Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on *09 November 2023 at 10:00AM* via video conference*.*

Present:

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Dr Murat Soncul	Alternate Vice Chair
Dr Joanne Bailey	CAG Expert Member
Dr Malcolm Booth	CAG Expert Member
Dr Sandra Duggan	CAG Lay Member
Dr Ben Gibbison	CAG Expert Member
Dr Rachel Knowles	CAG Expert Member
Dr Pauline Lyseight-Jones	CAG Lay Member
Dr Stephen Mullin	CAG Expert Member
Professor James Teo	CAG Expert Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Dayheem Sedighi	HRA Approvals Administrator
Ms Flora White	HRA Member Support Administrator (Observer)
Ms Rachael Maddocks	HRA Member Management and Development Specialist (Observer)

1. APOLOGIES FOR ABSENCE

Apologies for absence were received from: Professor James Teo, CAG member, as he only attended for the discussion of item 5a.

2. DECLARATIONS OF INTEREST

There were no declarations of interest.

3. SUPPORT DECISIONS

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the 05 October 2023 meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the 05 October 2023 meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website:

- September subcommittee
- Full CAG Meeting 05 October 2023

4. CONSIDERATION ITEMS

There were no items for consideration.

5. NEW APPLICATIONS FOR CAG CONSIDERATION

5.a	**23/CAG/0164**	**Under 16 Cancer Patient Survey 2023 to 2026**
	Contact:	Peter Williamson
	Data controller:	NHS England
	Application type:	Non-research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from NHS England set out the purpose of conducting a survey

into the experiences of patients under 16 years of age receiving treatment for cancer.

The National Cancer Patient Experience Survey (CPES), commissioned and managed by NHS England, is one of the ways that patient experience data for cancer patients in England is captured. The results of these surveys are used to help commissioners, providers and national policy makers to identify priority areas of improvement for services. The application supports the implementation of the NHS Long Term Plan, which recognises the importance of good patient experience alongside other outcomes. The plan specifically references obtaining patient experience feedback from children.

Picker will provide NHS Trusts (PTCs) with detailed sampling instructions to compile a sample of patients, a patient declaration list and a template in which to organise their data. Each participating NHS Trust will extract confidential patient information for the survey sample, taken from the Patient Administration System (PAS) and transfer a list of eligible patients to Picker. Picker will check the sample and create a single master file containing the mailing information (patient name and address), trust code, site code, trust name, site name, survey type, and unique reference number for each patient. This file will be securely transferred to Greens Ltd who will then mail out questionnaires to the home address of patients, addressed 'to the parent/carer of [patient name]'. An anonymous code will be used to track who responds so that two reminders can be sent to non-responders, with 2-3 weeks between mailings and any opt-outs removed. PECS Data Services Limited (PECS) will record the responses received, but this will be under patient consent.

Confidential information requested

Cohort	All children aged under 16 at the time of their care and discharge, with a confirmed primary diagnosis of cancer or a non-malignant brain, other central nervous system or intracranial tumour, who are aware of their diagnosis and have received NHS care and/or treatment for their cancer or tumour in England within a recent twelve-month period (e.g. Jan 1st – Dec 31st 2023 for the 2023 survey).
Data sources	1. NHS Principal Treatment Centres (PTCs)
Identifiers required for linkage purposes	1. Name 2. Address 3. NHS number 4. Sex 5. Ethnic group 6. Date of birth 7. Discharge date 8. Patient classification 9. ICD10 code or ICD11 code 10. ICD-O-3 site code

	11. ICD-O-3 morphology code 12. Specialty code 13. Site code 14. Trust code
Identifiers required for analysis purposes	1. Postcode
Additional information	Confidential patient information for analysis will be held with consent as the legal basis.

