Health Research Authority

Sub-Committee Minutes in Lieu of the 22 March 2018
Meeting of the Confidentiality Advisory Group

Application title: **National Clinical Audit of Rheumatoid and Early Inflammatory Arthritis Clinical Audit**

CAG reference: **18/CAG/0063 (Resubmission of 18/CAG/0017)**

Group Members:

Name	*Present*	*Notes*
Dr Patrick Coyle	Yes	Vice Chair
Dr Lorna Fraser	Yes	
Mr Anthony Kane	Yes	Lay
Mrs Diana Robbins	Yes	Lay

Also in attendance:

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

Context

Purpose of Application

This application from the British Society for Rheumatology (commissioned by HQIP) set out the purpose of the National Clinical Audit of Rheumatoid and Early Inflammatory Arthritis. The audit aims to improve the quality of care for patients with Rheumatoid and early inflammatory arthritis (EIA) in England and Wales. The current contract period is 1 October 2017 – 30 September 2020, with the possibility of a further two year extension.

Early diagnosis and treatment is a cornerstone of EIA management and is underpinned by NICE guidelines (CG79). The Healthcare Quality Improvement Partnership (HQIP) has commissioned the British Society for Rheumatology (BSR) to undertake a National clinical audit (NCA) to assess EIA services.

The NCA will collect prospective data including:

- Waiting times;

- Time to treatment;
- Provision of education;
- Collection of patient reported outcomes;
- Clinical response.

The collected data will be linked with NHS digital data access request service (hospital episode statistics), pending approval from NHS Digital. It will also be linked the patient episode database for Wales (PEDW), pending approval from the NHS Wales Informatics Service. This will enable ascertainment of joint replacements, unplanned hospitalisations, and death. These linkages will be repeated annually.

There will also be linkage to the Death Register held by the Office for National Statistics (ONS). The data will provide validated mortality information in England and Wales.

A recommendation for class 1, 4, 5 and 6 support was requested to cover activities as set out in the application.

Confidential Patient Information Requested

Cohort

Patients aged 16 years and over in England and Wales who present for the first time in rheumatology outpatient clinics with a suspected diagnosis of early inflammatory arthritis. The audit period is 1 October 2017 through 30 September 2020.

The following items of confidential patient information will be provided by the treating clinician when registering the patient within the audit:

- Name – sample validation and circulation of PROMS information,
- Date of birth – sample validation, linkage and analysis,
- NHS number – sample validation and linkage,
- Hospital number – sample validation,
- Post code – sample validation, linkage and analysis,
- Email address – circulation of PROMS information,
- Telephone number – to allow telephone contact for PROMS,
- Gender – analysis,
- Ethnicity – analysis,

The below additional data items will be provided by NHS Digital via linkage with ONS mortality data:

- Date of death – analysis,
- Cause of death – analysis.

Confidentiality Advisory Group Advice

The CAG acknowledged that this proposal was a resubmission of application 18/CAG/0017, which was initially considered at the CAG meeting held on 08 February 2018. The Group deferred recommendation on the application at this meeting, pending further information from the applicants. A Sub-Committee of the main CAG considered the written response provided by the applicants to the request for further information.

1. **Practicable Alternatives – further information is required in this area to enable an informed assessment to be undertaken against the practicable alternatives to seeking support under the Regulations. The following points should be addressed:**
   a. **Confirm the anticipated size of the patient cohort to be included within the audit,**

The applicants confirmed that it was planned to recruit 6500 patients in total in year one of the audit, with a view to increasing recruitment by at least 10% per year in each subsequent year of recruitment.

It was explained that the actual number of patients assessed with possible inflammatory arthritis is likely to be much higher than this. The applicants cited that data from the Clinical Practice Research Datalink (CPRD, a primary care research database) suggested the incidence of inflammatory arthritis was closer to 20,000 per year in England and Wales. The applicants stated that as the audit gained momentum, significant growth in the recruitment rate was anticipated as case capture improves.

