Minutes of the meeting of the Confidentiality Advisory Group

16 September 2021 – held via zoom

Present:

Name	
Dr William Bernal	CAG alternative vice-chair
Dr Patrick Coyle	CAG vice-chair
Professor Lorna Fraser	CAG member
Mr Tony Kane	CAG member
Dr Rachel Knowles	CAG member
Mr Marc Taylor	CAG member
Dr Sandra Duggan	CAG member
Mr Umar Sabat	CAG member
Mr Dan Roulstone	CAG member

Also in attendance:

Name	*Position (or reason for attending)*

Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Mr Michael Pate	HRA Confidentiality Advisor
Mrs Emma Marshall	HRA Confidentiality Specialist

1. Introduction, apologies and declarations of interest

2. 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 **19 August 2021** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **19 August 2021** meeting applications.

3. Minutes of Previous Meetings

The minutes of previous meetings have been agreed and updated to the website until 20 May 2021 for Full Meetings and 11 June 2021 for Precedent Set Meetings.

4. New Applications

a. 21/CAG/0136 – National Drug and Alcohol Treatment Monitoring System (NDTMS) & Criminal Justice Intervention Teams (CJIT) (replacing and extending National Drug Treatment Monitoring System collection ECC 5-05(e)/2012

Context

Purpose of application

This non-research audit application from Public Health England (PHE), on behalf of the Office for Health Improvement and Disparities (OHID) within the Department for Health and Social Care (DHSC) set out the purpose of continued processing of confidential patient information within The National Drug Treatment Monitoring System (NDTMS). The NDTMS collects information with the consent of the users of drug and alcohol treatment services across England to assess the need for services and to support the commissioning, planning and provision of effective treatment services and interventions.

'Section 251' Support was previously provided in 2012 (ECC 5-05(e)/2012 - National Drug Treatment Monitoring System (NDTMS)) for data collected by the National Treatment Agency (NTA) pre-PHE formation in 2013 to be processed by PHE, as the consent provided pre-2013 was not sufficient. There is also a consented cohort from 2013-2021. Whilst PHE currently hold the data, the controller is the Department for Health and Social Care (DHSC) which was reflected in the 2012 application. However this was not reflected in the consent forms and information sheets, which includes the statement "*All data matching is conducted by PHE and at no point is any identifiable information about service users passed onto other government departments*". The NDTMS dataset is going to move to DHSC on 01 October. The consent between 2013 – 2021 has been deemed to not cover NDTMS moving to DHSC. This application therefore covers both the pre-2013 cohort (ECC 5-05(e)/2012 will be expired), and the 2013-2021 cohort. The applicants have also requested support for newly consented patients between 1 October 2021 and April 2022, in order to ensure the consent materials are updated appropriately.

It is important that an ongoing legal basis is provided for DHSC to access the NDTMS dataset, as outputs inform the ongoing monitoring and quality improvement of drug and alcohol treatment services, interventions and policies at local and national levels. All routine and annual reporting takes place using pseudonymised datasets.

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

Confidential patient information requested

Cohort	All individuals being treated for drug and alcohol misuse (requiring support and / or interventions for their drug or alcohol use and this need meets the clinical or operational threshold as defined by the service and setting) People of all ages are included 1. 2005/2006 - 31 March 2013; National Drug Treatment Monitoring System consented cohort (approximately 965,000 individuals) 2. 1 April 2013- 30 September 2021; National Drug Treatment Monitoring System consented cohort (approximately 886,000 individuals) 3. 30 September 2021 – 6 April 2022 National Drug Treatment Monitoring System consented cohort (applicant would expect around ~58,000 individuals)
Data sources	Around 1,000 drug and alcohol treatment services in England (and additionally one Welsh prison) contribute to: • NDTMS data including NDTMS core dataset, and DIRWEB data collected by Home Office (DIR / DIP programmes) in early version of what would become the CJIT collection, collected by NTA (pre 2013) • NDTMS data including NDTMS core dataset, CJIT dataset and IPS dataset as collected by PHE (2013-30Sept2021), and the same collected at DHSC up to 6April2022. • NDTMS data including NDTMS core dataset, CJIT dataset and IPS dataset as collected by DHSC from 1 October 2021 to 6April2022. These datasets are currently held at PHE, and will be retained at UK Health Security Agency (UKHSA) after 1 October 2021, with DHSC as data controller. Linkage with HES (NHS Digital) and other datasets from Department for Work & Pensions (benefits claims

