Health Research Authority

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

November 2017

Present:

Name	Capacity	Items
Dr Tony Calland	Chair	1a, 1b, 2c
Mr Andrew Melville	Member	1a, 1b, 2c
Mr Anthony Kane	Member	1a, 1b, 2c
Dr Patrick Coyle	Chair	1c, 1e
Dr Lorna Fraser	Member	1c
Mrs Diana Robbins	Member	1c, 1d, 1e
Dr Harvey Marcovitch	Member	1e
Dr Malcolm Booth	Member	1d

Also in attendance:

Name	Position (or reason for attending)
Ms Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0187 The Street Triage Project v1

Context

Purpose of application

This research study from the University of Sheffield set out the purpose of exploring the experience of service users who have undergone 'Street Triage', and their understanding of its role, purpose and delivery. The research would include observations of practice in multi-disciplinary teams, and aimed to inform future practice in England and Wales.

Street Triage was a health and social care crisis intervention service, based on joint working between various agencies including the police, and designed to improve patient experiences during mental health crises.

The research aimed to build an evidence base for the effectiveness of the intervention and would seek the views of NHS patients as well as staff employed by NHS Trusts who were involved with the scheme and Police Officers who worked in collaboration with NHS staff on the scheme. The research was deemed important as this new model of care could be incorporated as part of the NHS 5-year Forward plan; joint working between the police and health and social care professionals was likely to become mandated by amendments to the Mental Health Act 1983 in the future.

Support was requested for two aspects of the study: recruitment, via a third party who would send out surveys to patients, and observations of staff working as part of Street Triage Schemes– the researcher would accompany staff on call-outs, and although they would not observe any interactions between patients and staff, there could be incidental disclosure of patient details during the period before and after the interaction.

A recommendation for class 3 and 6 support was requested to select and contact patients to seek their consent, and to allow an authorised user access for the above purpose.

Confidential patient information requested

Access was requested to:

1. Data from Sheffield triage Scheme in relation to patients who were subject to Sheffield Street Triage scheme over an 18-month period between 1st September 2016 and 1st March 2017 (estimated 1000)

   Name

   Date of birth

   Postcode

2. Incidental disclosures of patient details during observations undertaken by the researcher; no information relating to individual patients was to be recorded.

Confidentiality Advisory Group advice

Public interest

Members agreed that the study demonstrated a medical purpose. Although the police were involved, the objective was to evaluate and improve mental health services. This was deemed to be in the public interest, and members agreed that if its aims were achieved, the study would enable patient views to influence future policy and practice.

Scope of support

It was observed that Section 251 support was requested for two aspects of the activity: – firstly the identification of potential participants by the NHS Trust Information Manager and transfer of identifiable data to a third party mailing company for the mailing of questionnaires, and secondly, potential disclosure during observations of practice. Members agreed that both aspects required Section 251 support.

The research team stated that support was not required for any incidental disclosures during staff interviews. Members stressed that the research team must prevent discussion of individual cases during

these interviewed, and anticipated that the REC would also consider this issue during REC review of the application.

Practicable alternatives

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

- Feasibility of consent

The Sub-Committee considered the arguments for not seeking consent to be sound, particularly the problem of patients not knowing the name of the intervention they had received while in crisis. It was considered reasonable to contact patients directly to ensure that an adequate number were reached.

- Use of anonymised/pseudonymised data

It was noted that full contact details would be required, but deleted once questionnaires had been mailed out. No identifiable patient data would be recorded during observations of practice, and the focus would not be upon individual cases but on staff process.

Justification of identifiers

The Sub-Committee was satisfied with the proposed use of patient identifiers, but requested clarification with regards to the time frame. The suggested 18-month period appeared reasonable, however the dates listed (September 2016 to March 2017) were not consistent with this time period.

Clarification was required on this point before the recommendation of support could be confirmed.

Additional points

Public Involvement

Members commended the level of user involvement, noting that relevant groups and individuals had been consulted specifically about the issue of lack of consent. The work carried out was appropriate for the level of intrusion proposed.

Patient notifications and dissent

Members agreed that this issue had been satisfactorily addressed. In addition to respecting any existing dissent, notifications would be available on the Sheffield user network in relation to the potential use of data without consent, enabling any further dissent to the specific study to be registered. Each participant would be contacted and would have the purpose of the study explained; consent would be sought before proceeding further.

