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

12 February 2021

Present:

Name	Capacity	Items
Dr Murat Soncul	CAG Alternative Vice Chair	1a, 1b, 1c, 1d
Dr Rachel Knowles	CAG Member	1a, 1c, 1d
Prof Jennifer Kurinczuk	CAG Member	1a, 1b, 1d
Mr Marc Taylor	CAG Member	1b, 1c

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 21/CAG/0025 - Retrospective Review of the Use of Simplex High Viscosity Bone Cement for Joint Arthroplasty

Context

Purpose of application

This application from Royal Devon & Exeter NHS Foundation Trust set out the purpose of medical research which aims to evaluate the success rate of cemented Triathlon Total Knee Replacement surgery with fixation of components implanted using Simplex high viscosity bone cement (Simplex HV). Success is defined as absence of revision due to aseptic loosening in cemented Triathlon Total Knee components implanted with Simplex HV, at two years post initial surgery. This application is only for a retrospective, consecutive series, evaluation of medical records of patients who have undergone total knee replacement (TKR) at Royal Devon & Exeter NHS Foundation Trust. The study is sponsored by Stryker, and the anonymised dataset will be sent to Stryker for analysis, however this flow of data, and any other participating sites are not in scope for this application.

Nearly 100,000 primary TKR surgeries are performed per year in the UK. There has been concern that high viscosity (HV) cement could cause early loosening of the components in some patients. However, HV cement has advantages over low viscosity cement, including allowing more time to work with the cement during the handling and setting phases of surgery, which has potential to allow for greater operational/surgical efficiency. There is therefore a need to demonstrate the safety of HV cement used in TKR, as measured by the absence of loosening at two years after surgery.

As a part of routine care, Royal Devon & Exeter NHS Foundation Trust already keeps a clinical database of patients who have undergone TKR. The Chief Investigator (CI), who is part of the direct care team, will identify potential study cases from this database, therefore this element does not require support. The CI will then inform medical student researchers of eligible patients by disclosing confidential patient information. The subsequent extraction of the data for those meeting the inclusion criteria will be undertaken by medical student researchers; this element requires support under Regulation 5, as data extraction will be performed by members of staff who are not part of the direct care team, by searching the patient administration system, paper and electronic medical records and radiology systems. Name, date of birth, and hospital number will be used to ensure the information extracted is for the correct patient. The researchers will complete the paper case report forms, which are then pseudonymised by the CI with patient

code (randomly allocated starting AA etc – this is not related to the patients initials), centre number and subject number. These paper based forms are then disclosed to Stryker by entering into an electronic database, and then Stryker send to their statistician in the US for analysis. This disclosure can be considered anonymous and does not require support. A log linking the study number, and patient code attributed to each patient to their confidential patient information will be kept by the CI only until 6-12 months after the results are published (estimated date February 2023). The CI is a member of the direct care team, and therefore support not required for this.

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

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	100 Patients aged 18-100 years who have undergone total knee replacement as the treatment for end stage osteoarthritis of the knee in 2014-15. All will have had had anti-biotic loaded HV cement
Data sources	The hospital patient administration, paper and electronic medical records and radiology systems at Royal Devon & Exeter NHS Foundation Trust. Data collected as part of routine care
Identifiers required for the purposes of data extraction	1. Name 2. Date of Birth 3. Hospital number
Identifiers required for analysis purposes	1. Patient code (randomly allocated AA etc as described in application) 2. Centre # 3. Subject # 4. Age 5. Gender

	6. Diagnosis (This can be considered anonymous as Stryker will not be able to re-identify)
Additional information	The CI retains the key between the patient code, centre #, subject # and the identifiers, until after publication of results, in case the study team find unexpected and unreported adverse events.

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 that this research 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 applicants provide multiple justifications for not consenting this retrospective cohort; it would be logistically difficult for a clinical unit without the time or resources, as many of the patients will be elderly (average age of TKR is 69), some may have moved away from the address currently registered, and some may have passed away or be frail or ill with other conditions. Contacting them may induce distress or anxiety in either in the patients or their relatives that there may be a problem with their TKR. In addition, applicants are trying to keep patients away from unnecessary hospital visits due to COVID-19. The Sub-Committee were satisfied with these persuasive justifications.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to collect accurate data from medical records for the correct patients, before pseudonymising the dataset at the earliest opportunity. The format of the dataset disclosed on to Stryker can be considered anonymous. The members were content that this could not be performed in a manner that was less disclosive.

