

The British Thoracic Society (BTS)

BTS Multidrug-Resistant Tuberculosis Clinical Advice Service

Information for Parents and Guardians

Your child/the child in your care is being invited to take part in a project set up to improve the care of patients. They are being invited because they have multidrug-resistant tuberculosis (MDR-TB) or another complex TB or mycobacterium infection.

Before you decide whether they should take part, we want to make sure you understand what this project is and what it will involve. Please read this paper carefully. You can talk to others about it if you want to, or ask us if you would like more information or would like something explained.

Take time to decide whether or not they should take part in this project; it is entirely up to you.

What is the BTS MDR-TB Clinical Advice Service?

Infections involving bacteria called tuberculosis (or other similar bacteria) are treated with drugs. Sometimes some drugs cannot be used because they do not work on the infection (the infection is resistant). Sometimes they cannot be used for other reasons. This means it becomes more difficult for doctors to treat the infection.

The Clinical Advice Service helps doctors seek advice from experts with lots of experience treating MDR-TB. These experts discuss each patient and give advice on how best to care for them and to treat their infection. To do this we collect and hold information about patients.

We record the number of people, where they are and details about their health and treatment. The information is held on a secure and confidential computer database. The BTS MDR-TB Clinical Advice Service is paid for by the National Health Service (NHS), and small grants may be received to support this work.

Why have an MDR-TB Clinical Advice Service?

These infections are complicated and not very common. They are always discussed by doctors and others with expertise in infections, drugs, public health, etc. There are very few doctors with experience treating MDR-TB in the UK, and our Service helps them discuss cases together.

Since these infections are not very common, bringing together information on people across the UK is very useful. It means we can better understand how patients are treated and what their outcomes are. Doctors can learn from this and provide better care for people with MDR-TB in the future.

What information is kept in the MDR-TB Clinical Advice Service?

What we collect is similar to the information that is recorded during a visit to the clinic. Things like:

- Height and weight
- Test results (cultures, x-rays, blood test results and similar)
- What drugs and other treatments patients receive
- Any complications patients may have.

We also hold information which can be used to identify your child/the child in your care (such as name and date of birth, etc.). These 'identifiers' are **only** collected to allow the staff treating them at hospital to know which record is which. Information which could identify them is **never** released to anyone outside their care team (even BTS staff do not know who the patients are).

How is the information collected and what is it used for?

The information is taken from the notes doctors and nurses make at hospital visits. The team caring for your child/the child in your care enter the data into our Service, and they can use it to see results over time. Also, information about what drugs the infection could respond to may be included from the national laboratories which test TB samples from across the UK.

Our Service gives doctors access to the country's leading MDR-TB experts. Each case is reviewed by these experts as many times as needed, and advice is given on what treatment would be best. At BTS we analyse information from hospitals across the UK. Analysing this information helps to improve patient care by supporting us and the NHS in understanding:

- What drug treatment patients are given and what drugs they cannot take.
- How patients respond to the drugs they are given.
- National trends (which might not be obvious in just one hospital)

How does the Clinical Advice Service support research?

Researchers in other organisations may apply to BTS to access anonymous health information. Anonymous data will **only** be included if you also give consent for the data to be used in research.

The organisations may be universities, NHS trusts (HSC in Northern Ireland) or companies involved in research in the UK or abroad. Information will only be used to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify your child/the child in your care and will not be combined with other information in a way that could identify them. It will only be used in research; it cannot be used to contact them or to affect their care. It will not be used to make decisions about future services available to them, such as insurance.

BTS is planning to maintain the BTS MDR-TB Clinical Advice Service for the foreseeable future and will keep the data indefinitely.

Does my child/the child in my care have to take part?

No – it is completely your decision. If you choose for them to take part you will be given this sheet to keep and asked to sign a consent form. If you choose for them not to take part in this project their clinician will still be able to seek the views of colleagues when deciding their treatment.

Can I change my mind later?

Yes. If you agree for your child/the child in your care to take part you can withdraw them from the Service at any time in the future without giving any reason. If you choose to withdraw consent, their clinician will still be able to seek the views of colleagues when deciding their treatment.

You will also be asked if you are happy for the anonymous data of your child/the child in your care to be used in research. This means information which cannot identify them could be used to help us understand more about MDR-TB, complex TB and other mycobacterial infections in the UK. You do not have to agree to their information being used in research, but if you do then:

- If you withdraw consent **before** information was used in any research project:
All data relating to the entry on the Clinical Advice Service will be completely removed. Those data would never be used in any research studies.
- If you withdraw consent **after** information was used in any research project
All data relating to the entry on the Advice Service will be completely removed. Some fully anonymous data may still be archived as part of that research. This means if researchers just looked at drug resistance then that is the only information that would be kept. Those data would never be used in any other research studies.