Additional risks

While expressing concern for the well-being of participants asked to re-confront a mental health episode, members acknowledged that this area would be addressed by the REC.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. The applicant was asked to clarify the time frame for processing of identifiable patient data, for which Section 251 support was required.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.
2. Confirmation of data protection registration (DP Registration number) for all organisations processing identifiable data.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.
   Required for: imail, SHSC NHS Trust, Rotheram, Doncaster and South Humber NHS Trust and Derbyshire Health and Social Care NHS Trust.

b) 17/CAG/0186 REACH Pregnancy Circles

Context

Purpose of application

This research study from the University of East London set out the purpose of completing a randomised controlled trial (RCT) of a model of group antenatal care called Pregnancy Circles offered to women living in deprived and ethnically mixed parts of London, Essex and Bedfordshire. The trial aimed to test the effectiveness of the group-based care. This RCT followed a pilot trial which tested feasibility of, and best methods for, the trial.

A Pregnancy Circle involved about 12 pregnant women, who lived close to each other and were due to give birth around the same time, having their antenatal care together in a community setting. The groups were facilitated by 2 midwives who combined clinical care with antenatal education and peer support. Care was organized in this way for the groups of women throughout their pregnancy and replaced standard antenatal care. There was good evidence from other settings that group antenatal care had a positive impact on women's experiences of antenatal services and may lead to better health outcomes. This study would test the effectiveness of this model of care by primarily looking at any increases in rates of vaginal birth for these groups.

Section 251 support was sought to enable researchers to assist clinical care staff with recruitment. The research team would identify suitable participants from referral records, and provide information by post before consent was requested at direct care appointments.

A recommendation for class 3 and 6 was requested to select and contact participants to seek their consent, and to allow access to an authorised user for the above purpose

Confidential patient information requested

Access was requested to data from the referral record of participating maternity services, in relation to women who were currently pregnant and registered for antenatal care with one of the included maternity services, who also lived within the working area covered by the Pregnancy Circle trained midwives, had an estimated delivery date that fits with a proposed pregnancy circle, and were over 16:

Name

Address

NHS Number

Estimated date of delivery

Confidentiality Advisory Group advice

Public interest

It was agreed that the application demonstrated a clear medical purpose and public interest in the aim of testing the effectiveness of group-based antenatal care.

Practicable alternatives

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

- Feasibility of consent

Members noted that the application was made in order to identify and contact participants to provide study information prior to seeking informed consent.

- Use of anonymised/pseudonymised data

Full contact details would be required in order to send information by post; however no data would be retained.

Justification of identifiers

Members agreed that access to the referral record was reasonable and justified for the purpose of sending study information to potential participants.

Additional points

Members noted that the application followed a pilot study, and was thorough and detailed. The issues of patient involvement, notification and dissent had been fully addressed, and potential risks to participants were sensitively addressed.

The level of attention to detail was particularly apparent in the variety of options offered to patients (they had the option to request that study information was sent by Trust staff only and to avoid researchers looking at their referral, or to opt out of receiving the information altogether).

No concerns were raised by members.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmation was not required for each individual site, however support was recommended on the understanding that the applicant would ensure that the appropriate security assurances were in place at each site.**

c) 17/CAG/0188 DIAMOND-Lewy

Context

Purpose of application

This research application from the University of Cambridge aimed to review the impact of the assessment toolkit on diagnosis of Lewy body dementia.

Section 251 support was sought for one aspect of an over-arching programme, funded by The National Institute for Health Research (NIHR), which focused on Lewy Body dementia (LBD) which includes two related disorders: Dementia with Lewy bodies (DLB) and Parkinson's Disease Dementia (PDD). The signs and symptoms of LBD were often difficult to detect and currently only about one in three cases were diagnosed; As a result many patients with LBD received sub optimal management.

The programme had two main aims:

(i) To improve the recognition and prompt diagnosis of LBD through the introduction of a simple assessment tool.

(ii) To improve patient management and outcomes through the development and introduction of an evidence based toolkit for clinicians.