	records) and Ministry of Justice (Police National Computer records) are not currently in scope for CAG support.
Identifiers collected and required for linkage /de-duplication	1. Patient initials - **linkage & deduplication** 2. Date of Birth - **linkage & deduplication** 3. Sex - **linkage & deduplication** 4. Treatment clinic represented by a unique NDTMS agency code - **deduplication** 5. national prison (NOMS) ID number unique to the individual - **used for linkage once** 6. Local authority - **linkage & deduplication** 7. First part of postcode – **deduplication/ used for linkage once** 8. Ethnicity – **deduplication/ used for linkage once** 9. GP practice code – **deduplication/ used for linkage once** IPS data collection does not appear to be in scope.
Identifiers required for analysis purposes	1. Patient initials 2. date of birth, 3. partial postcode of residence, 4. treatment clinic and/or national prison (NOMS) ID number unique to the individual), 5. Ethnicity 6. Sex 7. Local authority The date of birth is not modified for regular analysis, nor are treatment provider (clinic) ID and prison ID as these are required for reporting to provider level. For specific projects requiring pseudonymised data, applicants remove date of birth to be replaced by age (or age band), remove initials, and apply k-3 anonymity, which could be considered pseudonymous for these external analyses.

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 considered that there was a clear medical purpose to the primary data collection, and the Members agreed the activity was in the public interest, noting benefits to individuals, families, and the wider community.

Scope

The Members felt that the data flow diagram was not very clear, and requested an updated data flow diagram to ensure they understood all the flows of data, and which required Regulation 5 support. For example it was not clear to the Committee if it was only the core dataset or the linked dataset that was disclosed to the University of Manchester.

The Committee were clear on what support was required regarding the retention of data, however they required further clarity regarding if support was required for linkages with datasets held by NHS Digital, and by DWP and MoJ. The Committee were agreed that support under Regulation 5 cannot be provided for a flow of confidential information that is not patient related, however it can be provided for linkages to health related confidential patient information. It appears that up until 1 October 2021, Regulation 3 has allowed linkages to be undertaken. It is not clear if Regulation 3 has also covered linkages with the dataset collected 2013. It is not clear if the linkages are one off or ongoing. It is also not clear exactly what Regulation 5 support is now being requested for, and the Members noted that due to organisational changes they understood that Regulation 3 may not be an option in the future. However, the applicant is required to confirm with CAG in more detail where regulation 5 support is required regarding the different linkages, and support is not yet in place for this element, as the Members wish to understand more about the request. It is considered that these linkages should all be undertaken with consent as the legal basis post April 2022, and the information sheets and consent forms should be developed to clearly include this processing.

Additionally, the Members noted that research appeared to be referred to in part of the application. The CAG would like to clarify that this application does not support research purposes.

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 reasons consent is not a practicable alternative due to the substantial practical challenges and risks of breaching confidentiality associated with reconsenting former service users. It would be burdensome both financially and in terms of administrative time, as approximately 670,000 drug and alcohol treatment service users were recorded on the NDTMS database over the period 2003/04 to 2012/13, and an estimated 337,000 annually since then. Additionally NDTMS do not retain address, so it would be far more disclosive to find out name and current contact details. The ICO supported this position with regards to the previous change of data controller. Additionally these patients have provided their consent to be in NDTMS, and the 's251' support is to clarify the legal entity holding the data, so to breach confidentiality further in order to write to the cohort would seem disproportionate The Committee agreed with the justification provided that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is required to avoid double counting and ensure accurate record linkage. It is not possible to undertake de-duplication or linkage with anonymous or pseudonymous information. The applicants have tried to minimise their use of confidential patient information where possible. The members were content with the justification provided.

'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.

In line with previous ICO advice, the applicant should use a revised consent statement for all new and returning service users, and additionally provide information materials for treatment providers to display in treatment clinics to inform former service users of the change of data controller. This should also be displayed on the NDTMS/gov.uk website.

The CAG have not been provided with the updated revised information sheets and consent statements for all new service users. These are being prepared still, in order that they are properly ‘futureproofed’. The applicant has stated these will not be ready until December, and then CAG support is required until April 2022 in order to ensure all 1000 providers are properly compliant with the new materials. The CAG were content with this, however a condition has been added to provide the updated information sheet and consent forms, as soon as they are prepared. The applicant should ensure that all linkages are covered in the consent materials, and that they are as ‘futureproofed’ as possible.

