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

21 October 2022

Present:

Name	Role	Items
Ms Clare Sanderson	CAG Alternate-Vice Chair	2a, 2b, 3a
Dr Malcolm Booth	CAG Member	2b
Mr Anthony Kane	CAG Member	2a, 3a
Mr Andrew Melville	CAG Member	2b, 3a
Mr Umar Sabat	CAG Member	2a

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. Expressions of interest

No expressions of interest were declared.

2.New Precedent Set Review Applications – Research

a. 22/CAG/0145 - Safety and Efficacy of Managing Acute Heart Failure without Hospital Admission (SAFE v6.0)

Context

Purpose of application

This application from Blackpool Teaching Hospitals NHS Foundation Trust (BTH) set out the purpose of medical research which aims to better understand short term outcomes, 60 days post treatment with intravenous furosemide in patients with heart failure (HF), in order to support feasibility of recruitment into a future multicentre randomised controlled trial (RCT) into the effectiveness and safety of out-patient based services for the management of Acute Heart Failure (AHF).

100,000 patients are admitted to hospital for AHF each year in the UK. HF is a progressive syndrome associated with substantial morbidity and mortality, and is the most common cause of hospitalisation for individuals aged 65 years and older in UK. AHF is usually managed in hospital, and is associated with 7-11% mortality rate. The NHS Long Term Plan recommended better, personalised planning for patients with the hope to reduce nights spent in hospital and reduce drug spend. Accelerated by the COVID pandemic, some hospitals are now developing out-patient based services for the management of AHF. Out-patient management (OPM) of AHF has gained popularity in the UK, however, the effectiveness and safety of this strategy is uncertain. There are no substantial randomised trials in order to inform clinicians, patients or clinical practice guidelines. A substantial multi-centre RCT to determine safety and cost-effectiveness is therefore needed to obtain robust evidence to justify more widespread investment in out-patient based treatment of AHF, and this application is testing the feasibility of a future RCT.

Eligible patients are retrospectively identified at participating sites by the direct care team from existing clinical databases. Data will be collected via excel spreadsheet. Names, postcodes, hospital/NHS numbers will be removed, but pertinent dates (of admission, discharge and death) remain. These dates mean that the data is not fully anonymised at this point, and therefore ‘s251’ support is required for this transfer of confidential patient information to the applicant. Once at BTH, the Trust statistician will fully anonymise the data after using the dates to calculate the required period of risk – “days alive and out of hospital within 60 days” measure – before analysis. Full dates will then be deleted.

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	all consecutive patients who have had acute/decompensated/worsening heart failure with a requirement for IV diuretics at participating sites (including inpatient stays and outpatient clinic visits) for the period 01 August 2019 to 31 January 2021. ~3000 (however possibly more, and exact number not yet known)
Data sources	1. Participating Trusts existing clinical databases; a. Buckinghamshire Healthcare NHS Trust b. Liverpool University Hospitals NHS Trust c. Manchester University hospitals NHS Foundation Trust d. North Tees & Hartlepool NHS Foundation Trust e. Croydon Health Services NHS Trust f. Lancashire Teaching Hospitals NHS Trust g. Oxfordshire University Hospitals NHS Foundation trust h. Dudley Group NHS Foundation Trust
Identifiers required to be disclosed from participating Trusts	1. Date of admission 2. Date of discharge 3. Date of death
Identifiers required for analysis purposes	1. N/A - Analysis will be undertaken on an anonymised dataset
Additional information	A second readmission from the same patient is classed as a new episode if the admission is more than 60 days from the previous episode, else it is classed as a readmission within 60 days.

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 CAG noted that this research application is a feasibility study for a much larger study which may take place depending on this study's results. The members were agreed that it has a clear medical purpose and is in the 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 applicant reasoned that as this is a retrospective cohort of 3000 patients, some of whom have passed away, that it is not practicable to seek consent. It would also be more disclosive to do so, as name and address would be used to do this. The CAG accepted that consent is not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Full dates are required to allow the uniform calculation of the number of days alive and out of hospital as required for a key endpoint of this study. As this calculation is quite complex, this would not be performed reliably at all participating sites, and will be done centrally by the statistician, and therefore full date of death is required. The data is anonymised at the earliest opportunity. The CAG accepted this justification.

'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 object 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.

There is currently no notification mechanism, or study specific opt out available. The applicant has misunderstood a CAT query regarding notification and answered as if a letter is expected to be sent to every patient; '*We do always consider the right of the patient, but for the size of cohort and the nature of the cohort (patients with a life-limiting condition from almost 3 years ago, many of whom will have died) feel the amount of work required to contact them is disproportionate to the amount of identifiable data requested. Furthermore it can be distressing to patients and their relatives to be contacted for this purpose'*

The National data opt out (NDO) will apply, as confirmed in query responses.

