Engagement Report

Topic details

Title of policy or policy statement: Treatment for defined patients with rifampicin resistant (RR) tuberculosis (TB), multidrug resistant (MDR) TB, pre-extensively drug-resistant (pre-XDR) TB and extensively drug-resistant (XDR) TB including bedaquiline and delamanid (All Ages)

Programme of Care: Blood and Infection

Clinical Reference Group: Infectious Diseases

URN: 2317

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy statement proposition, and how this feedback has been considered.

2. Background

Tuberculosis (TB) is a disease caused by the bacterium Mycobacterium tuberculosis (M.tuberculosis), which mainly affects the lungs, but can cause disease in other areas of the body. Rifampicin-resistant (RR) TB occurs when the TB bacterium is resistant to the antibiotic (anti-TB drug) rifampicin. Multidrug-resistant (MDR) TB is when the TB bacterium is resistant to rifampicin and isoniazid. Pre-extensively drug-resistant (pre-XDR) TB is a form of TB that is resistant to rifampicin and isoniazid, and that is also resistant to at least one fluoroquinolone (either levofloxacin or moxifloxacin). Extensively drug-resistant (XDR) TB, which is not covered in this proposition, occurs when the TB bacterium is resistant to rifampicin, isoniazid, at least one fluroquinolone and at least one other ‘Group A’ drug (bedaquiline or linezolid) (WHO, 2022).

There is a smaller subset of patients with RR-TB, MDR-TB, pre-XDR TB or XDR-TB, who are not covered by the standard treatment options. For these patients, it is not possible to construct a WHO recommended treatment regimen, either as a result of additional drug resistance (in the case of patients with confirmed, suspected or functional XDR-TB), or as a result of functional resistance. Current treatment options for these patients are limited and consist of individualised treatment regimens with a total treatment duration of 18–20 months suggested for most patients, but this may be modified according to the patient’s response to therapy (often continuing for 15–17 months after culture conversion). Bedaquiline and/or delamanid form part of these individualised treatment regimens.

Currently, bedaquiline or delamanid may be used sequentially and for a maximum duration of 24 weeks (six months) in the first instance. Treatment must be reviewed at least every six months and any extension(s) (up to six months at a time) must be agreed with the UK MDR-TB Clinical Advice Service (CAS) in conjunction with the treating MDR-TB Centre and submitted with justification through the prior approval system.

This updated policy statement proposition includes the additional concurrent use of bedaquiline and delamanid in defined patients who meet the below eligibility criteria. These drugs should be given for the necessary time and either concurrently or sequentially, if required, as determined on a case-by-case basis. The age range of individuals able to access treatment with bedaquiline and delamanid has been expanded, in line with the updated WHO Information Notes on bedaquiline and delamanid (2023). As a result of the 2024 update to this proposition, it is anticipated that 6 additional patients per year in England, for whom a WHO-recommended treatment regimen cannot be constructed, will be able to access treatment with bedaquiline and/or delamanid.

3. Engagement

The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

The policy proposition underwent a two-week stakeholder testing between 19th February and 4th March 2024 to registered stakeholders from the following Clinical Reference Groups:

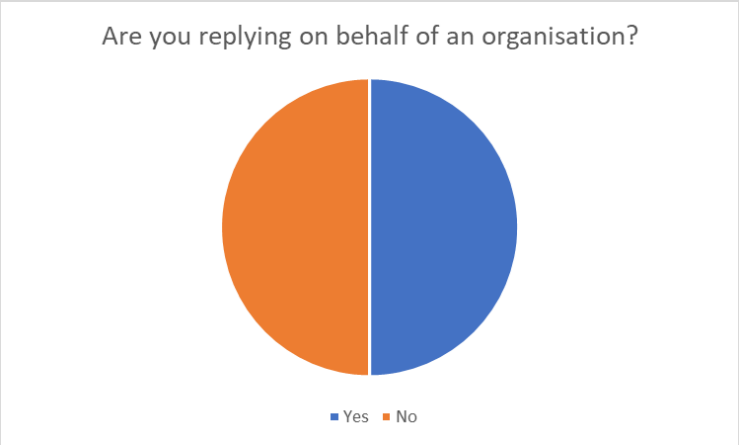
- Infectious Diseases
- Specialised Respiratory

