CLINICAL DATA POLICY

British Thoracic Society

Registered Office: 17 Doughty Street / London WC1N 2PL
T: +44 (0) 20 7831 8778 F: +44 (0) 20 7831 8766
bts@brit-thoracic.org.uk • www.brit-thoracic.org.uk

England and Wales Charity No.285174
Scottish Charity No. SC041209
Company Registration No. 1645201

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17/3/2017	V0	Draft for review by QIC
15/6/2017	V1.0	Approved by BTS Board
1/4/2018	V1.1	Publication version
26/10/2018	V1.2	Update

Contents

Appendices

1.   Background

1.1   This policy sets out information on the operation of the BTS Audit Programme, BTS ILD Registry and BTS MDR-TB Clinical Advice Service, including information on how data will be collected, reported and shared.

2.   Information Governance

2.1   This policy should be read in association with the BTS Information Governance Policy (https://www.brit-thoracic.org.uk/document-library/about-bts/documents/information-governance-policy-2017-2018/) which outlines the Society's policies and procedures for data protection, confidentiality, freedom of information, data security and related matters.

3.   Who this policy applies to

3.1   BTS Staff, members of BTS Committees, Specialist Advisory Groups, Guideline Groups and other groups (including the BTS Audit Programme and BTS Registry Programme) set up by BTS, in so far as the information in their hands has come through their involvement with BTS.

3.2   Users of the BTS Audit System, BTS ILD Registry and BTS MDR-TB Clinical Advice Service.

4.   Definitions

BTS Staff	BTS Staff encompasses BTS Head Office staff and associates.
BTS Audit Programme	The programme of BTS respiratory audits which are approved on an annual basis by the BTS QIC and overseen by the BTS Audit Programme Director.
BTS Audit System	The web-based tool for the collection and analysis of clinical audit data at: https://audits.brit-thoracic.org.uk/
Audit Data	Data entered onto the BTS Audit System after adoption of this policy.
Audit Users	Individuals registered and approved for an account on the BTS Audit System for a given institution or institutions.
Audit Lead	Audit Users who have registered as Audit Lead for a specific audit period and been approved for data entry access to that audit period by BTS Staff.
Audit Delegate	Audit Users nominated by an Audit Lead for a specific audit period who have been approved for data entry access to that audit period by BTS Staff.
BTS ILD Registry	The BTS programme which includes online data entry for the collection of information on patients with IPF and sarcoidosis, via the web-based tool at: https://www.brit-thoracic.org.uk/standards-of-care/lung-disease-registries/bts-ild-registry/
ILD Registry Data	Data entered on to the BTS ILD Registry website
BTS MDR-TB Clinical Advice Service (BTS MDRTB-CAS)	The BTS programme which includes online data entry for collection of information on patients with MDR-TB and the provision of clinical advice to registered clinicians, via the web-based tool at: https://www.brit-thoracic.org.uk/standards-of-care/lung-disease-registries/mdr-tb/
MDR-TB	Multidrug-Resistant Tuberculosis
MDRTB-CAS Data	Data entered on to the BTS MDRTB-CAS website
Personal data	Data which relate to a living individual who can be identified – (a) from those data, or (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.

5.   BTS Audit Programme

5.1   **Audit Data (Reporting and Access)**

5.1.1   Details of the data held on the BTS Audit System that the Society collects, reports and shares, are set out the BTS Audit System Terms and Conditions (Appendix 1). From 1 April 2018 Audit Users are required to accept the BTS Audit System Terms and Conditions in order to access the BTS Audit System.

5.1.2   Third parties may apply for access to data held on the BTS Audit System that was entered after 1 April 2018. Applications will be considered in accordance with the BTS Data Access Policy.

5.2   **Non-Participation**

5.2.1   BTS will write to UK institutions that do not participate in BTS national adult or paediatric audits. Details of non-participating institutions will be published.

5.3   **Outliers**

5.3.1   The Society will review data submitted during national audits and has adopted a policy for identifying and managing UK institutions that appear to be outliers. The BTS Outlier Policy is at Appendix 2.

