NHS
Health Research Authority

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

19 May 2017

Present:

Name	Capacity	Items
Ms Clare Sanderson	Chair	1a, 1b, 1c
Dr Rachel Knowles		1a
Dr Lorna Fraser		1a
Dr Martin Andrew		1b. 1c
Mr Andrew Melville		1b, 1c

Also in attendance:

Name	Position (or reason for attending)
Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0086 Patient Expectations and Perceived Justice in Healthcare Complaints – Are We Managing the Expectation Gap?

Context

Purpose of application

This research application from Leicester University, which was being completed as part of a Master's degree, set out the purpose of investigating the extent to which patient expectations were met in relation to complaints made against the Trust.

Over 175,000 complaints about healthcare were made every year and both the Parliamentary Ombudsman and Patient's Association has questioned whether the system for investigating complaints was functioning effectively. The application aimed to meet the 'expectations gap' arising between expectations of patients, and expectations of clinical staff and administrators in relation to satisfactory resolution of complaints. Research from other countries suggested that concerns of patients in relation to procedures and interactions with staff were not always acknowledged, and patient expectations not addressed in the response to complaints. The emotional content of the complaint letters was often not acknowledged or acted upon.

This research would potentially lead to improvements in the way that trusts reacted to patient complaints, enabling them to learn from mistakes made and improve the service overall. The University Hospitals of Leicester Trust intended to use the research findings as part of a service evaluation.

The researcher would analyse 100 complaint letters from patients to the Trust, and the response to the letters, in order to investigate whether patient expectations had been met, and lessons learned. The letters would be selected by the Complaints Officer at the Trust from the CHUGGS division concerning the cancer, urology, gastroenterology and general surgery departments. Redaction of the letters would take place on site.

Confidential patient information requested

Access was requested to data from University Hospitals of Leicester complaints department in relation to patients over 18 who had made a complaint about the hospital.

Name and hospital ID

Access to free text information contained within the letters which could potentially include details of medical conditions, hospital admissions and treatment dates.

Confidentiality Advisory Group advice

Public interest

Members agreed that this application was for a medical purpose, and there was value in the proposal to investigate the extent to which patient expectations were met in relation to complaints made against the Trust. The public interest was justified by the applicant, and improvements to the complaints procedure could result from the study.

There was some discussion in relation to whether support was required for the activity, given that the applicant was a member of staff in the clinical department to which the complaints would relate. However, as the complaints would be directed towards several different specialities within the department, it was unlikely that the patient would consider the applicant to be part of the direct care team for all of them – therefore support was required for this activity, regardless of whether the applicant might have access to the letters as part of his work role.

Clarification of Scope

It was noted that the applicant had changed his approach in relation to the selection of letters, to select letters randomly from a period of three years rather than taking the latest 100 letters. The applicant had stated that he would access 100 complaint letters and their associated response.

It was observed that there could be more than one letter and one response from the Trust associated with each complaint, therefore the if the applicant wished to access all the correspondence for each complaint the scope should be extended accordingly.

The Sub-Committee therefore requested a more realistic estimate with regards to how many letters the applicant was seeking access to, or clarification on this point.

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

The applicant had made the statement that consent was feasible but could involve greater disclosure of patient details. Members observed that this would not be the case if the complaints officer were to write and seek consent, as the complaints officer would access this level of patient information as part of their work role.

Although it was possible that seeking consent could cause other issues with regards to the effectiveness of the study, these issues had not been outlined by the applicant. It was agreed that further justification for not seeking consent was required.

- Use of anonymised/pseudonymised data

Members agreed that support could be given to enable the applicant to access patient complaint letters in order to anonymise them, by a process of redaction.

It was agreed that it was appropriate for the researcher himself to undertake this task, thus ensuring that disclosure was limited to one person only rather than a number of clinicians.

Justification of identifiers

As above, it was accepted that access to the full letter was required in order to anonymise them, and that this access would be limited to one person.

Additional points

Patient Involvement

It was noted that the applicant intended to seek the views of patients with regards to access to complaint letters, and members agreed that the results of this exercise should be fed back to the Sub-Committee before support could be recommended.