Work completed to date comprised the establishment of the proportion of cases of LBD diagnosed prior to use of the assessment tool, and development of the assessment tool including a pilot of the tool in NHS settings. To evaluate the impact of the assessment tool the researcher wished to re-examine the current diagnosis pathways of LBD.

This would necessitate access to medical records by the research team, as there was no diagnostic code for LBD. The applicant would request a list of all patients seen by participating memory/dementia

assessment services and movement disorder services over an over an 18-month period, in order to screen their clinical notes and extract the required information.

A recommendation for class 1 and 6 support was requested for the purpose of extracting and anonymising the information and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to:

Data from clinical teams and support staff (IT and administrative staff) to the research team:

Name

Date of birth

NHS/Hospital number

Data extracted from clinical notes:

Date of birth

Date of death

Gender

Diagnosis

Date of diagnosis

Cognitive score at diagnosis

Last 4 digits of NHS number

The above data items would be used to identify which service the patient was seen in, and to remove duplicate referrals (please see response to queries on advice form)

Checking for duplicate referrals would occur at NHS Trust sites. The data would be de-identified (date of birth reduced to age, data of death to age at death) prior to transfer to Newcastle University for analysis.

Confidentiality Advisory Group advice

Public interest

Members were of the opinion that the study had a clear medical purpose and demonstrated a public interest in the aim of evaluating the impact of the assessment tool, designed as part of a broader programme of work to improve the diagnosis and treatment of Lewy body dementia.

Practicable alternatives

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

- Feasibility of consent

It was observed that the applicant had considered practicable alternatives. The Sub-Committee was convinced that consent would not be feasible, due to the need for complete ascertainment and the time which would be required for the clinical care team to seek consent.

It was also agreed that it would not be feasible for the direct care team to extract and anonymise information from the patient notes.

- Use of anonymised/pseudonymised data

Members were satisfied that the data extracted from the patient notes would be de-identified prior to transfer outside of the direct care team.

Justification of identifiers

Although satisfied that identifiers would not be removed from the NHS sites, members had reservations about the amount of time that identifiers would be stored and the methods of storage.

The application stated that data extraction would take 9 months. This being the case, it was queried why the request was to retain identifiable data for 18 months.

It appeared that data would be stored on multiple laptops within sites. Members queried why one secure computer could not be used at each site.

Additional points

Patient notification and opt out

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Although patient notifications would be provided on the study website and newsletter, members agreed that these should also be in place at all memory clinics attended by participants, to enable them to express dissent if they so wished.

Public involvement

The level of public involvement was deemed adequate for the study.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. The applicant was asked provide copies of patient notifications to be placed in memory clinics, and confirm that they will be displayed at the clinics.
2. The applicant was asked to justify the storage of data on laptops, when data was to be stored on the NHS site until anonymised data was removed. The recommendation of the Sub-Committee was that all data be stored on one secure computer at each site.
3. The applicant was asked to justify the retention of data for 18 months when data extraction would take 9 months (after which the application stated that all data would be anonymised).

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Pending.**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Northumberland, Tyne and Wear NHS Trust – v14, published but no reviewed grade in place

The applicant was asked to provide details of all sites where identifiable data will be processed (ensuring acronyms are expanded) and ensure that all IG Toolkits are in place and have been reviewed by NHS Digital as satisfactory.

d) 17/CAG/0189 Surveillance of Incidence of first time diagnosis of Early Onset Depression in children aged 3-13 years the United Kingdom and Republic of Ireland (EOD-UK & ROI)

Context

Purpose of application

This epidemiological study from Northumberland Tyne and Wear NHS Trust set out the purpose of determining the incidence of first diagnosis of Early Onset Depression (EOD) in children between the ages of 3 years, and before the 13th birthday in the UK and Republic of Ireland, as reported by consultants in child and adolescent psychiatry using the Child Adolescent Psychiatry Surveillance System (CAPSS) methodology. In addition, the results of the study would provide detailed descriptions of the presentation and clinical features of children with EOD and the current management strategies in place, referral pathways and duration between symptom onset and diagnosis. The condition of EOD had not previously been investigated, and was considered to be rare, however it led to a fourfold increase of suicide attempts compared to later onset depression, and it was therefore important to recognise and treat the condition.

