

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group
September 2018

Present:

Name	Capacity	Items
Dr Patrick Coyle	Vice Chair	1.a. and 1.b.
Dr Malcolm Booth	Member	1.a. and 1.b.
Dr Harvey Marcovitch	Member	1.a. and 1.b.

Also in attendance:

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

1. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH
a) 18/CAG/0143 – Associations between frailty and outcomes after knee replacement
Purpose of application

This application from the Big Health Data Group at the University of Oxford sets out the purpose of service evaluation which aims determine the burden of frailty among patients undergoing primary knee replacement and any association between the level of frailty and post-operative outcomes following the replacement surgery.

The project will routinely collected clinical information for the purpose of the evaluation, using data collected by the National Joint Registry (NJR) linked with HES and ONS information and Patient Reported Outcome Measures (PROMs) data. Confidential patient information will be disclosed from the NJR to NHS Digital in order to facilitate linkage. Analysis will be undertaken by the research team on a pseudonymised dataset only.

This application is linked to 18/CAG/0144 as it will make use of the same dataset – separate applications were made to mirror the submissions to the NJR Committee and to ensure that any recommendation of support would extend to the two described purposes. The data flows/linkage will be performed only once.

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

Confidential patient information requested

Cohort

All adult patients in England and Wales aged 18 years and over recorded as having undergone primary knee replacement within the National Joint Registry, between 2003 to date of linkage with NHS Digital. The NJR currently holds data on 800,477 patients who have undergone primary knee replacement; however, the study sample will be less as patients from Northern Ireland and the Isle of Man will be excluded.

The following items of confidential patient information will be released from the National Joint Registry database, held by Northgate Information Solution, to NHS Digital to facilitate linkage with HES, ONS and PROMs:

- NHS number,
- Date of birth,
- Sex – also retained for analysis,
- Postcode,
- Ethnicity – for analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the project described an appropriate medical purpose through the management of health and social care services. It was commented that the proposed activity did border on research; however, it was recognised that the applicant had sought confirmation via the HRA decision tool around the project categorisation. Members were assured that there was public interest in the application proceeding as it would lead to a greater understanding of the burden of frailty on patients undergoing knee replacement surgery and the potential relationship of this to post-surgical outcomes. The Group recognised the crossover with the linked application 18/CAG/0144, which would make use of the same dataset as described here; however, it was noted that separate recommendations were required to mirror the application process via the National Joint Registry and to ensure the differing purposes were supported.

Practicable alternatives

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

- Feasibility of consent

It was recognised that the National Joint Registry held information on over 900,000 patients and on this basis; Members agreed that consent was not feasible for the project.

- Use of anonymised/pseudonymised data

Processing of confidential patient information was necessary to facilitate the proposed linkage by NHS Digital; however, it was recognised that the project analysis was being undertaken on a pseudonymised dataset only. No issues were raised in this area.

Justification of identifiers

The Group was assured that the items of confidential patient information requested were proportionate and appropriate to facilitate the proposed linkage. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Support is required to facilitate the data linkage process by NHS Digital only – the applicant will only receive a pseudonymised dataset for the purposes of analysis. No issues were raised in this area.

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 an unconsented activity should go ahead. Members recognised that the applicant had not undertaken any direct patient and public involvement and engagement activity specifically related to this project; however, it was agreed that the proposed activity would fall within the scope of generic activity which had been undertaken by the National Joint Registry. It was further noted the James Lind Alliance, a forum involving patients, carers and clinicians to identify the 'Top 10' questions regarding treatments, had identified the factors associated with positive and negative outcomes following a joint replacement to a key area requiring further understanding. The Group recognised that there was public and patient support in the project proceeding and raised no further queries in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection 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 Data Protection Act 2018. The applicant had provided generic text which was displayed on the Big Health Data Group website for patient's information; however, this did not include study-specific text. It was further explained that study-specific information would be displayed on the National Joint Registry website in order to facilitate any objections. Members commented that the proposed activity was likely to fall within the reasonable expectation of patients in relation to how their data would be used by the National Joint Registry, but it was agreed that in the interests of transparency, project-specific information should be made available also. The Group agreed that confirmation should be provided at the time of first annual review that information had been displayed as per the applicant's planned communication strategy.

