to the provision of fair processing in the long term to ensure that children and adults were informed of the long term retention of their data.

The applicants acknowledged that this was an important issue, to which a lot of thought had been given but is not one that can be easily tackled. CARIS records information to at least the end of the 1st year of life. This means that there is a gap of many years from infancy to adulthood, when the register has not revisited records. In the interim period many children will have been lost to follow-up by moving out of Wales or indeed moving out of the United Kingdom altogether.

The applicants advised that current practice was to notify mothers through antenatal literature, and with posters and leaflets. Posters are on display in antenatal clinics and paediatric outpatient clinics. There is no similar clinical system which would capture all 16-18 years olds in Wales. The applicants stated that they would explore ways information could be made available to this age group e.g. via GPs or pharmacies. In addition they advised that they would consider the approach other paediatric services in Wales have taken to see if there was any good practice which could be adopted.

The applicants stated that they would look at the feasibility of anonymising historic records after a period of time as children reach adulthood, in such a way that historic data became non-identifiable.

5. Confirmation of the methods of access to data sources and the extent of data collected from each.

The applicants advised that the success of CARIS was built largely on the fact that this was a multi-source reporting register. Many of the sources consulted did not inform about new cases, but helped to give a fuller picture of the cases already registered. Patient identifiers are needed to prevent duplicate registrations. The applicants provided a detailed overview in review to the data sources which would be accessed together with explanation of the value this added to the registry; the data utilised to facilitate access and the methodology of this access.

6. Continued review of the requirement for the use of confidential patient information and the retention of identifiable data items. This should be reported on at annual review stage.

The applicants confirmed that they were not complacent about the identifiable data held and as stated they would explore the feasibility of anonymising historic records after a period of time as children reach adulthood, in such a way that historic data becomes non-identifiable.

Security Assurance Arrangements

The CAG has been aware of significant external delays in reaching a position regarding equivalent security assurance arrangements for relevant entities where processing is to take place in Wales, as the English Information Governance Toolkit is not applicable within Wales. It is understood that it has been agreed with the Department of Health that the NHS Wales Information Service (NWIS) will review relevant Caldicott Principles Into Practice (CPiP) Assessments and provide an independent security assurance arrangement, similar to that of NHS Digital in England, to the CAG. The CAG has been provided with a report titled **System Level Security & Governance Assessment (SLSGA) Formal Response NWIS REF – 0317-01. The assessment score for Public Health Wales is 78% and this score has been provided in relation to this application.**

CAG has been informed that the Department of Health has agreed a percentage mark of 91% for a CPiP assessment is considered to be equivalent to the minimum standard of level 2 for the English Information Governance Toolkit. While Public Health Wales is not at this stage, provision of this document appears to provide confirmation that NWIS are taking responsibility for the assurance. The CAG has recommended to the decision maker that, in light of steps to be taken, approval be recommended for a one-year period, to enable Public Health Wales to reach the required level of assurance. This would be in alignment with the support provided to Public Health England and is intended to ensure that Public Health Wales is meeting the minimum standards necessary for adequate security assurance where processing confidential patient information without consent under support. This recommendation will be subject to the following:

- **The expectation is for the assessment to reach 91% within one year from final approval to avoid jeopardising the state of future approval.** It is understood that the report confirms that a report to the WIGB against the outstanding actions for this CPIP assessment will be required for the October 2017 meeting.
- **There should be full compliance with regards to a mechanism to respect patient objection.** The CAG will look specifically at this aspect at time of annual review.
- **A detailed report at time of annual review showing compliance with all outstanding actions.** If there is any possibility that at time of annual review that all aspects have not been achieved, or that an improvement plan exists, this must be flagged in advance with the Advice Team following the report to WIGB in October 2017.
- As the Head of IG is named as the lead for the outstanding aspects, to consider that this role be present at time of next consideration by the CAG.