The CAG agreed that patient notification in this case would be practicable and is required. Whilst these patients have already attended the hospital retrospectively, and some will be deceased, the understanding of the Members is that HF is an ongoing condition, that may be managed in hospital, and therefore it is likely that some of these patients will still be attending the hospital, and may see a poster in clinical areas. Based on the comments and queries from the applicant, the CAG would like to clarify that they do not expect or require the applicant to develop a notification to be sent to every patient. The Sub-Committee merely expect a patient notification to be developed and placed somewhere where it is possible that some of the eligible cohort might see it, and have the opportunity to opt out if they wish. The CAG therefore suggest that posters in the relevant outpatient clinics or hospital wards and details on hospital websites should suffice, these should describe the study, explain the legal basis under common law for processing identifiable information, and give a chance for patients to opt out if they wish.

As the National Data Opt Out will apply, the Members require confirmation that it will be made clear to participating Trusts that the NDO should be applied before they submit their data to the applicant.

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 has stated that the Heart Failure Patient and Public Involvement (PPI) group from the Lancashire cardiac centre are supportive of the study methodology. CAT queried the applicant for further information, and the applicant has elaborated to say that the Lancashire Cardiac Centre Patient and Public Involvement (PPI) group consists of patients, their carers and members of the public, diverse in terms of age, gender and ethnicity. They consist of heart failure patients, other cardiology patients, and healthy volunteers. The applicant has stated that they try to maximise participation by allowing them to join face-to-face, online or by telephone and attendance can be up to 7 people, however this is not clear if this section related to the specific project or is a general statement. The applicant states that this programme of work has been discussed with the Patient and Public Involvement (PPI) group and they specifically influenced the design of the study, its outcome measures and the size of difference that would be meaningful.'

The Members were broadly content with this response, but felt that this response was still quite general, and was not explanatory in terms of actually how many people have been consulted at what specific events, and no patient comments have been provided. The group of individuals who are part of the Lancashire Cardiac Centre Patient and Public Involvement (PPI) group do seem to be diverse, and they do seem to be representative of the cohort. The Sub-Committee therefore request further details on exactly how the PPI group was involved, and in particular how the 'design' was supported by the group, as CAG require evidence specifically that the use of confidential patient information without consent is supported by patients and the public.

The CAG would also like to make the point that if any larger study is to be commissioned, more significant Patient and Public Involvement would be required.

Exit strategy

The exit strategy is proposed to be anonymisation. Once the data is received at BTH, calculations will be performed prior to deleting the full dates. This is estimated to be 6-12 months in CAG form. The CAG were content with the proposed exit strategy, however the Members wished to confirm that the original spreadsheets containing dates received in full format from Trusts would be deleted at this time point, to ensure the exit strategy from 's251' support.

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.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please develop a notification poster for clinical areas of participating Trusts, that could also be displayed on trust websites, as per the advice in this letter.

2. Please provide confirmation that it will be made clear to participating Trusts that the NDO should be applied before they submit their data to the applicant.

3. Please provide further details on exactly how the Patient and Public Involvement group was involved, and in particular how the 'design' was supported by the group.

4. Please confirm that the original spreadsheets containing dates received in full format from Trusts will be deleted after calculations have been undertaken by the BTH statistician.

5. Please provide Favourable opinion from a Research Ethics Committee, as per standard condition of support below.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

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. **Pending**

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. **Confirmed:**

   The NHS Digital **21/22** DSPT review for **Blackpool Teaching Hospitals NHS Foundation Trust** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 03 November 2022)

   Due to the number of participating organisations involved it is the responsibility of Blackpool Teaching Hospitals NHS Foundation Trust, as controller, to ensure that participating Trusts meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

b. 22/CAG/0147 - A Randomised Phase III Trial to Determine the Role of FDG-PET Imaging in Clinical Stages IA/IIA Hodgkin's Disease (FDG-PET Study): RAPID

Context

Purpose of application

This application from The Christie NHS Foundation Trust set out the purpose of medical research which aims to compare the late consequences, especially vital status, second cancers, and cardiovascular disease, of the different treatments used in the RAPID trial with a view to informing future patients and guiding national/international treatment policy.