The CAG have also not been provided with notification materials for treatment providers to display in treatment clinics (and on NDTMS website) to inform former service users of the change of data controller, which the ICO has previously stated should be provided. This notification should describe how patients can opt out if they wish. As a response to queries the applicants have stated they agree to display this but haven’t provided the notification document. The applicant is therefore required to develop this as soon as possible for display, preferably before 1 October 2021, and provide to CAG for review.

Regarding patient dissent, it is stated that a service user may wish to remove some or all of their data from NDTMS, and this is the responsibility of the current or previous treatment provider. NDTMS is not part of NHS Digital’s national data opt out. This is due to the limitations of the dataset that is collected (initials and no NHS number) and due to a large proportion of the collection coming from third sector organisations. Consent would override the National data opt out, however any CAG supported application is usually required to apply it. As the applicant does not collect NHS number it would be very difficult to apply the national data opt out to the backdated dataset of consented patients. The CAG considered that this is a reasonable argument.

Currently there is no opt out for this specific breach, as no notification has been developed to describe it, however this should be in place from 1 October 2021.

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.

Extensive provider and service user consultation was undertaken by the former organisation the National Treatment Agency (NTA) prior to the commencement of NDTMS in 2003/04 to ensure broad-based support for the collection, however this is not relevant to this application.

In late-2016, PHE engaged with the service user group of one of the major national providers of local drug and alcohol treatment services, Change Grow Live (CGL). The number of service users were approximately 80 –100. PHE consulted:

1. On attitudes to the concept of contacting of clients discharged prior to 2013 in order to explain the incorporation of the NTA into PHE, and to seek refreshed consent for PHE as a part of government to use clients' individual data. The service user group agreed that their peers may well have moved from previous addresses and that there would be a high risk for letters from the treatment services to go astray or be opened by someone other than the intended recipient.
2. Generally on service users' preferences on access to information including channel, content and format.
3. Specifically on the production of materials (such as posters) for display in treatment services and in electronic form for local service user forums online.

This consultation also supported not obtaining consent for the change in data controller - the individuals consulted stated that the risks to confidentiality associated with NDTMS attempting to contact non-current service users to inform them of the change of data controller were likely to be very great.

This previous patient and public involvement seems to have discussed the use of confidential patient information without consent for the purposes of a change in data controller, however it was undertaken in 2016, and related to the specific purposes of ECC 5-05(e)/2012. It is not clear if applicants have engaged in any patient and public involvement regarding the use of confidential patient information without consent, in the context of the consent being deemed invalid for DHSC to process rather than PHE. As a response to queries, the applicant has responded;

'We are currently scoping the commissioning of service user engagement to ascertain a temperature check of service user opinions on the transitional change. This will be discussed at our upcoming project assurance team meeting on the 9th September, this group includes various stakeholders including commissioners and representation from most of the big treatment providers in the country. We plan on having this service user input by November 2021'

The Committee considered that the planned patient and public involvement does not appear to involve patients, as it seems more clinician focussed. Therefore without any

patient and public involvement, the CAG were concerned about public confidence. Some patient and public involvement activities should be undertaken with patients representative of the cohort. This should be focussed on the reason that CAG support is requested, ie. the change in data controller which is not sufficiently covered by the current consent. The acceptability of the change in data controller without having an updated consent process should be discussed, and the opinion of the public should be provided to CAG, to evidence the public interest in CAG supporting the activity. The new consent materials, and the notification should also be discussed.

Exit strategy

To ensure the ongoing value of the NDTMS collection, there is currently no projected end date for the requirement for 'Section 251' support. Despite support not being required for prospective data collection after April 2022, support will be required for ongoing retention or retrospective data. Support will be provided for 5 years in the first instance, to ensure any legislative changes are covered.

However the CAG did query if it was possible for the applicant to start removing the confidential patient information regarding deceased patients, as this would negate the need for continued support for these people.

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. Please provide a patient notification describing the change in data controller, clearly indicating the differences between pre 2013, 2103-2021, and 2021-2022. This notification should be displayed on the NDTMS website, and in clinics. This is required to be provided to CAG as soon as possible, preferably prior to 1 October 2021, and should also provide a mechanism for patients to object to this processing.

