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

08 July 2022

Present:

Name	Capacity	Items
Ms. Clare Sanderson	CAG Alternate Vice Chair	1a, 2a
Dr Martin Andrew	CAG Member	1a, 2a
Dr Malcolm Booth	CAG Member	2a
Mr David Evans	CAG Member	1a

Also in attendance:

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

Conflicts of interest - Mr David Evans, CAG member declared a conflict of interest with item 2a, as he is employed by NHS England and NHS Improvement. He did not participate in the development of the recommendation provided by the CAG.

1. New Precedent Set Review Applications – Research

a. 22/CAG/0102 – Exploring use and implementation of rehabilitation prescriptions for individuals admitted to UK major trauma centres: a mixed-methods study

Context

Purpose of application

This application from University of Nottingham set out the purpose of medical research that seeks to explore the current use and intended purpose of the 'Rehabilitation Prescription' (RP) following major trauma, including the context for its implementation. Findings will inform the development of a future grant application, in which a solution to improve the implementation of the rehabilitation prescription will be developed and tested.

Traumatic injuries can be life changing with many survivors experiencing a range of physical and psychological problems. More people are surviving traumatic injury following the opening of UK Major Trauma Centres in 2012, however more individuals are living with the long-term effects of trauma, often requiring rehabilitation. The RP was developed in 2010, designed to support the identification of patient rehabilitation needs. The trauma survivor and family should be involved in its completion with the aim to improve continuity of community care following hospital discharge. However, research suggests that the RP is not being used properly. Patients often feel as if they have been abandoned when they leave hospital with limited knowledge about their rehabilitation plans. The RP is not always being completed by rehabilitation experts and is not always shared with relevant healthcare professionals (e.g. GPs).

The applicant is undertaking a number of different methodologies at 3 participating trauma centres, including consented interviews and focus groups. These elements do not require 's251' support. However the applicant is also undertaking ethnographic observations, of 3 major trauma centre meetings, observed twice at each site, and observations of clinical staff completing rehabilitation prescriptions. Support under Regulation 5 is required for this aspect of the study as the applicants may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded. Any identifiable data that is recorded (including names of clinical staff and services) will be pseudonymised.

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	The participants in the study are NHS staff participating in MDT meetings, and completing the rehabilitation prescription in three trauma centres. However the researchers undertaking observations of MDT meetings may be exposed to confidential patient information relating to patients discussed at the MDT meetings. These will be patients admitted to one of the three major trauma centres (Nottingham, Cambridge, St. George's London), and will have received a rehabilitation prescription.
Data sources	1. Clinical meetings in major trauma centres recorded via written field notes, at the following Trusts; • Nottingham University Hospitals NHS Trust • Cambridge University Hospitals NHS Foundation Trust • St. George's University Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be recorded for analysis purposes

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 agreed there was a clear medical purpose which was 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 researcher conducting the observations of clinical meetings will not know in advance which patients under the care of the organisation may be discussed by staff in meetings, or will be having rehab prescriptions written during observations. Therefore, seeking consent in advance of observations taking place is not possible. The CAG Members accepted this justification.

- **Use of anonymised/pseudonymised data**

Patient data is not the focus of the research activity and no patient data will be recorded or used for research purposes in the study. During observations of clinical meetings, the researcher may be incidentally exposed to identifiable patient information, however this data is not being collected and no identifiable information will be recorded by the researcher. Any recorded data (via written field notes) will use a pseudonym where necessary to record information about the patient being discussed during the meeting. The researcher will not write down any personal information about the patient. The CAG accepted there was not a practicable alternative to undertake the study without this use of 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.

The study observations will be advertised to all staff and patients through posters displayed in all areas the researchers will be based. The poster will instruct all staff and service users that they can contact the researcher should they not wish to be included in the observations. The poster will contain a picture of the researcher. A study specific opt out is on posters displayed in clinical areas. It has previously been accepted by CAG that it is not possible to apply the NDO to incidental disclosures.

The Sub-Committee were broadly content with the notification documents, methodology and opt out options, noting that the inclusion of a photo of the researcher, and also the dates in which the observations will be happening is a strong positive. However the Members noted that although the applicant has stated that the poster will instruct patients that they can contact the researcher if they wish not to be included in the observations, they felt that this was not clear on the poster provided and the wording should therefore be revised.

Although noting that if the applicants are not able to know in advance who is being discussed they could not guarantee no exposure to the patient's discussion, however there is a potential mechanism whereby opt out could be managed, which has been presented in a different application;

‘The text [of the poster] advises patients who wish to dissent to contact the researcher, and telephone and email contact details are given. When a patient contacts the research team to opt out/dissent, the researcher will record their initials and date of birth. In advance of each meeting observation, the researcher will ask the MDT lead if any patients to be discussed have this date of birth and if so, if they also have these initials. If they confirm a match for these details, then researchers will ask to be removed from the meeting when this patient is discussed. If the patient does not want to disclose their initials and date of birth to the research team, they will be provided with the contact details of the NHS site PI to request dissent via the same method.’

