Health Research Authority

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

July 2019

Present:

Name	Capacity	Items
Ms Clare Sanderson	Alternate Vice-Chair	1.a., 1.b, 1.c. 2.a.
Dr Martin Andrew	CAG Member	1.b.
Dr Malcolm Booth	CAG Member	1.a.
Miss Sophie Brannan	CAG Lay Member	2.a.
Dr Barry Evans	CAG Member	1.c.
Mr David Evans	CAG Member	1.c.
Dr Rachel Knowles	CAG Member	1.a.
Dr Simon Kolstoe	CAG Member	2.a.
Ms Dianna Robbins	CAG Lay Member	1.b.

Also in attendance:

Name	Position (or reason for attending)
Miss Katy Cassidy	Confidentiality Advisor, HRA
Miss Kathryn Murray	Senior Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a. 19/CAG/0104 - OPTIPREM: Optimising neonatal service provision for preterm babies born between 27 and 31 weeks of gestation in England using national data, qualitative research and economic analysis.

Context

Purpose of application

This application from the Royal Wolverhampton NHS Trust set out the purpose of medical research to determine if babies born at 27-31 weeks of gestation and admitted to a Neonatal Intensive Care Unit (NICU) show improved survival and reduced major morbidity compared to babies admitted to a Local Neonatal Unit (LNU).

It was explained that new evidence had shown that for babies born at between 23 and 26 weeks, care in one of two types of neonatal units, NICU, as compared to an LNU improves survival to discharge. In contrast, there is no evidence to guide location of care for the next most vulnerable group, babies born between 27 and 31 weeks, whose care is currently spread between 45 NICU and 84 LNU in England. This group accounts for four times more neonatal unit admissions than those born at 23 to 26 weeks, and 12% of all preterm births in England. The primary objective in this study is to assess, for babies born at 27 to 31 weeks and admitted to a neonatal unit, whether care in a NICU versus a LNU impacts on survival and key morbidities up to two years of age at each gestational age in weeks.

The project will analyse routinely recorded data extracted from real-time, point-of-care patient management systems and held in the National Neonatal Research Data (NNRD), Hospital Episode Statistics (HES) and Office for National Statistics (ONS).

Information on all admissions to NHS neonatal units in England, Wales and Scotland are held in the National Neonatal Research Database (NNRD), established and managed at the Neonatal Data Analysis Unit (NDAU), an academic research group from Imperial College London, which is based within the Chelsea and Westminster Hospital NHS Foundation Trust. Project-specific objections will be applied to the dataset by the NNRD, following which, confidential patient information relating to the study cohort will be disclosed to NHS Digital. NHS Digital will apply any national opt-outs and undertake linkage to HES and ONS data for up to two years. Pseudonymised linked data will then be returned to NDAU to be linked with its data. The linked pseudonymised data will then be distributed by NDAU to the Opti-Prem teams working at the Universities of Leicester and Oxford.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the

application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	30,000 male and female pre-term babies, aged 27+0 to 31+6 weeks, born in England and admitted to neonatal units, and whose records are held in the National Neonatal Research database, between 01/01/2014 and 31/12/2018.
Data sources	1. The National Neonatal Research Database (NNRD), held by Chelsea & Westminster Hospital NHS Foundation Trust, 2. HES and ONS data held by NHS Digital
Identifiers required for linkage purposes	1. NHS number 2. Hospital ID number 3. Date of birth 4. Date of death 5. Postcode – unit level 6. Date of event 7. Age at event 8. Type of event 9. Type of care 10. Hospital of care 11. NHS number of mother 12. Ethnicity of Mother
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – unit level 4. Gender 5. Ethnicity 6. Date of admission and discharge from NIC/LNU 7. Date of event up to second year of life 8. Type of event 9. Type of care received 10. Hospital of care 11. NHS number of mother

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The applicants were seeking to improve the neonatal care of pre-term babies. The Sub-Committee agreed that the application had a clear public interest

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicants anticipate that 30,000 patients will be included in the study and that it would not be feasible to obtain consent for this number of patients. The Sub-Committee accepted the rationale for not seeking consent due to the size of the cohort.