2. Provide a clearer data flow diagram, which clarifies legal bases, which flows are confidential patient information, and clearly define the organisations involved, both now and in the future. Provide this to the CAG within 3 months from the date of this letter.

3. Please clarify the scope of Regulation 5 support requested regarding linkages with HES, MoJ, and DWP datasets, for the pre 2013 cohort, the 2013-2021 cohort, and the 2021-2022 cohort, within 3 months from the date of this letter.

4. Please provide the updated information sheets and consent forms, ensuring linkages are clearly described, and they are as 'futureproofed' as possible. These should be provided to CAG as soon as possible, although noting this is planned for December.

5. Please consider if the confidential patient information regarding deceased people can begin to be deleted, and inform CAG within 3 months from the date of this letter.

6. Please undertake patient and public involvement activities with patients representative of the cohort. The acceptability of the change in data controller without having an updated consent process should be discussed, and the opinion of the public should be provided to CAG. The new consent materials, and the notification should also be discussed. Please provide an update within 3 months from the date of this letter.

7. The support commences on the 1st October 2021 when PHE is replaced by the Office for Health Improvement and Disparities (OHID) within DHSC.

8. This support supersedes ECC 5-05 (e)/2012.

9. Support provided for 5 years in the first instance, and will require an amendment at this point to continue support.

10. 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 **20/21** DSPT reviews for **PHE, and NDEC at the University of Manchester** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 27 September 2021). UKHSA will supersede PHE when security assurances are in place, however application can be supported using PHE DSPT until UKHSA DSPT is in place.

b. 21/CAG/0138 - GP Management After Transition Events (GP-MATE) - Developing an intervention to assist older patients' communication with their GP practice after discharge from hospital in order to improve patient safety

Context

Purpose of application

This application from the University of Warwick set out the purpose of medical research that seeks to create an intervention to assist older patients in communicating with their GP practice after discharge from hospital.

Discharge from hospital is a risky part of the patient journey, particularly for older patients with multi-morbidity and poly-pharmacy. Of the 20.8 million patients admitted to hospital in England in 2018-19, a quarter were aged 75 and over. As the population of older patients increases, pressure increases in all areas of the NHS, including on primary care post-discharge. The risk of harm for individuals is also increasing. The applicants aim to produce a tool for older patients and their carers, called GP-Mate, to be used to assist in better communication with their GP practice about care after discharge.

The study will have four objectives; preparing a "patient experiences" video, producing the GP-MATE intervention and a learning set to educate primary care providers, undertaking a feasibility study of use of GP-MATE in specific GP practices and undertaking workshops with primary and secondary care stakeholders. Support is required for aspects of objective three, where the records of patients aged 65 years and over will be reviewed by the research team without consent being sought from patients. A retrospective and prospective cohort will be included.

For the retrospective cohort, support is required for members of the research team to access records at participating GP surgeries to determine the rates of readmission. Links between the index admission and subsequent admissions will be investigated. An automated search will be undertaken to identify patients and to exclude those who have dissented from use of their records in research. The research team will access the electronic health record, the document management record and its audit trail.

The prospective cohort will be sent the intervention and the general practice will be encouraged to offer all of them a GP-MATE appointment, unless the staff screening the record feel this is inappropriate for the patient. The records for this cohort will then be examined by members of the research team, the same as described for the

retrospective cohort. Support is also required for members of the research team to assist staff at the GP practices in sending out the intervention packs.

A recommendation for class 1, 2, 3, 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	Patients aged 65 years and over who have been discharge from hospital in the year of data collection, and are patients of the 8 GP practices involved in objective 3. The prospective cohort is planned to run between 01 September 2023 and 01 September 2024. The retrospective cohort will include patients treated in the previous year. It is estimated that 300 patients will be included in each cohort, totalling 600 patients.
Data sources	1. Patient records held at participating GP practices. The GP practices have not yet been identified.
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of death

Identifiers required for analysis purposes	1. GP practice of origin 2. Gender 3. Ethnicity

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 the public interest in improving communication between GPs and patients who have been recently discharged from hospital. However, members agreed that the application was not yet ready to be reviewed by the CAG. Members observed that the elements requiring support under section 251 would not be undertaken until 2023 and asked that further preparatory work was undertaken. Members noted that the intervention may be a paper-based communication tool, however, they agreed that further details were required. The CAG asked that further preparation work was carried out and that a re-application to the CAG was made once more information on the planned intervention was available. Details would also need to be provided on how the intervention would be used with patients who lacked capacity.