Further information was provided to explain that an average Trust, with a catchment population of 500,000, published incidence data predicted five confirmed cases of early inflammatory arthritis per week. The proportion of suspected early inflammatory arthritis (EIA) referrals that actually have rheumatoid arthritis is estimated at between 30% and 50%. Total new EIA assessments per week would typically be up to 15 cases for an average trust.

The Sub-Committee received the response and acknowledged the estimated recruitment number within the first year and plans to increase the uptake as the audit progressed. No further issues were raised in this area.

b. Further consideration should be undertaken around the feasibility of operating a consented model for the audit programme, particularly in relation to the follow-up contact for PROMs questionnaires presenting a further opportunity to take consent. If this was not determined to be feasible, a strong rationale should be provided to support this decision.

The applicants explained that the bulk of appointments (between 75 – 80%) within rheumatology services were dedicated to patients with established disease, which limited the time available for new patient appointments. It was explained that the majority of new patient appointments were scheduled for 30 minutes, within which a full history and examination needs to be undertaken, a diagnosis confirmed along with confirmation of important co-morbidities that may influence treatment options. The diagnosis has to be relayed to the patient, most of whom will have many questions about the implications of a chronic disease and also about the treatments recommended. NICE require prompt provision of education and treatment from these first appointments. The applicants explained that feedback from the established patient panel indicated that this first appointment was highly stressful to patients and that requesting written consent for an audit was likely to be a barrier to recruitment.

The applicants explained that it was anticipated that too few patients would return PROMs data to enable this additional contact to be an appropriate mechanism for obtaining consent. It was explained that the resulting selection bias would fundamentally undermine the audit results.

The applicants referenced the experience from the first HQIP EIA audit (2014-16), which operated on verbal consent basis, during which follow up PROMs was only captured from 24% of participants. The applicant further explained that in the recent pilot of the new audit, a lower response rate of 20% return was observed from patients directly. The applicants concluded from this evidence that the PROMs follow-up was unlikely to provide a feasible opportunity to seek consent from patient for their involvement in the audit programme; as such low return rates would undermine the overall results. It was further explained that this methodology was also therefore unlikely to be sufficient for return of the PROMs data and the inclusion of other methods of capturing this information within the audit (i.e. from the clinician) would be necessary.

The Sub-Committee received the response and was assured that operating solely via a consented model at the point of PROMs data collection would impact on the validity of the audit programme.

2. PROMs Questionnaire Follow-Up – further information is required in this area to address the following issues:

a. Confirm who would be carrying out the PROMs follow-up – will this be undertaken by the clinical care team or by the team operating the clinical audit,

The applicants explained that PROMs data would be collected through any of the following mechanisms, based upon patient preference:

- Email: details will be sent directly from the team operating the audit with a link to the secure patient portal,
- Paper forms: handed to patients by the clinical team for completion and return to the clinical team, who will upload the data to the audit website (this is model most frequently used in clinic currently),
- Real time data entry: the clinical team would enter information directly onto the audit website with the patient present.

It was confirmed that the recommended route of collection was via email. This enabled patients to complete the forms in their own home in a less pressured environment than a busy clinic. The information the patient uploads will be immediately visible to their clinicians via the secure web portal. It was explained that members of the audit patient panel had indicated that they would anticipate that allowing completion via email would improve PROMs data capture.

It was explained that the other mechanisms for PROMs data collection were in place to maximize equality within the audit, offering alternatives to patients without email access.

The applicants explained that, in response to national initiatives, PROMs were increasingly collected routinely by the clinical team as an element of clinical care for patients with inflammatory arthritis. The provision of a process to collect this information at a time convenient to the patient has been viewed by the patient panel as a benefit of this audit as it should mean this data was more reliably obtained.