'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.

A patient notification leaflet has been provided, which would be displayed on the Trust website. It has an opt out option to contact the CI, however this is only via email. Additionally if there is any record on the patient's medical notes, that they do not wish their data to be used for research purposes, the applicants will respect this and exclude their data from the study. In answer to queries the applicants have stated they will not be applying the national data opt out.

The members considered the notification and opt out option provided to be broadly acceptable, however there is only an email address provided as a means of contact. Generally it is accepted that a telephone number and address should also be provided.

The Sub-Committee considered the response of the applicant regarding not applying the national data opt out. Although it is not yet a requirement for Trusts to have implemented this,

it likely will be enforced within the 2 year support period. Therefore the CAG felt that when the national data opt out is made mandatory for Trusts then the applicants will have to apply it from that point forward, as a condition of support.

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 have undertaken PPI with a group of 11 patients from a patient research panel, via email. They have specifically asked about the use of confidential patient information without consent, and explained that CAG support is required because it will not be the direct care team. The patients were supportive of this study, and had no issues regarding confidentiality.

The members were impressed with the very good Patient and Public Involvement undertaken with an engaged patient panel, as the full reasons for not seeking consent were explored, and it was confirmed that the proposal to seek Regulation 5 support is acceptable.

Exit strategy

Identifiers are retained until six to twelve months after publication (as key is held by CI) however, this does not require support as retained by direct care team. The exit strategy for this application is the time point at which the researchers are able to transfer the data from medical records to the case report form, which will not contain any identifiers. The timescale for this is estimated at two years, therefore support will be required until early 2023.

The Sub-Committee were content with the proposed exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required

prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

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

Request for further information

1. Please provide alternatives to email contact, such as postal address and phone number as a mechanism for patients to object, and provide an updated patient notification within one month from the date of this letter.

2. Please provide evidence of NHS Digital confirming 'Standards met' for the 19/20 DSPT review for Royal Devon & Exeter NHS Foundation Trust, see standard conditions of support below.

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

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. It is a condition of support that the applicant comply with the national data opt out once this is mandated for NHS Trusts.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 09 February 2021**

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.

Pending: The NHS Digital **19/20** DSPT review for **Royal Devon & Exeter NHS Foundation Trust** was pending on the NHS Digital DSPT Tracker (checked 25 February 2021)

b. 21/CAG/0026 - High intensity treatment at the end of life in children with cancer: retrospective, national,data linkage study

Context

Purpose of application

This application from the University of York set out the purpose of medical research that seeks to determine whether the use of high intensity treatment at the end of life for children, teenagers and young adults with cancer, varies depending on the model of end of life care available.

Approximately 4,500 babies, children and teenagers in England and Wales require end of life care each year. The provision of this care varies across the country and little is currently known about how this variation impacts on children and their families. This project in comprised of three studies. The first study is a survey, conducted with relevant cancer services and other wards to provide specialist care to children, to identify the different models of providing care to patients aged 0-18 within England and Wales. The second study will involve interviews with bereaved parents about their experience of their child's end of life care. These two studies are outside the scope of support sought.

The third study will investigate the impacts of the different models of end of life care on children and their families. The findings from study 2 will help the applicants to decide which outcomes to measure, but they are likely to include quality of care at the end of life, place of death, whether care is planned and the treatments given at the end of life. Information will be collected from the medical records of approximately 4000 children treated in cancer services. Information from around 800 bereaved parents, whose child received care in neonatal or paediatric units, will also be collected.

The applicants are seeking support for the transfer of confidential patient information from PICANet and ICNARC to Public Health England. Public Health England will link the individual level data with cancer registry, death certificate data, treatment information and hospital episodes data. Public Health England will then transfer a pseudonymised dataset to the research team at the University of York.