Patient Notification and opt out

In addition to placing public notifications on the department website and the Research and Innovation Department website, members requested that these were also placed on the complaints website (Patient Information Liaison Service or PALS) as this was where patient information would be accessed. The suggestion was made the the information on the Research and Innovation department website and the PALS website could link to the surgery department website.

The notification should be available at least four weeks prior to data extraction to enable patients to object.

In relation to the Opt-out procedure, it was agreed that patients should be advised to contact the Complaints Officer rather than the applicant, to avoid further identification of the patient. The Complaints Officer had access to the complaint letters and could ensure that details of any dissenting patient would not be included in the selected letters passed on to the researcher.

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 Health Research Authority, 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

1. If more than 200 letters would be accessed (comprising one complaint letter from each patient and one corresponding response letter from the Trust), the applicant was asked to make this clear and ensure that a clear description of the scope of the application to be approved had been provided.
2. The applicant was asked to provide further justification as to why it would not be practicable to seek consent.
3. The applicant was asked to feedback the results of the patient involvement work to the Sub-Committee, once complete.
4. The applicant was asked to confirm that the Opt-out procedure will be managed by the Complaints Officer.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **V14 confirmed published and reviewed.**

b) 17/CAG/0087 Pilot Study for the Tight K Study

Context

Purpose of application

This research study from Barts Health NHS Trust set out the purpose of investigating the effectiveness of administering potassium to patients after heart surgery, in order to prevent hearth rhythm problems. Although this treatment was commonly used, there was no scientific evidence that it worked. The applicant stated that the treatment was expensive, unpleasant for patients, and could lead to (unspecified) additional risks.

The study was a pilot which the applicant intended to run with 160 patients in order to test the feasibility of a further randomised controlled trial with 1770 patients. The pilot would specifically test the recruitment procedure and whether it would be possible to recruit an adequate number of patients within the timescale allowed, as well as testing data collection and highlighting any safety issues.

Support was requested to enable the research team to access identifiable data in order to screen for eligible patients, who would be approached either at their pre-surgery appointments by the clinician and the researcher in order to seek consent, or by the researcher via telephone, email or post.

A recommendation for Class 3 and Class 6 support was requested to select and contact patients to seek their consent, and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from hospital waiting lists and theatre lists initially, and then from the medical notes of potentially eligible patients, in relation to those patients who would be undergoing elective coronary artery bypass surgery.

The full medical record would be accessed in order to check the following:

- history of previous AF.
- previous use of medication to manage cardiac rhythm.
- preoperative high-degree AV block.
- preoperative serum potassium level above 5.5 mEq/L.

The research team would also access the patient's contact details including phone number, email and address, in order to contact them to seek consent for the trial.

Confidentiality Advisory Group advice

Public interest

Members considered the study proposal and agreed that it had a clear medical purpose and that the applicant had demonstrated the public interest in the study.

The request for Class 3 and 6 support was deemed appropriate.

The feasibility study aimed to test the recruitment process as well as data collection and safety issues. The recruitment process was within the remit of CAG as it involved researchers looking through hospital lists, and patient medical notes. Members agreed that the feasibility study could help to determine patient attitudes towards this recruitment process, which would be an important part of CAG considerations with regards to the future larger trial.

Scope

The Sub-Committee agreed that the scope should be clarified in terms of the number of patient medical records to be accessed. It was clear that 160 patients would need to be recruited; however no estimate had been given in relation to the number of records that would be screened in order to achieve this number.

Patient Contact

The CAG raised concerns in relation to the proposed method of contact, which included telephone calls from researchers to patients before they had received any information about the study. Patients would be less surprised to receive a phone call after receiving information through the post.

The CAG agreed that this should be addressed by the REC, and evidence would be required that the REC approved this approach.

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

Access to identifiable data was requested in order to identify eligible patients and seek consent. The alternative would be for the clinician to screen notes and seek consent from the patient, and this would be done in some cases – however support was requested for sites where clinicians would not have the time or resource to do this. The Sub-Committee accepted the arguments put forward with regards to lack of clinician time, and it was acknowledged that this could be more of an issue in relation to the larger trial.

It was emphasised that the patient notifications should clearly explain the respective roles of clinician and researcher and reassure patients that their care would not be affected should they opt out of this screening or choose not to participate in the study.