6.   BTS ILD Registry

6.1   Details of the data held on the BTS ILD Registry are included in the BTS ILD Registry Terms and Conditions available on the BTS ILD Registry website. The BTS ILD Registry holds ethical approval for the collection of data (REC Reference: 17/EE/0346).

6.2   Third parties may apply for access to ILD Registry Data in accordance with the BTS Data Access Policy.

7.   BTS MDR-TB Clinical Advice Service

7.1   Details of the data held by the BTS MDRTB-CAS are included in the BTS MDRTB-CAS Terms and Conditions available on the MDRTB-CAS website from January 2018. The BTS MDRTB-CAS holds ethical approval for the collection of data (REC Reference: 17/LO/1539).

7.2   Third parties may apply for access to MDRTB-CAS Data in accordance with the BTS Data Access Policy.

8.   Approval and Review

8.1   This Policy was approved by the BTS Board on 15 June 2017, and will be reviewed again in April 2021.

BTS Clinical Data Policy Appendix 1

BTS AUDIT SYSTEM TERMS AND CONDITIONS

These Terms and Conditions apply from 1 April 2018 until further notice.

For data entered before 1 April 2018 the previous Terms and Conditions ("BTS Audit System – Important Information") will continue to apply.

1.   BTS Audit System

1.1   The BTS Audit System provides an online platform for registered users ("Audit Users") to enter clinical audit data ("Audit Data") and generate reports, as described at clause 5 below. The audits are developed by the British Thoracic Society ("BTS") as part of the "BTS Audit Programme".

1.2   Audits in the BTS Audit Programme run for designated audit periods – either "National Audits", when all eligible providers are encouraged to participate, or "Local Audits" when the same tools are available to enable re-audit at a local level.

1.3   BTS holds NHS IG Toolkit compliance at level 2 and the BTS Audit System is one of the BTS systems to which this applies. The BTS Audit System is accessed via a secure (https) website. Audit Data are stored on servers administered by Westcliff Solutions Limited in line with the BTS Data Security Policy and System Level Security Policy, which are set out at Appendices 3 and 5 of the BTS Information Governance Policy.

2.   Audit Registration and Audit User Obligations

2.1   In order to access the BTS Audit System Audit Users must first register to create an account for a specified institution or institutions which will allow them to view information about the BTS Audit Programme.

2.2   In order to participate in either a Local or National Audit and access the data entry tools, a Registration Form must be submitted confirming the name of an Audit Lead who has consented to act as such, and naming any Audit Delegates.

2.3   Registration Forms must be submitted separately for each audit period. Access to the data entry tools will lapse at the end of the named audit period and Audit Users will be required to re-register for access to further audit periods. (Audit Users' accounts on the BTS Audit System will remain active and they will still be able to log in to view information about the BTS Audit Programme.)

2.4   Audit Users must:

a)   provide a valid NHS email address for use with their account.

b)   notify BTS if they move institution, and not continue to access data submitted for a former employer.

c)   keep account details secure and confidential, and not share accounts.

d)   not enter NHS numbers, hospital numbers or other patient identifiers onto the BTS Audit System unless instructed to do so.

e)   ensure appropriate storage, usage and destruction of Audit Data downloaded from the BTS Audit System in accordance with local policies on data handling.

f)   complete annual NHS IG training offered through their employer.

g)   confirm acceptance of these BTS Audit System Terms and Conditions in order to access the BTS Audit System.

3.   Deletion of Audit Data and Local Identifiers

3.1   At the end of an audit period, Audit Users must "commit" their records – this locks the record and submits it for inclusion in the reporting for that audit. Records that have not been committed after the end of an audit period will be deleted by BTS. When records are "committed", some data items (e.g. local identifiers) may be deleted from the BTS Audit System or converted to an alternative format (e.g. date of birth data may be converted to age and the date of birth deleted).

3.2   Audit Users are required to export all Audit Data for their institution before it is committed and to retain this, together with any further information needed to identify the patient, so that they are able to locate the patient notes in future if needed e.g. as part of any potential outlier review. These data exports should be kept in accordance with the Audit User's local policies on the retention of data.