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

b. If this will be undertaken outside of the clinical care team, provide further information around how and by who this would be operated together with confirmation that the patients would be explicitly informed of this contact,

The applicants clarified that when data entry would take place outside of the clinical care team, this would be made explicit to patients via the patient information sheet to ensure fair processing. Clinicians would ask patients their preferred method of contact for supplying PROMs information and record this preference in the clinician portal.

If patients choose to be contacted by email, the clinician will enter the patient's email address into the web portal. This would generate an automated message from the audit website containing an audit unique identifier and a link to patient portal. The patient would then use their NHS number and date of birth to obtain a secure password and log in to the patient website. It was clarified that the patient portal front pages contain the patient information as well as instructions to support use of the website. Patients would then enter their own PROMs information. The data entered by the patient are accessible to their clinical team and the audit team.

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

c. Clarify that the PROMS follow-up will be carried out at an appropriate point in the clinical pathway when the patient had received a clinical diagnosis.

It was confirmed that PROMs data would be collected at 0, 3 and 12 months. It was noted that the 3-month follow up would coincide with routine clinical assessment. It was explained that in early arthritis care the clinical standard is that patients would be seen every month until disease control is achieved. Few patients would achieve disease control prior to 3 months (due to the speed of action of anti-rheumatic therapies), and so it is expected that all patients would have a routine visit scheduled around this time point. The applicants explained that to change the PROMs follow-up to an earlier point would be too early to assess response to treatment, but delaying the follow-up may mean that this did not coincide with routine care. The 12-month assessment would coincide with the first annual review, a component of routine clinical care pathway.

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

3. **Duration of support – further information is required to clarify the duration of support which is being requested under the Regulations to support the audit programme. The following issues should be addressed:**
   a. **Clarification should be provided around the intended retention period of confidential patient information collated as part of the national audit programme,**

The applicants clarified that support was requested to hold confidential patient information to cover the period that we have a contract with HQIP, which was currently until September 30th 2020.

Members queried the response as it had previously been stated that confidential patient information would be retained for a period of 12 months following the final data collection, which would suggest that support would be required up to 30 September 2021. It was agreed that clarification on this point would be required from the applicants to ensure that support was recommended for the appropriate duration.

   b. **Support can only be recommended for the initial audit period which is currently contracted. Any extension to this period would need to be managed via an amendment at a later stage should the application activity receive a recommendation of support.**

The applicants acknowledged that an amendment would need to be submitted to extend the duration of support under the Regulations, should the audit period be extended.

No further queries were raised in this area.

4. **Consideration should be given to ways in which the identifiability of the data retained for a patient can be reduced once a date of death has been recorded and survival calculations have been undertaken. Provide an overview of steps which will be taken in order to reduce the identifiability of data retained in these circumstances. If it is determined that the dataset cannot be reduced, strong rationale should be provided to support this requirement.**

The applicants provided an overview of the proposed steps which would be undertaken to reduce the identifiability of all retained data following the linkage via NHS Digital. It was explained that the only mechanism by which a patient's death would be reported to the audit team would be via linkage with ONS mortality data at NHS Digital. When a patient's death was identified following linkage, name, email address, and postcode would be removed from the audit database.

The applicants explained that in order to report on the occurrence of adverse events (hospitalization, joint replacement and mortality), an offset date would be calculated for the deceased patient. All dates (including date of birth, date of visits, and dates of all events) for that individual would be replaced with a new date generated using a random offset. By using one offset for all dates for a participant, the relative distance between a participant's dates would be maintained from their original dates to their de-identified dates. The offset value will be irreversibly destroyed following data transformation.

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

5. **Data Flows – a revised data flow chart should be provided which includes a comprehensive overview of all proposed data flows which would form part of the audit programme. This should include all organisations which will be involved and highlight the flow of and access to confidential patient information at each stage of the programme.**

The applicants provided a revised data flow chart for review.

