Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group -14 January 2016

Reviewers:

Name	Capacity	Items
Dr Kambiz Boomla	Chair	1a
Tony Calland	Reviewer	1a
Marc Taylor	Reviewer	1a

1. NEW AMENDMENTS - Research

a) Missed Diagnostic Opportunities-14/CAG/0141

Context

This application from the University of Manchester set out the purpose of reviewing General Practice patient records to study Missed Diagnostic Opportunities (MDO) to estimate the MDO rate in UK general practice. Patient safety and in particular the occurrence of medical errors, has received considerable global attention since the publication of the landmark report 'To Err is Human' in 1999. Within the range of possible errors, medication related errors and diagnostic errors have been identified as the most common types of error in the primary care (e.g. general practice) setting. Despite their potential for, and actual significant impact, diagnostic errors (now termed missed diagnostic opportunities (MDOs)) have received relatively limited attention by academic researchers. Data on the numbers, types and causes of such MDOs encountered in general practice are limited and there are no large-scale studies in the UK that provide an accurate measure of MDO and harm rates in UK general practice. From what is known globally, it seems that MDOs are more common in general practice than in hospitals and there is a wide range of estimates of the actual rate of harm. Recent work in the United States combining data from three large studies puts the MDO rate at 5% of all patient-doctor encounters, but similar data from the UK is lacking.

Class 1, 5 and 6 support was requested to allow access to an authorised user for the process of extracting and anonymising the information and to audit, monitor and analyse patient care and treatment.

Amendment request

This amendment request was described by the applicant as an amendment to System Level Security Policy as to the location of the GP reviewers when conducting their reviews.

The original application set out that access to data would be from within each GP practice however the amendment requested that access to data would now happen from an EMIS terminal within the NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre at the University of Manchester, or from within each GP practice.

The Confidentiality Advice Team (CAT)

The CAT was of the opinion the amendment request was a change to the methodology therefore forwarded the request to a member of the CAG who reviewed the original application for their opinion.

The CAG member agreed with this opinion and requested the amendment to be reviewed by sub-committee.

Confidentiality Advisory Group sub-committee conclusion

Members discussed the original study about missed diagnostic opportunities involving the researchers looking at the GP computer records of some 5000 patients in the surgery premises.

Members noted that it has since now been discovered that in some practices there is not enough space or computer terminals to do this and this is prejudicing recruitment. The applicant would now like, in some practices, to view the clinical records from an EMIS terminal in their academic offices, not in the practice, but on a secure N3 connection. Using the EMIS Anywhere product, no clinical EMIS information remains on the computer when the connection is closed down, apart from the data they extract deliberately as part of the study.

There is a second element to the amendment involving a the list of 100 patients from each practice, where the EMIS number is linked to the study unique ID is to be kept, for these remotely accessed patient records, on a secure university remote drive, for the duration of the study before being deleted.

Members were in agreement that the applicants propose solutions to the problem they have encountered is acceptable.

In line with the considerations above, the sub-committee agreed that the minimum criteria under the Regulations appeared to have been met for this

amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 02/11/2015**