

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

May 2020

1. New applications

- a. **20/CAG/0050 – What is the prevalence of distal surface caries (DSC) in the lower second molar when screening patients with bitewing radiographs: A multi-centre study**

Name	Notes
Ms Clare Sanderson	CAG Alternative Vice-Chair
Dr Murat Soncul	CAG Alternative Vice-Chair
Dr Liliane Field	CAG Member
Ms Diana Robbins	CAG Member
Dr Paul Mills	Senior Confidentiality Advisor

Context

Purpose of application

This application from the University of Manchester sets out the purpose of medical research which aims to investigate the prevalence of distal surface caries (DSC) in the second mandibular molar adjacent to an impacted wisdom tooth.

In the UK, clinical guidelines state that impacted wisdom teeth should be left in place unless strict criteria are met. As a result, some clinicians feel that there is an increasing incidence of caries that develops in both teeth. Evidence suggests a high reported prevalence of distal surface caries (DSC) in second mandibular molars. But this prevalence may be high because it represents a population of referred hospital patients and does not relate to the prevalence in the general population. The wisdom tooth guidelines in the USA and Brazil recommend early removal of wisdom teeth with an emphasis on prevention unlike the UK.

This study proposes to investigate the prevalence of distal surface caries (DSC) in the second mandibular molar adjacent to an impacted wisdom tooth by examining existing radiographs of patients who attended the Manchester Dental Hospital for routine dental examination. The researcher will access the Trust Picture Archiving and Communication System (PACS) and review radiographs of 1012 consecutive patients meeting the inclusion/exclusion criteria. The hospital ID will also be provided to the student supervisor and head of the radiology department to also review the radiographs to ensure the findings are accurately recorded.

In addition, the study is working with centres in Brazil and the USA to compare the prevalence of DSC in the UK vs US and Brazil, due to differing guidelines.

A recommendation for class 1 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	1012 consecutive patients meeting the inclusion/exclusion criteria between 01/01/2009 – 31/12/2019.
Data sources	1. Manchester University NHS Foundation Trust (Manchester Dental Hospital)
Identifiers required for linkage purposes	1. Hospital ID
Identifiers required for analysis purposes	1. Postcode (to calculate deprivation scores on site)

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

- 1. Clarify the exact role of the student supervisor and head of the radiology department, and whether they have a legal basis to access identifiable information without consent. Please clarify if support should be extended to cover the activities of these people.**

The applicant provided email confirmation from the student supervisor and head of the radiology department that they already have a legal basis to access the confidential patient information requested.

Members were largely content with this but wished to confirm in this letter that s251 support does not extend to the student supervisor and head of the radiology department activities, and it is the Trust responsibility to prove a legal basis is challenged.

2. Provide clarity on the proposed patient notification approach, as well as providing the materials to be used. Any patient notification must include detail on an opt out process.

The applicant provided an updated poster which was further commented on by members. A final version (version 3) was agreed upon with members, who were content for its use.

3. Provide clarity on the lower age limit of participants.

The applicant clarified that the lower age limit of participants is 18 years, which the sub-committee were content with.

4. Confirm whether any further Patient and Public Involvement and Engagement is planned. If not, provide a justification.

The applicant clarified that they had sought further Patient and Public Involvement and Engagement from numerous sources, but due to the ongoing COVID-19 pandemic all groups were either not responding or were unable to help.

Members considered this response, mindful of the ongoing situation. They were somewhat content with the response, but only agreed to no further Patient and Public Involvement and Engagement due to the ongoing pandemic and wished to remind the applicant of the importance of Patient and Public Involvement and Engagement for future research.