- Use of anonymised/pseudonymised data

Confidential patient information was required so that data from the National Neonatal Research Database and NHS Digital can be linked together. Pseudonymised, linked data would be shared with the research team for analysis.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Parent Information leaflets, indicating the nature of the study, were included in the pack given to all parents as part of their child's admission to the neonatal units across the OptiPREM study recruitment period. Posters were also displayed in the neo-natal units. The applicants retained details of those parents who had registered a dissent around the use of data within the study, which would be respected as part of the follow-up via NHS Digital. A parent opt-out form was also available to notify the National Neonatal Research Database of any further objections. The Sub-Committee was satisfied with the process described and raised no queries.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants explained that they had actively engaged with parents of preterm babies who were admitted into a variety of neonatal units in England and a parent was a co-applicant on the project. A Parent Advisory Panel involving 10 parents had helped design the project and would continue to guide its progress and assess validity of the results and interpretations. These activities were carried out in partnership with BLISS, the National Preterm charity in England, who had provided advice and guidance on the parent information leaflet and the inclusion of a parent co-applicant. The Sub-Committee recognised the activity which had been undertaken in this area, which it agreed was appropriate and proportionate to the study aims.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 23 May 2019**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Pending NHS Digital has a confirmed Standards Met grade. DPST remains pending for Chelsea & Westminster Hospital NHS Foundation Trust**

b. 19/CAG/0105 - Partners at Care Transitions (PACT): Improving patient experience and safety at transitions of care - Assessing the feasibility of using the PACT intervention to improve safety and experience of the transition process in a randomised controlled trial setting.

Context

Purpose of application

This application from the University of Leeds set out the purpose of medical research to improve the safety of experience of transitions from hospital to home for patients aged 75 years and over.

Transitions of care from hospital to home can be risky, especially for older people with multiple health conditions. Previous research has suggested that the post-discharge period may be improved by better involving patients and families in their care. This study forms part of a programme of research which aims to develop an intervention to improve the safety and experience of transitions from hospital to home for people aged 75 years and over. In this study a feasibility cluster Randomised Control Trial will be conducted to explore the feasibility of using the intervention and trial methodology. As the applicants have progressed through this programme of work they have identified a problem in accessing accurate routine readmission data, as the way in which hospitals code discharge information does not always accurately record whether patients were admitted from and discharged to their own home, rather than a nursing or care home. This programme of work is designed to assist patients discharged home, therefore the applicants intend to assess the extent to which this coding issue will affect the accuracy of the primary outcome measure for the target population.

In order to test the processes as part of the full cluster Randomised Control Trial, the applicant first intends to identify the most efficient, cost effective and accurate way of identifying readmission data for patients who are discharged to their own homes rather than other usual places of residence, such as nursing homes. Information Services in each Trust will create a list of 10 patients per participating ward who are aged 75 years or over, consecutively admitted to the participating ward, and discharged from anywhere in the hospital to 'usual place of residence' as per hospital coding. Confidential patient information on these patients will be shared with a Trust research nurse. The research nurse will then check the medical records and categorise patients as discharged to either their own/a relative's home, a nursing home, intermediate care or another residence. This data will be aggregated at ward level and all personal information removed before the data is shared with the research team.

A recommendation for class 1, 2 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	100 male and female participants, aged 75 years and over, admitted to 10 participating wards.
Data sources	Electronic and paper records held in participating Trusts.

Identifiers required for linkage purposes	3. NHS Number 4. Hospital ID Number 5. Date of birth 6. Postcode (unit level) 7. Address of patients' usual residence 8. Date of admission to hospital 9. Ward admitted to
Identifiers required for analysis purposes	The applicant confirmed that no items of confidential patient information were required for analysis purposes
Additional information	The overarching research programme will operate on a consented basis and is out of scope for the CAG application.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members recognised that there was a clear public interest in the proposed activity as this will inform a wider trial aiming to improve the safety of and experience for elderly patients when transitioning care provision from hospital to home.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Minimising flows of identifiable information

The applicant had taken steps to minimise access to and flow of confidential patient information by limiting access to patient records to research nurses working within the participating Trusts. An anonymised dataset would be extracted and disclosed to the research team to inform analysis.

