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

18 February 2022

Present:

Name	Capacity	Items
Ms Clare Sanderson	CAG Alternate-Vice Chair	1a
Mr Andrew Melville	CAG Member	1a
Ms Diana Robbins	CAG Member	1a

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 22/CAG/0031– Magnetic Foreign Body Ingestion in Children (MAGNETIC): a prospective surveillance study

Context

Purpose of application

This application from the University Hospital Southampton NHS Foundation Trust set out the purpose of medical research that seeks to establish the incidence of ingestion of magnetic foreign body by children aged 16 years and under within the UK and Ireland.

Magnetic objects are known to be dangerous when swallowed by children, particularly when multiple magnets are ingested. Ingestion can lead to significant morbidity, including bowel obstruction, fistulation and perforation, which require emergency surgery to treat. Recent published research has shown that rates of magnetic foreign body ingestions are increasing globally. Studies from the UK have highlighted a significant burden of morbidity, but the exact scale of the problem in terms of actual incidence, burden of morbidity, risk factors and outcomes is currently unknown in the UK and Ireland. The applicants seek to conduct a prospective surveillance study across the UK and Ireland to collect data to establish the incidence rate of magnet ingestion, which investigations are best at diagnosing magnet ingestion and its complications, the treatment modality that is most effective, and the complications that may occur as a result of magnet ingestion.

Clinicians in participating trusts will be made aware of the study and inclusion criteria through relevant research networks and organizations. Children swallowing magnetic foreign bodies will be identified on initial presentation in emergency departments, or on presentation to paediatric medical or surgical teams. Clinicians will then complete a case report form on RedCap. At this point the patient's NHS number will be collected, along with other relevant routinely collected clinical data from the patient's health record. The NHS number will be held until the end of the study and used to check for duplicate entries, as patients may move between trusts when receiving treatment. At the end of the study, duplicate entries will be removed using NHS numbers within RedCap. This anonymised dataset will then be used for analysis.

A recommendation for class 1, 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	Patients aged 16 years and under who attended hospital **in England or Wales** having ingested at least one magnetic foreign body - confirmed on radiology or by clinical features.
Data sources	1. Electronic and paper patient records at participating trusts.
Identifiers required for linkage purposes	1. NHS number 2. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level
Additional information	Patient sex, ethnicity, postcode and age in months at presentation will also be recorded to meet the study objectives. Data will also be collected for patients treated for ingestion of a magnetic foreign body in Scotland and Northern Ireland. The applicants will ensure that the appropriate support is in place for this data collection.

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 CAG agreed that the application had a medical purpose and was in the public interest.

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 applicants explained that, due to the often emergent nature of the presenting complaint, the rarity of the presenting complaint, and the need to collect data on every presentation to accurately determine incidence and current management, it was not practicable to seek consent. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicants require access to patients NHS numbers in order to check for duplicate entries, if patients received treatment in more than one trust. Once the check for duplicates has taken place, the NHS number will be deleted. The CAG agreed that the application activity could not be undertaken in any other way.

Justification of identifires

It was unclear whether the applicants would obtain full postcodes or the first part of the postcode only. Members requested clarification on this. If full postcode (which is an identifier) was required, justification on why this was needed was to be provided.

'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 object 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.

The applicants provided a poster, which would be displayed in emergency departments and paediatric inpatient areas. This poster explained the study and that patients can dissent. Telephone, email and postal contacts were given. The CAG asked that the information on the poster was also included on the websites of participating trusts.

Patients who expressed dissent at their NHS Trust to participation in NHS research would not be included in the study or would have their data removed from the database, depending on when the expression of dissent was received.

The applicants advised that the National Data Opt-Out would not be applied, but a project-specific opt-out mechanism would be in place. The CAG accepted that accessing the National Data Opt-Out during data collection would be difficult, and noted that a local, project-specific dissent mechanism would be used.

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 explained that they had discussed the acceptability of collecting NHS numbers and routine clinical data for the purpose of the study, without seeking consent, with the parents of four children who had recently been admitted to the sponsor organisation having ingested magnetic foreign bodies. None raised any objection of the proposed data collection without consent as proposed in the study. None objected to the use of NHS number by the research team to check for duplicates. All of them, having been previously unaware of the risks posed by foreign body ingestion, stated how important they felt the study was.

The patient and public involvement conducted is small in scale, however it has been carried out with a relevant group. The breach in the common law duty of confidentiality is also minor, therefore the patient and public involvement is proportionate to the aims of the study.

The CAG noted that the patient and public involvement undertaken was small in scale but proportionate to the scope of the study and the limited breach of the common law duty of confidentiality. Members asked that the applicants continued to undertake consultations with relevant organisations and patient groups as the study continues and provide feedback from these discussions when submitting annual reviews.

Exit Strategy

NHS numbers will be held securely on REDCap (hosted on Bristol NHS servers) until the end of the data collection period. At which time duplicate entries will be removed and case report forms will be linked between sites, if necessary. The NHS numbers will then be no longer necessary and the data will be anonymised for analysis. The CAG raised no queries under this heading.

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. It was unclear whether the applicants would obtain full postcodes or the first part of the postcode only. Members requested clarification on this. If full postcode was required, justification on why this was needed is to be provided.

2. The CAG asked that the information on the poster was also included on the websites of participating trusts.

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. Consultations with relevant organisations and patient groups are to be undertaken as the study continues and feedback from these discussions provided when submitting annual reviews.

2. Favourable opinion from a Research Ethics Committee. **Confirmed: 18 February 2022**

3. 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:**

   The NHS Digital **2020/21** DSPT review for University Hospital Southampton NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (28 February 2022).

Minutes signed off as accurate by correspondence from Ms Clare Sanderson, CAG Alternate-Vice Chair		*18 March 2022*
Signed – Officers of CAG		Date
Caroline Watchurst		*16 March 2022*
Signed – Confidentiality Advice Team		Date