If the applicant feels this opt out mechanism could apply to this application, then this should be made clear on the poster.

The Members commented that the poster also needs revising to state that no individual data about patients is being collected.

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.

Two trauma survivors and one carer of a trauma survivor were consulted about being incidentally exposed to patient data without obtaining consent. All agreed that it would be acceptable to not obtain consent if patient data was not being recorded during the observations of clinical meetings, and if any information was to be recorded, then it would need to be anonymised, so that patients were not identifiable outside of the meeting. The Sub-Committee agreed that the patient and public involvement undertake was acceptable and proportionate, noting that even though it was only with three individuals, there seems a good PPI setup overall, and the three people consulted were supportive.

Exit Strategy

No items of confidential patient information will be recorded. Therefore the exit strategy will be the time point that the applicant stops the observations. Observations of MDT meetings are estimated to be completed by the end of November 2022. 's251' support required until this point. 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 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. Please provide Favourable Opinion from the REC when it is available, as per standard condition of support below.

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. Please update the poster to make it clearer how to opt out (taking into account the proposed opt out mechanism), and to make it clear that patient data is not collected,

and provide the updated poster to CAG within 1 month of final support being provided.

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

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 **Nottingham University Hospitals NHS Trust**, **Cambridge University Hospitals NHS Foundation Trust**, and **St. George's University Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' by email to the CAG inbox (received 26 July 2022)

   The NHS Digital **20/21** DSPT review for **Royal United Hospitals Bath NHS Foundation Trust and Netsolving Ltd (on behalf of NEIAA)** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 29 June 2022)

2. New Precedent Set Review Applications – Non-Research

a. 22/CAG/0107 – The 2022 Urgent and Emergency Care Survey

Context

Purpose of application

This non-research application submitted by Picker Institute Europe, (on behalf of the Care Quality Commission), sets out the purpose of conducting the 2022 Urgent and Emergency Care Survey.

The 2022 Urgent and Emergency Care Survey will be the ninth carried out to date, 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 CQC have commissioned the Survey Coordination Centre for Existing Methods (SCCEM) at Picker to manage and coordinate the survey programme under the title of the SCCEM. All eligible trusts will be asked to conduct the survey with preparations expected to begin in September 2022 and fieldwork expected to start from November 2022. 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 methodology for the 2022 survey is unchanged from the 2020 survey. The Same Day Emergency Care (SDEC) indicator will no longer be requested for the 2022 survey. The SCCEM will use an online sample checking platform for the 2022 survey.

NHS Trusts will submit the combined mailing and sample file to the approved contractor. The complete mailing data will then be removed, except for the full postcode, which will be sent to the SCCEM as part of the sample file. Both the approved contractors and the SCCEM will not open a sample file until a satisfactory sample declaration form has been received. Any outputs provided will be anonymous. This statistical dataset is used for a wide variety of purposes, with the ultimate aim of supporting the improvement of patient experience in England.

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	People aged 16 and over who attended a Type 1 emergency department in September 2022 or a Type 3 urgent care department in September 2022. Trusts can sample back to August 2022 if required to fulfil sample. For trusts with only Type 1 departments, the sample size will remain at 1250. Trusts who have both departments will have a sample size of 950 for Type 1 and 420 for Type 3. The applicants anticipate that 126 trusts will be involved. The Sampling Instructions will ask trusts to exclude: - deceased patients

	- children or young persons aged under 16 years at the date of their attendance at the emergency department - any patients who are known to be current inpatients - planned attendances at outpatient clinics which are run within the Emergency Department (such as fracture clinics) - patients without a UK postal address - patients attending primarily to obtain contraception (e.g. the morning after pill), patients who suffered a miscarriage or another form of abortive pregnancy outcome whilst at the hospital, and patients with a concealed pregnancy* - any patient known to have requested their details are not used for any purpose other than their clinical care - any patients who were admitted to hospital via Medical or Surgical Admissions Units and therefore have not visited the emergency department - Any attendances at Walk-in Centre's - Any attendances at Type 3 departments not wholly managed by the sampling trust. - Patients who attended or were streamed to a separate Same Day Emergency Care unit (i.e. not the A&E department or Urgent Treatment Centre).
Data sources	1. Electronic patient records within all eligible Trusts in England (126 trusts)
Identifiers required for contact purposes	1. A standardised unique identifier code, to be constructed as survey identifier, trust code followed by a whole number (consecutive across the sample of patients from each trust), e.g. UEC22XXXNNNN where XXX is the trusts 3 digit trust code and NNNN is the 4 digit serial number relating to sampled patients. 2. Title (Mr, Mrs, Ms, etc.) 3. First name 4. Surname 5. Address Fields 6. Full Postcode

