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

MONTH YEAR

Present:

Name	Capacity	Items
Ms Clare Sanderson	CAG alternative vice-chair	1.a, 1.b, 1.c
Professor Jenny Kurinczuk	CAG member	1.a, 1.b
Dr Katie Harron	CAG member	1.a, 1.c
Mr Andrew Melville	CAG member	1.b, 1.c

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor

1. New precedent set review applications – research

a. 19/CAG/0215 - Fractional Flow Reserve versus Angiographically Guided Management to Optimise Outcomes in Unstable Coronary Syndromes: a developmental clinical study of management guided by coronary angiography combined with fractional flow reserve (FFR) measurement versus management guided by coronary angiography alone(standard care) in patients with non-ST elevation MI

Context

Purpose of application

This application from the University of Glasgow set out the purpose of medical research that seeks to obtain information on how coronary fractional flow reserve (FFR) data relate to clinical decisions based on visual assessment of the coronary angiogram in order to guide the design of a future clinical trial of FFR-guided decisions in non-ST elevated myocardial infarction (NSTEMI).

NSTEMI is the commonest type of acute myocardial infarction (MI) / acute coronary syndrome and MI is a leading cause of premature ill health and death in the community. The morbidity and mortality rate in patients with NSTEMI is high and 5-10% of patients had die or experience a recurrent NSTEMI within 12 months of the original NSTEMI. Coronary fractional flow reserve is the pressure drop across a narrowed coronary artery. FFR is measured using a coronary ‘pressure wire’, similar to that used in coronary angiography and angioplasty. The pressure wire is commonly used in angina patients but not in patients who have had a recent heart attack, due to a lack of evidence of its effectiveness in this patient group. The applicants sought to gather information on whether use of the pressure wire in patients who have had a recent heart attack can alter and improve treatment decisions made in the catheter lab

A pilot study ran between October 2011 to May 2014, to collect information about the potential usefulness of the pressure wire and inform whether a larger scale trial was feasible. A two-centre study was run and recruited 350 patients who received coronary angiography and angioplasty following a heart attack. The pressure wire was used in all patients, however the FFR value would be disclosed in half of the patients (FFR group) but not in the 'usual care' group. Doctors in the FFR group were given an FFR result which they may or may not choose to guide decision-making. Clinical decisions were made in the normal way in the 'usual care' patients. Patients were recruited into

the pilot study on a consented basis and followed-up for at least 6 months. Enrolment completed in 2013. NHS Digital have reviewed the patient information and consent materials used at the time and determined that it was not explicitly stated that data would be held and analysed at the University of Glasgow. Section 251 support was therefore sought for the continued holding of this data and linkage to HES data held by NHS Digital.

A recommendation for class 4 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	167 patients aged 18 and over who had experienced a myocardial infarction and were recruited into the pilot study.
Data sources	1. Study data collected for the pilot study and held at the University of Glasgow 2. HES and ONS data held by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Postcode – unit level 5. FAMOUS study ID
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Gender 4. FAMOUS study ID

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 Group noted the clear public interest in 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

All patients gave consent to be included in the FAMOUS study. However, it was not made clear in the patient information and consent documents that patient data would be held and analysed at the University of Glasgow. Enrolment to the study completed in 2013 and it was not practicable to re-consent patients. The Sub-Committee noted that a number of participants were likely to be deceased and that the applicants would be unaware of this until the data linkage via NHS Digital was complete. Contacting participants may cause distress to the relatives of deceased participants. Members accepted that it was not feasible to seek consent.

- Use of anonymised/pseudonymised data

Confidential patient information is required to link confidential patient information collected for the FAMOUS study to HES data held by NHS Digital. This linkage cannot be undertaken in any other way.

Exit strategy

The main FAMOUS Study has already closed and the applicants advised that they had funding for the longer-term follow-up, including this data linkage. The clinical trial data has already been pseudonymised and a pseudonymised dataset will be returned from NHS Digital to the research team.

Members requested clarification on when all data collected for the study will be anonymised. The application referred to the study data being destroyed 20 years after the end of the study The Sub-Committee requested clarification on when this 20-year period began from and when the applicant expected that all study data would be destroyed.