Summary

The CAG acknowledged the delays which had been caused by the implementation of the CPiP assurance programme and the impact this had for applicants. The response was received and considered by the Chair, and it was agreed that proceeding to final support for processing under the Regulations was recommended.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support (Final)

1. Security assurance arrangements:
   a. **The expectation is for the assessment to reach 91% within one year from final approval to avoid jeopardising the state of future approval.** It is understood that the report confirms that a report to the WIGB on the progress made against the outstanding actions against the CPIP assessment will be required in the October 2017 meeting.
   b. **There should be full compliance with regards to a mechanism to respect patient objection.** The CAG will look specifically at this aspect at time of annual review.
   c. **A detailed report at time of annual review showing compliance with all outstanding actions.** If there is any possibility that at time of annual review that all aspects have not been achieved, or that an improvement plan exists, this must be flagged in advance with the Advice Team following the report to WIGB in October 2017.
   d. As the Head of IG is named as the lead for the outstanding aspects, to consider that this role be present at time of next consideration.
2. Continued review of the requirement for the use of confidential patient information and the retention of identifiable data items. This should be reported on at annual review stage.

Reviewers:

Name	Capacity
Dr Mark Taylor	Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **Wales Abdominal Aortic Aneurysm Screening Programme (WAAASP)**

CAG reference: **CAG 6-06(c)/2014**

Context

Purpose of Application

This application from Public Health Wales set out the purpose of the Wales Abdominal Aortic Aneurysm Screening Programme (WAAASP), a public health screening programme which aimed to reduce mortality by 50% by 2015.

A recommendation for class 4, 5 and 6 support was requested to cover access to confidential patient information from the Welsh Demographic Service to Public Health Wales in order to send invitations for screening. Data would be held on the Abdominal Aortic Aneurysm Screening Information System. In addition, data was requested from the Public Health Mortality Files, Patient Episode Database for Wales and the National Vascular Registry in order to determine outcomes within 30 days and 1 year of treatment for all men invited to take part in screening.

The application also sought information in relation to patients who had aortic aneurysms not detected by screening from ONS mortality data and various NHS organisations.

Confidential patient information requested

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

Confidentiality Advisory Group Advice

Background

This application was originally considered by the CAG at a meeting held on 28 August 2014, following which a provisionally supported outcome was issued to the applicants on 18 September 2014. A response to this outcome was received on 18 November 2014; however, it was acknowledged within this correspondence that the MoU between DH and NWIS around security assurance remained outstanding. Final support was not issued at this stage due to this outstanding condition of support.

In the interim, one amendment and two annual review submissions were made in connection to the application activity and there appears to have been some correspondence in relation to the outstanding final support between the Confidentiality Advice Team and Public Health Wales, as applicants, within this time period.

NWIS submitted a CPiP assurance report in relation to the application on 13 March 2017. Following receipt of this outstanding assurance report, a letter was issued to the applicants on 04 April 2017 by the Confidentiality Advice Team, requesting a status update on the

application, as it appeared from the correspondence which had been received in the interim, that activity had been undertaken in relation to the application when final support was not yet in place.

Application Status

An interim response was received from the applicants on 18 April 2017, with a final response submitted on 10 August 2017. Public Health Wales confirmed that activity had proceeded for the programme in the intervening period since the conditional support recommendation was issued. The applicants clarified that the processing which had been undertaken in connection to this long-term health intelligence programme was essential in the public interest of the people of Wales. As such, the applicants did not believe that this processing was in breach of the Common Law of Confidentiality.

Following receipt of the above clarifications, an acknowledgement was sent to applicants on 21 August 2017 and it was queried, in light of all outstanding points of the original conditional support having now been addressed, whether it was intended for the application for support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to be progressed. Confirmation was received on 24 August 2017 from Public Health Wales that the application for support under the Regulations should proceed to full support, to enable the legal basis for the application activity to be established under the Regulations.

Specific Conditions of Support

As part of the initial outcome which recommended provisional support to the project, issued to the applicants on 18 September 2014, the following point required response, in addition to the security assurance issue.

1. Provision of revised patient information in line with issues outlined above in relation to non-responders and patient objection.

The applicants revised the information included in the general information leaflet and invitation letter in line with the guidance provided the CAG – revised copies of the documentation were shared for information purposes.