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 REC **Confirmed 30 January 2020**
2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **University of Manchester (email received from NHS Digital) and Manchester University NHS Foundation Trust (email received from NHS Digital 21 April 2020) have been confirmed as 'Standards Met' by NHS Digital.**

b. 20/CAG/0067 – Learning Disability Mortality Review (LeDeR) programme

Name	Notes
Paul Mills	Senior Confidentiality Advisor
Natasha Dunkley	Head of Confidentiality Service

Amendment scope

1. This submitted information represented a new application from NHS England in relation to an existing activity under application reference 16/CAG/0056. As a result of a change in the commissioning of the programme the primary change is that of controller, from HQIP to NHS England. The intention is to replace 16/CAG/0056 with this new application once support is in place
2. While not flagged at time of submission, the Advice Team identified that there is also a change to the processors, with an addition of a new processor: South Central and West Commissioning Support Unit (CSU). It has been confirmed that NHS Digital has satisfactorily reviewed their DSPT submission (checked 04 May 2020).

Excluded from current amendment request

1. There was a specific request to waive the requirement for relevant bodies to respect the National Data Opt Out, once this is in force (currently extended to September 2020 implementation). However, this would represent a significant change and cannot be processed at time of processing this change. The reason for this is that this amendment has been submitted as an administrative change (change of controller and processor), however waiver of the National Data Opt Out would represent a significant change requiring detailed justification. To progress that element, and to avoid delay to processing of the current changes, please submit a detailed amendment setting out the reason for change, providing relevant evidence to support the case. That element will be considered at a full CAG meeting so please note the relevant submission dates published on the website. We advise that you make contact with Natasha Dunkley prior to submitting this amendment to talk through the type of information that would be needed.
2. The new application mentions (in section 1j) that “*NHS numbers and dates of birth to share with the national Cancer Registry....*”. However, no mention of this data flow to Public Health England can be found in the original application, nor any subsequent amendments. As this represents a new data flow, it is outside the current scope of support. Please submit a separate amendment which should include details of this data flow to PHE, specific confirmation of the identifiers sent, and the information received back, and the justification for it in the context of this application. Please also provide with the amendment an updated data flow diagram to reflect this data flow.
3. The new application makes reference to three other CSUs (Arden and Greater East Midlands CSU, Midlands and Lancashire CSU and North East London CSU) potentially undertaking data processing in the future. Please note these are currently excluded as the application made clear these are not currently in place to undertake processing. When these entities are ready, please submit an amendment, including evidence of satisfactory DSPT review by NHS Digital, and these will be processed at that time.
4. Note that support covers the specified confidential patient information only. It is noted that other relevant information will be obtained in relation to next of kin or

relatives. Please note these are third parties, not necessarily patients and are typically not within scope of support.

5. Members noted that although the application states that South Central and West Commissioning CSU was undertaking processing there was no record of their being covered by the original support. As such, it is highlighted that any processing undertaken by this CSU from start until date of this letter, has not been covered by support and a different legal basis needs to be identified to legitimise that processing prior to this letter in terms of avoidance of a breach of the common law duty of confidence.

Confidentiality Advice Team advice conclusion

It was noted that no other changes to people, purposes, data and flows were flagged to the CAG by the applicant. It was noted that this was largely the case, however, some inconsistencies were identified, as set out in the exclusions and conditions of support sections.

The Confidentiality Advice Team therefore recommended to the Secretary of State for Health and Social Care that the activity be conditionally supported, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support. Please provide a response to points 1 and 2 **within 5 working days**.

1. The legal status of the controller. Our understanding is that the controller is NHS England until evidenced otherwise. However, we are aware there are steps to become the entity NHS England and Improvement. In terms of clarifying the correct legal status so support can be given to entities that exist, please confirm the current legal name of the data controller.

2. We would welcome clarity on the data flows surrounding linking in to other existing reviews. It is noted the LeDeR Process Flowchart (V4.1), submitted with the current application, refers to the local reviewer checking to see if the individual is subject to any other existing review process and, if so, they will link into this existing review. This data flow (which presumably involves the use of confidential patient information) is not apparent in the initial 16/CAG/0056 application. It was present in the flowchart submitted with an amendment in September 2019, but no mention of this was made as part of the amendment. Please clarify this data flow and the processors involved.