Main issues considered, discussed and outcomes

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

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG suggested that it would be good practice if the invitation letter included a mechanism that gave participants the opportunity to express whether they wanted to receive the letters inviting them into similar surveys in the future. **(Recommendation 1)**

The CAG also recommended that it would good practice to include more information in the patient notification to explain how the data flows to Picker and how it is used, and the legal basis for not being consented. **(Recommendation 2)**

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Secretary of State for Health and Social Care for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Security assurances for 2022/23 are outstanding for the following organisations. • *Picker Europe Ltd*	

	Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

Recommendations:	
1	The CAG suggested that it would be good practice if the invitation letter included a mechanism that gave participants the opportunity to express whether they wanted to receive the letters inviting them into similar surveys in the future.
2	The CAG also recommended that it would be good practice to include more information in the patient notification to explain how the data flows to Picker and how it is used, and the legal basis for not being consented..

5.b	**23/CAG/0166**	**National Diabetes Experience Survey 2023**
	Contact:	Shaun Crowe
	Data controller:	NHS England
	Application type:	Non-research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from NHS England set out the purpose of a national survey exploring patients experience of diabetes treatment.

NHS England has commissioned Ipsos UK to deliver the first national survey of patients with diabetes. The survey will be used to provide insight into patients experience of diabetes care and collect information on preferences on how services should be delivered.

Ipsos UK and NHS England will advertise the survey, including details on how patients can dissent. AGEM DSCRO will remove patients who have dissented and will use the National Diabetes Audit database to create a dataset of eligible patients. The dataset will be disclosed to Ipsos UK. Ipsos UK will run a sampling methodology and select around 105,000 individuals who will be invited to take part in the survey. Ipsos UK will send NHS number of those selected to the PDS team at NHS England to obtain patient contact details. Ipsos UK undertakes eligibility checks via the PDS team using NHS number, including checking for deceased individuals. Ineligible or deceased individuals are removed from the sample by Ipsos UK before the invitation letters and text

messages are sent out, inviting patients to take part in the survey. Ahead of the first mailing, Ipsos send a file with limited data to each of their sub-processors (Formara and Text Local). An invitation letter is sent by Formara, and, where the patient's mobile number is available, a text message is sent by Text Local to eligible participants to invite them to take part in the survey. Ahead of each reminder mailing, Ipsos UK will undertake eligibility checks via the PDS team by sharing NHS numbers and requesting a refresh of the data supplied in the initial sample. The survey responses will be shared with NHS England, but this will be under consent.

Confidential information requested

Cohort	Adults living with type 1 or type 2 diabetes - the sampling age will be 18+ and those who were diagnosed at least 12 months ago.
Data sources	1. The National Diabetes Audit (NDA) and the Personal Demographic Service (PDS) – NHS England
Identifiers required for linkage purposes	1. NHS number 2. Type of diabetes 3. Date of diabetes diagnosis 4. Age band (at the sampling stage) / Month and year of birth (for those selected to take part in the survey – see section 2(1) below) 5. Sex 6. Ethnicity 7. Treatment type for the individual (insulin, metformin, other diabetes drugs, or no drugs) 8. Care processes/clinical outcomes 9. Treatment targets 10. Lower Layer Super Output Areas (LSOAs) 11. GP practice code 12. Full name 13. Address including postcode 14. Phone number
Identifiers required for analysis purposes	Identifiers for analysis will be processed under consent.

Main issues considered, discussed and outcomes

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.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG commended the applicant regarding their work around the Patient & Public Involvement (PPI). However, the CAG noted that there was no detailed feedback from this work particularly around the specific issue of use of confidential patient information without consent. The CAG requested to see the feedback particularly around the specific issue of use of confidential patient information without consent. **(Condition 1)**

The CAG noted that an email address was provided in the poster for patients to opt-out from the study. The CAG requested that a telephone number and postal address should be included as well as an email address, should patients have queries or wish to opt-out. The CAG also requested that this information should also be included on any notifications going to the patients. **(Condition 2)**

With regard to the notification materials, CAG requested that the applicant should reflect the wording recommended in the National Data Guardian response outcome letter in the 'How did you get my details?' section of the National Diabetes Experience Survey website **(Condition 3)**

