



Health Research Authority

Skipton House
80 London Road
London
SE1 6LH

Telephone: 020 7972 2557
Email: HRA.CAG@nhs.net

22 October 2018

Ms Sally Welham
Deputy Chief Executive
British Thoracic Society
17 Doughty Street
London
WC1N 2PL

Dear Ms Welham

Application title: National Adult Community Acquired Pneumonia Audit
2018-19
CAG reference: 18/CAG/0147

Thank you for your audit application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Secretary of State (SofS) for Health and Social Care on whether an application should be approved, and if so, any relevant conditions. This application was considered at the CAG meeting held on 06 September 2018.

Secretary of State for Health and Social Care approval decision

The Secretary of State, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is conditionally approved, subject to compliance with the standard and specific conditions of approval outlined below.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

This letter should be read in conjunction with the outcome issued on 24 September 2018.

Context

Purpose of application

This application from the British Thoracic Society set out purpose of a national audit programme into community acquired pneumonia in adults. The first British Thoracic Society (BTS) CAP audit took place in 2009/10, with re-audits in 2010/11, 2011/12, 2012/13 and 2014/15. The standards for the audits were derived from the 2009 update to the BTS Guidelines for the management of community acquired pneumonia in adults (the 'BTS Guidelines'). Over the years, a total of over 120 acute trusts have participated in the audit, involving over 24,000 cases of pneumonia.

To date, the CAP audit has not collected confidential patient information so has not required support under the Regulations. Data from the audits have shown a decreasing trend in mortality from CAP associated with improved processes of care. There is however evidence from GP databases and from HES data that variation in care of adults hospitalised with pneumonia exists across the UK. Previous BTS CAP audits have not assessed variation between sites. In contrast, recent national UK audits in both lung cancer and COPD have compared performance between sites to assess for variation in care and outcomes.

The aim with the BTS CAP audit 2018/19 is to assess variation in the care of patients hospitalised with pneumonia in the UK and seek explanations for any variation observed. In order to increase the value and data quality of the audit, it is proposed to link the BTS CAP audit data to routinely collected HES and ONS data. The BTS CAP audit dataset is rich in process of care measures whilst the HES dataset is strong in relation to patient baseline parameters and hospital outcome measures, but fails to capture CAP process of care measures. Linkage of these data sources will enable:

1. Analysis of variation of care according to a wider range of important outcome measures, including mortality, ICU admissions, hospital re-admissions and healthcare costs.
2. Improved case-mix adjustment of the audit cohort according to underlying co-morbidities and socio-economic parameters.
3. Health economic analyses.

The core aim of the project is to drive improvements in care, particularly in relation to the quality improvement objectives identified in 2014/15, by allowing participants to monitor their progress against these targets. In this round of audit (2018/2019) additional information will be provided on where variation exists in relation to these targets and performance generally, to allow sites to identify where quality improvement initiatives are needed locally.

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

The study population is hospitalised adults (16 years or older) admitted with a clinical radiographic diagnosis of Community Acquired Pneumonia (CAP) from 1 December 2018 to 31 January 2019. 150 Trusts are expected to participate in the audit and will be asked to enter as many cases as possible, with a minimum requirement of 60 cases per Trust. Limited information will be collected on patients who are deemed ineligible for inclusion in

the audit; however, these patients are out of scope as confidential patient information will not be requested.

The following items of confidential patient information will be entered into the audit platform to facilitate linkage with HES and ONS datasets by NHS Digital:

- NHS Number,
- Home Postcode,
- Sex,
- Date of birth,
- Date of death.

Confidentiality Advisory Group advice

A Sub-Committee of the main CAG considered the applicant's below written response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. Confirm that the patient diagnosis review would be undertaken by a member of the direct care team.

The applicant confirmed that the audit would be undertaken on a retrospective basis, with case lists generated using ICD10 codes and screened against the further inclusion/exclusion criteria. It was confirmed that participating Trusts would be informed that the audit should be led by a Consultant Physician and the screening process/diagnosis review undertaken by a member of the direct care team.

The Sub-Committee was assured by the applicant's response and raised no issues in this area.

2. Confirm what lawful basis is being relied upon for the processing of data and special category data in order to show compliance against principle A of the GDPR.

The applicant confirmed that the British Thoracic Society relied on GDPR Article 6(1)(f) to support its data processing – legitimate interests.

The Sub-Committee received the response and no queries were raised.

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. Patient and Public Involvement and Engagement strategy should be extended to enable additional activity to be undertaken as the audit progressed. An overview of the actual activity which has been carried out, together with details of the feedback provided, should be provided at the time of first annual review. If the responses given

are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.

2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - British Thoracic Society and Westcliff Solutions Ltd have a satisfactory reviewed grade on V14.1, 2017/18**).

As the above conditions have been accepted or met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Annual Review

Please note that your approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided no later than **22 October 2019** and preferably 4 weeks before this date.

Reviewed documents

The documents reviewed at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
CAG application from (signed/authorised) [CAG Application 18GAG0147]		15 August 2018
Covering letter on headed paper [Letter to CAG]		15 August 2018
Data Protection Registration [British Thoracic Society Registration Certificate]		05 March 2003
Other [Table 1]		
Other [Table 2 (new)]		
Other [PPI Feedback]		17 May 2018
Other [RE_ DARS-NIC-219944-G9X4V]		09 August 2018
Other [Appendix 8 - Audit Dataset (update #2)]		
Other [IGT v14.1 assessment - WESTCLIFF SOLUTIONS (8JR26)]		10 October 2018
Other [IGT v14.1 assessment - British Thoracic Society]		04 October 2018
Other [Letter to CAG 11 October 2018]		11 October 2018
Patient Information Materials [Audit Poster]		
Patient Information Materials [Patient Information Sheet (updated)]		
Research protocol or project proposal [Data Flow (updated)]		
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [Caldicott Guardian Letter]		04 July 2018

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item or submitted written comments are listed below.

There were no declarations of interest in relation to this item.

Yours sincerely

Confidentiality Advisory Group Sub-Committee Meeting in Correspondence

Group Members:

<i>Name</i>	<i>Present</i>	<i>Notes</i>
Dr. Liliane Field	Yes	
Mrs Diana Robbins	Yes	Lay Member
Dr Murat Soncul	Yes	Alternate Vice-Chair
Mr Marc Taylor	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Kathryn Murray	Senior Confidentiality Advisor

Standard conditions of support

Support to process confidential patient information without consent, given by the Secretary of State for Health and Social Care, is subject to the following standard conditions of support.

The applicant and those processing the information will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.
2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.
3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.
4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.
5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities.
6. Activities remain consistent with the General Data Protection Regulation and Data Protection Act 2018.
7. Audit of data processing by a designated agent is facilitated and supported.
8. The wishes of patients who have withheld or withdrawn their consent are respected.
9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.
10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.
11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken / to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.