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

January 2017

Reviewers:

Name	Capacity
Dr Murat Soncul	Chair
Ms Rachel Heron	Confidentiality Advisor

Application title: **Breast-Screening After Radiotherapy Database - Questionnaire (BARD-Q)**

CAG reference: **15/CAG/0149**

Context

This application from the University of Manchester and The Christie NHS Foundation Trust set out the purpose of a study to investigate women who have had radiotherapy to the upper chest under the age of thirty-six years as treatment for Hodgkin Lymphoma as they are at a higher risk of developing secondary breast cancer. The study would also include a review into women who may be at a higher risk and are attending breast screening in accordance to the national breast screening protocol and the likely deviations from the protocol. The applicant would like to invite and obtain consent from participants of a previous similar study to complete a questionnaire.

A recommendation for class 3 and 6 support was requested to allow an authorised user access for the purpose of selecting and contacting patients to seek their consent.

Access was requested to obtain current contact details from Cancer Registry North West, Public Health England (PHE) for individuals who were consented participants of the previous questionnaire but for whom contact information is no longer accurate.

The applicant was also seeking support in order for PHE to extract date of death from the Cancer Analysis System (CAS) to ensure that the questionnaire and associate materials are not sent through the post to deceased patients and to also complete the overall study. The applicant would need to submit a list of the previous participant's NHS numbers to Cancer Registry North West, PHE and the applicant would receive name, NHS number, Hospital ID number, date of birth, date of death and patient full address and postcode.

Amendment Request

Although the applicant had anticipated screening eligible subjects against the Cancer Analysis System via the Cancer Registration Service (NCRS) North West to exclude those who had died and to access an up to date postal address, they had later discovered that addresses were only recorded at the time of diagnosis.

The amendment requested was to access updated vital status and postal address data using the SPINE system. One of the research team, Dr Kate Vaughan, held an honorary PHE contract and had access to work within the section 251 office at NCRS North West. She also held an honorary NHS contract and would be provided access to SPINE by The Christie NHS Foundation Trust.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who agreed that the request was reasonable. This would reduce risk of misdirected correspondence, which could be upsetting for individuals.

On the understanding that no information on the date of death would be recorded or retained and that this information was accessed in order to find out whether an individual was deceased, the Chair recommended support 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 Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission.
2. Confirmation of a favourable opinion from a Research Ethics Committee.

Reviewers:

Name	Capacity
Dr Mark Taylor	Chair
Dr Rachel Knowles	
Ms Diana Robbins	
Ms Laura Frisby	Senior Confidentiality Advisor

Study title: **Intraoperative hypotension in elder patients**

CAG reference: **16/CAG/0126**

Amendment Request

The purpose of the amendment is to update the study dates specified in the application to bring the protocol in line with actual data collection. The amendment seeks to extend the study period from an initial 2 week window (48 hour recruitment period still in place) to a 10 week period. This has been deemed a non-substantial amendment by REC/HRA so does not require an additional REC review.

Confidentiality Advisory Group advice

Members acknowledged the study date update and the extended study period and felt this was justified.

Public Interest

The sub-committee agreed that the application continued to have a strong public interest and this was an appropriate amendment.

Patient Notification

Members acknowledged that the appropriate trial documentation had been updated to keep patients informed.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission.
2. Confirmation of a favourable opinion from a Research Ethics Committee.

Reviewers:

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

Application title: **The Two Week Wait (2WW) study - an investigation of patient non-attendance at urgent referral appointments for suspected cancer.**

CAG reference: **16/CAG/0060**

REC reference: **16/NE/0146**

This application from the Department of Health Sciences at the University of York set out the purpose to investigate the reasons for non-attendance at clinical appointments as part of the two week wait process of referrals for suspected cancer as well as to identify interventions to improve timely access to urgent care. Since 2000, NHS patients with suspected cancer have been guaranteed to see a hospital specialist within two weeks of the GP requesting an urgent referral - a Two Week Wait (2WW) appointment. This policy intended to shorten time to diagnosis and treatment, and ultimately improve survival rates. However, a significant minority of patients are not seen within two weeks, largely due to patients not attending, cancelling or postponing the appointment. Despite audit data identifying the scope of the problem, reasons for patients not attending or cancelling are unknown and no current studies have been identified which are examining this issue.