- Use of anonymised/pseudonymised data

The data flows had been clearly outlined in a data flow chart which members found clear and useful. Consent would be sought at the earliest practicable juncture, therefore this rather than anonymisation of data would comprise the exit strategy.

Justification of identifiers

The Sub-Committee acknowledged that the contact details were required to seek consent from patients, and reviewed and accepted the proposed data to be accessed for screening patients to be necessary and appropriate for the purpose.

Additional points

Patient Notification

The CAG considered whether the applicant had made sufficient attempts to notify the patient population that their records could be screened, and to allow them to opt out if they wished.

Although patient notification materials were being produced for the website, it was agreed that these were unlikely to be accessed by patients and therefore would not be sufficient. In addition to this information, leaflets and posters should be produced and made accessible to patients at least on relevant wards and out-patient clinics. All patient notifications should make it clear to applicants that their care would not be affected should they decide to opt out.

User involvement.

Members expressed a strong view that the patient and public involvement had been limited and was insufficient. Although it was noted that the views of the patient consulted had been incorporated into the study design, the views of one patient could not be considered representative.

Given that the application was for a feasibility trial, this provided an opportunity to seek patient views as part of the work. Members commented that there was likely to be positive interest from patients in the trial, should they be consulted.

Therefore, it was stipulated that patient and public forums should be approached for their views on the recruitment process during the pilot trial, and the results fed back to the Sub-Committee at review stage, and in any future application to CAG for the main trial.

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 Health Research Authority, 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

1. The applicant was asked to provide an estimate of the scope of support required, i.e. how many records would be screened in order to recruit the required number of patients?
2. The applicant was asked to provide patient notification posters and leaflets and explain how dissent via this route would be respected. These should make it clear that patient care would not be affected by any decision to opt out of screening.
3. The applicant was asked to provide evidence that the REC had approved this recruitment method.

Specific conditions of support

3. Public involvement work should be carried out to gauge the views of patients and the public on this recruitment method, and reported back to the CAG at annual review and as part of future applications.
4. Favourable opinion from a Research Ethics Committee.
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.

c) 17/CAG/009 FEASIBILITY of IBIS 3. An International Breast Intervention Study investigating Prevention Of Late Recurrence in ER+ breast cancer survivors following 5 years of adjuvant treatment

Context

Purpose of application

This research application, a CTIMP (Clinical Trial of an Investigational Medicinal Product) run by Barts Clinical Trials Unit, was a feasibility study to test the effectiveness of recruitment methods, adherence to treatment and methods for collecting questionnaire data. The overall aim of the trial was to investigate the effectiveness of 3 types of medicine in preventing recurrence of breast cancer. These are metformin, zoledronic acid and a group of medicines called aromatase inhibitors (anastrozole, letrozole or exemestane). The drugs would be given separately or in combination with each other resulting in eight different treatment groups, including a ‘no continued treatment’ group which was current standard care. The results would address late recurrence in women with hormonal breast cancer which was a recognised problem, with recurrence rates remaining constant for at least 20 years following diagnosis. The importance of late recurrence had been recognised by many clinicians, researchers and patient groups and there was a consensus that action needed to be taken to address this.

The recruitment method to be tested required support under s251 in order for the research team to assist with the identification of potential participants by searching hospital databases and clinical notes, at sites where clinical staff were not able to do this. Screening of databases could also take place at the coordinating centre, Barts Clinical Trials Unit.

Class 1 and 6 support was requested for the process of extracting and anonymising the information, and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from hospital databases and clinical notes at participating NHS Sites in relation to post- menopausal, hormonal breast cancer survivors who had already had 5 years of hormonal therapy (at least 4 years of treatment with an aromatase inhibitor) completed within the last 6 years. They must be without, but at increased risk of, a breast cancer recurrence.