A recommendation for class 1, 2, 4, 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	Any child, teenager of young adult (0-24 years) with a diagnoses of cancer who died between 01/01/2012 and 31/12/2020 in England and Wales. 4000 patients will be included.
Data sources	1. PICANet (held by the University of Leeds) 2. ICNARC 3. National Cancer and Registration System (NCRAS), ONS death certificate data, treatment information and hospital episodes datasets held by Public Health England
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Date of death 5. Postcode – unit level
Identifiers required for analysis purposes	1. Lower super output area 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 agreed that the application was in the public interest and had a clear medical purpose.

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**

This is a retrospective review of records belonging to patients who died between 2012 and 2020. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link data across ICNARC, PICANet and the PHE held datasets. A pseudonymised dataset will be provided to the applicants. The CAG agreed that the linkage could not be undertaken 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.

A study specific opt-out will be advertised via PHE, the University of York, and the Children's Cancer and Leukaemia Group (CCLG) websites for 6 weeks prior to data extraction, directing the parents to contact PHE with any request to opt-out.

The applicant advised that existing opt-out notifications on the PHE datasets, HES datasets, PICANet and ICNARC datasets will be respected. A study specific opt-out will be advertised via PHE, the University of York, and the Children's Cancer and Leukaemia Group (CCLG) websites for 6 weeks prior to data extraction, directing the parents to contact PHE with any request to opt-out.

The Lay Summary, which has been reviewed by patient and public involvement representatives, was provided for review. This will also be used as the website text.

The CAG reviewed the Lay Summary. The Lay Summary was long and members asked that the language was revised to be simpler and more direct.

Further information on who Public Health England are and their role in the application needed to be given. Members suggested that a link to an appropriate part of the PHE website, which explains why PHE hold data and how they preserve confidentiality, was provided. Members also suggested that links to the PICANet and ICNARC websites were also provided.

The CAG agreed that telephone, postal and email contacts needed to be provided for patients to register dissent. Further details also needed to be provided on how patients would find their way to the contact details to register dissent, as members noted that it was not easy to navigate to the correct section of CCLG pages on the University of York website.

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 research proposal was discussed at the Childhood Cancer Conference in June 2018 and by the Martin House Research Centre Family Advisory Board. Feedback was that research into end of life care was important.

The patient and public involvement programme was designed with reference to the NIHR INVOLVE National Standards for Public Information. A parent representative was a co-applicant on the application. They reviewed the Plain English summary, and will attend management team meetings and work alongside the other patient and public representatives. A parent advisory panel will be established. They will review the three outcome measures proposed for inclusion in study 3 to check with parents as to which ones include the dimensions most relevant to them. They will also assist with the interpretation and integration of findings.

The specific issue of the use of confidential patient information without consent was discussed with four bereaved parents of children who had cancer, selected from the Martin House Research Centre Family Advisory Board and PORT (Paediatric Oncology Reference Team). These parents were all supportive of the use of their child's data without consent for linkage of these datasets. The CAG agreed that the patient and public involvement carried out was good and 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. The patient notification materials need to be revised as follows:

    a. The language in the Lay Summary needs to be simpler and more direct.
    b. The notification webpage needs to direct patients to information on how to dissent.
    c. A description of Public Health England, including a link to their website, needs to be included in the Lay Summary.
    d. The applicants are to consider including links to the ICNARC and PICANet websites in the Lay Summary.

2. Further details need to be provided on how patients can navigate to the right section of the CCLG pages on the University of York website to access the information on how to opt-out.

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

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 18 January 2021**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

    Confirmed: The NHS Digital 2019/20 DSPT reviews for ICNARC and Public Health England were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (by check of the NHS Digital DSPT Tracker on 23 February 2021)

    Pending: The NHS Digital 2019/20 DSPT reviews for University of York (Department of Health Sciences) and PICANet (University of Leeds) have not been confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (by check of the NHS Digital DSPT Tracker on 23 February 2021)

c. 21/CAG/0029 - BOSU Study on Newly Presenting Visual Loss Secondary to myopic maculopathy

Context

Purpose of application

This application from South Tyneside and Sunderland NHS Foundation Trust set out the purpose of medical research which aims to describe the incidence of patients newly presenting with visual loss secondary to myopic maculopathy in the UK, over a one-year surveillance programme operating via the British Ophthalmological Surveillance Unit (BOSU) methodology, using the monthly reporting card amongst UK ophthalmologists. This is a replacement of a previous application (19/CAG/0133), which was given a provisional outcome in 2019. There are no changes to the study design, however the applicant was required to resubmit as the application had been withdrawn due to the time elapsed.