4.   Data Access

4.1   Access to Audit Data is restricted to BTS Staff, the BTS Audit Programme Director and the nominated BTS clinical lead(s) and associates for each audit. Limited access to Audit Data is available to Audit Users as described at clauses 5 and 6 below.

4.2   Audit Data may also be shared with third parties and/or made public in accordance with the BTS Outlier Policy (Appendix 2) and the BTS Data Access Policy.

5.   Data Reporting

5.1   Reports of aggregated national and site-level data will be produced for National and Local Audits to allow benchmarking to take place. For National Audits only, a National Report of aggregated data will be made publically available on the BTS website, and further reports, including those that identify individual hospital performance, may also be published by BTS and made publically available.

5.2   Third parties may publish material using Audit Data obtained via the BTS Data Access Policy.

6.   Data Exports

6.1   Audit Users who have registered and been approved for access to a given audit, can export data for their own institution as CSV files until their registration for that audit has lapsed. All other requests for access to CSV exports will be considered in accordance with the BTS Data Access Policy.

7.   Participation

7.1   BTS will publish details of participation and non-participation (including case ascertainment) for each audit.

8.   Data and Intellectual Property Ownership

8.1   BTS is the owner of all intellectual property rights in the BTS Audit System and associated reports, audit documentation and other materials produced as part of the BTS Audit Programme.

8.2   BTS is the owner of all data entered and held on the BTS Audit System.

8.3   Audit Users may share their institution's data or reports with third parties. BTS encourages the sharing of reports and data, for example locally or with similar peers to promote Quality Improvement.

9.   Data Protection

9.1   BTS adheres to the General Data Protection Regulation (GDPR). The Data Controller is the BTS Chief Executive.

9.2   Further information on how BTS manages personal data is contained in the BTS Privacy Policy (https://audits.brit-thoracic.org.uk/WebPages/Help/frmHelpPrivacy.aspx) and the BTS Information Governance Policy (https://www.brit-thoracic.org.uk/document-library/about-bts/documents/information-governance-policy-2017-2018/).

10.   Freedom of Information

10.1   As the British Thoracic Society is not a public body, it is not required to comply with the Freedom of Information Act 2000 (FOI), however, where the Society acts as a data processor under the DPA, data may be subject to Freedom of Information. Any requests for information about the BTS Audit Programme under FOI, should be forwarded to: audittools@brit-thoracic.org.uk.

11.   Ethical and Governance Approvals

11.1   Clinical audit does not require ethical approval from a Research Ethics Committee. Further guidance on the distinction between research and audit is available here: http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research/

11.2   Any information governance or other approvals that apply or may be required, for example Section 251 or Caldicott Guardian approvals, will be notified on an audit by audit basis.

12.   Approval and Review

12.1   These Terms and Conditions were approved by the BTS Board on 15 June 2017, and will be reviewed again in April 2021.

BTS Clinical Data Policy Appendix 2

BTS AUDIT PROGRAMME OUTLIER POLICY

This policy sets out how BTS will assess the performance of hospitals participating in BTS audits and the process that will be followed in the event that a hospital is identified as a potential outlier. The policy only applies to data collected during national audit periods. Data collected during local periods will not be analysed by BTS.

Performance indicators and expected performance

The standards assessed by BTS audits are drawn from BTS Guidelines and Quality Standards and other published Guidance. Details of the standards for each audit are available in the relevant audit protocol. BTS will look at organisational, process and outcome measures derived from these standards to select a limited number of performance indicators for each audit which may include, but are not limited to: timeliness of interventions, length of stay and mortality.

Expected performance against these indicators will normally be based on a comparison with the total UK audit data using statistical analysis methods. There may however be occasions where expected performance will be determined on the basis of clinical judgement or other external evidence, for example where a hospital's performance is outside of expected performance when assessed against peers, but the performance still meets the relevant standards compatible with safe and effective clinical care.

Data Quality

Individual hospitals are responsible for the quality of data submitted to BTS audits in terms of accuracy, completeness and case ascertainment. Any deficiencies in data quality have the potential to distort results. BTS will provide information on data accuracy, completeness and case ascertainment to inform interpretation of published data and will aim to incorporate measures to improve data quality as follows:

Data accuracy – range checks and restrictions are used to improve the accuracy of data.