The applicants also provided a new document, which would be sent to any man who raised an objection to the retention of his data and opted out of the programme, to confirm that this had been accepted. The document was provided for information purposes.

The applicant further confirmed that a change had been implemented in the ASIMS programme, which was the Information Management System by which WAAASP managed the programme. The change developed a flag that will be manually activated against a man's details to ensure that the Screening Division Information Team did not use a man's details for evaluation of the programme if an objection was raised.

Security Assurance Arrangements

The CAG has been aware of significant external delays in reaching a position regarding equivalent security assurance arrangements for relevant entities where processing is to take place in Wales, as the English Information Governance Toolkit is not applicable within Wales. It is understood that it has been agreed with the Department of Health that the NHS Wales Information Service (NWIS) will review relevant Caldicott Principles Into Practice (CPiP) Assessments and provide an independent security assurance arrangement, similar to that of NHS Digital in England, to the CAG. The CAG has been provided with a report titled **System Level Security & Governance Assessment (SLSGA) Formal Response NWIS REF –**

0317-01. The assessment score for Public Health Wales is 78% and this score has been provided in relation to this application.

CAG has been informed that the Department of Health has agreed a percentage mark of 91% for a CPiP assessment is considered to be equivalent to the minimum standard of level 2 for the English Information Governance Toolkit. While Public Health Wales is not at this stage, provision of this document appears to provide confirmation that NWIS are taking responsibility for the assurance. The CAG has recommended to the decision maker that, in light of steps to be taken, approval be recommended for a one-year period, to enable Public Health Wales to reach the required level of assurance. This would be in alignment with the support provided to Public Health England and is intended to ensure that Public Health Wales is meeting the minimum standards necessary for adequate security assurance where processing confidential patient information without consent under support. This recommendation will be subject to the following:

- **The expectation is for the assessment to reach 91% within one year from final approval to avoid jeopardising the state of future approval.** It is understood that the report confirms that a report to the WIGB against the outstanding actions for this CPIP assessment will be required for the October 2017 meeting.
- **There should be full compliance with regards to a mechanism to respect patient objection.** The CAG will look specifically at this aspect at time of annual review.
- **A detailed report at time of annual review showing compliance with all outstanding actions.** If there is any possibility that at time of annual review that all aspects have not been achieved, or that an improvement plan exists, this must be flagged in advance with the Advice Team following the report to WIGB in October 2017.
- As the Head of IG is named as the lead for the outstanding aspects, to consider that this role be present at time of next consideration by the CAG.

Summary

The CAG acknowledged the delays which had been caused by the implementation of the CPiP assurance programme and the impact this had for applicants. The response was received and considered by the Chair, and it was agreed that proceeding to final support for processing under the Regulations was recommended.

CAG advice conclusion

In line with the considerations above, 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 provisional support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support and request for further documents as set out below.

Specific Conditions of Support (Final)

1. Security assurance arrangements:
   a. **The expectation is for the assessment to reach 91% within one year from final approval to avoid jeopardising the state of future approval.** It is understood that the report confirms that a report to the WIGB on the progress made against the outstanding actions against the CPIP assessment will be required in the October 2017 meeting.
   b. **There should be full compliance with regards to a mechanism to respect patient objection.** The CAG will look specifically at this aspect at time of annual review.
   c. **A detailed report at time of annual review showing compliance with all outstanding actions.** If there is any possibility that at time of annual review that all aspects have not been achieved, or that an improvement plan exists, this must be flagged in advance with the Advice Team following the report to WIGB in October 2017.

d. As the Head of IG is named as the lead for the outstanding aspects, to consider that this role be present at time of next consideration.

2. Continued review of the requirement for the use of confidential patient information and the retention of identifiable data items. This should be reported on at annual review stage.

Reviewers:

Name	Capacity
Dr Mark Taylor	Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Application title: **Barts Health (NICOR) UK Transcatheter Aortic Valve Implantation (TAVI)**

CAG reference: **17/CAG/0152 (Replacement of CAG 5-07(c)/2013)**

Context

Purpose of application

This application from Bart's Health NHS Trust set out the purpose of transferring audit registries in relation to the NICOR UK Transcatheter Aortic Valve Implantation (TAVI), previously held by University College London to Bart's Health NHS Trust.