- Feasibility of consent

The applicants explained that consenting patients to this aspect of the study would prevent them from gathering data on a representative sample of patients discharged

to their usual place of residence, as there was a risk that the sample could be biased towards patients who had capacity and were willing to take part. Operation of a consenting mechanism may prevent the most vulnerable patients, who were the key focus of the study, from being included in the initial pilot analysis. The CAG accepted the rationale for not seeking consent and, due to the low-risk and limited disclosure involved in the study, were supportive of proceeding on this basis.

- Use of anonymised/pseudonymised data

Access to confidential patient information in records was necessary to enable identification of patients and the required data to be extracted for analysis, which could not be otherwise achieved. The applicant would only be required with an anonymised dataset for analysis purposes.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicant had provided a detailed overview to explain why operating a communications mechanism was not feasible for the study. However, the rationale provided here appeared to focus on a requirement to make contact with individual patients. Members commented that there appeared to be scope to display a poster within the relevant wards from the outset of the sampling period, to inform patients that their records may be viewed for these purposes and provide a contact mechanism to enable objection to be raised. The applicant would be asked to establish this mechanism and provide relevant supporting documentation for consideration.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicant explained that the research programme had its own dedicated patient panel comprising of eight older people (aged 75 years or over), who had played an active role in the proposal. It was reported that a clear discussion had been carried out with four members of the panel around the acceptability of accessing confidential patient information without consent for the purposes of the study. Detailed feedback was provided from this activity which was supportive of the proposal. The CAG was assured that the activity carried out in this area was appropriate and proportionate to the proposed activity.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

Request for further information

1. A mechanism should be established to inform patients about the research study and provide a means for dissent to be raised against their data being accessed in this manner. Copies of any documentation to support this should be provided for consideration.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 27 June 2019**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Pending for the following organisations:**

    a. Leeds Teaching Hospitals NHS Trust
    b. Airedale NHS Foundation Trust
    c. The Mid Yorkshire Hospitals NHS Trust

c) 19/CAG/0115 - Suspected Stroke Clinical and radiological data base (SSCRaD)

Context

Purpose of application

This application from Ashford & St Peter's Hospitals NHS Foundation Trust set out the purpose of establishing a research database of patients with suspected stroke or intracranial haemorrhage.

Only pre-existing clinical data will be collected for patients who have undergone radiological imaging due to suspicion of stroke or to investigate a known stroke. The data collected will include fully anonymised radiological images, including CT and MRI scans, and the anonymised radiological report. The patients age, gender, presenting symptoms, treatment and clinical outcome will also be collected and included in the database. Any identifiable or sensitive information would be removed.

This data will be used for research purposes to apply computational analysis to explore if the radiological images can be automatically diagnosed, or if lesions in the images can be automatically segmented. This could potentially lead to computer programmes that can reduce radiological reporting time for stroke and increase understanding of the brain and how it is affected by stroke.

The data will be collected at Ashford & St Peter's Hospitals NHS Foundation Trust. Data will be collected up to 10 years in the past and up to five years in the future.

A recommendation for class 1 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients admitted to Ashford & St Peter's Hospitals NHS Foundation Trust with known or suspected stroke from 01/01/2009 to 31/12/2018.
Data sources	10. Clinical data, radiology imaging and neuroimaging in patient records held at Ashford & St Peter's Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. Hospital Number 2. Gender 3. Date of scan 4. Age at time of scan
Identifiers required for analysis purposes	12. Gender 13. Age at time of scan
Additional information	The study will also include a prospective patient cohort seen by the Trust from 01/01/2019 to 31/12/2024; however, this sub-group will be collected by the direct care team and it out with the application for support.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members were assured that the application defined an important public interest, through the creation of a research database which will be utilised to attempt to develop computational diagnostic programmes for patients with suspected stroke or intracranial haemorrhage.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicant advised that informed consent could not be sought as 10-20,000 patients would be included in the database. The applicant was collecting data over the previous 10 year period and patients in this historic cohort may be lost to follow-up or deceased. The CAG was assured that consent was not feasible for the retrospective cohort.

- Use of anonymised/pseudonymised data

Access to confidential patient information was required to enable eligible patients to be identified and data to be collected for inclusion in the database.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicant explained that information was being drafted for inclusion on the Trust website. Members agreed that sight of this text was required prior to any final recommendation of support coming into effect.