Respondents were asked the following consultation questions:

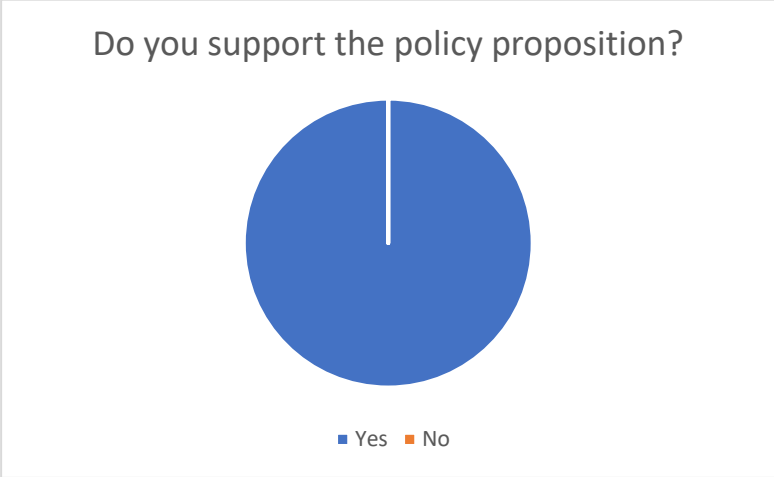
- Do you support the proposal for the additional concurrent use of bedaquiline and delamanid to be available for routine commissioning for patients with rifampicin resistant (RR) tuberculosis (TB), multidrug resistant (MDR) TB, pre-extensively drug-resistant (pre-XDR) TB and extensively drug-resistant (XDR) TB, within the criteria outlined in this document?
- Do you believe that there is any additional information that we should have considered in updating this policy?
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available?
- Do you support the Equalities and Health Inequalities Impact Assessment?
- Do you have any further comments on the policy proposal? If so, please submit these in under 500 words.

Engagement Results

In total, 2 respondents engaged with stakeholder testing for this proposition. This consisted of 1 organisation and 1 individual.



All respondents were supportive of the policy proposition.



In line with the 13Q assessment it was deemed that further public consultation was not required.

4. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Blood and Infection PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Current Patient Pathway	
Previous feedback from stakeholders on the (related) 2310 BPaLM policy advised that the UK MDRTB CAS should be referred to as the UK BTS MDRTB CAS.	This was noted and all appropriate references were amended throughout this policy proposition and supporting documents.
Potential impact on equality and health inequalities (EHIA)	
All respondents agreed with the EHIA and no additional comments were provided.	No further action required.
Changes/addition to policy	
One stakeholder commented that the names of Group A drugs should be added to the plain language summary for additional context.	This was discussed with the PWG. The names of Group A, B and C drugs were added to the plain language summary of the proposition.
One stakeholder commented that 'or equivalent' should be added to the following statement in the 'Starting Criteria': *The patient must be managed effectively with close supervision and follow up, and where appropriate offered directly observed therapy (DOT) or video observed therapy (VOT)* ***or equivalent***	The addition of the phrase *'or equivalent'* was discussed with the PWG and added.
One stakeholder commented with a request to add '*methadone'* as an example of a drug that may prolong cardiac QT interval. This was discussed with the PWG and added.	This was discussed with the PWG and added.

5. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following change(s) based on the engagement responses has (have) been made to the policy proposition and/or supporting documents:

Policy Proposition	
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One stakeholder commented that the names of Group A drugs should be added to the plain language summary for additional context.	This was discussed with the PWG. The names of Group A, B and C drugs were added to the plain language summary of the proposition.

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6. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No.