'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 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 General Data Protection Regulation and Data Protection Act 2018.

There are no plans to re-contact patients for consent for further data linkages. The applicants confirmed that patients would not be re-contacted to seek consent for the described changes.

Patients consented to inclusion in the FAMOUS trial. The applicants had agreed with DARS that University of Glasgow will produce a website detailing how the data are being used. The Sub-Committee asked that the text to be used on the website was provided for review. This text needed to include information on how patients can withdraw their consent to the ongoing processing of their data and clarity on what will happen to their data if they do.

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 advised that the study had been discussed with staff members from a variety of backgrounds within Hairmyres Hospital and with patients in the catheter labs and relevant wards.

The original application for the pilot study had been reviewed by British Heart Foundation and the British Cardiovascular Intervention Society Research and Development Group. The feedback received was positive.

The plans for record linkage have been described in the Patient and Public Involvement meetings and discussions with lay and service user had also taken place. The Sub-Committee agreed that the patient and public involvement carried out was proportionate to the scope of the application.

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 text to be used on the study website at the University of Glasgow is to be provided for review. This text needs to include information on how patients can withdraw their consent to the ongoing processing of their data and clarity on what will happen to their data if they do.

2. Clarify when all confidential patient information collected for the study will be pseudonymised.

3. Confirm when the 20-year period of data retention period is counted from and when the study data will be destroyed.

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

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. **Pending**

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. **Pending for University of Glasgow.**

3. **Confirmed – NHS Digital has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 10 June 2019.**

4. **Pending – a confirmed 'Standards Met' grade on the DSPT submission for the University of Glasgow is required.**

b. 19/CAG/0230 - Advanced analytics in primary care: provision of actionable information for quality improvement for antibiotic reduction, care advice and medication safety (ACTION)

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to evaluate the impact of online feedback dashboards, used by health professional, on improvements in patient care, the rate of antibiotic prescriptions and the incidence of potentially hazardous prescribing and monitoring.

The applicants are seeking to make better use of the data available in Electronic Health Records (EHRs) and to present it in more user-friendly ways to health professionals. Three eLab dashboards will be created, the PINGR (Performance Improvement plaN GeneratoR), SMASH (Smart MedicAtion Safety dashboard) and Building Rapid Interventions to reduce antimicrobial resistance & over-prescribing of antibiotics (BRIT). GP practices and other NHS sites in Greater Manchester and the Wirral will be recruited to the study and sign up to the service. Each practice involved will receive the eLab dashboards. The effectiveness of using the intervention will be evaluated quantitatively using an interrupted time series study design, by comparing the numbers of patients who receive an appropriate antibiotic in each practice before and after implementation of the eLab dashboards. Log files of the eLab dashboards will be examined to investigate the frequency with which the dashboards are used and how this varies between practices and over time.

ResearchOne will generate pseudonyms for primary care data, using a SALT, and transfer this to NHS Digital, who will generate HES data with pseudonyms and the research team at the University of Manchester will receive de-identified primary and secondary care data. It would be technically possible for NHS Digital to identify

patients in the ResearchOne cohort, therefore the applicants sought support under Section 251 for this data linkage.

A recommendation for class 1 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	Male and female patients from birth upwards with an infection whose data was included in ResearchOne. Greater Manchester and Wirral has a population of 3 million people, and the applicant noted that this was the potential maximum number of patients whose data would be included.
Data sources	3. ResearchOne 4. HES data held by NHS Digital
Identifiers required for linkage purposes	No items of confidential patient information are required for data linkage. Linkage will be performed using a SALT ID number.
Identifiers required for analysis purposes	No items of confidential patient information will be required for analysis.

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 Group noted the clear public interest in 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

The applicant noted that the population of Greater Manchester and the Wirral was 3 million people. Potentially all patients in these areas could be included in the study, meaning that approximately 26 million patient records would be accessed. The Sub-Committee agreed that it was unfeasible to contact all patients to seek consent.

- Use of anonymised/pseudonymised data

Confidential patient information is required for the linkage between ResearchOne and NHS Digital datasets. Anonymised data will be returned to the applicants. This linkage cannot be undertaken 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 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 General Data Protection Regulation and Data Protection Act 2018.