This study will be completed in five phases:

Phase 1 - Categorisation of patients not seen within two weeks of referral drawing on Leeds NHS Hospital Trust data for approximately 6,000 patients in 2014 and 2015.

Phase 2 - Analyse variation in factors between patients who postpone or cancel their appointment, and those who do attend, to identify predictors of non-attendance. This will use cross-sectional analyses within the same data set as Phase 1.

Phase 3 - Compare rates of cancer diagnosis (and cancer stage at diagnosis) in attending patients with those who postpone, cancel or do not attend to assess the significance of non-attendance. Health outcome data for patients referred in 2009 will be analysed 1, 2,3,4,5 and 6 years later and 1 year later for patients referred in 2014. This data will be compared to similar data from attending patients.

Phase 4 – Explore the views of patients and GPs as to why patients do not attend 2WW appointments and interventions to improve attendance.

Phase 5 – Gain consensus from GP and patient stakeholder groups on the top 3 proposed interventions to improve attendance rates.

Amendment Request

The amendment requested a change to the recruitment process in connection with the qualitative interviews outlined within phase four of the project. The existing support only allowed for the applicants to make contact with patients if the individual was registered to a GP practice which had consented to be involved in the study; however, the applicants confirmed that they had limited uptake from GP practices and as such potential patient participants were being missed.

The amendment requested approval to change the recruitment procedure in connection with the GP practice recruitment and it was noted that the patient recruitment procedure would remain the same. The amendment requested support to allow the applicants to be provided with the GP practice details (not the patient details) should a patient be identified as eligible in all respects aside from the their GP practice having consented to participate in the study. The GP practice would then be provided with a personalised and targeted invitation in the hope of improving the recruitment rates and enabling approach to eligible patients.

Confidentiality Advisory Group Advice

The amendment request was forwarded to the Chair agreed that the applicants were justified in attempting to improve recruitment and their proposal did not cause any issue with confidentiality as the patients being recruited would still be approached by their own general practice.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed – Version 13 (2015-16) reported at a reviewed grade of satisfactory (96%).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Pending confirmation of amendment approval.**

Reviewers:

Name	Capacity
Dr Murat Soncul	Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Application title: **Understanding the Nature and Frequency of Avoidable Significant Harm in Primary Care (Phase 2)**

CAG reference: **15/CAG/0182**

REC reference: **15/EM/0411**

Context

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

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

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

The stated aims were:

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

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

<u>Confidential patient information requested</u>

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

Amendment Request

The final approval for the application, which was issued in February 2016, attached a condition to the support which stated that support to process confidential patient information was only in place until 31/12/2016, as by this time it was anticipated that pseudonymised

data only will be processed. The amendment requested an extension to the duration of support to provide cover up to 31 March 2017, which is the projected study end date. It was recommended in the original outcome that should the applicants require an extension to the duration of the support, this request should be submitted four weeks in advance of the proposed end date.

The applicants explained that the amendment was required as due to delays in the study set-up, the data collection had not yet begun. The amendment was submitted in line with the previously advised timeframe ahead of the expiration of the existing support.

Confidentiality Advisory Group Advice

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

Confidentiality Advisory Group Conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed – Reviewed grade was confirmed satisfactory at 91% on version 13 (2015/16).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed – REC will not issue formal letter to confirm extension (21/12/16)**

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **NCEPOD**

CAG reference: **PIAG 4-08(b)/2003**

Context

Purpose of application

This application from the NCEPOD set out the purpose of reviewing clinical practice and identifying potentially remediable factors in the practice of medical and surgical care. NCEPOD examines the quality of the delivery of care, not specifically cause of death; this is done by reviewing the provision of care and treatment and the management of health services. The commentary and recommendations made in each report are based on peer review of the data submitted to them. A recommendation for class 1, 4, 5 and 6 support was requested to achieve the purposes set out in the application.