Pathological myopia describes a series of degenerative disease processes that can result in severe loss of visual function. A recent Biobank study showed 4% of the population are highly myopic and that this is increasing, being more common amongst younger people. Previous studies that have estimated the UK incidence of sight loss secondary to pathological myopia has been extrapolated from large scale epidemiological studies performed in other countries, however little is known of the UK data.

The BOSU methodology is established and has received support in principle from the CAG. Ophthalmologists will indicate that they have seen a new patient who has experienced visual loss from myopic maculopathy through the BOSU reporting system. The BOSU collects no patient identifying information but will notify the study investigator of all ophthalmologists who report new cases. The researcher will then contact the reporting ophthalmologist directly and will send a questionnaire requesting information to determine the incidence. Follow-up will be conducted at six-months following initial reporting.

Each case will be given a unique study number by the BOSU study centre. Hospital number, year of birth, gender, and ethnicity will be recorded alongside clinical data on paper questionnaires. These will be sent to the Sunderland Eye Infirmary, and all paper forms will be stored in a locked cabinet. All identifying data will be stored electronically and separated from

the clinical dataset, linked only by the unique study number. All identifies will be deleted once the follow-up is completed and duplicates identified.

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

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	Approximately 254 patients who have experienced visual loss from myopic maculopathy Patients with high myopia (-6.00DS or worse) presenting with new vision loss to a level of 6/18 (logMAR 0.50, 60 ETDRS letters) or worse in their better eye, secondary to myopic maculopathy who report to a treating ophthalmologist across the 12 months reporting period, expected to be between June 2021 to June 2022.
Data sources	1. Clinical records at the Trusts of BOSU reporting ophthalmologists
Identifiers required for linkage purposes	1. Hospital number (identify duplicates and identify same patient for follow up) 2. unique study number
Identifiers required for analysis purposes	1. Year of birth 2. Gender 3. Ethnicity 4. unique study number
Additional information	1 year of baseline collection (June 2021 to June 2022) and then additional 6 month follow up until December 2022.

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.

It was commented that there is a small sample size, however the applicants are undertaking a descriptive analysis of a rare condition, and the Members agreed that this research is in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

The applicants reason that due to the rarity of the condition, complete case ascertainment is required to inform prevalence. A previous study carried out on the basis of consent demonstrated the introduction of bias.

The CAG accepted the justification provided for not seeking consent.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for identifying duplications, identification of correct patient and linkage with follow-up records. The applicants are collecting the minimum amount

of data required to probability match reports to identify duplicates. The applicant is using the standardised BOSU methodology to ensure that the use of identifiers is minimised as much as possible.

The CAG agreed there was no practicable alternative that could be any less disclosive.

'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.

A standard BOSU patient information leaflet and poster have been provided for review. The BOSU information sheet is placed on the BOSU website, and in all Eye Departments Outpatient units. The study will also be publicised in professional meetings (RCOphth Annual Congress) as well as patient magazines including Macula Society magazine. Both the poster and the information sheet will be made available in Hospital Eye Units to inform patients of the study.

Both the information sheet and poster include a study specific opt out mechanism. Patients can inform their doctor they wish to opt out, and the applicant has confirmed that the national data opt out will apply.

The CAG were content with the patient notification materials and proposed dissent mechanism.

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.

It is known that there is lay representation as part of the BOSU review process. Feedback from a 'PRA' group has been provided as part of the application in the form of a summary of a meeting which took place in February 2020, in Sunderland Royal Hospital, in collaboration with the Research and Development team. Five members of the group were invited to attend. Additionally the CI has conducted consultations with patients attending his medical retina clinic in February 2021, and explained the project and its methodology.