The RAPID trial is a consented Randomised Controlled Trial (RCT) which compared standard treatment for limited stage Hodgkin lymphoma (chemotherapy + radiotherapy) with a new approach (chemotherapy alone) guided by PET scanning. Trial results published in 2015 showed a good outcome for chemotherapy alone, however long term follow up, annually until 25 years after the first patient was registered to the trial (until 2028) is required, as it may take years for any long term outcomes to be detected.

Follow up was consented and planned to be undertaken via participating hospitals. However the applicant has found that as patients are now mostly discharged from conventional care, they have been lost to conventional follow-up, and are requesting 's251' support for a new method of collecting follow up data which will be via NHS Digital's DigiTrials service.

Understanding the late consequences of chemotherapy and radiotherapy is of great importance when considering treatment options for patients and clinicians, and for policy makers. 's251' support is requested to enable UCL cancer trials centre to disclose RAPID ID, NHS number and date of birth to The Christie NHS Foundation Trust. The Christie NHS Foundation Trust with then disclose this list onwards to NHS Digital (via the NHS DigiTrials service) for linkage with HES, NCRAS, and to NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) & Redcentric (Harrogate) for linkage with the NICOR database. 's251' support is also required for the flow of data back to the applicant, at The Christie NHS Foundation Trust, as the dataset contains full date of death, and additionally the applicant retains identifiers and can re-identify the patients. The dataset will then be disclosed to UCL cancer centre for analysis, and returned to the Christie post analysis.

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 who participated in the RAPID FDG-PET study 88.9% of the rapid cohort are English and Welsh patients, and therefore relevant to this CAG application - This is 535 patients.
Data sources	2. RAPID trial database retained at the UCL Cancer trials centre 3. NHS Digital – a. HES b. NCRAS 4. NICOR database - (NHSE/I controllers, but processors are NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) & Redcentric (Harrogate)

Identifiers required for linkage purposes	4. NHS number 5. Date of birth 6. RAPID participant ID
Identifiers required for analysis purposes	2. Date of death
Additional information	Data linkage extracts will be provided by NHS Digital and NICOR twice. Once in 2022/2023 and again in 2028.

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 Members were agreed that the application has a clear medical purpose and is in the 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.

- **Minimising flows of identifiable information**

This point is also relevant to the scope of the application. The CAG queried why the design was a two-step process, and stated that the data flows should be changed, unless NHS Digital will not accept that design. The Members commented that data flowing through the Christie seems unnecessary and should go directly from and to UCL. The applicant is to clarify if this is possible.

- **Feasibility of consent**

The applicant reasons that it is not practicable to re-consent this consented patient group, who were recruited 2003-2010, as many will have died, and are no longer attending hospital for conventional follow up. The patients did consent initially to follow up until 2028, but as NHS Digital did not exist at the time of consent, these national datasets/central linkages were not specified. The CAG agreed that consent did not seem practicable.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage, and full date of death is required for analysis. The members agreed that the use of anonymised information was not a practicable alternative.

'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 object 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 initial application was submitted with no patient notification. CAT Requested a patient notification regarding the central follow up undertaken as part of this CAG application, potentially to be displayed on website, however the applicant responded with a letter, that appeared as if it will be sent to all individuals in the trial. 's251' support is not mentioned, and there is no opt out option on the notification, and therefore there is no study specific opt out available for this processing. The applicant has confirmed as part of further queries, that this would be displayed on a study website.

The National Data opt out (NDO) will be applied by NHS Digital.

The CAG were confused as to why this notification had been provided in a letter format, which was then confirmed to be displayed on the trial website, as this would not seem to be the correct format to be displayed on a website, and in addition the applicant has confirmed that consent was not practicable, which if planning to write to all participants, would surely be a practicable option. The applicant is to re-write the notification to be

the correct format to be placed on the study website. This notification should describe the approach to the linkage with NHS Digital and NICOR and the fact that 's251' has been provided for this processing, and the notification should include the right for patients to opt out from the follow up now it is being done in this way via NHS Digital/NICOR.

The notification should at least be on the trial website, and those of the contributing hospitals if this is possible.

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 Chief investigator has had a meeting with Lymphoma action, and informed CAG that there are around 10-15 patients in the Lymphoma Action UK Lymphoma Patient Group (2022). The Applicant states that the group gave support for this use of confidential patient information without specific consent. The members agreed that although the Patient and Public Involvement is not extensive, it is sufficient to support, noting that these patients were consented initially to the trial with the knowledge that they would be followed up, albeit in a different manner to this CAG application.

