Health Research Authority

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10 May 2018

Mr. Mike Reed
Consultant Orthopaedic Surgeon
Northumbria Healthcare NHS Trust
NE63 9JJ

Dear Mr. Reed

Application title: **National Bone and Joint Infection Registry**
CAG reference: **18/CAG/0064**

Thank you for your non-research application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Secretary of State (SofS) for Health and Social Care on whether an application should be approved, and if so, any relevant conditions. This application was considered at the CAG meeting held in correspondence.

Secretary of State for Health and Social Care Approval Decision

The Secretary of State for Health and Social Care, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is conditionally approved, subject to compliance with the standard and specific conditions of approval outlined below.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

This outcome should be read in conjunction with the previously issued letter of 10 October 2017.

Context

Purpose of Application

This application from the Northumbria Healthcare NHS Foundation Trust sets out the purpose the development and establishment of a national registry for Bone and Joint Infections in the United Kingdom, which is intended to be used for audit and service evaluation. Bone and joint infections are a significant cause of morbidity and mortality that affect patients of all ages. Understanding current standards for care and effectiveness of interventions and care pathways is a major challenge for surgeons, physicians, microbiologists and patients. This project seeks to capture data about affected patients and the care they receive for these debilitating and often fatal conditions. Linkage with the HES dataset is proposed via NHS Digital; however, this element is outside of the CAG's remit as patients will be asked to consent to this element. This will enable robust understanding of the current care pathways, insight into which treatments are most effective and comparisons between different units of the patient outcomes they achieve.

A recommendation for class 1, 4, 5 and 5 support was requested to cover activities as described within the application.

Confidential Patient Information Requested

Cohort

All patients aged over 18 who suffer from infection involving native bones and/or joints or related to medical devices in bones or joints within England and Wales.

Data will be provided from individual treating Trusts by entry into a web-based registry.

The following items of confidential patient information will be requested, together with a wider clinical dataset, for the purposes as detailed:

- Date of Birth – validation and linkage,
- NHS number – validation and linkage,
- Age – analysis,
- Sex – analysis,
- Date of death – analysis,
- Ethnicity – analysis,
- Hospital Unit Identifier – validation and analysis,
- Date of admission – validation and analysis,
- Date and time of discharge – validation and analysis.

Confidentiality Advisory Group Advice

The application was a resubmission of the project previously considered under reference 17/CAG/0140, which was initially considered at the CAG meeting held on 28 September 2017. The CAG deferred recommendation on the proposal at this meeting, pending further information from the applicants. The applicants provided a written response to the request for further information, which was reviewed by a Sub-Committee of the CAG in correspondence.

1. **Further information is required around the data collection methodology – a clearer articulation of the proposed methodology should be provided, taking the following points into account:**

a. **Clarify how case ascertainment will be maximised, also addressing how it will be known how accurate the captured sample if against the true patient cohort,**

The applicants explained that there were two aspects to case ascertainment. The first was to detect that all the relevant cases are included on the registry. The second is that those who are registered have comprehensive record of all subsequent care episodes. The following points were made to emphasise how case ascertainment would be maximised:

1. There is a national push to refine bone and joint infection services, which is being directed by the 'Getting It Right First Time' programme. AS such, each Trust has a clear incentive to register all possible cases of bone and joint infection in order to justify their service and its subsequent funding.
2. Each Trust will be asked to review cases submitted to the registry on an annual basis via a PAS export that will identify any further clinical activity on the BAJIR registered patients. Where PAS suggests further intervention, the local registry representative will be asked to clarify all further relevant intervention. This method will ensure all post registration care is recorded with best possible accuracy.

The Sub-Committee received the response and no further issues were raised in this area.

b. **Explain what additional purposes this proposed registry will fulfil that are not currently achieved by the national surgical infections audit,**
c. **Confirm if there has been any previous correspondence with Public Health England and/or HQIP around potential crossover with existing audit programmes.**

The applicants explained that the current Public Health England Programme related to surveillance of surgical site infection. In the context of bone and joint infection this relates to infection after fixation of long bones, joint replacement surgery and neck of femur surgery. This programme only surveys the incidence and prevalence of infection after surgery. It has no remit involving the treatment and management of these infections beyond diagnosis after initial surgery. Furthermore it has no remit on native bone and joint infection. The applicants confirmed that, as such, there had not been any communication with PHE or HQIP.