None of the patients raised any objections or queries regarding the use of confidential patient information without consent. As representatives of the relevant patient cohort, they were happy to support the project.

The Sub-committee were content with the patient and public involvement undertaken.

Exit strategy

The applicants have proposed a study timeline of June 2021 to June 2022, with a six month follow up to December 2022. The exit strategy for support required is when hospital number is deleted – this is planned for six to twelve months after study ends. Therefore support is requested until December 2023. The CAG felt this exit strategy seemed reasonable.

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 30 September 2019**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed**

The NHS Digital **19/20** DSPT review for **South Tyneside and Sunderland NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 25 February 2021).

The study includes 5+ reporting ophthalmologists – security assurances will not be checked by the Confidentiality Advice Team (CAT) team for all participating sites. Support is recommended on the basis that the applicant is responsible for seeking assurance that the appropriate security arrangements are in place.

d. 21/CAG/0030 - Experiences of gestational trophoblastic disease: reconciling cancer, pregnancy and loss

Context

Purpose of application

This application from The University of Sheffield set out the purpose of medical research which aims to undertake observations of Multi-Disciplinary Team meetings (MDTs) and pathology laboratories, and interviews with staff and patients in order to understand their experiences of gestational trophoblastic disease (GTD). The study is funded by the Wellcome Trust. This study will primarily be based at the GTD specialist centre at Weston Park Hospital, Sheffield, and will also involve participation from the GTD screening centre in Dundee, which is out of scope for CAG support.

Gestational trophoblastic disease (GTD) is a rare condition that can arise following conception, causing abnormal cells to develop within the womb. Some forms of GTD can become cancerous, with these termed gestational trophoblastic neoplasia (GTN). GTD and GTN are umbrella terms for a number of individual diseases, which together have an incidence in the UK of approximately 1 in 714 live births. GTD can mean that though a woman may receive a positive test and experience pregnancy symptoms, she might not be carrying a baby. Some women require chemotherapy, and all must have their hormone levels monitored for a specific amount of time. Research has shown evidence of impacts on health-related quality of life, including physical effects of chemotherapy, fear and anxiety surrounding recurrence, death, and future fertility. However, experiences of GTD are poorly understood. Qualitative sociological perspectives on GTD/GTN are important, as they help to make sense of the wider factors shaping women's experiences of the condition, and clinical approaches to managing the disease. Improved understanding of these factors can inform patient support, and interactions between health professionals and patents, ensuring these are sensitive to

patient experience of this rare and complex condition. This study will improve understanding of patients experiences of GTD, raise awareness of the condition, and it is hoped that the research will feed into GTD practice and care.

Observations will be made of staff, both in pathology laboratories and MDTs in the GTD specialist centre, which is part of Sheffield Teaching Hospitals NHS Foundation Trust. Interviews will be undertaken with staff and consented patients. The MDT and lab observations will not be audio recorded, and the researcher will not record any confidential patient information in field notes. The researcher will observe by encrypted video link, if it is not possible to attend in person due to the pandemic. Interviews are planned to take place face-to-face, at a time and location convenient to participants. However, should 'lockdown' COVID-19 restrictions be in force, these interviews will take place via telephone or via encrypted video. The interviews will be audio-recorded and then transcribed and anonymised, however if incidental disclosure takes place, this will be 'bleeped out', to ensure no confidential patient information without consent is sent to the transcription company. The study is expected to consist of approximately 20 MDT observation sessions, 10 observations in pathology settings, 20 staff interviews and 20 patient interviews over a period of thirty-one months, and a total of around 60 participants are expected to be observed and interviewed.

All observations of MDTs and pathology settings, and interviews with patients and staff will be undertaken with informed consent, however it is possible that the researcher may be incidentally exposed to confidential patient information. Support under the regulations is required in case of accidental disclosure of confidential patient information regarding a non-consented patient during either observations or interviews with staff and consented patients. The researchers have put in a number of safeguards to protect patient confidentiality including consent where possible, ceasing observations when requested, and reminding all staff participants to respect patient confidentiality during interviews. However the potential incidental disclosure that is likely during MDT and pathology laboratory observations are regarding patients other than those who have been consented, and so Regulation 5 support is required as it is not possible for the researcher to predict these disclosures in advance of observations.