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. **NHS England (Controller), University of Bristol (Processor), North of England CSU (Processor), South Central and West Commissioning Support Unit (Processor). Confirmed via DSPT tracker, checked 04 May 2020.**

2. New amendments

a. 16/CAG/0153 – UK Renal Registry

Amendment request

The UK Renal Registry are seeking support to capture data on how COVID-19 infections impact on the health treatments and outcomes of patients with kidney disease. This data will be used to create timely audit reports to support the work already undertaken by the Renal Association and the UK Renal Registry (UKRR), and to provide renal centres, renal regional working structures, commissioners and NHS England with high quality data to assist in more effective handling of the COVID-19 pandemic.

The applicants plan to expand the cohort of patients that the UKRR collects data for to include patients diagnosed with Chronic Kidney Disease (CKD) Stage 1. The data flow will also be revised to enable the real time data collected by the Renal Association from renal centres to be processed for audit purposes. These real time flows would be

used to support Patientview, an online portal where patients can view test results and manage medication, and the National Registry of Rare Kidney Diseases.

The applicants also seek to increase the frequency of its existing linkages with Public Health England from an annual linkage to monthly, or more frequently should this be sustainable. The linkage will also be explained to include reported cases of Covid-19, alongside the data collected on other Health Associated Infections (HCAIs). No additional identifiers will be required for this linkage.

The UKRR also seek to establish a linkage with the Intensive Care National Audit and Research Centre (ICNARC), to allow the UKRR to understand how many renal patients were admitted to intensive care as a result of Covid-19 and the length of their stay. To link the data, the UKRR and ICNARC will use an agreed hashing protocol on the identifiers of their respective datasets. The UKRR will send the hashed identifiers for its patients to ICNARC who will match against the hashed IDs for their dataset, returning data for those patients who match.

The UKRR will also collaborate with the Getting It Right First Time (GIRFT) program, supported by NHS England and NHS Improvement to analyse the Covid1-9 data in a timely manner and in a way that can be meaningful and actionable for renal centres. This collaboration will be subject to a data sharing agreement.

The applicants also seek support to collect additional data from the renal centres, to support regional efforts to manage cases of Covid-19 while continuing to deliver renal services. The UKRR will request that renal centres report positive cases of Covid-19 via NHS.net, providing the registry with patient identifiers, and the date of the positive test. The UKRR will then aggregate this data and feed the number of cases back to renal centres to allow them to work together to manage resources across a region.

In making the above changes, the applicants hope to assess the impact of the pandemic on renal centres, who have to contend with the needs of their patients' regular dialysis appointments and limiting the spread of the virus amongst a population that are at a higher risk of developing severe symptoms. In particular, as staff resources provide regular lifesaving dialysis care in centres become more and stretched it is essential for regions to be able to plan and allocate staff resources, transport and dialysis facilities. Having regional understanding of the epidemic will help

to isolate infected dialysis patients to dedicated facilities. Developing understanding of risk factors for COVID related mortality in dialysis patients will be required, should clinicians need to triage patients according to chances of survival. This type of understanding can also assist with advance care decision making, if patients prefer to opt to maximum conservative care and not come to a high risk setting for dialysis.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group agreed that there was a clear medical purpose in expanding the cohort to include those with Stage 1 CKD. Increasing the frequency of data collected and uploaded to patient facing websites, and linkage to the ICNARC database, will help to develop understanding of the effects of Covid-19 on patients with renal disease.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

1. Confirmation of suitable security arrangements via Data Security and Protection Toolkit submission. **(Confirmed – the Renal Association has a confirmed ‘Standards Met’ grade on DSPT submission 2018/19 by NHS Digital email dated 14 October 2019).**

b. CAG 8-03 (PR11)/2013

Notified 12 May 2020 that an additional question will be added to the dataset that will ask about the COVID-status of patients submitted to the database. The relevant cohort of patients will not change.