Practicable alternatives

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

- Minimising flows of identifiable information

The CAG agreed that the applicants should consider and explore whether any practicable alternatives, that would remove or minimise the need for processing of confidential patient information outside the direct care without consent being sought from patients, can be implemented.

- Feasibility of consent

The applicants advised that it is not feasible to contact the patients involved in the retrospective cohort, as a number of patients may have died or moved away.

The applicants explained that, for the prospective cohort, the GP-MATE intervention will be applied at a practice level. Consent will not be sought from patients to apply the intervention or to access their records. However, study information will be sent to patients so that they understand the project. The applicants advised that an opt-out, rather than a consent process, was in place as an unbiased cohort was needed. The opt-out process had been included due to a suggestion made during the University of Warwick's internal sponsorship process. The applicants also note that patients in the prospective cohort may die during the study period and that contacting patients is potentially burdensome due to the patients' frailty.

The CAG noted that the applicants had cited that patients may lack capacity and a difficulty in contacting consultees. The applicants also wanted to involve carers, even if the patient they were caring for was not able to consent. The CAG also noted that it was not appropriate to seek support under Regulation 5 if patients did not have capacity to consent, as the research provisions of the Mental Capacity Act allow for this eventuality.

Members agreed that a clearer explanation was needed as to why consent was not feasible. This needed to include an explanation on why patients' carers could be contacted about participating in the project as participants but could not be contacted to provide a consultee opinion.

The CAG noted that the applicants intended to recruit 600 patients in total to the prospective and retrospective cohorts, and that response rates to questionnaires tended to be low. Members queried if the risk of low response was the reason for not consenting, rather than lack of capacity.

- Use of anonymised/pseudonymised data

The researchers require access to confidential patient information in order to extract an anonymised dataset for the retrospective cohort and a pseudonymised dataset for the

prospective cohort. Access to confidential patient information is also required for the applicants to assist GP practice staff in sending the intervention to the prospective cohort.

'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 applicants advised that they had created information to address peoples' anxiety around what would happen to their data in the form of Patient Information Leaflets and posters/web page material for practices. These contain clear information on how to opt-out of the study.

People that have opted out of research previously will be excluded from the study.

All study information packs that are mailed out to patients will include an opt-out letter, the GP-MATE intervention, a Patient Information Leaflet, an expression of interest form for the interview and questionnaires relating to the use of GP-Mate.

The applicants advised that they will work with general practices to ensure that patients who have previously refused consent for their records to be used for research will be excluded from the searches. This process had been added to the data flow diagrams.

The poster included postal, email and telephone contacts for patients to contact the study team with queries. Patients wishing to opt-out from use of their records are advised to ask a practice receptionist or look on the practice website for ways to opt-out. Wording for the GP practice websites was provided. This directs patients to the study website. The GP practice website will be included for objections and the Chief Investigators email is provided for queries.

Members observed that the information sheets suggested that consent would be sought from patients, but also that it was unclear which information sheet would be sent to patients in the prospective cohort, but who would not be asked for consent. Revised patient notification documents, written to inform the retrospective and prospective cohorts whose records would be reviewed, need to be provided. This notification will also need to explain how patients can register dissent to inclusion.

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 patient and public involvement has been undertaking when developing the GP-MATE intervention. Two GP patient participation groups were invited to comment on a prototype GP-MATE. Of those participating, eight were aged over 65. The PPI-E co-ordinator at the University of Warwick has publicised the study via the departmental PPI-E newsletter. This led to the Warwickshire U3A choosing the project as a priority for discussion at a PPI workshop. The project was also advertised on the People in Research, generating seven ethnically diverse PPO-E participants from across the UK who were enthusiastic to support the research. The applicants also intend to establish an ethnically and socially diverse PPI-E panel, who will meet at six-monthly intervals to inform the study design, conduct and dissemination plans. Three regional PPI-E subpanels will also be convened in Coventry and Warwick, Manchester and Nottingham.

Members agreed that it was unclear whether the patient and public involvement undertaken had included discussion of the processing of confidential patient information without consent. The CAG asked that further patient and public involvement was undertaken before any resubmission was made, and that this activity included discussion of the use of confidential patient information without consent and a review of the patient notification materials created for patients who will be included in the medical record review.