The CAPSS methodology is based on the British Paediatric Surveillance Unit (BPSU) methodology and has been approved in principle by the CAG:

A recommendation for class 1 and 6 support was requested to cover the process of accessing and anonymising the information and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from all clinicians registered with CAPSS in relation to children exhibiting early onset depression between the ages of 3 and 13:

- NHS number, date of birth, gender, partial postcode and ethnicity to allow the removal of duplicate reports
- Partial postcode and gender retained for analysis to allow investigation of geographical and demographic influences

Confidentiality Advisory Group advice

Public interest

Members agreed that there was a medical purpose and public interest in the aim of determining the incidence of first diagnosis of Early Onset Depression (EOD) in children between the ages of 3 and 13 years.

The study would cover the whole of the UK and Northern Ireland, however the CAG remit related only to England and Wales.

Practicable alternatives

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

- Feasibility of consent

Members accepted that consent was not feasible for this study. Studies undertaken using the CAPSS methodology were concerned with rare conditions and as such were reliant upon full ascertainment to ensure their validity and usefulness. This study looking at depression in younger children met this criterion.

- Use of anonymised/pseudonymised data

The data returned from clinician to researcher included date of birth to enable the removal of duplicate records. Members queried the inclusion of this identifier in the data returned. It was agreed that date of birth should be truncated to age at the earliest point.

Justification of identifiers

Members were content with the retention of gender and ethnicity for analysis, but did not consider the retention of date of birth to be justified. It was agreed that further explanation was required on this aspect of the study.

Additional points

Patient notification and opt out

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Although patient information sheets were provided, they did not contain any information on how to opt out of the study (or how parents could opt out on behalf of their child). Members agreed that this should be addressed.

The information sheets should also be placed in CAMHS clinics and not only online.

Public involvement

Public involvement was described; however it did not appear that opinions had been sought specifically in relation to the use of data. Members requested further information from relevant groups in relation to this aspect, or confirmation that this issue had been addressed in discussions with PPI groups.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. The applicant was asked to provide copies of the updated participant information sheets as requested under the Patient Notification' heading above, and confirm whether these can be placed in CAMHS clinics.
2. The applicant was asked to provide further evidence of PPI work that has been done, or will be carried out in the future, to gauge the opinions of patients in relation to this use of identifiable data without consent.

Specific conditions of support

1. Please note that support from CAG only extends to England and Wales

2. Favourable opinion from a Research Ethics Committee. **Confirmed.**

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Not requested for each site; support was based on the assumption that the applicant will ensure that satisfactory security assurances are in place for each site.**

e) 17/CAG/0191 DETERMINE-PD

Context

Purpose of application

This application from Newcastle University set out the purpose of running a pilot study to discover the level of incidence of delirium in Parkinson's, how well the methods used to collect the data have worked and whether they could be used in a larger study.

Delirium had not been previously studied in Parkinson's. Delirium has overlapping features with Parkinson's, such as confusion, hallucinations and sleep disturbances. This made it difficult to diagnose; thus delirium in Parkinson's may be more common than previously thought. It could cause permanent damage to the brain, making people more likely to develop dementia in the future, or worse for those who already have dementia. It was important that delirium was recognised quickly as it was treatable and early identification could lead to better outcomes.

The pilot study would be run at hospitals in Newcastle upon Tyne. Patients with Parkinson's would be invited to take part if they were admitted to hospital.

Section 251 was required to enable recruitment to the study: in the first instance the research team would send out an introductory letter to all patients at the Trust who were currently treated for Parkinson's. The letter would give a brief summary of the study and advise that if the patient was admitted to hospital they would be approached about the study – this would provide the opportunity to opt out of the approach. Secondly, researchers would be notified if any of the patients were admitted to hospital through an electronic alert; a system already in use by the hospitals (Recurring Admission Patient Alerts or RAPA).

They would then visit the patient in hospital in order to seek their consent for the study, providing no dissent had been expressed.

A recommendation for class 3 and 6 support is requested to select and contact patients to seek their consent and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from Newcastle upon Tyne NHS Trust in relation to patients attending clinics for Parkinson's:

- Name and address for sending information to each patient.
- RAPA alert advising the researcher of the name and ward of a Parkinson's patient admitted to hospital, enabling them to identify and visit the patient to seek consent

Confidentiality Advisory Group advice

Public interest

Members agreed that the application demonstrated an important medical purpose and public interest in its aim of increasing recognition of delirium in patients with Parkinsons disease, which would ultimately improve outcomes for these patients.

