British Thoracic Society (BTS) Multidrug Resistant Tuberculosis Clinical Advice Service

Patients Lacking Capacity to Consent: Guidance for Healthcare Professionals

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 (CAS). 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*.

For patients to be included in the BTS MDR-TB CAS when they are unable to consent, the patient must lack the capacity ('competence') to give or withhold consent **AND** inclusion in the CAS must be in the patient's best interest.

Please read this form carefully, as it explains:

1) what a 'lack of capacity to consent' means;
2) what the patient's 'best interest' means;
3) that a personal consultee should provide advice wherever possible;
4) that patients lacking capacity will only be included in the advice element of the CAS (**not** research);
5) how to approach situations where the patient's consent fluctuates; AND
6) how to include patients who lack capacity to consent.

1) 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.

2) 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.

3) Seeking advice from a Personal Consultee

If you wish to include an incapacitated adult in the CAS you must take 'reasonable steps' to identify & seek advice (not consent) from a Personal Consultee. This advice must be fully informed and obtained in the same way that consent would have been.

A Personal Consultee should someone who knows the incapacitated adult well, either a friend or a family member. They are asked to set aside their personal feelings and advise the clinical team on what the incapacitated adult is likely to have decided had they retained capacity. The role of a Consultee is voluntary: individuals should not feel pressured into offering their advice.

Personal Consultees cannot be a professional engaged to care for the incapacitated adult. Where all reasonable steps have been taken and a Personal Consultee cannot be identified, you may seek a Nominated Consultee. Typically, this will be a healthcare professional engaged in caring for the individual. Nominated Consultees cannot have any connection with the CAS.

4) Patients lacking capacity will not have data processed for research

There are two elements to the BTS MDR-TB CAS: advice and research. All patients included in the CAS have their information processed for the purpose of advice regarding their care and treatment.

Patients lacking capacity to consent will **not** have their data processed for the purpose of research. This is to ensure data processing is kept to a minimum for those who are not able to provide consent.

5) Fluctuating consent

If a participant regains capacity they should be fully informed about the CAS and their inclusion in it. It should also be made clear to them that while their data were processed for the purpose of advice they have **not** been included in any analysis for research.

The patient's consent should then be sought to be included in the CAS and to retain any data entered in relation to them. If they indicate that they do not wish to be included in the CAS, their record should be deleted.

As part of the process for seeking patient consent, patients who have regained capacity will have the opportunity to consent to (or opt out from) their data being processed for the purpose of research.

6) Including patients who lack capacity to consent

To include a patient who lacks capacity to consent please:

a) Assess the patient's capacity to consent (*page 3*)
b) Identify a Personal Consultee and explain the CAS to them (*pages 4-6*)
c) Seek assent from the Personal Consultee (*page 7*)

If you have any questions about this process, please contact BTS at mdrtb@brit-thoracic.org.uk

HEALTHCARE PROFESSIONAL'S DECLARATION
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):

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):

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.

BTS MDR-TB Clinical Advice Service

Information for Personal Consultees

(Persons acting on behalf of patients who lack capacity to consent)

We feel your relative/friend is unable to decide for himself or herself whether to participate in the BTS MDR-TB Clinical Advice Service.

To help decide if he or she should be included, we would like to ask your opinion whether or not they would want to be involved. We ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating as this should take precedence.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration on the last page of this document. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or if you think your relative/friend should be withdrawn.

If you decide that your friend/relative would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice. We will understand if you do not want to take on this responsibility.

*The following information is the same as would have been provided to your relative/friend with one exception: when patients are able to consent for themselves we also ask them if they would like their data to be used in research. As your relative/friend cannot consent for themselves we would **not** be using their information for research, only for providing advice about their treatment.*

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. 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). 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 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 your relative/friend being discussed 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.

13/11/2022

CONSULTEE ASSENT 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):

Personal Consultee name:
Relationship to patient:

		Please Initial
1.	I confirm that I have read and understood the information sheet dated November 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 relative/friend's medical care or legal rights will not be affected.	
3.	I understand my relative/friend'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.	
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 relative/friend's health status.	
5.	I understand that information that can identify my relative/friend will **never** be given to anyone else or published by the BTS MDR-TB Clinical Advice Service.	
7.	**In my opinion my relative/friend would have no objection to taking part in the BTS MDR-TB Clinical Advice Service.**	

Personal Consultee Name	Signature	Date

Name of Person Taking Consent	Signature	Date

For the Personal Consultee: 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 Personal Consultee, one to be kept in the patient's medical notes, and one (the original, if signed) for the site file.