Amendment Request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes this year. This amendment covered the first which involved heart failure. The methodology follows the standard retrospective case identification case note review as previous reviews, but the topic is new.

Confidentiality Advisory Team Advice

The amendment request was reviewed by the Confidentiality Advice Team who noted that the request was for an extension to apply the same methodology that had been previously used and for which the applicant already has support.

Confidentiality Advisory Team Conclusion

In line with the considerations above, the Confidentiality Advice Team 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.
2. Confirmation of a favourable opinion from a Research Ethics Committee.

Reviewers:

Name	Capacity
Ms Gillian Wells	Reviewer
Ms Clare Sanderson	Reviewer
Dr Murat Soncul	Chair
Ms Rachel Heron	Confidentiality Advisor

Study Title: **National Diabetes Audit (Adults)**

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

Context

The National Diabetes Audit measured whether people with diabetes were receiving the NICE recommended guidelines for annual care processes (blood pressure, blood glucose, BMI, cholesterol, foot checks, smoking status, urine albumin and creatinine) and treatment targets (cholesterol, blood pressure and blood glucose). The Audit was able to look at differences between patient groups receiving care processes or achieving treatment targets based on the age of the patient, ethnicity, or the deprivation of the area they lived in.

Amendment request

The applicant requested a change in data flows to enable them to share audit data with researchers. The data collected by the audit was mostly used for quality improvement however if the audit data could be shared for research purposes this could help with understanding more about diabetes, e.g. linkage with research projects to help identify who was most likely to be affected by Type 2 diabetes, and any differences in outcomes for different groups of people which could help to tailor or improve care.

Confidentiality Advisory Group advice

The CAG agreed that the change of data flows was in the public interest and recommended support, subject to approval from a Research Ethics Committee.

It was noted that the patient information provided by the applicant had already been approved in relation to other audits – however, the CAG agreed that the patient poster should make reference to the fact that anonymised data may be used for research purposes.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. NHS Digital toolkit published and reviewed as satisfactory.
2. Confirmation of a favourable opinion from a Research Ethics Committee.

3. The CAG suggested that the patient poster should include the information that anonymised data may be used for research purposes. This point was a recommendation only, and support was not conditional on this point.

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor

Application title: **Developing methods for assessing avoidable severe harm attributable to problems in care**

CAG reference: **16/CAG/0017**

IRAS project ID: **139667**

REC reference: **15/NW/0941**

Context

Purpose of application

This application from the London School of Hygiene and Tropical Medicine set out the purpose of this study to test if it was feasible to identify high risk patients using routine data, identify a pool of such patients from 5 different hospitals and retrieve case notes to undertake a review to confirm whether patient harm has occurred. If the applicant can show this route works then it will pave the way for much larger validation studies.

Recent studies using retrospective case record reviews (RCRR) have demonstrated that a proportion of hospital deaths are avoidable. However, the amount of (severe) harm caused by health care may reflect a greater quality of care problem.

The researchers were to first draw up a list of the types of severe harm that occur based on previous research, information from routine reports to the NHS National Reporting and Learning System and the opinions of clinical experts and patients. Next, ways of using existing routine health and social care databases to identify those patients who suffered severe harm as a result of their hospital in-patient care will be developed.

Finally the researchers will develop and test how they will determine which of these incidents of severe harm was due to poor quality care and could, therefore, have been avoided. This was to be done by detailed review of the patients' case records by experienced doctors trained to undertake this task. This would also provide information on the hospital factors that contributed to the event.