Identifiers required for analysis purposes	1. The unique identifier code (as above) 2. NHS Trust code 3. Date and time of attendance 4. NHS Site code 5. Department type (Type 1 or Type 3) 6. Ethnicity 7. Gender 8. Year of birth 9. CCG code 10. Patients full postcode – to use to map to deprivation index 11. Mobile phone indicator
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 SCCEM. Please note that the SCCEM 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 CAG noted that the methodology has been tried and tested, the survey 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**

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 CAG were content with the justifications provided.

- **Use of anonymised/pseudonymised data**

The applicants advised that the approved survey contractors required confidential patient information in order to send questionnaires to selected patients. The CAG agreed that this could not be done without the use of confidential patient information. The CAG also noted that phone number itself is not collected, only if the mobile number was available or not, and were content with this proposal.

'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.

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 14 other languages to improve accessibility. Trusts are asked to think carefully about where to place them appropriately. Although the provision of posters is

the primary method of informing the study population of the survey, the Survey Handbook will also recommend that trusts issue a local press release prior to mailing questionnaires out, to raise awareness of the survey and to gain publicity. This will contain a helpline number and email address, should people wish to opt out or have any questions. The content of these documents is the same as for the fully supported 2020 survey.

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. The surveys have a policy exemption from the national data opt out. It is suggested that the National Data Opt-Out exemption should be explained in the patient notification materials. This should include an explanation that the exemption had not been granted by CAG, but via policy consideration. A link to the information around the exemption on the NHS Digital website, 7. Policy considerations for specific organisations or purposes - NHS Digital also should be included on the patient notification materials.

The Members were content with the methodology and content of the patient notifications and opt out mechanism. However it was commented that the poster on how to opt out is available in 14 languages, but it seems unlikely that any emergency Department would have room to display all of the posters relevant to the local community. It would seem sensible to say that is available in other languages on the poster and have a QR code or straightforward web link to a page with all of the available languages, or translated leaflets available on request. The CAG are not making this a condition of support, but merely recommend that the applicants re-visit the approach to investigate if there are better ways of displaying the multiple language options. It is commented that the applicants and the individuals they discuss the surveys with, will likely be able to develop a better way of doing this. This is a comment for future iterations of the survey.

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 the methodology used in the 2022 survey is broadly similar to that used since the NHS Patient Survey Programme was established in 2002. The first Emergency Department survey was developed in 2003. Consultations with relevant policy stakeholders and patient involvement was undertaken when designing the questionnaire. Where possible, questions are kept the same to facilitate year-on-year comparisons. However, the questionnaire content is reviewed before each survey

to consider if any questions are not working and if new questions are needed to ensure the questionnaire is up to date and in line with current policy and practice. Questionnaire development is underway, and the applicant has involved a significant number of patients and the public.

The use of confidential patient information without consent was also discussed. The applicant undertook focus groups with patients who had attended an A&E department or Urgent Treatment Centre in the last 6 months. Four focus groups were held with 15 patients from different geographical areas across England (London, South West, South East, Midlands, North East), ages (26 to 56 year olds), and ethnic backgrounds (White, Black/Black British, Asian/Asian British). Overall, patients did not hold any concerns or worries with confidential patient information being shared without their consent for the purposes of completing a questionnaire.

The Members were content with the patient and public involvement undertaken, noting that it has been ongoing for several years, and has appeared quite effective.

Exit Strategy

The mailing file, containing patient names and addresses, is to be kept encrypted at all times and destroyed when the survey is complete. The original data drawn from trust records may need to be reviewed if any anomalies or errors are identified at any stage throughout the course of the survey, up to the point by which the survey response data is checked and finalised. For this reason, the mailing files may be kept until the reporting stage of the survey. This will be no longer than 6 months after the end of fieldwork, for all contractors.

The SCCEM will destroy the only identifier they retain (full postcode), approximately 6 months after the end of fieldwork, retaining it only for the purpose of checking for any errors that arise following publication.

The Sub-committee were content with this 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. 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 **Patient Perspective Ltd, Picker Institute Europe and Quality Health Ltd** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 27 July 2022)

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Ms Clare Sanderson, CAG Alternate Vice-Chair		*09 August 2022*
Signed – Confidentiality Advice Team		Date
Caroline Watchurst, HRA Confidentiality Advisor		*04 August 2022*