The Sub-Committee reviewed the revised document and it was noted that this presented some queries. In relation to the data entry column within the diagram, it was suggested that the data entered by the Trusts and the patients into the online audit platform both required support under the Regulations to support the

disclosure to Net Solving, the data processor for the audit. Members were content that the information entered by the Trust required support under the Regulations; however, it was commented that the PROMs information which was flowing direct from the patients, must be provided with the patient's consent and was therefore out of scope.

It was agreed that a revised data flow chart would be required which accurately highlighted that the PROMs data provided by patients was done so with consent.

The Group also considered the outputs of the audit programme as it was stated that peer-reviewed articles would form part of the audit outputs. The current application had been submitted to seek support under the Regulations for non-research purposes only to support the audit program. Any support which was recommended against this application did not support the wider use of data collated via the audit for research purposes. A separate application would be required via the IRAS system to seek support for the use of the data for research purposes. Members agreed that confirmation would be required from the applicant that the peer-reviewed articles would not be the product of research activity.

6. Linkage with wider NHS datasets – further information is required around the proposed linkage with datasets held by NHS Digital and NWIS to address the following issues:

a. Provide an overview of how this data linkage will be facilitated and the items of confidential patient information which will be required,

The applicants confirmed that an application would be made to both NHS Digital and NWIS at the point the proposal received a recommendation of support. It was explained that data linkage had been budgeted within the project and preliminary discussions had been undertaken with NHS Digital and NWIS regarding the process. The unique identifiers for linkage would be shared w via an approved secure manner.

The applicants explained that following linkage, pseudonymised data would be shared with King's College London for analysis either via secure file transfer or via the HES Data Interrogation System, whichever route is advised by NHS Digital following final approval.

It was clarified that linkage would be undertaken on an annual basis, to enable analysis for the production of the annual report. Linkage would be undertaken using a deterministic approach using the following identifiers: national audit unique identifier, NHS number, date of birth and postcode.

b. Additional information is required around the additional clinical information which will be returned following linkage,

The applicants provided an overview of the information which would be returned from the HES and PEDW datasets. This would cover the following areas:

Admitted care episodes (unplanned admissions only):

- Primary diagnosis chapter
- Diagnostic codes
- Date of episode start
- Episode duration

Joint replacements (restricted to joint replacement codes for using the Classification of Interventions and Procedures version 4):

- Operative procedure codes
- Operative procedure date
- Date of admitted patient care event

The following information would be provided following linkage with ONS mortality information:

- Date of Death
- Original underlying cause of death
- Cause of death row position

It was confirmed that these data fields reflected the minimum dataset to satisfy the requirements of the HQIP specification, enabling reports on mortality, unplanned hospital admissions and joint replacements.

c. An approach should be made to both data controllers to seek agreement in principle to the proposed linkage.

It was confirmed that the data controllers, NHS Digital and NWIS, had been informed of the linkage plans and have confirmed the feasibility of these proposals, pending confirmation of a legal basis for data transfer.

The Sub-Committee received the response in relation to the proposed linkage with wider NHS datasets and no further issues were raised.

7. Patient Notifications and Dissent – further information is required in this area to address the following points:

a. A revised patient information leaflet should be provided which provides a clear overview of the audit programme, what items of confidential patient information will be collected and retained, informs of the intended linkage with wider NHS datasets and provides details of how an objection can be raised,

A revised participant information sheet was provided for review.

Members agreed that the language used within the document was too technical and would benefit from further revision. It was also commented that the layout of the document was confusing. The Group recommended that the patient panel was approached to review the document in order to seek views around how the document could be simplified to make this accessible to a wider audience. It was agreed that this work could be undertaken over the first year of the audit programme, with the revised information leaflet being provided for review at the time of first annual review.