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 (Final)

1. Study-specific information should be displayed on the National Joint Registry website, together with details of how a patient can raise an objection to the use of their information for the project purposes. Confirmation should be provided at the time of first annual review that this was undertaken.

2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital acting as processor, published satisfactory grade on V14.1, 2017/18**).

b) 18/CAG/0144 – Reconstructive strategy and implant design in knee replacement

Purpose of application

This application from the Big Health Data Group at the University of Oxford sets out the purpose of service evaluation which aims determine associations between the choice of surgical reconstructive strategy (use of uni-compartmental knee replacement where possible vs. routine use of total knee replacement in all cases) and health outcomes in patients undergoing primary knee replacement for osteoarthritis. The project will also determine associations between knee replacement designs and health outcomes after knee replacement for osteoarthritis.

The project will routinely collected clinical information for the purpose of the evaluation, using data collected by the National Joint Registry (NJR) linked with HES and ONS information and Patient Reported Outcome Measures (PROMs) data. Confidential patient information will be disclosed from the NJR to NHS Digital in order to facilitate linkage. Analysis will be undertaken by the research team on a pseudonymised dataset only.

This application is linked to 18/CAG/0143 as it will make use of the same dataset – separate applications were made to mirror the submissions to the NJR Committee and to ensure that any recommendation of support would extend to the two described purposes. The data flows/linkage will be performed only once.

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

Confidential patient information requested

Cohort

All adult patients in England and Wales aged 18 years and over recorded as having undergone primary knee replacement within the National Joint Registry, between 2003 to date of linkage with NHS Digital. The NJR currently holds data on 800,477 patients who have undergone primary knee replacement; however, the study sample will be less as patients from Northern Ireland and the Isle of Man will be excluded.

The following items of confidential patient information will be released from the National Joint Registry database, held by Northgate Information Solution, to NHS Digital to facilitate linkage with HES, ONS and PROMs:

- NHS number,
- Date of birth,
- Sex – also retained for analysis,
- Postcode,
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Confidentiality Advisory Group advice

Public interest

The CAG was assured that the project described an appropriate medical purpose through the management of health and social care services. It was commented that the proposed activity did border on research; however, it was recognised that the applicant had sought confirmation via the HRA decision tool around the project categorisation. Members were assured that there was public interest in the application proceeding as it would lead to a greater understanding of the associations between knee replacement designs and health outcomes after knee replacement for osteoarthritis. The Group recognised the crossover with the linked application 18/CAG/0143, which would make use of the same dataset as described here; however, it was noted that separate recommendations were required to mirror the application process via the National Joint Registry and to ensure the differing purposes were supported.

Practicable alternatives

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

- Feasibility of consent

It was recognised that the National Joint Registry held information on over 900,000 patients and on this basis; Members agreed that consent was not feasible for the project.

- Use of anonymised/pseudonymised data

Processing of confidential patient information was necessary to facilitate the proposed linkage by NHS Digital; however, it was recognised that the project analysis was being undertaken on a pseudonymised dataset only. No issues were raised in this area.

Justification of identifiers

The Group was assured that the items of confidential patient information requested were proportionate and appropriate to facilitate the proposed linkage. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Support is required to facilitate the data linkage process by NHS Digital only – the applicant will only receive a pseudonymised dataset for the purposes of analysis. No issues were raised in this area.

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 an unconsented activity should go ahead. Members recognised that the applicant had not undertaken any direct patient and public involvement and engagement activity specifically related to this project; however, it was agreed that the proposed activity would fall within the scope of generic activity which had been undertaken by the National Joint Registry. It was further noted the James Lind Alliance, a forum involving patients, carers and clinicians to identify the 'Top 10' questions regarding treatments, had identified the factors associated with positive and negative outcomes following a joint replacement

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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 (Final)

1. Study-specific information should be displayed on the National Joint Registry website, together with details of how a patient can raise an objection to the use of their information for the project purposes. Confirmation should be provided at the time of first annual review that this was undertaken.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital acting as processor, published satisfactory grade on V14.1, 2017/18**).