The Sub-Committee received the response and it was agreed that this had highlighted the differences between the proposed registry and existing audit work facilitated by Public Health England. No further issues were raised in this area.

2. **Further information is required around the data flows and proposed linkages within the project – response should be provided, addressing the following points:**
   a. **Confirm how often it is proposed to facilitate data linkage with the HES dataset held by NHS Digital and detail what information will be returned when linkage is undertaken,**
   b. **Clarify whether there has been any correspondence with NHS Digital around this proposed data linkage and provide an overview of this,**

The applicants confirmed that they would only undertake linkage via HES for those patients who have provided informed consent to this element. As such, an application to facilitate this linkage would only be made to NHS Digital once patient's had been registered and provided consent to their ongoing inclusion in the registry.

The response was received and no further issues were raised in this area.

c. **It is unclear whether data sharing agreements have been drawn up between the organisations involved in the project, i.e. Dendrite, participating Trusts and NHS Digital – provide confirmation and copies of any documentation where appropriate, to provide an overview of the various responsibilities within the project.**

The applicants provided a draft data-sharing agreement for consideration by the CAG which outlined the proposed format.

The document was received and no further issues were raised by the Sub-Committee.

3. **Further information is required in relation to the exit strategy to move away from support under the Regulations for the registry – response should be provided addressing the following points:**
   a. **A more definitive plan should be provided in relation to future data linkages, providing detail of what data sources it would be anticipated that the registry would seek linkage with and for what purposes,**
   b. **Consider others ways in which the identifiability of the dataset retained could be reduced,**
   c. **Provide a more definitive plan in relation to the anonymisation of the dataset,**
   d. **Consider ways in which a consenting mechanism could be developed for the registry, to enable an exit strategy from support under the Regulations to be achieved through consent.**

The applicants confirmed that seeking patient consent was the basis of the exit strategy from holding confidential patient information with support under the Regulations. The applicants explained that, following the acute phase of the illness, patients are frequently cared for in the outpatient setting where seeking patient consent is more feasible. The applicants confirmed that they intended to seek patient consent once their treating site had advised that the patient was suitably recovered from their acute admission and treatment. It was confirmed that the registry team would undertake the process of seeking informed consent from patients. It was confirmed that the aim would be to complete this within an upper limit of 18 months from entry into the registry. However, it was noted that the plan was to seek consent as early as possible from patients – most likely within six months of registration.

Patients would be asked about on-going participation, collection of patient reported outcome measures and data linkage. Those patients who do not wish to participate would be asked about the use of data already collected, use of routine data or complete withdrawal from the registry.

Where to contact with patients within the 18-month window from registration was not possible, the applicants confirmed that their data would be anonymised permanently and no linkage would be performed. This process was outlined in the revised application form. The applicants also provided a consent form for review, which would be appended to the patient information sheet.

The Sub-Committee received the response and supplementary documents. The establishment of the exit strategy from support under the Regulations was commended. No further issues were raised in this area.

4. **Public and Patient Involvement and Engagement – provide a detailed plan of how activity in this area will be continued as the project progresses and the registry is established.**

The applicants confirmed that a patient representative would be appointed to the registry steering committee. In addition, patient feedback on the process of registration and consent would be sought. It was also clarified that patient facing pages would be made available on the registry website, which will be designed with support from patient representatives.

The response was received and Members commented that the information provided did not provide the detailed plan of patient and public involvement and engagement activity which was expected. The Group agreed that this additional requirement should not delay the project from commencing; however, it was agreed that submission of a thorough strategy would be required as a six-month interim report. This would need to provide a detailed plan of what activity would be undertaken at various time points as the project progressed, in order for structured feedback to be given.