The CAG also asked that the applicant consider wider ways of promoting the study to ensure this was accessible to patients who do not use the internet. It was suggested that outpatient posters or contact with patient associations may be helpful ways of progressing this. The applicant would be asked to describe wider communication mechanisms and provide copies of relevant documentation to support this for consideration.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicant explained that they had not involved patients or the public in the study to date. It was explained that there was a patient panel member present at the local R&D review. The CAG agreed that this was not an acceptable level activity when recognising the scope of patient records which would be accessed and included within the database.

Members agreed that the applicant would be asked to undertake specific patient and public involvement and engagement activity to explore the acceptability of using confidential patient information for the purposes set out in the application without consent. An overview of the activity carried out, together with the demographics of those present, would be required together with detail of the discussion held and feedback provided. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended or whether further action is required.

Database Access

The Group noted that a research database would be established as a result of the data extraction processes. It was noted within the application form that the applicant had sought generic approval from the Research Ethics Committee, so those applying to use the database would not be required to obtain an independent ethical opinion for their proposed research.

Members commented that the application did not provide clear information around how access to the database would be managed, the governance arrangements which were in place for this or what the established approval criteria was when assessing applications to access the database. It was commented that, as applicants to use the research database would not be expected to obtain an independent ethical opinion for their proposal, the review and approval process should involve patient or public representation.

The CAG agreed that further information was required in this area to understand the subsequent management of the database.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

Request for further information

1. Provide copies of the text which will be displayed on the Trust website to promote the project.

2. Consider wider communications mechanisms to promote the research database to patients and the public. Provide an overview of additional mechanisms established here, together with copies of any documentation to facilitate this.

3. Specific patient and public involvement and engagement activity should be carried out to explore the acceptability of using confidential patient information without consent for the study aims. An overview of the activity carried out, together with the demographics of those present, would be required together with detail of the discussion held and feedback provided.

4. Provide further information around the management, governance and data access approval processes for the database. Copies of any associated documentation should be provided for information purposes.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed: 05 July 2019**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Pending: Ashford & St Peter's Hospitals NHS Foundation Trust**

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON-RESEARCH

a. 19/CAG/0097 - 2019 NHS Adult Inpatient Survey

Context

Purpose of application

This non-research application from the Care Quality Commission set out the purpose of conducting the 2019 NHS Adult Inpatient Survey, using standardised methodology to build up a national picture of patient experiences. The outputs of this survey will be a set of aggregate statistical data that does not contain patient identifiable information.

This statistical dataset is used for a wide variety of purposes to support ongoing improvement in overall patient experience. The survey data will be used extensively by NHS trusts and Clinical Commissioning Groups (CCGs) in local improvement. The CQC will use data as part of its regulatory activities, as well as any other relevant functions. Individual level data for respondents will be shared with NHS England and the Department of Health and Social Care, containing sample file information. Individual level data for respondents and non-responders will be shared with NHS England to understand patients' experiences of NHS services and to drive improvements to them. The Department of Health and NHS England may use the results to generate aggregate indicators at local, regional and national level. These indicators form part of the range of Outcome Frameworks and other publications. The data will also be shared with the Health and Social Care Information Centre, or other organisations, working on behalf of Department of Health or NHS England for the purpose of generating these indicators. NHS Improvement will use the trust level results (scored data) to inform their oversight model for NHS Trusts.

The 2019 Inpatient survey will be the sixteenth carried out to date. All trusts will draw a sample of patients according to set criteria and follow standardised materials and procedures for all stages of the survey. The methods for the 2019 survey are unchanged from the 2018 survey. The methodology is well-established and has been supported by CAG in previous years.

When administering the survey, NHS trusts will be advised to employ the service of one of four approved contractors to reduce the cost, burden and risk in the provision of survey data. In doing so, it is expected that the risks to data quality and delay to the timetable are reduced dramatically, as evidenced throughout the application. Some NHS trusts may opt to undertake the mailing of questionnaires themselves, avoiding the need to employ an approved survey contractor.