Exit strategy

Only anonymised information will be disclosed from the GP practices to the University of Warwick.

The exit strategy for the prospective cohort is that only anonymised information will be removed from the practice for patients who are not approached for consent, and that the exit strategy is consent for patients who consent to take part in the study.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Health Research Authority recommended that the application was deferred.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Further preparatory work need to be undertaken, including further development of the intervention, before a re-application to the CAG is made.

2. Details also need to be provided on how the intervention would be used with patients who lacked capacity.

3. Any practicable alternatives, which could be implemented to remove or minimise the need for processing of confidential patient information outside the direct care without consent being sought from patients, need to be considered.

4. A clearer explanation needs to be provided as to why consent is not feasible for the prospective cohort. This needs to include an explanation on why patients' carers could be contacted about participating in the project as participants but not to provide a consultee opinion.

5. If the reason for not consenting is that a low response rate is expected, if consent is sought, this should be specified.

6. Revised patient notification documents, written to inform the retrospective and prospective cohorts whose records would be reviewed, need to be provided. This notification will also need to explain how patients can register dissent to inclusion.

7. Further patient and public involvement needs to be undertaken. This activity needs to include specific discussion of the use of confidential patient information without consent and a review of the patient notification materials.

c. 21/CAG/0133 – Mortality and morbidity outcomes after aorto-vascular surgery in patients with Marfan Syndrome: A UK experience

Context

Purpose of application

This application from Barts Health NHS Trust sets out the purpose of medical research that seeks to investigate the UK incidence of aorto-vascular surgery in patients with Marfan Syndrome and patients' mortality outcome one-year after surgery.

Marfan Syndrome (MFS) is a genetic disease which affects the eyes, skeleton, heart and arteries. Although MFS affects multiple organ systems, cardiovascular manifestations are the most serious and life-threatening. Approximately 80% of adults MFS patients will have a dilated aortic root by 40 years, with aortic aneurysm and dissection the leading causes of morbidity and mortality. Improvements in diagnostics and medical and surgical interventions have increased life expectancy. However, the natural history and the influence of medical or surgical interventions in the UK population are not fully described. Further, the incidence of aorto-vascular surgery in this patient group is unknown, as MFS is not routinely documented in the National Institute of Cardiovascular Outcome Research (NICOR) national cardiac surgery dataset and, therefore, there is currently no mechanism for exploring the aorto-vascular outcomes for this patient group.

The applicants will undertake a 10-year secondary analysis of linked national data, provided from the National Institute of Cardiovascular Outcome Research (NICOR), the Office of National Statistics (ONS) and HES data from NHS Digital, in order to identify the UK incidence and outcome of aorto-vascular surgery in patients with MFS. This includes associated hospital length of stay, mortality and morbidity rates, to provide information on the burdens that the aorto-vascular manifestations may place on the MFS population.

NHS Digital will be asked to identify patients with MFS within the HES database between January 2010 and December 2019. NHS Digital will then undertake linkage to HES and ONS datasets, and transfer the dataset to Barts Heart Centre (BHC) using secure electronic transfer. Research staff at BHC will then identify MFS patients who have aorto-vascular diseases from the data received from NHS Digital. Patients' NHS

number, date of birth and date of surgery will then be transferred to NICOR to be linked to surgery specific data. NICOR is hosted by Barts Health NHS Trust and support is required for the transfer of confidential patient information between departments within the same organisation. NICOR will then transfer the linked dataset back to Barts Heart Centre and linked to the mortality and morbidity data, previously supplied by NHS Digital. Confidential patient information will be deleted from the dataset once the linkage is complete.

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

Confidential patient information requested

Cohort	Patients aged 18 years and over, diagnosed with Marfan Syndrome and who had aorto-vascular surgery in England and Wales between 01 January 2010 and 31 December 2019. The applicants advised that a sample size could not be estimated, as it was unknown how many patients with MFS underwent aorto-vascular surgery.
Data sources	2. HES and ONS data, held by NHS Digital 3. The National Adult Cardiac Surgery Audit within NICOR, held by Barts Health NHS Trust
Identifiers required for linkage purposes	4. NHS number 5. Date of birth 6. Date of surgery
Identifiers required for analysis purposes	No identifiers will be retained in the dataset used for analysis.