Will my child/the child in my care's information be confidential?

Yes – all the information in our Service is held confidentially. The Clinical Advice Service is registered under the Data Protection Act (2018) and has Research Ethics Committee approval (renewed November 2022 22/LO/0698). It is managed in accordance with relevant laws and ethical guidelines.

- Information which can be used to identify your child/the child in your care (such as name and date of birth, etc.) will be visible to the team treating them at hospital.
- The only other people who will see **any** identifiable information are a small number of staff at the national health bodies. They already hold data on all cases of TB in the country, and they test TB samples to find out what drugs will work. We just give them a list of identifying numbers (e.g. NHS number). This is so they can give us extra information, like what drugs would be likely to help.
- Even the team at BTS cannot identify patients, we only see an anonymous Patient ID number.
- If you also agree to your child/the child in your care's data being used in research the researchers are not even given the anonymous Patient ID. They only see a random one-time ID which they cannot use to identify patients in any database.

A very small number of experienced staff are responsible for protecting patient identifiers. They encrypt them on the database, which means the information is converted into a highly complex code which nobody is able to read. Only the staff at your hospital have access to read it through their secure accounts. These staff maintain the system, in accordance with Data Protection legislation.

Will the information in the Advice Service be linked to information from any other datasets?

We may also like to use health information collected by other organisations. This means the Office for National Statistics, NHS Digital or similar. To obtain this information we will need to disclose date of birth and National Health Service number only; these details will be treated in confidence and in accordance with the Data Protection Act (2018).

You may also separately consent to other projects. These could include a registry, a biobank, a clinical trial or similar. Researchers may request information from these datasets be 'linked'. For example, linking genetics to how well the patient responds to treatment. This means researchers from the other project could see information such as drug treatment. We will only ever link these datasets if you or your child/the child in your care have specifically given consent for both projects.

The use of any information from our Service requires the approval of a formal BTS Committee. Information that can identify patients will **never** be given to anyone else or published.

Your data rights

The British Thoracic Society is the data controller for this project. If you have any questions, if you want to make a complaint or if you want your child/the child in your care's information removed from the BTS MDR-TB Clinical Advice Service, please contact our Data Protection Officer at mdrtb@brit-thoracic.org.uk or at the British Thoracic Society, 17 Doughty Street, London WC1N 2PL.

If you are not satisfied with our response or believe we are processing personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Thank you for taking time to read this information sheet and for considering taking part in the BTS MDR-TB Clinical Advice Service. If you have any questions or require any further information please talk to a member of the care team at your hospital or contact the BTS MDR-TB Clinical Advice Service Manager at the British Thoracic Society on 020 7831 8778.

28/07/2022

PARENT/GUARDIAN CONSENT FORM
British Thoracic Society MDR-TB Clinical Advice Service

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| Patient name: |
| NHS/CHI number: |
| Patient ID number (for hospital to complete): |

Please
Initial

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| 1. | I confirm that I have read and understood the information sheet dated July 2022 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | |
| 2. | I understand I do not have to agree and can change my mind at any time, without giving any reason. My child/the child in my care's medical care or legal rights will not be affected. | |
| 3. | I understand my child/the child in my care's health and care information may be looked at by a small number of responsible people from the medical team, the group of MDR-TB experts and the British Thoracic Society. I give permission for these people to have access to the records. | |
| 4. | I understand that information held by the NHS (or HSC in Northern Ireland) and records maintained by organisations such as the national public health bodies may be used to follow my child/the child in my care's health status | |
| 5. | I understand that information that can identify my child/the child in my care will never be given to anyone else or published by the BTS MDR-TB Clinical Advice Service. | |
| 6. | I understand that – unless I opt out of data being used for research – anonymised data that cannot identify my child/the child in my care may be shared with researchers, both in the UK and in other countries, for further analysis. | |
| 7. | I understand that my child/the child in my care can take part in the MDR-TB Clinical Advice Service even if I do not agree for their anonymised data to be used in research. | |
| 8. | I agree to take part in the BTS MDR-TB Clinical Advice Service. | |

MDR-TB research opt-out

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| 9. | Although I agree to my child/the child in my care taking part in the Clinical Advice Service I do not agree to their anonymised data being analysed for research purposes. | |
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| Parent/Guardian Name | Signature | Date |

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| Name of Person Taking Consent | Signature | Date |

For the parent/guardian: you may have been given this sheet to complete at home. Please complete the form and return to the team at the hospital. You can complete/return the form:

- By signing a physical copy then returning it to your hospital team by post, or scanning or photographing it and returning by email.
- By signing an electronic copy either by pasting or typing in your signature, then returning it to your hospital team by email.

For the hospital: when completed please have three copies – one for the parent/guardian, one to be kept in the patient's medical notes, and one (the original, if signed) for the site file.