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

<u>Confidential patient information requested</u>

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in

	July 2019 (and earlier for smaller trusts), having had one overnight stay in hospital. Exclusions: • deceased patients • children or young persons aged under 16 years at the time of sampling • obstetrics/maternity service users, including spontaneous miscarriages • patients admitted for planned termination of pregnancy • psychiatry patients • day cases • private patients (non-NHS) • any patients who are known to be current inpatients patients without a UK postal address • any patient known to have requested their details are not used for any purpose other than their clinical care, including those responding to posters displayed on hospital wards referring to the survey (the survey instructions request that all responses to posters are logged and used for this purpose).
Data sources	148 acute and specialist NHS trusts
Identifiers required for linkage purposes	The mailing data is used to address questionnaires to the appropriate person. It contains: • Trust code. • A standardised unique identifier code, to be constructed as survey identifier, trust code followed by a whole number (consecutive across the sample of 1,250 patients from each trust), • Title (Mr, Mrs, Ms, etc.) • First name • Surname • Address Fields • Postcode (where available)
Identifiers required for analysis purposes	The sample data file is used to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn. This file contains: • The unique identifier code (as above) • Admission/discharge dates • Length of stay (this is calculated from the admission and discharge dates).

	• Whether admission from Treatment Centre • Route of admission • NHS Site code on admission and discharge • Ethnicity • Gender • Year of birth • CCG Code: to enable analysis at this level by stakeholders for the production of relevant indicators • ICD-11 code

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The Sub-Committee agreed that the application had a clear public interest. The data collected provided important insights into patient experiences while in hospital and would be used by NHS England and the Department of Health and Social Care to inform changes in practice and service improvement.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicant explained that seeking consent for the study would not be practicable. Individual Trusts would need to arrange the mailout to patients, which would be potentially burdensome given the size of the cohort. It was further explained that due to the busy nature of hospitals and the volume of patients it could be viewed as an unrealistic burden on staff to seek prior consent for this survey. The Sub-Committee agreed with the explanation provided by the applicant and was assured that prior consent was not feasible for the project.

- Use of anonymised/pseudonymised data

The Sub-Committee accepted that the processing of confidential patient information was required so that the approved contractors could send the questionnaires out to relevant patients.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A poster was provided which would be utilised by participating sites to inform patients about the future survey. Trusts were asked to provide both telephone and e-mail contact details, if available, for patients to use if they had queries about the survey or wished to dissent from the use of their data for these purposes. The Group was satisfied with this process which was in line with previously supported applications within the NHS Patient Survey Programme.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicant explained that a number of patient representatives sat on the Inpatient Survey Advisory Group, which reviewed and fed into the development of the survey processes and the questionnaire itself.

The applicants had also conducted focus group discussions and face-to-face interviews with recent inpatients. Patients with a recent inpatient stay were asked to complete an "Importance Study" to rate topics in terms of their importance to patients using the service.

The applicant noted that the questionnaire used for the 2019 Inpatients survey was largely unchanged from the questionnaire used in 2018. As minimal changes had been made the applicant had run a sampling consultation with stakeholders, rather than the standard advisory group, around the questionnaire content. This included interviews with Trust survey leads and contractors, in order to review the sampling instructions and materials, and identify challenges from the 2018 cycle. The finalised survey was provided to the Group for review. Members acknowledged the minimal revisions which had been implemented since the previous iteration of the survey and were satisfied with the level of engagement for this submission.

Exit strategy

The mailing file, containing names and addresses, would be kept encrypted at all times and destroyed when the survey was complete. The original data drawn from Trust records may need to be reviewed if any anomalies or errors were identified at any stage throughout the course of the survey, up to the point by which the survey response data was checked and finalised. For this reason, the mailing files may be kept until the reporting stage of the survey is complete. This would be no longer than 12 months after initial collection, for all contractors.

In addition, contractors would be instructed to check that trusts have destroyed their copy of the mailing file before returning any respondent level survey data to them, to prevent the possibility of matched to mailing files and identify patients. The Sub-Committee was satisfied with the described retention period and resulting exit strategy from the requirement for support under the Regulations.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Secretary of State for Health and Social Care that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **DSPT required for:**

- **Picker Institute Europe – confirmed by NHS Digital email on 17 July 2019,**
- **Quality Health – confirmed by NHS Digital email on 24 July 2019,**
- **Patient Perspective – pending NHS Digital confirmation.**