The CAG noted a slight error in the description of CAG and requested that the applicant amend the National Diabetes Experience Survey website for accuracy, removing the terminology section 251 'approval' in section 1.4. As CAG was not the decision maker, it would be more accurate to use the term 'support'. **(Condition 4)**

The CAG noted that an invitation letter was sent by Formara, and, where the patient's mobile number was available, a text message would be sent by Text Local to eligible participants to invite them to take part in the survey. The CAG requested that the applicant clarify whether it was possible to implement local opt out via a text link within the text message. **(Condition 5)**

The CAG noted that some data would be kept for two months and then deleted and some pseudonymised data would be kept longer. The CAG requested that the applicant to clarify how long the pseudonymised data was going to be kept. **(Condition 6)**

Confidentiality Advisory Group advice: Conditionally supported

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.

Number	Condition	Response from the applicant

1.	Provide detailed feedback on the outcomes of the recommendations that were discussed by representatives from PPI group, particularly around the specific issue of use of confidential patient information without consent. This should be provided to CAG within 1 month.	
2.	The CAG requested that a telephone number and postal address, as well as an email address are provided in poster, leaflet and letters sent to the patients, should patients have queries or wish to opt out. This should be provided to CAG within 1 month.	
3.	The CAG requested that the website needs to reflect the wording stated in the National Data Guardian advice letter. This should be provided to CAG within 1 month.	
4.	Please change the wording on website where mentions section 251 'approval' to 'support'. This should be provided to CAG within 1 month.	
5.	Provide clarification in the invitation text message on whether it is possible to implement local opt out via a text link. This should be provided to CAG within 1 month.	
6.	Provide clarification as to how long the pseudonymised data is going to be kept. This should be provided to CAG within 1 month.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

5.c	**23/CAG/0167**	**National Respiratory Audit Programme (NRAP) Pulmonary Rehabilitation Audit**
	Contact:	Lara Amusan
	Data controller:	Healthcare Quality Improvement Partnership (HQIP)
	Application type:	Non-research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from The Royal College of Physicians set out the purpose of continuing the HQIP commissioned National Respiratory Audit Programme Pulmonary Rehabilitation Audit.

The National Respiratory Audit Programme (NRAP), which launched on 1 June 2023, is a continuation of the National Asthma and COPD audit programme (NACAP). This 3-year programme covers secondary care workstreams for adult asthma (AA), children and young people asthma (CYPA), COPD, pulmonary rehabilitation (PR) in England and Wales, and primary care in Wales only. Applications have been supported for the adult asthma and chronic obstructive pulmonary disease (COPD) secondary care audit workstreams and the children and young people asthma (CYPA) secondary care audit workstream. The applicants are now seeking support for an audit into Pulmonary Rehabilitation. The overarching aims of the programme are to identify areas of variation and deficiencies in care, support improvement of the care given to patients and improvement of outcomes for patients admitted to hospital with an exacerbation in England and Wales.

Services providing Pulmonary Rehabilitation (PR) will enter confidential patient information into the NRAP audit webtool. Once a year, Crown Informatics Ltd will extract confidential patient information from the webtool. Crown Informatics will anonymise the data by replacing NHS numbers with a study ID, amending the postcode to Lower Super Output Area (LSOA) and amending date of birth to age at assessment. The anonymised dataset will be disclosed to Imperial College London for analysis. Crown Information Ltd also disclose confidential patient information to NHS England on a monthly basis for inclusion on the National Pulmonary Rehabilitation Dashboard.