- Practicable alternatives

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

- Feasibility of consent

Members noted that the consent approach had been discussed with patients and carers of people with Parkinsons. Including consent slips for patients to consent to the approach by the researcher in the information sent to patient's address was considered, however it was determined that this would bias the study – the response rate was likely to be low and unlikely to include those lacking capacity. Members accepted this rationale.

- Use of anonymised/pseudonymised data

It was evident that the full contact details would be needed in order to contact patients prior to the recruitment approach, and to identify the correct patient in order to approach them.

Justification of identifiers

Members accepted that the identifiers were needed for the specified purpose, which met the public interest threshold.

Additional points

Patient notification and opt out

Support was requested in order to notify patients of the study and enable them to opt out of being approached for consent while in hospital. Although content to approve this approach, members observed that the language was formal in places ('we are writing to inform you'), and that confusion could arise from the two statements 'you do not have to do anything now' and the instructions that dissent must be expressed within 7 days.

It was also agreed that the phrase 'with your permission' should be removed from the following sentence: 'With your permission, if you are admitted to hospital in the next four months, a member of the DETERMINE-PD study team will see you in hospital and talk to you more about the study,' as this sentence gave the impression that the letter was asking for consent rather than giving the opportunity to opt out.

Public involvement

Members noted that sensitivity of the proposed approach to people with Parkinson's in hospital had been thought through carefully, with the collaboration of a PPI group of Parkinson's sufferers. Members raised no concerns in relation to the level of public involvement for this pilot study.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional

support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. The applicant was asked to provide updated patient notifications, once the phrase 'with your permission' had been removed.
2. Members recommended that the time limit for expressing dissent be removed or the phrase 'you do not have to do anything now' be removed in order to avoid confusion. The applicant was advised that this was a recommendation only and final support was not conditional on this point.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Newcastle upon Tyne Hospitals NHS Trust, v14 confirmed published and reviewed**

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 17/CAG/0185 2018 Community Mental Health Survey

Context

Purpose of application

This non-research application from Picker, CQC and NHS England set out the purpose of administering the 2018 Community Mental Health Survey, to gauge patient experience and views of the service they received. A recommendation of support was requested to enable the transfer of patient identifiable data from mental health providers, to an approved survey contractor for the purpose of mailing out questionnaires. The vast majority of trusts involved were expected to opt to use an approved survey contractor, either: Picker, Quality Health, Patient Perspective, CAPITA Surveys & Research or Membership Engagement Services.

The end product from the survey would be a set of aggregate statistical data that did not contain patient identifiable information. This statistical dataset was used for a wide variety of purposes to support ongoing improvement in overall patient experience by NHS Trusts and CCGs and by CQC, to inform its regulatory functions.

NHS Patient Survey Programme

This survey was part of the NHS Patient Survey Programme, and as such followed the same methodology as other surveys within the programme. The methodology was approved in principle by the CAG, and applications usually considered via the Precedent Set pathway.

New approaches were often piloted within the NHS Patient Survey Programme. The 2017 Adult Inpatient Survey (which is referred to throughout the application) trialled the use of text message reminders to

complete the survey, and was escalated to full CAG meeting as there was no precedent for the use of text messages. Support was given at the meeting for this approach.

Breaches reported for the 2017 Adult Inpatient Survey were considered, as the same methodology and applicant were involved; any changes made to NHS Patient Survey Programme methodology as a result of breaches were considered relevant to this application despite the fact that the breaches occurred in a different survey.

For the current application (Community Mental Health Survey 2018), the following interventions would be added as part of a pilot:

Pilot Study

A shorter questionnaire

An online survey – link to be sent to patients in a text mesage

SMS (text message) reminders

No CQC Flyer

The aim was to increase response rates overall and from lesser heard groups

A recommendation for class 3 and 6 was requested in order to select and contact participants to seek their consent, and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from mental health providers in relation to people aged 18 and over who had been in contact with NHS mental health services in the three month period, 1 September to 30 November 2017, and who were receiving specialist care or treatment for a mental health condition, including those who received care under the Care Programme Approach (CPA).