The CAG agreed that there was one revision which would be required to the document prior to final support coming into effect. The following section was noted within the document: *"The NEIAA has permission to collect personal identifiers from patients presenting with inflammatory arthritis without taking explicit (written) consent. This was granted by the NHS Health Research Authority Confidentiality Advisory Group." The Group noted that this sentence was incorrect and should be revised to state that support under the Regulations had been approved by the Secretary of State for Health and Social Care. A revised document would be requested.*

b. A detailed overview is required around how a patient can raise an objection to the use of their confidential patient information for the purposes of the audit, together with an explanation of how this will be respected,

It was confirmed that patients could raise an objection to the use of their data within the audit via the following channels:

1. Notification to any member of the local clinical team by email, in writing or be telephone. The clinical team will ensure that details are not entered in the audit. If they have already been entered, they will be removed by Net Solving.

2. Contacting the audit team directly. The team will contact the hospital to make sure that they do not enter details into the audit by flagging the clinical record. If they have already entered details, they will be removed and deleted by Net Solving.

It was confirmed that information around dissent would be made available in the patient information sheet and on the audit website.

Members received the response and were satisfied with the overview provide; however, a query was raised in relation detail included within the advice form as part of the previous submission. It was previously stated that when a patient raised an objection, the audit team would contact the individual to establish the reasons for their objection and address any unfounded concerns. At this stage, should the individual wish to proceed we will cease to process their data and ensure that it is appropriately removed. The Group expressed concerns around the potential for this contact to appear coercive to the patient, as it was commented that a patient did not need to give any reason to support their objection. The CAG agreed that clarification was required from the applicant around whether this contact was still intended, as it had not been described in the revised application. If it was intended that patients would be contacted, assurance would be required that this would be managed in a way to ensure the applicant did not feel pressured into providing wider information or remaining within the audit against their wishes.

c. **Details of any wider communication plans to promote the audit should also be provided for consideration together with any supporting documentation.**

The applicants provided a copy of the audit's formal communications plan for consideration. It was explained that the following methods of communication would be used to support delivery of the audit:

- Patient organisation leads and e-newsletters (National Rheumatoid Arthritis Society);
- Direct mail to commissioners and providers promoting the audit and participation;
- BSR website (www.rheumatology.org.uk)
- BSR Regional Chairs and champions;
- Partner organisations;
- Quarterly e-bulletins to acute trust chief executives, clinicians, commissioners, patient organisations;
- News releases to trade journals and medical practitioner journals to target non-members;
- Social media campaigns;
- Webinars (3 delivered, 3 more planned for March);
- Annual national (May 2018) and regional meetings to promote participation, disseminate findings and promote implementation of recommendations.

The Sub-Committee received the information and agreed that the wider communications strategy appeared appropriate to the proposed activity. It was agreed that these activities should proceed as planned as the audit progressed.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Secretary of State for Health and Social Care, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for Further Information (Summary)

1. Clarify whether support is required to extend to 30 September 2021, to include the 12 month analysis period following the last data entry.
2. Submit a revised dataflow chart to distinguish between information entered into the audit database by Trusts (requiring support under the Regulations) and patients (provided with consent).
3. Provide confirmation that there is no intention to use the data collated under this application for wider research purposes. This is with reference to the peer-reviewed articles referenced as outputs of the audit within the data flow chart.
4. Revise the patient information leaflet to correctly reference that support under the Regulations has been approved by the Secretary of State for Health and Social Care – submit a copy of the revised document.
5. With reference to the patient dissent mechanism – clarify whether it is still intended to contact patients who raise an objection to discuss the rationale for this. If so, provide assurances that this conversation would be managed in such a way that it did not appear coercive to the patient.

Once received, the information will be reviewed by the Confidentiality Advice Team 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, the Secretary of State for Health and Social Care will confirm approval.

Specific Conditions of Support (Provisional)

1. Further work should be undertaken, with involvement from the patient panel, to revise the patient information leaflet to make this more accessible to a wider audience. A report will be required at the time of first annual review of the work which was undertaken in this area, together with the revised document for consideration.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Net Solving Ltd. shows a reviewed grade of satisfactory on Version 14, 2016/17).**

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