Exit strategy

Longer term follow-up will continue beyond 60 months on an annual basis from Trusts if possible, which will continue until 25 years after the first patient was registered to the trial (therefore until 2028). For the CAG application purposes, the final extract of linked data will be received in 2028. 's251' support is required until 2029, as the applicant stated date of death will be deleted following final data analysis in 2029. The CAG were content with this exit strategy.

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.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please clarify if the data can flow directly from and to UCL, instead of being required to flow though the Christie, to minimise the flows of confidential patient information. A new data flow diagram should be provided alongside this confirmation.

2. Please update the patient notification document to be suitable for display on the study website, to include the data flows, the use of 's251', and an opt out option. Please confirm where this will be displayed.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

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 via Substantial Amendment 9 on 29 April 2022**

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. **Confirmed:**

   The NHS Digital **21/22** DSPT reviews for **The Christie NHS Foundation Trust, University College London – School of Life and Medical Sciences, NHS Digital,** & on behalf of NICOR**; NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) and Redcentric (Harrogate)** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 03 November 2022)

3.New Precedent Set Review Applications – Non-Research

a. 22/CAG/0152 - 2022 NHS Adult Inpatient Main Stage Survey – Mixed Methods

Context

Purpose of application

This non-research application submitted by Ipsos MORI on behalf of the Care Quality Commission, sets out the purpose of conducting the 2022 NHS Adult Inpatient Survey. The Adult Inpatient Survey started in 2002 and falls within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England. The 2022 Adult Inpatient survey will be the twentieth carried out to date, and the third mainstage to be completed using a mixed method approach.

All eligible trusts (134) will be asked to conduct the survey, with preparations expected to begin in the autumn of 2022 and fieldwork expected to start from January 2023. Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (IPSOS MORI) and one of three approved contractors (Patient Perspective, Quality Health or Picker Institute Europe). The contractors will distribute questionnaires to patients using the approach detailed below:

	Mode of contact
Contact 1	Postal letter inviting the patient to take part online (and a paper questionnaire included for those over 80 years old)
Contact 1.1	Three days later an SMS reminder will be sent, including a direct link to the online survey
Contact 2	In week 2, a reminder letter will be sent to non-responders

Contact 2.2	Three days later an SMS reminder will be sent, including a direct link to the online survey
Contact 3	Final, postal reminder sent, along with a paper questionnaire

Ahead of each reminder mailing, it will be necessary to remove all respondents who have completed the survey already, and to conduct a DBS or local check on the full sample. If anyone has requested to be opted out of further reminders, they should also be removed at these timepoints.

A recommendation for class 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	Inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in November (and earlier for smaller trusts), having had at least one overnight stay in hospital. A list of reasons for exclusion, such as deceased patients and those under 16 years of age at the time of sampling, was included in the application.
Data sources	1. Electronic patient records with acute and specialist trusts in England (134).
Identifiers required for contact purposes	1. Name 2. Address fields including postcode 3. Mobile phone number 4. Patient unique identifier

Identifiers required for analysis purposes	1. Unique identifier (a three digit Trust code and 4 digital serial number related to sampled patient) 2. Postcode 3. Trust code 4. Year of birth 5. Gender 6. Ethnic category 7. Date of admission 8. Date of discharge 9. Length of Stay 10. Treatment Function Code 11. ICD-10 Chapter Code 12. Treatment Centre Admission 13. Admission method 14. NHS Site code-Admitted 15. NHS Site code-Discharged 16. 'Decided to admit' date
Additional information	Trusts may also choose to collect additional sample variables outside of those detailed in the Survey Handbook. This can be valuable to trusts in enabling them to make greater use of their survey locally to target quality improvements. *Sample and mailing data will be submitted by trusts to approved contractors in a single file. The file which contains both mailing and sample information will be split into separate files by the contractor before submitting only the sample information to the Coordination Centre for checking and approval.* Please note that the Survey Coordination Centre does **not** receive any names or full addresses

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 Members agreed the public interest in this activity is clear.

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**

There are three central arguments as to why consent is not practicable, and which have been accepted across the National Survey Programme:

  - Trusts will not benefit from the expertise of a specialist survey contractor,
  - Potential to introduce bias into the survey findings,
  - Potential burden on clinical staff through the requirement to take consent.

The Members agreed with the justification provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to facilitate the invitation process which could not be otherwise achieved. For analysis, postcode is deleted after mapping to LSOA and local authority, as per previous surveys. The CAG agreed that It is not practicable to undertake these activities without confidential patient information

'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 object 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.

As per previous surveys, posters will be displayed in participating Trusts throughout the sampling period to inform patients that they may be approached to participate in the survey and provide a means for prior dissent to be raised. These have been produced in English and translated into 11 other languages to improve accessibility. Although the provision of posters is the primary method of informing the study population of the survey, Trusts will also be informed that they can undertake their own additional promotional activities, where considered appropriate, for example through press releases and local social media.

