Caldicott Approval Form – for SAMBA Data Transfer

Society for Acute Medicine Benchmarking Audit

Description of proposal:

National benchmarking exercise using multiple 24-hour cross-sections of patient data from UK Acute Medicine Units

About SAMBA

The aim of this project is to describe the severity of illness of patients in the Acute Medicine Unit (AMU, or equivalent), the speed of their assessment and their progress after seven days and to provide a comparison for each unit with the national average (or 'benchmark'). Each unit is asked to collect data on all patients presenting to the AMU within a specified 24-hour period for inclusion in the national dataset.

The audit is registered with the **Healthcare Quality and Improvement Partnership (HQIP)** and is listed in their **National Clinical Audit and Enquiries Directory**. The secure data collection portal for initial analysis, prior to transfer for storage and subsequent analyses, is provided by REDCap, hosted at the University of Birmingham (REDCap (bham.ac.uk)) a secure online database designed for the delivery of audit and research, widely used in healthcare settings.

Indicate which patient data items have been requested:

The only demographic data will be age (**in decades after 30 years, 5 year age bands from 16 – 30 years**) and gender. We will request index of multiple deprivation decile for patients' address, but post code will not be collected. In addition, we will collect:

- The total number of admissions in each unit
- Medical and nursing levels
- Efficiency of logistics – including data relating to date and time. For patients who die we will not record date or time of death
- Severity of illness and frailty.

None of the following data items will be entered on the electronic database:

- Forename
- Surname
- Date of Birth
- Address or Postcode
- Hospital or NHS number

The patient will be identified on the database by a study number. The study number will correspond to

the patient's name, and hospital registration number on an audit Masterlist that will be securely stored on-site at each participating hospital by the local lead. The Masterlist and anonymised paper data collection will both be stored securely and separately at each site.

Name of organisation receiving data:

Society for Acute Medicine

Person responsible for release of data (local Lead):

Name: **Job title:**

Person responsible for receipt of data:

Name: Dr Catherine Atkin

Job title: Assistant Clinical Professor in Acute Medicine, University of Birmingham and Lead for SAMBA

Organisation: Society for Acute Medicine

For what time period is data transfer required:

Start date: 22/06/23 (starting at 00:00hrs)

End date: 7/07/24

Please state regularity:

Data is collected on pre-specified 24 hour periods, with follow-up data collected at seven days, and uploaded to the secure database within three weeks of the specified 24 hour period.

Dates of data collection are determined nationally by the SAMBA team. Data collection & upload is limited to these dates.

Multiple periods of data collection occur during the year, to allow assessment of trends in performance.

Contact details in relation to this form:

Name:

Address:

Telephone:

Email:

How will the data be transferred?

Paper records ☐

Computer record x

Clinical staff in the Acute Medicine Unit and Ambulatory Emergency Care unit (or your local equivalent, e.g. MAU, AMAU, EAU etc.) will collect data on custom designed paper study proformas and will subsequently upload data through a secure portal hosted through HTTPS on UK based servers

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Who else will have access to the data?

(*If data recipients are not employed by the NHS please state whether NHS honorary contracts are in place. If not – detail confidentiality agreements.*)

No-one outside the [insert Trust name] clinical team will have access to **patient identifiable** data

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Where will the data be stored?

Within the Trust data will be securely stored on paper for one year by the local SAMBA Lead.

Data uploaded to the REDCap database hosted at the University of Birmingham (REDCap (bham.ac.uk)), an established secure database service that is used in the delivery of many national audits and research projects with the NHS, will be subject to a primary analysis with software specifically designed for the audit. Data will subsequently be transferred securely to the Health Data Research UK funded PIONEER Health Data Hub provided by University Hospitals Birmingham NHS Foundation Trust for secondary analysis, led by the lead for the Society for Acute Medicine Benchmarking Audit.

How will data be protected? (Please detail security measures to be taken)

Data will be protected at source in accordance with the [insert Trust name] local procedures: [refer to the specific local data protection policy/procedures]. The patient will be identified on the database by a study number. The study number will correspond to the patient's name, and hospital registration number on an audit Masterlist that will be securely stored on-site at each participating hospital by the local lead. The Masterlist and anonymised paper data collection will both be stored securely (locked) and separately.

Paper proformas will be stored securely for one year at each participating site. A Masterlist of each patient entered and their study number will also be stored securely for one year and the Masterlist will be stored separately from the study proformas. After one year all paper documents with patient details will be destroyed appropriately.

The data collection database in operation during the upload time window (see above) has been constructed by applying current best security practice.

Data will be kept securely for five years in order to make trend comparisons and then appropriately destroyed.

If the data is on a computer is there access via a network?

The Society for Acute Medicine Benchmarking Audit team will have password protected access to the database for the purposes of analysis of data and preparation of reports. Only named users will be able to access data.

How long will the data be stored?

All anonymized electronic data will be stored securely for five years.

At the end of this period how will the data be disposed?

Local Leads will ensure the Masterlist and study proformas are destroyed in accordance with the local best practice protocols for the disposal of confidential waste.

The electronic database will be wiped and cleansed of all data.

Who will be responsible to ensure that the data is disposed of in a confidential manner?

Local Leads and the Society for Acute Medicine for the local paper data and central electronic database respectively.

Other supporting information e.g. Ethics approval, correspondence etc

This project does not require Research Ethics Committee (REC) approval for its conduct as it is an Audit. It involves only the use of anonymised patient data collected as part of routine care by the clinical treating team and as such does not require REC review (see ref).

1 Ref - Governance Arrangements for Research Ethics Committees (GAfREC) 2011. Available at:

I confirm that the data will be held and used according to the conditions and information given as described within this approval form.

Name: …………………………………..…. (local investigator)

Title: ……………………………………….

Signature: ……………………………………….

Date: ……………………………………......

For Office Use Only

The release and use of data as described above: **approved / not approved**

Caldicott   Guardian / Deputy:………………………..……………Date:…………………….

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1. The data will be treated as confidential.

2. The data will be used only for the purposes described.

3. In the case of anonymised or confidential aggregated data, no attempt will be made to identify or contact individuals or organisations identified through these data.

4. The data may be disclosed to staff of the above organisation but only for the purposes described.

5. The data may not be disclosed to any third party, unless requested by law.

6. The data will be stored in secure condition at all times whether held on computer medium or as a printed copy.

7. The organisation to which the data are released will maintain and comply with a Data Protection Registration which encompasses the data and data usage described.

8. The data will be destroyed after five years: any printed copies will be destroyed, and files deleted from computer systems (including any copies held on backup or archive media).

9. All staff given access to the data will be made aware of these conditions

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Please keep this signed form with your other SAMBA forms.