It was expected that this research will guide NHS England in their approach to monitoring severe harm in health care and complement the emerging measure of avoidable hospital mortality (section 5c NHS Outcomes Framework 2014/15).

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to allow the disclosure of confidential patient information to 5 Trusts involved and to clinicians not involved in the care of the patients in order to carry out a case note review.

Confidential Patient Information Requested

Access was requested to patient clinical records. No confidential patient data was to be extracted from the patient records.

Amendment Request

The amendment requests an extension to the end date of the project to be in line with the revised grant end date of 30 June 2017. The request was not a duration extension to the time period for which support is requested.

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 was requested purely due to delays in receiving the relevant approvals to enable the study to begin.

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. **(Received – London School of Hygiene & Tropical Medicine, Version 13 2015/16, Reviewed Grade Satisfactory at 78%)**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Amendment Categorisation received 09/02/17)**

Reviewed documents

Document	*Version*	*Date*
Amendment Request Form (From Dr Helen Hogan)		03 January 2017

Study title: **Welsh Cancer Intelligence and Surveillance Unit (WCISU)**

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

Reviewers:

Name	Capacity
Ms Laura Frisby	Senior Confidentiality Advisor

Context

Purpose of application

This application from Public Health Wales set out the purpose of a population-based national cancer register for Wales.

WCISU's role was to provide cancer-specific health intelligence for public health and population health action related to:

- Root causes of poor health and health inequalities
- Population health improvement
- Disease prevention
- Population health needs assessment
- Health care service planning
- Evaluation, research and development.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to confidential patient information from sources including general hospitals, cancer centres, hospices, private hospitals, cancer screening programmes, other cancer registers, primary care, nursing homes and death certificates.

Confidential patient information requested

Access was requested to data from multiple sources in relation to patients within Wales diagnosed with cancer. Name, postcode, NHS number, date of birth and date of death were requested in order to carry out linkage of data from multiple sources over long time periods.

Amendment Request

The amendment requested the following changes to the existing supported project:

a. Notify of a change of organisation address – as of September 2016
b. Inform of a change of IT support to Public Health Wales informatics – which simplifies and strengthens all security arrangements and brings IT support and security for WCISU within the same legal authority
c. Implementation of Public Health Wales ENCORE – this is a migration of the Welsh system onto Public Health Englands system
d. A request for additional data sources with new data items;
e. SACT (systemic anticancer treatment)
f. Private hospitals
g. Primary care
h. Wales cancer patient experience survey (WCPES)
i. National Audit Data
j. Prescribing data

k. Patient related outcome surveys
l. National imaging results

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 CAG 6-06(a)/2014.

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 Advice

The amendment request was forwarded to the members for consideration and agreement was made to support the amendment however it was decided that the primary care data source should be removed from this amendment and should be the subject of a further amendment submission if the applicant wished to proceed. The members felt that were a further amendment to be made to use primary care as a data source it would require a more targeted patient notification and explicit instructions on how to opt out/object.

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. If the applicant wishes to extract data from primary care a further amendment would need to be submitted to CAG for review which would require a targeted patient notification with specific instructions on how individuals could opt out/object
2. 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.

Reviewed Documents

Document	*Version*	*Date*
CAG amendment submission form		19/10/16
Applicant response to queries		
DSA phase 1	V0.2	15/03/16
Confidentiality disclosure policy	V1	06/06/14
Final DSA ABMU SACT	V3	27/06/16
Final DSA Picker		23/06/16
Information Governance Policy		March 2015
MoU PHW PHE		
New Data Flows Wales		
SACT Dataset		
SACT DSA with PHW and Hywel Dda		June 2016
SLSP 18254 EnCORE		
SLSP 18255 Cancer Analysis System		
Wales About Cancer Registration Leaflet English Language		
WCPES dataset		

Study title: **National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme – covering secondary care clinical audit and primary care clinical audit**

CAG reference: **CAG 8-06(b)/2013**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Context

This application from the Royal College of Physicians (RCP) of London set out the purpose of collecting primary care clinical audit data and secondary care clinical audit data to inform the National COPD Audit. The data would be used to improve the quality of care and rehabilitation for COPD patients.