5. **Patient Notifications and Dissent – revise the documentation as follows to address the outstanding issues:**
    a. **Patient Information Leaflet – revisions should be made to the document as follows:**
    i. **Revise the list of confidential patient information items to include details of all patient identifiers which will be collated within the registry,**
    ii. **Provide a clear and accurate overview of the organisations involved with the registry, explaining who will have access to the data and in what format (identifiable, aggregated anonymised etc.) and what it will be used for, including an overview of links with wider NHS datasets.**

The applicants submitted a revised information sheet for consideration.

The Sub-Committee considered the revised information sheet and it was noted that the document appeared to relate to the consented information, rather than the initial entry into the registry. It was agreed that further revisions would be required to explain how and when patients are entered into the registry and provide an overview that consent is sought for continued participation. Members confirmed that the required revisions should not delay the project from commencing, but it was agreed that submission of a revised document would be required at the six-month interim report. Engagement with patients and the public should be undertaken to improve the document and ensure that this was accessible to a wider public audience.

    b. **Poster – revisions should be made to the document as follows:**
    i. **Provide a clear and accurate overview of the organisations involved with the registry, explaining who will have access to the data and in what format (identifiable, aggregated anonymised etc.) and what it will be used for, including an overview of links with wider NHS datasets.**

The applicants submitted a revised poster for consideration.

Members considered the document and it was agreed that further revision was required. It was noted that the document incorrectly stated that ‘no one’ would have access to confidential patient information, which was not accurate as administrative staff performing the pseudonymisation process would have access to the complete dataset, as referenced at section (q) of the application form. The CAG agreed that this reference required revision. It was also commented that it would be helpful to explain within the section entitled ‘Patient Consent’ that consent was being sought for ongoing participation, rather than initial inclusion. The Group agreed that this should not delay the project from

commencing and confirmed that the revised document could be provided with the six-month interim report.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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. Patient and Public Involvement and Engagement – submission of a detailed overview of activity planned in this area is required as an interim report within six months of the date of this outcome. Defined activities should be set out within a specific timescale to enable structured feedback to be gathered.
2. Patient Notification Materials – revisions are required to the patient-facing documents, which should be informed by the patient and public involvement and engagement activity. Revised documentation should be submitted for CAG review within six months of the date of this outcome.
    a. Patient Information Leaflet – requires revisions to provide a clearer explanation of when patients are included within the registry, and to explain that consent would be sought at a future date around continued participation,
    b. Poster – requires revision to accurately articulate who will have access to confidential patient information when data is entered into the registry and to provide a clearer explanation of the consenting procedure.
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed Dendrite Clinical Systems & Northumbria Healthcare NHS Foundation Trust, Version 14.1, 2017/18, shows a reviewed grade of satisfactory)**

As the above conditions have been accepted and/or met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Annual Review

Please note that your approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided no later than **10 May 2019** and preferably 4 weeks before this date.

Reviewed Documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*	
CAG application from (signed/authorised) [Section 251 Form]		01 November 2017	
Covering letter on headed paper [Letter to CAG (re: Outcome)]		01 March 2018	
Other [16CAG0152 Deferred Outcome Letter]		22 December 2016	
Other [17CAG0140 Deferred Outcome Letter]		10 October 2017	

Other [Information Sharing Agreement BAJIR]	1		
Patient Information Materials [BAJIR Patient Information Consent Form]			
Patient Information Materials [OPD Poster BAJIR]			

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item or submitted written comments are listed below.

Yours sincerely

Miss Kathryn Murray
Senior Confidentiality Advisor

On behalf of the Secretary of State for Health and Social Care

Email: HRA.CAG@nhs.net

Enclosures: *List of members who considered application*
Standard conditions of approval

Confidentiality Advisory Group [sub-committee] meeting 14 March 2018

Group Members:

Name	*Profession*	*Present*	*Notes*	
Ms Sophie Brannan		Yes		
Dr Tony Calland		Yes		
Mr Anthony Kane		Yes		

Also in attendance:

Name	*Position (or reason for attending)*	
Miss Kathryn Murray	Senior Confidentiality Advisor	

Standard conditions of approval

The approval provided by the Secretary of State for Health is subject to the following standard conditions.

The applicant will ensure that:

1. The specified patient identifiable information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant.

4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities are consistent with the Data Protection Act 1998.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.