Data completeness – wherever possible data fields will be mandatory to improve data completeness.

Case ascertainment – details of eligible patient numbers will be collected from participating hospitals and, where possible, external sources (HES) to enable case ascertainment to be estimated.

Case-mix adjustment

BTS does not incorporate case mix adjustment into reported data or data analysis for the purposes of identifying outliers. BTS will consider possible case mix variation when selecting performance indicators and will consider case mix issues as part of the outlier management process set out below on a case by case basis.

Outlier detection

For the purposes of the BTS Outlier Policy, an outlier is defined as performance that is 3 standard deviations (3SD) or more below expected performance.

Standard deviation identifies statistical outliers but there is a distinction between statistical and clinical outliers – identification of a statistical outlier raises questions for clinical judgement, and may require control limits to be refined, for example if performance is very good across the board. Where low numbers are entered for an audit it will not be possible to produce a robust outlier analysis. Set out below are details of the approach taken by BTS after the close of an audit to identify and manage any potential outliers.

Management of potential outliers

Stage	Action	Who	Timeframe (working days)
1	BTS to review/scrutinise data handling and analysis and determine whether there is: **'no case to answer'** • Results revised and details on non-outlier status formally recorded. **'case to answer'** • Proceed to stage 2.	BTS audit team and BTS Audit Programme Director	20
2	Lead Clinician and Clinical Governance Lead contacted by BTS and informed of potential outlier status and asked to identify any data errors and/or provide any other explanation. All relevant data and analyses to be made available for this purpose.	BTS audit team and BTS Audit Programme Director	5
3	Lead Clinician to provide written response to BTS.	Lead Clinician	30
4	Review of Lead Clinician's Response by BTS to determine: **'no case to answer'** • Data errors identified and re-analysis of corrected data indicates performance within 3SD. • Results revised and details on non-outlier status formally recorded. • Lead Clinician notified in writing by BTS. **'case to answer'** • Original data confirmed as accurate or performance still 3SD or more on re-analysis of corrected data and provider is confirmed as an outlier. • Proceed to stage 5.	BTS audit team	30
5	Contact Lead Clinician by telephone prior to written confirmation of outlier status. Letter to inform that Medical Director and Chief Executive will be contacted. Letter to be copied to Clinical Governance Lead. Letter to Medical Director and Chief Executive informing of outlier status and requesting them to undertake a local investigation and advising that BTS will proceed to publish data identifying outliers.	BTS audit team and BTS Audit Programme Director	5
6	Chief Executive to provide written acknowledgement to BTS within 10 working days.	Chief Executive	10
7	Chase Acknowledgement from Chief Executive if not received within 10 working days.	BTS audit team	
8	Public disclosure of comparative performance data identifying providers.	BTS audit team	

Potential outliers

Hospitals identified as potential outliers i.e. those found to be 3SD or more below expected performance, should invest time and resources reviewing their data and providing updated data and other relevant information to BTS, and this may include re-audit with a greater number of patients. Hospitals that fall between 2 and 3 SD below expected performance will not be contacted as part of the BTS Outlier process but are encouraged to examine their performance locally and take steps to improve where appropriate.

Positive outliers

Hospitals found to be 3SD or more above expected practice may be contacted for feedback to be shared with other Hospitals to help them improve their practice.

The Role of BTS

BTS has a duty to report on the data it holds, however, the Society is not responsible for the accuracy and completeness of the data submitted. This responsibility rests with the teams participating in BTS audits and issues with data quality must be addressed by the hospital concerned. The role of BTS is to provide consistent analysis and to make reports on the process and outcome of care publically available.

The BTS Audit Team aims to support clinical teams in providing high-quality, robust clinical audit data and it is not expected that outliers will be identified frequently. Where potential outliers are identified, the BTS Audit Team will provide additional help to hospitals wanting to review data entry and data quality where possible. Hospitals or clinicians with concerns about data quality are urged to contact the BTS Audit Team at the earliest opportunity.

Approval and review

This Outlier Policy was approved by the BTS Board on 15 June 2017, and will be reviewed again in April 2021.