The original application covered the collection and processing of secondary care clinical audit data. An amendment was requested in 2014 to allow the use of primary care data.

Confidential patient information requested

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

Amendment request

The primary care approval covered the annual extraction of patient identifiable audit data from routinely collected general practice data. Data collection was managed under contract by NHS Digital (formerly the HSCIC).

As a condition of the original approval, CAG had requested that the applicant continue to explore the feasibility of using a pseudonymised approach to data collection for primary care. Consequently, for the 2016-2018 rounds of primary care audit (which would only take place in Wales) it was proposed that NHS Wales Informatics Service (NWIS) would manage the extraction of patient-level data (for all patients aged 35 and over with a recorded diagnosis of COPD on primary care registers) from general practice clinical systems.

Pseudonymisation of identifiable fields would be undertaken at source: NHS number would be replaced by a study ID, postcode would be transformed to LSOA and WIMD index, date of birth would be transformed to patient age and date of death (if recorded) would be transformed to age at death.The pseudonymised data would be transferred securely to the NWIS ‘safe haven’ central repository, from where it would be securely transferred to the RCP for cleaning, analysis and reporting.

In line with the conditions of support, the change in data flows and data processor provided an exit strategy from the S251 approval for the primary care audit, as patient identifiable data would no longer be transferred out of participating GP practices.

The secondary care audit procedures would remain the same. Data would continue to be held by NHS Digital from the first round of the audit as per the original approval.

Confidentiality Advice Team advice

It was noted that a practicable alternative had been found to the transfer of identifiable data from GP practices. As NWIS had the capacity to complete pseudonymisation of the data at source, change of data processor from NHS Digital to NWIS was in the public interest. The amendment formalised an exit strategy, from the Section 251 approval which was in place for the primary care audit.

Therefore the CAT recommended support for the amendment.

From spring 2017, primary care data would be collected under the management of NWIS. (A second data collection may take place in autumn 2017, dependent on feasibility and the results of the first data collection). The activity would then cease. This activity did not require Section 251 approval.

Data collection for the secondary care audit would continue under the terms of the originalapproval, and the retention of data already collected under the management of NHS Digital would continue in line with the terms of the original support from CAG, which was still in place for these activities.

Confidentiality Advice Team conclusion

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

Future data collection for the primary care audit is no longer supported under Section 251, however support continues for all other aspects of the activity.

Specific conditions of support

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

   Through policy direction, approved applications require appropriate security assurances to be provided. In England, this is achieved through satisfactory review of the Information Governance Toolkit. Work was undertaken by NHS Digital, NHS England, the Department of Health and NHS Wales Information Services (NWIS) that is hosted by Velindre NHS Trust, to develop a memorandum of understanding so that the Welsh Caldicott Principles into Practice (CPiP) would be accepted as a relevant security assurance mechanism, and to ensure that any applications that received support under Regulation 5 could reach final support.

   Assurances have been provided by NWIS that appropriate security assurances through the CPiP assessment have been provided and therefore security arrangements for the activities specified in this application are confirmed as suitable.

   Please note that at time of annual review and/or amendment, the onus remains upon the applicant (HQIP) to provide evidence of appropriate security assurance as part of the standard process. At time of relevant amendment or annual review, please ensure you liaise with Darren Lloyd at NWIS, prior to formally submitting, to ensure that the CPIP assurance remains current and where a CPiP version has changed, for the appropriate report to be provided to the CAG, along with any improvement plans. Please note any annual review or amendment will not be considered valid unless there is evidence provided by NWIS of ongoing satisfactory CPiP assessment. Please ensure this is taken into account for future submissions to prevent delay.