A patient leaflet had been created and will be sent to all practices involved in the study for GPs to provide to patients. The applicant noted that ResearchOne determined who was included in their dataset and had their own procedures for patients to dissent from inclusion. The Group noted the information provided and raised no further queries.

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 explained that the project is part of a large programme of research at Connected Health Cities (CHC). An active public and patient involvement and engagement (PPIE) group worked along-side all the projects for CHC, and project updates and development plans are frequently communicated to this group and members are invited to join project team meetings. PPIE members and stakeholders are involved in all aspects of the research plans, design and interpretation.

Focus groups and workshops were carried out as part of the initial research to address concerns around use of data in this way from other research data sets used and the process for receiving, processing and analysing the data was discussed in depth and help to create the existing procedures. The other data sets used are already linked to HES. The Group noted the information provided and raised no further queries.

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. Clarify that the lawful basis relied on for the processing of personal data is: Article 6(1)(e) Processing is necessary for the performance of a task carried

out in the public interest or in the exercise of official authority vested in the controller.

2. Clarify that the lawful basis relied on for the processing of special category data is Article (9)(2)(j) Processing is necessary for scientific research purposes in accordance with Article 89(1).

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. **Pending**

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. **It was confirmed that the relevant DSPT submission related only to NHS Digital.**

c. 19/CAG/0215 - Functional outcomes In Trauma (FIT) Study

Context

Purpose of application

This application from the University of Leeds set out the purpose of medical research that seeks to assess the impact of major trauma, especially polytrauma, on the physical aspect of functional outcome and how this changes over time.

Little information is available in the UK on how well patients who sustain major trauma function afterwards. Major trauma is defined as significant injuries with a calculated

‘injury severity score’ (ISS) over 15 and a maximum score of 75. The applicants will assess how well patients function physically, psychologically and socially after trauma. The study is comprised to two phases, involving two patient cohorts, a prospective cohort and a retrospective cohort.

Patents in the Phase 1 prospective cohort will complete questionnaires at 3. 6. 9 and 12 months. Patients in this group will be identified by the research team, who are also members of the direct care team, from the daily trauma meeting and major trauma ward lists and will be approached while on the ward in the weeks following the trauma. Patients will be given a participant information sheet. If interested, they then complete the consent form on the online questionnaire service, QTool, and their participation will proceed on a consented basis. Because the research team are part of the direct care team and therefore regular attendees at these meetings Section 251 support is not required for this cohort.

The Phase 1 retrospective cohort will be comprised of patients who sustained major trauma between 1 and 10 years previously. The research team will screen the Trauma Audit Research Network (TARN) database and Electronic Hospital Records (EHR) at Leeds Teaching Hospitals NHS Foundation Trust to identify suitable patients. A recruitment pack, containing an invitation letter, participant information sheet and instructions on how to access QTool to complete the questionnaires will be sent to selected patients. Patients will be contacted up to 4 times by post and also contacted by telephone at least 14 days after the pack was sent to see if they are happy to take part or if they would like further information. Their participation will then proceed on a consented basis. Section 251 support is sought for members of the research team to screen the records for suitable patients and make contact to seek consent.

5 to 10 patients from each cohort will also be invited to take part in qualitative interviews. Section 251 support is not sought for this aspect of the study.

In Phase 2, patients who have taken part in Phase 1 will automatically be enrolled to take part. New prospective patients will be recruited into the study, using the same methodology as in Phase 1, and support under Section 251 was required for this. These patients will be known as Group A. Group A will complete the same set of questionnaires as the prospective patients in Phase 1. Once completed, the patients will then be included in Group B, along with the prospective patient group from Phase 1. Group B will repeat the standard PROMs, however one questionnaire, the Leeds Trauma Questionnaire, will have been amended slightly so that questions are not repeated.

A recommendation for class 1, 2, 3, 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	440 patients aged between 18 and 65 who have sustained a major trauma and have an injury severity score of over 15. 320 patients will be recruited to the retrospective cohort. The120 patients recruited to the prospective study do not require s251 support
Data sources	5. Trauma Audit Research Network (TARN) 6. Electronic Health Records (EHR) at Leeds Teaching Hospitals NHS Foundation Trust 7. Major trauma ward lists at Leeds Teaching Hospitals NHS Foundation Trust 8. Daily trauma meetings held at Leeds Teaching Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	6. Name 7. NHS Number 8. Hospital ID number 9. GP registration 10. Date of birth 11. Date of death 12. Postcode – unit level 13. Address
Identifiers required for analysis purposes	5. Date of birth 6. Postcode – sub-sector level 7. Gender 8. Occupation 9. 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 Group noted the clear public interest in the study.