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	Applicants will observe and interview approximately 60 participants, made up of patients over the age of 18 diagnosed with gestational trophoblastic disease (GTD), and staff involved in diagnosis, treatment and care of GTD. However these will be consented observations/interviews, and are out of scope for CAG support. Support for CAG purposes is provided regarding any patient whose confidential patient information may be incidentally disclosed without consent whilst these observations and interviews are taking place.
Data sources	Interviews and observations carried out in the participating NHS Trust: 1. Sheffield Teaching Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information will be collected for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be collected 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 members agreed that the research appeared to be in the public interest.

Scope

During the review the members were not clear regarding the scope of support required under Regulation 5, as they felt that if patients were being consented, then the potential for incidental disclosure could be explained to them at the time of consent. However, on querying this with the applicant, it was confirmed that the patients whose confidential patient information may be inadvertently viewed by the researcher during MDT and pathology laboratory observations were a different subset of patients to those who were consented. The applicant advised it was not practicable to identify and consent those patients for incidental disclosure of confidential patient information, as it was not possible to predict what the disclosures would be, and the CAG accepted this response, and were content to support the application.

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**

Staff and patient participants will be consented for interviews. Staff in MDTs and pathology laboratories will be consented for observations. It is not possible to consent for the incidental disclosure of CPI as it is not possible to accurately predict what the exposure might be. For example, prior to the observation it will not be clear to the researcher which patients will be discussed during the MDT, or which samples will be observed during pathology examinations. Gaining this information, and contact details for permission, would in itself require the researcher to access patient information.

The Sub-Committee accepted this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is not required for the purpose of the study, but researchers may be exposed to confidential patient information incidentally while observing MDTs and pathology labs and interviewing consented clinical staff, and consented patients. No items of confidential patient information will be collected or recorded by the researchers, without

written consent. If incidental disclosure takes place during a recorded interview, the audio recording will be anonymised by beeping out any confidential patient information recorded without consent before sending to the transcription company.

Potential disclosures are minimal and all efforts have been made to ensure that staff are sufficiently aware of the observer to reduce the likelihood of inadvertent disclosure.

The Group accepted that it is not possible to anonymise or pseudonymise all data that could be disclosed incidentally.

'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.

Healthcare professionals will be identified by key gatekeepers at the Trust. Staff participants will provide consent before any observations or interviews are undertaken.

Direct care team staff will identify patients they encounter in their routine practice who may be suitable for an interview, and consent is sought from the patient in order for the researcher to make contact, via the 'consent to contact' form. The patient will then be contacted by the researcher and consented before an interview. A GDPR statement will also be provided to all participants.

A Poster has been provided to display in the clinical areas where MDT observations will take place - Including an opt out option. This is to try to inform the relevant population regarding the potential for incidental disclosures. It is not possible to apply the national data opt out.

The Members were content with these notification materials.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicant has provided a summary of the research protocol, outlining the proposed observations and describing the potential for incidental disclosure to three patients. They were satisfied with the approach and did not raise concerns about observations of MDT meetings of pathology settings. The applicant also contacted a former patient contact, to request their thoughts specifically on the possibility of incidentally observing patient records without the patients' consent. The email response form the patient is strongly in favour of the research.

Although the Patient and Public Involvement is limited, the Members felt it is favourable and proportionate to the study and level of disclosure.

Exit strategy

The observations will be undertaken between 1 March 2021 and 30 September 2023, and the study is expected to consist of approximately 20 observations of MDTs, 10 observations of pathology labs, 20 staff interviews, and 20 patient interviews over a period of thirty-one months at which timepoint support under the Regulations will no longer be required, as observations and interviews will have completed. No items of confidential patient information will be collected or recorded by the researchers, without consent

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 16 February 2021**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **19/20** DSPT review for **Sheffield Teaching Hospitals NHS Foundation Trust** was confirmed as '**Standards met'** by email from NHS Digital to the CAG inbox (on 26 February 2021)

Signed – Officers of CAG	Date
Signed – Confidentiality Advice Team	Date