This historic audit application described three national audit datasets; however, it was confirmed that only one of these remained ongoing to be taken forward. This is the UK Transcatheter Aortic Valve Implantation (TAVI) registry – a record of all TAVI procedures performed in the UK since the introduction of the technique in 2007. The dataset included demographic data, indications, procedural details and outcomes up to hospital discharge. Follow up data would be collected at 1 and 3 years.

The datasets would be analysed with the aim to drive improvements in the quality of care. Findings would be shared with participating Trusts and aggregate analysis reports published.

A recommendation for class 4, 5 and 6 support was requested to cover access by NICOR to identifiable data on patients undergoing the relevant procedures, to track patients across NHS organisations and to link to national datasets such as Hospital Episode Statistics (HES) and ONS mortality data.

Confidential Patient Information Requested

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

Confidentiality Advisory Group Advice

From 1st July 2017, the data controller and data processor responsibilities for the TAVI Registry transferred from University College London to Bart's Health NHS Trust (Bart's Health). This included the transferring of the existing data from UCL to Bart's Health relating to this programme and the ongoing collection of data at Bart's Health.

The applicants clarified that there was no actual transfer of data as the IT and data storage systems remain the same (remote external storage). It was clarified that the only aspect that changed was that the sub-contract was now with Bart's Health. It was confirmed that NICOR staff were TUPED to Bart's Health from July 1st 2017 to ensure business continuity and maintenance of IG standard.

The CAG acknowledged that an interim arrangement to support this transfer was put in place from 01 July 2017 under the historic reference CAG 5-07(c)/2013, pending submission of this

revised application. This interim arrangement will cease and the historic application will be expired. This new application had been submitted that sought to combine all information and amendments approved under reference CAG 5-07(c)/2013, with the removal of the expired audit programmes.

The CAG noted the change and recognised that this involved minimal risks as all other arrangements remained as previously approved.

Within the revised submission, the applicants had stated intent to provide the CAG with updates in relation to public and patient engagement activities. It was agreed that this information should be provided in line with the standard annual review process.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support

1. All pre-existing conditions of support related to CAG 5-07(c)/2013 remain applicable
2. The pre-existing annual review cycle remains applicable, with the next annual review to be received 4 weeks before 31/12/2017, and then on an annual basis to this schedule.
3. Updates around public and patient engagement activities should be provided as part of the standard annual review submission.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Barts Health reports an assessed satisfactory score at 77% (version 14 (2016-2017).**

Reviewers:

Name	Capacity
Dr Mark Taylor	Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Application title: **NICOR Commissioning through Evaluation (CtE) Registries/Audits**

CAG reference: **17/CAG/0153 (Previously CAG 10-07(b)/2014)**

Context

Purpose of Application

This application from Bart's Health NHS Trust set out the purpose of transferring audit registries in relation to the NICOR Commissioning through Evaluation Registries/Audits previously held by University College London to Bart's Health NHS Trust.

This application set out the purpose of undertaking three audits for the NHS England Commissioning through Evaluation (CtE) programme. The CtE programme comprises the following registries:

1. Percutaneous Mitral Valve Repair: a catheter-based device which is used to repair heart valves, providing an alternative to open heart for those patients who are clinically appropriate
2. Left Atrial Appendage Occlusion: a device used to prevent stroke in patients with atrial fibrillation (irregular and rapid heartbeat)
3. Patent Foramen Ovale Closure in Adults: a procedure to close a hole, or potential hole, between the upper chambers of the heart, to prevent stroke

A recommendation for class 4, 5 and 6 support was requested to allow access to patients undergoing the procedures. Data would be collected from NHS organisations undertaking procedures, NHS Digital (Hospital Episode Statistics) and the Office of National Statistics.

Confidential Patient Information Requested

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

Confidentiality Advisory Group Advice

From 1st July 2017, the data controller and data processor responsibilities for the Commissioning through Evaluation Registries/Audits transferred from University College London to Bart's Health NHS Trust (Bart's Health). This included the transferring of the existing data from UCL to Bart's Health relating to this programme and the ongoing collection of data at Bart's Health.