Confidential information requested

Cohort	All patients referred to PR are included who: • attend an initial assessment for pulmonary rehabilitation. • are 18 years or over on the date of assessment.
Data sources	1. NHS England: a. Hospital Episode Statistics (HES) b. Admitted Patient Care (APC) dataset c. Office of National Statistics mortality data 2. Digital Health and Care Wales a. Patient Episode Database for Wales

Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Home postcode
Identifiers required for analysis purposes	1. None
Additional information	Data that is returned to Imperial College London for analysis by NHSE and DHCW has been anonymised, removing patient identifiers: • NHS Number is changed to audit ID number • Date of birth is changed to age • Postcode is changed to lower layer super output area (LSOA)

Main issues considered, discussed and outcomes

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.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG noted that Crown Informatics Ltd was planning to disclose confidential patient information to NHS England monthly for inclusion on the national pulmonary rehabilitation dashboards. The CAG was unclear why this was required and requested that the applicant to explain why NHS England required confidential patient information. **(Action 1)**

The CAG noted that the application stated that Crown Informatics Ltd would transfer confidential patient information “if requested” to NHS England for linkage to Hospital Episode Statistics (HES) Admitted Patient Care (APC) dataset and Office of National Statistics mortality data, and to DHCW, for linkage to Patient Episode Database for Wales (PEDW). These linkages were currently undertaken for the adult asthma, children and young people’s asthma and COPD audits but no formal data requests with either NHSE or DHCW are in place for the Pulmonary Rehabilitation (PR) audit. However, this was likely to change, once the full PR expansion was in place and the applicants anticipate that there would be one linkage request for HES and ONS made to NHSE, and for PEDW made to DHCW made during the contract period of 01 June 2023 to 31 May 2026. The CAG requested that the applicant to clarify whether this linkage was required. The CAG agreed that if this linkage was required in the future, then the applicant will need to submit an amendment requesting support

for the linkage to NHS England and DHCW at that time. Otherwise if confirmation is provided as a response to provisional outcome, these linkages can be included in the scope of 's251' support. **(Action 2)**

The CAG noted that notifications provided were outdated and inadequate for the purposes of a patient notification mechanism for this application. The CAG requested a layered approach to patient notification, to include a newly developed patient notification document which was specific to this project, rather than direct care purposes. The notifications should also state that 'section 251 support' was recommended by the Secretary of State for Health and Social Care, on advice from the Confidentiality Advisory Group (CAG). The notification should also clearly explain the mechanism of application specific opt-out. The CAG requested that the notifications should promote use of the application specific opt-out, whilst still stating the National Data Opt-Out would be respected. Finally, all notifications should be reviewed by the patients and the public group for accessibility. **(Action 3)**

The CAG requested that proportionate specific patient and public involvement was undertaken with representative groups, to discuss the acceptability of this use of confidential patient information without consent. **(Action 4)**

The CAG also noted that the application was planning to collect mental health data. The CAG requested that the applicant justify the collection of mental health data. **(Action 5)**

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Secretary of State for Health and Social Care for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Provide an explanation as to why NHS England requires confidential patient information from Crown Informatics Ltd each month for inclusion on the national pulmonary rehabilitation dashboards.	
2.	Provide clarification as to whether 's251' support is required for linkage to NHS England and DHCW datasets as part of this application at this time.	
3.	Update the patient notification materials as follows and provide to CAG for review.	

	a. Produce a new patient notification which clearly describes the purpose and content of this application, distinct from any notification relating to direct care purposes. b. A layered approach is advised. c. The notifications should also state that 'section 251 support' was recommended by the Secretary of State for Health and Social Care, on advice from the Confidentiality Advisory Group (CAG). d. An explanation on how patients can request removal of their data for this application should be included. Use of an application specific opt-out should be promoted, whilst noting that the National Data Opt-Out will be respected. The CAG usually expects that telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data. e. All newly developed patient notification materials should be reviewed by a patient and public involvement group	
4.	Further proportionate patient and public involvement, particularly around the specific issue of use of confidential patient information without consent is to be undertaken and feedback provided to the CAG for review.	
5.	Provide justification for the collection of mental health data.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

6. ANY OTHER BUSINESS

There was no other business for discussion.

Dr Patrick Coyle	19 November 2023
…….	……..
Signed – CAG Vice Chair	*Date*
Mr Dayheem Sedighi	14 November 2023
…….	……..
Signed – HRA Approvals Administrator	*Date*