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 applicant advised that the patient group who were the focus of the study will have sustained serious injuries, which may have led to serious cognitive impairment or death. The applicants sought support to screen patient records to ensure that patients were alive and to check they were not cognitively impaired prior to contacting to avoid causing distress to patients or relatives. The applicant noted that writing to patients to seek consent to access their records may also cause distress to patients or their families.

The Sub-Committee agreed that the proposed methodology of screening records in order to approach eligible patients and to seek consent was reasonable.

- Use of anonymised/pseudonymised data

Access to confidential patient information is required in order for the research team to identify and make contact with patients suitable for the FIT study. This cannot be undertaken in any other way.

Flow of confidential patient information

The Sub-Committee reviewed the data flow diagram provided and noted that it was unclear how the patients in the retrospective group will be identified and which databases will be accessed. Members asked that a revised data flow was provided, setting out clearly the flow of confidential patient information for patients in the retrospective group, the data sources involved and which aspects of this support under Section 251 was requested for, and which aspects were undertaken with patient consent.

'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 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 General Data Protection Regulation and Data Protection Act 2018.

Patients records will be screened for suitability under Section 251 support. Selected patients will then be sent an information pack in the post or given an information sheet while on the ward. This information will explain that their records have been screened. Patients who do not consent will not be included in the research.

The applicant advised that patient's records would be checked for evidence of historic dissent to the use of their confidential patient information in research. Retrospective patients will also be contacted by telephone and post to seek consent. Prospective patients would be approached for consent while on the ward. Patients would not be included in the study if they did not consent. Any information collected would be removed from the study, expect for their NHS number and Study ID, which would be retained in the study log.

The Sub-Committee reviewed the participant information provided and queried whether the applicant planned to publicise the study, so that patients could dissent prior to their record being screened, such as by providing a study poster or website notification.

The invitation letter for Group A did not mention that patients do not have to take part and the Sub-Committee asked that this was made clear.

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 advised that focus groups had been held with patients in order to obtain their input into the design of the study. The screening of patient medical records for the study was discussed during the focus group and the group noted that they were supportive of this, as long as it was undertaken as part of an approved study and by members of the orthopaedic research team at the Leeds Major Trauma Centre. A summary of the discussion at the main focus group was provided, alongside a poster that was presented at the PROMS UK conference in June 2019.

No specific changes were made to the proposed screening methods as a result of this consultation, as the focus group were supportive of the methods described in the protocol. The focus group advised that a letter informing patients that they had been selected for the study and what this selection had been based on would be helpful, therefore this had been created. The focus group also agreed that they would be happy to receive a reminder telephone call from the research team and that two weeks was sufficient time to read and digest the information. The Sub-Committee noted that the patient and public involvement carried out was proportionate to the scope of the study.

Dissemination and publication of study results

The applicants stated that all data would be anonymised prior to publication and that it would not be possible to re-identify patients. The Sub-Committee noted that the Information Commissioner's Office recommended that small cells sizes (e.g. patient numbers less than 5) were suppressed and queried whether the applicant intended to follow this recommendation.

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. Provide a revised data flow diagram for patients in the retrospective group, the data sources involved and which aspects of this support under Section 251 was requested for, and which aspects were undertaken with patient consent.

2. Advise if there are plans to publicise the study, so that patients can dissent prior to their records being screened. If so, please provide any materials, such as posters or website text.

3. Revise the Participant Information Leaflet for Group A to make it explicit that patients do not have to take part in the study.

4. Provide clarification on whether the Information Commissioner's Office recommendation on suppressing small cell sizes will be followed.

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. **Pending**

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: University of Leeds (by NHS Digital email 28 August 2019) and Leeds Teaching Hospitals**

NHS Foundation Trust (by NHS Digital email 12 July 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).

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