The applicants clarified that there was no actual transfer of data as the IT and data storage systems remain the same (remote external storage). It was clarified that the only aspect that changed was that the sub-contract was now with Bart's Health. It was confirmed that NICOR staff were TUPED to Bart's Health from July 1st 2017 to ensure business continuity and maintenance of IG standard.

The CAG acknowledged that an interim arrangement to support this transfer was put in place from 01 July 2017 under the historic reference CAG 10-07(b)/2014, pending submission of this revised application. This interim arrangement will cease and the historic application will be expired. This new application had been submitted that sought to combine all information and amendments approved under reference CAG 10-07(b)/2014.

The CAG noted the change and recognised that this involved minimal risks as all other arrangements remained as previously approved.

Within the revised submission, the applicants had stated intent to provide the CAG with updates in relation to public and patient engagement activities. It was agreed that this information should be provided in line with the standard annual review process.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support

1. All pre-existing conditions of support related to CAG 10-07(b)/2014 remain applicable.
2. The pre-existing annual review cycle remains applicable, with the next annual review to be received 4 weeks before 31/08/2018, and then on an annual basis to this schedule.
3. Updates around public and patient engagement activities should be provided as part of the standard annual review submission.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Barts Health reports an assessed satisfactory score at 77% (version 14 (2016-2017).**

Reviewers:

Name	Capacity
Ms Clare Sanderson	Alternate Vice Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **The Manchester Self-Harm (MaSH) Project**

CAG reference: **PIAG 2-07(c)/2004**

Context

Purpose of Application

The Manchester Self-Harm Project (MaSH) has approval to collect patient identifiable information of patients attending A&E Departments at three different Trusts following self-harm. Identifiers collected are name, address, date of birth, postcode, NHS number and hospital number. In 2009, an amendment was approved to link patient information collected, from 2000 to 2007, to MRIS data and to also receive date of death, cause of death (ICD10 code), place of death, registration district, occupation and address.

Amendment Request

The amendment requested support to submit further cohorts to NHS Digital for mortality tracing of individuals that visited the emergency department in their specified study hospitals for the first time during the period from 2011 to 2015 inclusive. The current support and funding for the project is in place until 31 March 2018 only.

Confidentiality Advisory Group Advice

The amendment request was forwarded to the Alternate Vice-Chair, who was assured that the request was in line with the existing support that was in place. It was acknowledged that the applicants would be seeking continued funding for the programme and future similar requests may be made. Support was recommended for 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 Secretary of State for Health.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(University of Manchester – Manchester Self-Harm Project IGTK – V14, 2016/17 – reviewed grade of 100% satisfactory).**

Reviewers:

Name	Capacity
Dr Kambiz Boomla	CAG Member
Dr Patrick Coyle	Vice Chair
Mr Anthony Kane	CAG Member
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **Inflammatory Bowel Disease Registry**

CAG reference: **CAG 6-07(d)/2013**

Context

The original audit application from the British Society of Gastroenterology set out the purpose of establishing a national IBD Registry which would feed into national service development planning and fulfil national audit, IBD standards and quality improvement benchmarks. The application also detailed using the registry to allow patients to be identified for research purposes and for the Health and Social Care Information Centre (HSCIC) to write to patients on behalf of the applicant. A recommendation for class 4, 5 and 6 support was requested in order to access data, including NHS number, date of birth and postcode in relation to all patients in the UK who had been diagnosed with IBD. Data sources included HES, ONS, Bowel Cancer audit, cancer registries, IBD Registry patient management system and data collected via a web portal system. Data would be collected by the HSCIC and only pseudonymised data would be disclosed to the British Society of Gastroenterology for analysis purposes.

Amendment Request

The applicant submitted the following two amendments to the original application:

1. **Extension to support** – the applicants requested an extension to the duration of support under the Regulations while further work is undertaken to improve the approach adopted to gain patient's consent for their data being linked, pseudonymised and processed by the Registry.
2. **Additional purpose** – the applicants requested an extension of the purposes for which the pseudonymised data held in the IBD Registry can be used. The request is that the Registry be allowed to provide anonymised, aggregate reports to companies that have or are developing healthcare products (e.g. drugs or medical devices) for use in Inflammatory Bowel Disease.