The mailing file was used to address questionnaires to the appropriate person, and is sent to the Approved Contractor. It contained:

- Trustcode
- A standardised unique identifier code, to be constructed as survey identifier, trust code followed by a whole number (consecutive across the sample of 850 service users from each trust), e.g. MH18XXXnnnnn where XXX is the trusts 3 digit trust code and nnnnn is the 5 digit serial number relating to sampled service users
- Title (Mr, Mrs, Ms, etc.)
- First name
- Surname
- Address Fields
- Postcode

The sample data file was 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 and was sent to the Coordination Centre. This file contained:

- Trustcode
- The unique identifier code (as above)

- Year of birth
- Gender
- Ethnic category
- Day of last contact
- Month of last contact
- Year of last contact
- CPA status
- CCG code
  Mental Health Care Cluster Codes

The inclusion of mental health care cluster codes in the sample file was a deviation from the previous method, which had been to send this information to the coordination centre separately. This would simplify the process for trusts and avoid errors (previous errors included a Trust sending the care cluster code along with patient identifiers, and mismatching the care cluster code with the patient record, due to having separated it from the sample file).

There was precedent for a similar approach to be supported by the CAG in the Adult Inpatient Survey, where ICD-10 codes were included with the sample file.

Pilot study

As part of the pilot work, pilot trusts would also be asked to include the following:

- Indicator to show whether service users have a mobile phone number or not (main / control sample);
- Mobile phone number (for the pilot sample only)

Confidentiality Advisory Group advice

Public interest

The Sub-Committee agreed that there was an obvious medical purpose inherent in the application, and that a public interest was demonstrated in the stated purpose of seeking patient experience and views of the service they received, particularly if this eventually influenced policy and practice.

Pilot study

Members noted that innovations and updates to the survey methodology had been implemented over time, and that the use of text message reminders had been previously supported by the CAG. Members raised no concerns about the current pilot study which would include a shorter questionnaire, text message reminders and SMS links to the survey. No additional identifiers would be transferred to the Coordination Centre as a result of the change.

Practicable alternatives

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

- Feasibility of consent

Members accepted that obtaining consent would not be practicable, and could bias the outcomes, particularly from this type of survey.

- Use of anonymised/pseudonymised data

It was observed that the process of administering the surveys was well-established and efficient, from identifying those to whom questionnaires were sent to the receipt, linkage, analysis and validation of the data. Pseudonymised data was used where appropriate and data was anonymised at the earliest possible point.

The addition of Mental Health cluster codes to the pseudonymised data sent to the Coordination centre and used for validation of the data was noted and no concerns were raised in relation to the change.

Justification of identifiers

Members accepted that identifiers were required in order to send out surveys.

It was agreed that there were no other practicable alternatives.

Additional points

Public involvement

Members commented that user involvement was not extensive – however, there was evidence that patient views and suggestions had been taken account of, not least in the development of the pilot study. This was deemed adequate and overall, no concerns were raised.

Patient notification and dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Instructions to individual trusts contained a 'recommendation' to display a poster with contact details to enable patients to opt out. Members were of the opinion that this should be more strongly worded in order to comply with the CAG principle of support. Rather than 'recommended', the instructions should state that this was a 'request' or an 'expectation'. Although not all patients would see the poster, this was not an adequate reason for failing to display the poster, and the profile of the survey could be raised via trust newsletters and websites.

The Sub-Committee stressed that these actions were important in order to retain public trust in the use of patient data without consent.

Breaches

Breaches reported over the previous year for the NHS Patient Survey programme were considered as part of the application, whether or not they originated from the Mental Health Survey, as the methodology and applicant were the same.

There had been several breaches, many resulting from a failure by individual trusts to follow the instructions provided. The applicant had, as a result, simplified the manuals and supporting documentation with clearer explanations of Section 251 support and the importance of following the process.

The Sub-Committee was therefore satisfied that steps had been taken to reduce the risk of error.

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. The applicant was asked to ensure that instructions to individual trusts went beyond 'recommending' that they display patient notifications, making clear that they were requested to ensure patients were aware of the survey and could opt out if they so wish. The applicant was asked to report back on this at annual review stage, including numbers of patients who have opted out.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.