

The British Thoracic Society (BTS)

BTS Multidrug Resistant Tuberculosis Clinical Advice Service

Information on the Service

The BTS MDR-TB Clinical Advice Service is a project set up to improve patient care. Patients with multidrug-resistant tuberculosis (MDR-TB) and some other complex TB/mycobacterium infections can take part. Leading TB specialists from across the UK review cases and provide advice on what treatment would be most suitable.

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.

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

What we collect is similar to the information that is recorded during a clinic visit 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 patients (such as name and date of birth, etc.). These 'identifiers' are **only** collected to allow hospital staff to know which record is which. Information which could identify you is **never** released to anyone outside the 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 during a hospital visit. Hospital staff enter data into our Service, and they can use it to see patient 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.

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

Researchers in other organisations may apply to BTS to access anonymous health information. However, the data of patients who lack capacity to consent will **never** be used in research. Their data will only be used to provide treatment advice and to monitor the running of the Clinical Advice Service.

Will the 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 patients (such as name and date of birth, etc.) will be visible to the team treating them at their own hospital.
- The only other people who will see **any** identifiable information are a small number of staff at the national health bodies, such as UK Health Security Agency (UKHSA). 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. your NHS number and date of birth). This is so they can give us extra information, like what drugs would be likely to help each patient.
- The team at BTS cannot identify the patients, we only see an anonymous Patient ID number.

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 be linked to information from any other datasets?

We may also like to use patient health information collected by other organisations. This means the Office for National Statistics, NHS Digital, UKHSA 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).

The patient's 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 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

**CONSENT FORM
PATIENTS LACKING CAPACITY TO CONSENT**

British Thoracic Society MDR-TB Clinical Advice Service

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

Section 1: Assessment of patient’s capacity to consent

I confirm that the patient lacks capacity to give or withhold consent to their inclusion in the BTS MDR-TB Clinical Advice Service because:

- The patient is unable to comprehend and retain information material to the decision; and/or
- The patient is unable to use and weigh this information in the decision-making process; or
- The patient is unconscious

If the patient is conscious, please provide further information on how the above judgements were reached (e.g. which colleagues were consulted, what attempts were made to assist the patient to make his or her own decision, and why this was not successful):

Section 2: Assessment of patient’s best interests

To the best of my knowledge, the patient has not refused to participate in the BTS MDR-TB Clinical Advice Service in a valid advance directive. Where possible and appropriate, I have consulted with colleagues and those close to the patient, and I believe including the patient in the BTS MDR-TB Clinical Advice Service to be in the patient’s best interests because:

Where the patient’s incapacity is likely to be temporary (for example, if the patient is unconscious or has fluctuating capacity):

The treatment cannot wait until the patient recovers capacity because:

Section 3: Involvement of the patient’s family and others close to the patient

The final responsibility for determining whether inclusion in the BTS MDR-TB Clinical Advice Service is in an incapacitated patient’s best interests lies with the treating healthcare professional. However, it is good practice to consult with those close to the patient (including spouse/partner, family, friends, carer, supporter or advocate) unless there is good reason to believe the patient would not have wanted particular individuals to be consulted, or unless the urgency of their situation prevents this.

‘Best interests’ go far wider than ‘best medical interests’ and includes factors such as the patient’s wishes and beliefs when competent, their current wishes, their general wellbeing and their spiritual and religious welfare.

This section is to be signed by a person or persons close to the patient, if they wish:

I/we have been involved in a discussion with the relevant healthcare professionals over the treatment of _____ [patient’s name].

I/we understand that he/she is unable to give his/her own consent, based on the criteria set out in this form. I/we also understand that treatment can lawfully be provided if it is in his/her best interests to receive it.

Any other comments (including any concerns about the decision):

Name:

Relationship to patient:

Address (if not the same as the patient):

Signature:

Date:

If a person close to the patient was not available in person, has this matter been discussed in any other way (e.g. over the telephone)?

- Yes
- No

Details:

Section 4: Signature of healthcare professional proposing inclusion in the BTS MDR-TB Clinical Advice Service

Inclusion in the BTS MDR-TB Clinical Advice Service is, in my clinical judgement, in the best interests of the patient, who lacks capacity to consent for himself or herself. Where possible and appropriate I have discussed the patient's condition with those close to him or her, and I have taken their knowledge of the patient's views and beliefs into account in determining his or her best interests.

I have sought a second opinion: Yes No

Signature:

Date:

Name (please print):

Job title:

Where a second opinion was sought, he or she should sign below to confirm agreement:

Signature:

Date:

Name (please print):

Job title:

For the hospital: when completed please have two copies – one to be kept in the patient's medical notes, and one (the original, if signed) for the site file. An additional copy may be given to the patient's family/carer if appropriate.

Guidance to Healthcare Professionals

British Thoracic Society MDR-TB Clinical Advice Service

This form should only be used where an adult patient (16 or over) lacks capacity to give or withhold consent to inclusion in the BTS MDR-TB Clinical Advice Service. If an adult **has** the capacity to accept or refuse treatment, you should use the standard consent form and respect any refusal.

If the adult now lacks capacity, but has clearly refused consent in advance of their loss of capacity, then you must abide by that refusal if it was validly made and is applicable to the circumstances. For further information on the law on consent, see the Department of Health's *Reference guide to consent for examination or treatment*.

When patients unable to consent can be included in the BTS MDR-TB Clinical Advice Service

For patients to be included in the BTS MDR-TB Clinical Advice Service when they are unable to consent, the following must apply:

- The patient must lack the capacity ('competence') to give or withhold consent AND
- Inclusion in the BTS MDR-TB Clinical Advice Service is in the patient's best interest

Capacity

A patient will lack capacity to consent to a particular intervention if he or she is:

- Unable to comprehend and retain information material to the decision, especially as to the consequences of having or not having the intervention in question; and/or
- Unable to use and weigh this information in the decision-making process

Before making a judgement that a patient lacks capacity you must take all steps reasonable in the circumstances to assist the patient in taking their own decisions (this will clearly not apply if the patient is unconscious). This may involve explaining what is involved in very simple language, using pictures and communication and decision aids as appropriate. People close to the patient (spouse/partner, family, friends and carers) may often be able to help, as may specialist colleagues such as speech and language therapists or learning disability teams, and independent advocates or supporters.

Capacity is 'decision-specific': a patient may lack capacity to take a particular complex decision, but be quite able to take other, more straightforward, decisions or parts of decisions.

Best interests

A patient's best interests are not limited to their best medical interests. Other factors which form part of the best interest decision include: the wishes and beliefs of the patient when competent, their current wishes, their general wellbeing, their spiritual and religious welfare. Two incapacitated patients, whose *physical* condition is identical, may therefore have different best interests.

Unless the patient has clearly indicated that particular individuals should not be involved in their care, or unless the urgency of their situation prevents it, you should attempt to involve people close to the patient (spouse/ partner, family, friends, carer, supporter or advocate) in the decision-making process. Those close to the patient cannot require you to provide particular treatment which you do not believe to be clinically appropriate. However, they will know the patient much better than you do, and therefore are likely to provide valuable information about the patient's wishes and values.

Second opinions and court involvement

Where treatment is complex and/or people close to the patient express doubts about the proposed treatment, a second opinion should be sought (unless the urgency of the patient's condition prevents this). High Court approval can also be sought where there are doubts about the patient's capacity or best interests.