Confidentiality Advisory Group Advice

The amendment request was shared with a Sub-Committee of the CAG for consideration. It was acknowledged that submission of the amendment request had been prompted by queries identified on the annual review submission.

<u>Duration of Support Extension</u>

Members considered the history of the project and it was acknowledged that support was initially intended for an 18 month period, on the basis that after this time, the Registry would

progress on a fully consented basis. Due to delays in the set-up of the Registry, the start date of the project was amended to January 2015, with the intention that support would expire in June 2016. At this time the applicants submitted an amendment as part of the annual review submission, requesting a 12 month extension to the support duration.

At the time of annual review 2017, the applicants requested a further 12 month extension to the duration of support, as they continue to work towards a fully-consented model for inclusion in the registry.

The Sub-Committee considered the progress report the applicants had provided in this area and it was acknowledged that considerable work had been achieved here. Members were assured that the applicants had demonstrated that they continued to strive towards increasing consent levels through various new methodologies to achieve this.

Members discussed the attempts which had been undertaken by the applicants to achieve consent via mailing to patients; however, it was commented that the applicants should be mindful of the Information Commissioners Office (ICO) position around non-response to a direct approach for consent, which should be taken into account when considering new ways to seek consent. It was acknowledged a previous attempt to gain consent via postal methods had achieved a low-response rate; however, the Sub-Committee agreed that as those individuals who had been approached for consent and not responded, were initially covered by this approved application for support under the Regulations, the applicants could continue to retain data in relation to this sub-cohort of patients. It was recommended that the applicants were mindful of this existing ICO position moving forward.

The Sub-Committee was assured of the rationale provided by the applicants to support the extension to the duration of support for a further 12 months and recommended support for this part of the amendment. The applicants would be asked to provide a further update at the time of annual review around the progress made with the consenting model. If a further extension to support was envisaged, this would need to be made in advance of the expiration of existing support and be supported by strong rationale for its requirement.

Additional Purpose

Members considered the request to extend the purpose of the application, to enable the applicants to provide anonymised, aggregated reports of registry data to companies which have or are in the process of developing healthcare products. It was acknowledged that whilst the request did not concern the sharing of confidential patient information, it was an extension to the purposes for which the registry data could be used.

The Sub-Committee agreed that the patient and public notification materials which were in place to promote the application activity would need to be updated to reflect this additional purpose. It was commented that patients were usually less supportive of the use of their data to promote commercial interests and as such, Members recommended that the applicants monitor whether the introduction of this additional purpose leads to an increase in objections raised by patients already included within the Registry or who declined to provide consent for inclusion. It was also agreed that the consenting materials should be updated to include a clear consent option around this secondary use of anonymised data, to which patients can decline.

The Group was assured by the rationale provided to support the inclusion of the additional purpose and agreed that support was recommended for this extension. Members agreed that this recommendation was conditional on the revision of patient and public information materials around the registry, which should be updated to include this additional purpose and a clear mechanism to opt-out of this additional data use.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was acknowledged that the British Society of Gastroenterology had received assurance from NHS Digital on Version 14 of the IG Toolkit submission with an improvement plan in place. Members considered the outstanding items on the improvement plan which were in relation to staff IG training and corporate records management. It was recognised that the improvement plan would be followed up directly between the applicants and NHS Digital and updated position would be provided by the applicants as standard as part of the next annual review.

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 Secretary of State for Health.