The data items were not listed on the application, but were listed in response to queries on the advice form, as follows:

Identifiable data items necessary for screening:

- Age
- Diagnosis of ER and breast cancer
- TNM stage (size of breast tumour)
- Progress of cancer (whether it has reached lymph nodes or metastasized
- Date of diagnoses
- Treatment received
- Recurrence of cancer

Identifiable items to be provided to the clinical care team in order for them to identify the patient and contact them to seek consent:

- Medical record number
- Initials

Confidentiality Advisory Group advice

Public interest

The Sub-Committee agreed that the study had a medical purpose and had demonstrated a clear public interest in the aim of preventing recurrence of breast cancer.

Scope

The applicant had clarified that the involvement of research staff in the recruitment process would extend to no more than 6 sites. Members stressed that an amendment would need to be submitted to extend the scope of the application, if more than 6 sites were to be included.

It was noted that patients would also be identified by GPs through the patient record. This could raise some issues, such as anxiety in patients who had thought they were cured, difficulties around referring patients to hospital for research purposes and patients being contacted twice, by both the GP surgery and the hospital. It was agreed that these were issues to be considered by the REC.

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

Although the approach to accessing patient data seemed initially to be haphazard, given that the sites at which this would occur were not specified, members were reassured that consent issues had been taken seriously on reading the Protocol and the full considerations that had been given to the process, including likely numbers of sites where access by researchers would occur. Research staff would only access the patient record to screen for eligible patients at sites where clinical staff were not able to do so, and consent would then be sought by the clinical care team.

- Use of anonymised/pseudonymised data

Members observed that consideration had been given to limiting the identifiers which would be passed from the researchers to the clinical care staff in order for consent to be sought – only medical record number and initials would be extracted from the patient record.

However, a concern was expressed in relation to the following statement in the Protocol:

'If any patient information needs to be sent to a third party (including correspondence / communication to central laboratories or sponsor) the PI and the study team will adhere to patient pseudo-anonymous parameters. This includes the patient initials, date of birth as well as the unique study randomisation and/or screening number. Any information that is to be collected by these third parties will use these coded details for any relevant documents as well as maintaining databases.
Identifiable data will also be collected and stored in an encrypted database or password protected file with restricted access to authorised staff on a secure server. Identifiable data will be stored separately from the clinical data. This will include name, address, email, telephone number, GP details NHS number and date of birth'.

This indicated some confusion with regards to date of birth, which was an identifier and therefore could not be considered pseudonymous.

Another area of concern was in relation to the transfer of data outside the European Economic Area (EEA). The study was part funded from Australia and New Zealand, and two of the key investigators were situated outside the EEA. Further detail regarding the data items to be transferred to these investigators was required. In the case of transfer of pseudonymised data, appropriate safeguards would be necessary.

<u>Justification of identifiers</u>

Members agreed that the identifiers listed were justifiable and appropriate in terms of the purpose for which they were to be accessed. It was commented that a data flow chart would have been useful although the process was simple, given the different sites involved.

<u>Additional points</u>

<u>Patient notification</u>

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 and mechanism to respect 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 1998.

The applicant had not demonstrated an awareness of the need to make reasonable measures to notify potential participants that their data could be screened by researchers, and enable them to opt out if they so wished. However reference had been made elsewhere to a study website, patient information sheets and posters in breast screening clinics. These should include information about

the screening of notes and details of how patients could opt out of researcher access to their notes for the purpose of screening for suitability for the study.

Patient and public engagement

Patient and public involvement work had been carried out, some with an independent advocacy group; however, this had not been in relation to the recruitment aspect of the study.

Members agreed that it was important to seek patient views on access by researchers to their medical notes, and that this work should be completed before proceeding with the study.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, 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

1. The applicant was asked to clarify the data items to be transferred outside the EEA, and confirm that agreements would be put in place, where pseudonymous data was to be transferred, requiring the recipient to put appropriate safeguards in place.
2. The applicant was asked to report back on patient and public involvement, outlining the responses of patients to the proposed method of screening in order to recruit participants.
3. Details of patient notifications and opt out from recruitment screening were required.
4. The applicant was asked to provide evidence that the REC have approved all methods of recruitment.

Specific conditions of support

6. Favourable opinion from a Research Ethics Committee.
7. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

The applicant withdrew this application on the 9 June 2017, confirming that they would not be following the method of recruitment outlined in the application, and that this would be removed from the Protocol and no patient identifiable data would be accessed by persons outside the care team without consent.