The poster provides information about how a patient can opt out of the survey. Trusts are also asked to remove any records where existing dissent has been recorded. Contractors and those trusts that administer the survey themselves, will provide a freephone telephone line, email address and postal address on survey materials and posters (which must be displayed in trusts throughout the sampling period) for people to call for advice, assistance or to opt-out of future mailings.

Applicants have considered the feasibility of including an opt-out mechanism within the SMS reminders but have ruled it out for reasons detailed in the application form. CAG accepted the reasons for not using an SMS opt out mechanism for previous surveys, and the same reasoning applies to this application. There is a helpline number included in the SMS which applicants can call to opt-out if required.

The surveys have exemption from the national data opt out – see here.

As part of a previous application, 21/CAG/0147, the CAG '*advised that the applicants work directly with the participating Trusts to promote the use of all available, innovative ways of notifying the public',* and a condition was applied; '*More work should be done with participating Trusts to encourage effective notification, and an account of this should be fed back at Annual Review.*'

The applicant's response on this issue to CAT states: '*We are encouraging trusts to share information about the survey on social media and their websites to allow more people to see that the survey is happening (and therefore opt out if needed). Unfortunately, due the nature of the survey, further notification or targeted notification of those sampled would be impractical.'*

The Members felt that although the applicant has stated that Trusts are encouraged to share information on social media and their websites, the instructions to Trusts on how to publicise the survey do not mention this aspect, although it appears this issue is addressed in webinars for Trusts. The Members mentioned that it would be helpful to know if this actually takes place at Trust level. The Members were agreed that moving beyond just posters is better practice, and again encourage the applicant to investigate developing broader notification methods, and request that the applicant advise CAG on

whether this has been incorporated within the publicity instruction documentation provided to Trusts, and if not, why not.

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 application form provides a detailed overview of the patient and public involvement in the development of this survey. In addition to the usual work undertaken, the applicant has undertaken some discussions with patients specifically around the use of confidential patient information without consent, as a response to a condition applied to previous survey 21/CAG/0147; '*Patient and public involvement around the specific issue of processing of confidential patient information without consent needs to be conducted and fed-back to the CAG at the first annual review.'*

In August 2022, 15 scoping interviews were conducted with patients to obtain feedback the following areas:

- Use of patients' personal information to invite them to participate
- Contacting patients via SMS/text to participate as well as to remind participants to complete the questionnaire
- Recontacting participants via SMS/text to participate in future research.
- Patients' personal information being linked, confidentially, to their questionnaire responses
- Their experience and journey during their stay at hospital

The results found:

- Patients were happy to be contacted to take part in NHS Patient Survey Programme without having given their express permission. They found the current contact methods of either paper invites of SMS invites acceptable and did not cause any concern.
- Patients were open to the idea of being asked to participate in follow up research and their contact details being passed to CQC. They were also open to being asked about linking their survey responses to their contact details, to allow CQC to follow up on particular experiences.

Ahead of the 2022 Adult Inpatient Survey, three rounds of cognitive testing will be undertaken with patients to ensure that any revisions to the questionnaire continue to reflect their experiences and are also easy to read and understand. The questionnaire will be updated based on the feedback between each round of testing.

The members were content that the condition from 21/CAG/0147 has been addressed as part of this application, as further patient and public involvement has taken place during the last year as requested, including about the use of confidential patient information without consent, and that this was sufficient to recommend support for this application.

Exit strategy

Identifiable information (used to send out the survey) will be destroyed within 12 months from the receipt of the sample files. Post code will be deleted after mapping to LSOA and local authority, no later than 4 weeks from the respondent level dataset being signed off. The Sub-Committee were content with the proposed exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. The applicant is encouraged to develop further patient notification methods, and report back on doing so within 6 months from the date of this letter.

2. Please advise CAG if instructions '*to share information about the survey on social media and Trust websites'* has been incorporated into the publicity instruction documentation provided to Trusts, and if not, why not, within one month from the date of this letter.

3. 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. **Confirmed:**

   The NHS Digital **21/22** DSPT reviews for **Ipsos MORI, Patient Perspective, Quality Health Limited, and Picker Institute Europe** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 03 November 2022)

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Ms Clare Sanderson, CAG Alternate Vice-Chair		*28 November 2022*
Signed – Confidentiality Advice Team		Date
Caroline Watchurst, HRA Confidentiality Advisor		*22 November 2022*