Specific Conditions of Support

1. Support is extended for a further 12 months from the data of this outcome letter.
2. The applicants are required to provide an update on progress towards the fully consented model within the next annual review.
3. If it becomes apparent that a further extension to the duration of support is required beyond the period covered within this amendment, the applicants are advised that the amendment request should be submitted in advance of the expiration of support. A strong rationale would be required to justify the further duration extension.
4. Patient and public notification materials should be updated to include clear information around the additional purpose for supply of anonymised aggregated data to commercial companies and provide a mechanism to raise objection to the use of data in this way. An interim report, together with submission of the revised notification materials is required within six months of this date of this outcome.
5. Patient consent materials should be updated to include a specific consent point in relation to the additional purpose for supply of anonymised aggregated data to commercial companies. Patients should be able to withhold consent for this purpose, whilst agreeing to inclusion in the Registry. An interim report, together with submission of the revised notification materials is required within six months of this date of this outcome.
6. Confirmation of suitable security arrangements via IG Toolkit submission of University of Liverpool and Chameleon Information Management Services Ltd. **(Confirmed - British Society of Gastroenterology, Version 14, 2016-17, satisfactory at 63% with an improvement plan in place)**.

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **Congenital Anomaly Register and Information Service for Wales (CARIS)**

CAG reference: **CAG 6-06(b)/2014**

Context

Purpose of Application

This application from Public Health Wales set out the purpose of a systematic collection, registration and publication of population level data of congenital anomalies in Wales. The data would be used to assess patterns of anomalies, possible clusters of anomalies and their causes, antenatal screening and other healthcare interventions and health service provision for affected babies and children.

A recommendation for class 3, 4, 5 and 6 support was requested to allow the disclosure of confidential patient information from a number of different sources to Public Health Wales.

Confidential Patient Information Requested

Confidential patient information from a range of sources was requested in relation to any foetus or baby who had or was suspected of having a congenital anomaly and whose mother was normally resident in Wales at time of birth.

Data items including mother and baby name, postcode, NHS number, date of birth and date of death and father name were requested.

Amendment Request

The applicant submitted the following amendments to the original application:

1. The addition of Father's NHS number to the dataset.
2. Additional linkage with BadgerNet to improve the pickup rates of congenital abnormalities.
3. CARIS has applied to part of the EUROlinkCAT study – this is a European-wide study (Part of Horizon 2020), using data linkage methods, to look at long-term survival, hospital stays, medications used, education and co-morbidities and mortality of congenital anomalies. The project was approved by the EU in July 2016. The project will start in 2017 and run through until 2020. The applicants clarified that CARIS data will be linked through SAIL, but analysed locally and combined at a European level by an agreed methodology in a similar manner as the previous EUROmediCAT Project.

Confidentiality Advisory Group Advice

The amendment request was shared with the Vice Chair for consideration. It was acknowledged that the collation of father's NHS Number was as important as collecting the mother's NHS number, as this would enable the applicants to examine the inheritance of

abnormalities. It was noted that the linkage with BadgerNet was utilising an existing patient care system to improve ascertainment. The Vice Chair commented that linkage via SAIL for the inclusion in the EUROlinkCAT study appeared appropriate as this was a known system for achieving linkage pseudonymously. Support was recommended for all aspects of the amendment.

Security Assurance Arrangements

The CAG has been aware of significant external delays in reaching a position regarding equivalent security assurance arrangements for relevant entities where processing is to take place in Wales, as the English Information Governance Toolkit is not applicable within Wales. It is understood that it has been agreed with the Department of Health that the NHS Wales Information Service (NWIS) will review relevant Caldicott Principles Into Practice (CPiP) Assessments and provide an independent security assurance arrangement, similar to that of NHS Digital in England, to the CAG. The CAG has been provided with a report titled **System Level Security & Governance Assessment (SLSGA) Formal Response NWIS REF – 1016-01. The assessment score for Public Health Wales is 78% and this score has been provided in relation to reference 0371-01.**

CAG has been informed that the Department of Health has agreed a percentage mark of 91% for a CPiP assessment is considered to be equivalent to the minimum standard of level 2 for the English Information Governance Toolkit. While Public Health Wales is not at this stage, provision of this document appears to provide confirmation that NWIS are taking responsibility for the assurance. The CAG has recommended to the decision maker that, in light of steps to be taken, approval be recommended for a one-year period, to enable Public Health Wales to reach the required level of assurance. This would be in alignment with the support provided to Public Health England and is intended to ensure that Public Health Wales is meeting the minimum standards necessary for adequate security assurance where processing confidential patient information without consent under support. This recommendation will be subject to the following:

- **The expectation is for the assessment to reach 91% within one year from final approval to avoid jeopardising the state of future approval.** It is understood that the report confirms that a report to the WIGB against the outstanding actions for this CPIP assessment will be required for the October 2017 meeting.
- **There should be full compliance with regards to a mechanism to respect patient objection.** The CAG will look specifically at this aspect at time of annual review.
- **A detailed report at time of annual review showing compliance with all outstanding actions.** If there is any possibility that at time of annual review that all aspects have not been achieved, or that an improvement plan exists, this must be flagged in advance with the Advice Team following the report to WIGB in October 2017.
- As the Head of IG is named as the lead for the outstanding aspects, to consider that this role be present at time of next consideration by the CAG.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. Security assurance arrangements:

a. **The expectation is for the assessment to reach 91% within one year from final approval to avoid jeopardising the state of future approval.** It is understood that the

report confirms that a report to the WIGB on the progress made against the outstanding actions against the CPIP assessment will be required in the October 2017 meeting.

b. **There should be full compliance with regards to a mechanism to respect patient objection.** The CAG will look specifically at this aspect at time of annual review.
c. **A detailed report at time of annual review showing compliance with all outstanding actions.** If there is any possibility that at time of annual review that all aspects have not been achieved, or that an improvement plan exists, this must be flagged in advance with the Advice Team following the report to WIGB in October 2017.
d. As the Head of IG is named as the lead for the outstanding aspects, to consider that this role be present at time of next consideration.

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **National Paediatric Diabetes Audit (NPDA)**

CAG reference: **ECC 2-03(c)/2012**

Context

This application was submitted by the Royal College of Paediatrics (data processors) on behalf of the Healthcare Quality Improvement Partnership (HQIP), who would act as data controllers, and detailed the transfer of data controller responsibilities from the Health and Social Care Information Centre (HSCIC) to HQIP. It was confirmed that the purposes of the application remained the same.

Confidential patient information was requested to track patients throughout care pathways and to remove duplicate entries. Identifiable information was also requested to link with national datasets, HES and child mortality data. NHS number, date of birth, postcode and date of death were required. Postcode would be deleted once deprivation score had been calculated.

Amendment Request

An amendment was requested to extend the currently approved data amendment to add the 2014/15 and 2015/16 datasets. This data flow is to audit diabetes transition care from paediatric diabetes services to adult diabetes services, which is a key deliverable for both the NDA and NPDA as part of the National Clinical Audit Programme of work which is commissioned by NHS England and managed by the Healthcare Quality Improvement Partnership.

The amendment also sought support for NHS Digital to keep the identifiable data for up to one year, following receipt of data until July 2018, to allow for linkage to the National Diabetes Audit and Patient Episode Database for Wales and Hospital Episodes Statistics.

Confidentiality Advice Team Advice

The Confidentiality Advice Team (CAT) considered the amendment and it was acknowledged that the request was in line with the principles of the original approval.

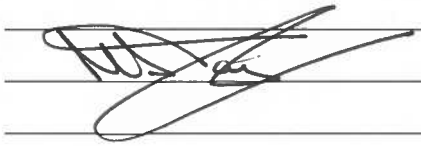
It was acknowledged that the applicants had previously sought approval for the 2014/15 dataset to flow; however, this was prepared in time to be sent for analysis. The applicants had confirmed that this dataset had been included within this amendment submission as support had been granted over 12 months ago for this dataflow. The CAT agreed that the previous dataset could be included in the recommendation of support for this amendment to bring this recommendation up to date.

Confidentiality Advice Team Conclusion

In line with the considerations above, the Confidentiality Advice Team (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

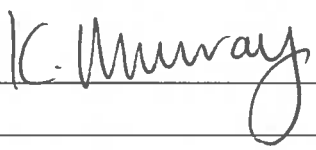
1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – The Royal College of Paediatrics and Child Health, reviewed reported grade of 82% satisfactory on Version 14, 2016-17).**



26/10/17

Signed – Officers of CAG

Date



26/10/2017

Signed – Confidentiality Advice Team

Date