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.

Scope

An estimation of the number of patients that would be involved in the study had not been provided. The CAG noted that this was because one of the reasons for conducting the reason was to establish how many patients with MFS undergo aorto-vascular surgery, and raised no queries in this area.

Practicable alternatives

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

- Minimising flows of identifiable information

The CAG queried whether any changes could be made to the data flow. Members suggested that the applicants discuss with NHS Digital whether NHS Digital can apply a unique identifier, rather than NHS number, before transferring data to Barts Heart Centre for linkage to NICOR, reducing the flows of confidential patient information.

- Feasibility of consent

The applicants explained that the project utilises retrospective data and it would be difficult to obtain contact details to seek consent. The applicants also noted the potential risk of bias. The CAG agreed that consent was not feasible.

- Use of anonymised/pseudonymised data

Confidential patient information is required to link the HES and ONS datasets provided by NHS Digital to the NICOR dataset. The CAG agreed that the research could not be conducted in any other way.

'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 applicants advised that they did not have a platform at Barts Health Trust to facilitate patient notification and dissent. The applicants had discussed hosting information on the websites for Aortic Dissection Awareness UK (ADUK) and Marfan's Foundation. ADUK have agreed to host information and a reply is awaited from the Marfan's Foundation. The applicants are working with ADUK to develop a poster.

The applicants advised that NHS Digital will apply the National Data Opt-Out. NICOR will also be asked to check for any record of dissent.

The applicants noted that the study is a retrospective study and patients may no longer be active patients. The applicants were therefore unsure how useful a communications strategy and dissent mechanism would be. NHS Digital would apply the National Data Opt-Out and NICOR has a dissent mechanism.

The CAG noted this information and agreed that further steps need to be undertaken to promote the study. Members suggested that information was included on relevant websites, such as support organisation or charities related to Aortic Dissection and MFS. The CAG also suggested that posters were displayed in relevant treatment areas, however it was noted that this may not be feasible. The notification needed to include information on how patients can dissent to the inclusion of their data in this specific study, rather than opting-out via NICOR or the National Data Opt-Out, which would require patients to opt-out of other research projects.

The patient notification materials, including those being developed with ADUK, need to be provided for review.

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 Aortic Dissection Awareness UK are collaborators on the project. They have been involved in the design of the study and provided insights on the significance of the study and the acceptability of the use of confidential patient information without consent. They will also be involved in developing the patient and public dissemination strategy.

The applicants also conducted a survey with their local PPI group at Barts Heart Centre. These patients had previously undergone cardiac surgery. They also provided views on the use of confidential patient information without consent and were supportive.

The applicants provided further details on the feedback received, noting that 93% (14 of the 15 respondents) were in favour of using confidential patient information without consent. The person who was not in favour did not provide any details on why they did not agree.

The CAG agreed that further patient and public involvement should be carried out. This should include review of the patient notification documents and ways patients can dissent. Members also suggested that patients with MFS were included in the patient and public involvement.

Exit strategy

The disclosure from NHS Digital to Barts Health and NICOR will be undertaken on a one-off basis. The data linkage process is anticipated to take a maximum of three months, time from the receipt of data from NICOR.

The confidential patient information will be deleted at Barts Health Trust and NICOR immediately after the data linkage has taken place. The CAG raised no queries in this area.

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. Ways of minimising the flows of confidential patient information need to be explored with NHS Digital.

2. Further steps need to be taken to promote the study:

    a. Information about the study needs to be included on relevant websites.

    b. The feasibility of displaying posters in relevant treatment areas should be explored.

    c. The patient notification materials, including those being developed with ADUK, need to be provided for review.

    d. The notification needs to include information on how patients can dissent to the inclusion of their data in this specific study.

    e. The patient notification materials, including those being developed with ADUK, need to be provided for review.

3. Further patient and public involvement needs to be carried out, covering the below areas;

    a. The patient notification documents need to be reviewed.

    b. As study-specific dissent mechanism needs to be created and feedback sought.

c. Patients with MFS need to be included in the patient and public involvement.

5. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Minutes signed off as accurate by Vice Chair Dr Patrick Coyle and Alternate Vice Chair Dr Will Bernal	12/10/2021
Signed – Confidentiality Advice Team *KM Cassidy*	Date 12/10/2021