NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION SUMMARY REPORT

1 Quality standard title

Tuberculosis

Date of quality standards advisory committee post-consultation meeting:
06 October 2016

2 Introduction

The draft quality standard for tuberculosis (TB) was made available on the NICE website for a 4-week public consultation period between 12 July and 09 August 2016. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 19 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?

3. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.

4. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement specific questions:

5. For draft quality statement 1: Is there a need to focus the population more for this statement by specifying an age range?

6. For draft quality statement 2: Should the statement focus on a specific group?

7. For draft quality statement 5: Would this statement be achievable by local services given the potential resource impact of providing accommodation?

8. For draft quality statement 5: How would you describe suitable living accommodation for people with active TB?

9. For draft quality statement 6: Is there a specific action relating to cohort review that the statement could focus on, rather than having a broad statement on this area?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- The quality standard does accurately reflect the key areas for quality improvement.
- One stakeholder felt the quality standard does not reflect the key areas for quality improvement.
- There are issues regarding access to high quality diagnostics and clinical services, especially in areas of low or very low incidence, that are not captured by these standards.
- For these quality statements to be of value to TB service providers and commissioners, fewer quality statements are required.
- The focus on under-served groups throughout this draft document is not supported by fact. The larger group (at least 85%) of people who have TB are not in this group and this risks distorting priorities away from the 85% with TB.
- The measures for the statements are repetitive.

- The quality standard has a sensible approach to a medical/social problem.
- It would be helpful to discuss the epidemiology in more detail and the estimated size of the problem with late diagnosis and secondary cases resulting.

Consultation comments on data collection

- For the majority of these quality measures, local systems and data collection systems are in development. Some additional administration resources may be needed to deliver the required data.
- Considerable work is being undertaken to look at local provision against the national service specification and to bring this to the attention of commissioners with the support of TB control boards to improve commissioning. The work has demonstrated issues with gaps in routine data collection along the entirety of the pathway as currently defined (which differs between areas).
- Systems are in place for the data relating to statement 4 and 5 to be collected (information collected for Enhanced tuberculosis surveillance (ETS) reporting or London Tuberculosis register LTBR).
- Concerns were raised that some of the definitions in the quality statements need clarification in order to enable data to be collected.
- Some data collection can be accomplished through participation in cohort review.

Consultation comments on resource impact

- Additional data collection and resources such as equipment, information systems, housing and TB team and administrative capacity would be required to achieve the statements.
- This is a work in progress but it is evident that this is a poorly resourced area for commissioning in both low and high incidence areas. The expectations of the strategy have not been matched by any increase in investment and in many areas TB is not seen as a priority for commissioning. At this stage – with TB control boards undertaking gap analysis against the national specification – it is not possible to quantify the resource requirements and it is unlikely that this information will be made available in any meaningful way for several months.
- The quality standard will not be achievable without changes to the statements. Statement 1 will require significant increase in resources if the current definitions are not changed.
- Statement 2 is achievable as even if NAAT is not available locally it should be available via reference laboratories.
- Statement 6 is achievable.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People who have arrived in the country within the past 5 years, from countries with a high incidence of tuberculosis (TB), are tested for latent TB infection when they first present to healthcare services.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- The implementation of the statement would require a highly significant increase in resources.
- It may not be practical and/or realistic to expect various healthcare professionals to be responsible for identifying and referring new entrants for LTBI testing.
- The statement should focus on people first registering with a primary care provider.
- There may be a lack of expertise and experience within general practice to undertake the tests required.
- In many areas there is limited or no new entrant screening. This is therefore an area for quality improvement. However, by trying to reach too large a group for screening, the risk is that the priority for screening the highest risk group will be missed.
- A definition of 40 cases of TB per 100,000 people per year would be unachievable. A definition of 150 cases of TB per 100,000 people per year would align the statement with Collaborative tuberculosis strategy for England: 2015 to 2020. A different figure would also be confusing.
- There are data collections for the national programme that could support the process.
- With the current measures it will be difficult to collect the data required to measure the statement.
- Patients starting cytotoxic drugs and long term steroids may also need screening for latent TB.

- TB latent in bones, kidneys etc. should also be considered and managed.

Consultation question 5: Is there a need to focus the population more for this statement by specifying an age range?

Stakeholders made the following comments in relation to consultation question 5:

- Make the population more focused in order to prevent health services from being overwhelmed and ensure people who tested positive could be given treatment.
- Focus the population on people aged 16 to 35 years in line with the national strategy and the current NHS England funded national LTBI testing and treatment programme. Funding a programme for a wider population would need further financial assessment.
- Focus on people aged 0 to 65 years as latent TB infection treatment is not offered to people over the age of 65 years.
- Be more explicit about including children and have a focus on testing the family unit.
- It may not make clinical sense to specify an age range.
- Age range may not necessarily be reflective of level of exposure. Without clear evidence an age range should not be specified.

5.2 Draft statement 2

People who are referred to a TB service, who meet specific criteria, have rapid diagnostic nucleic acid amplification tests (NAATs) for the M. tuberculosis complex on primary specimens.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- The statement should be more specific about the population, e.g. use the population 'people suspected to have tuberculosis'.
- Situations where NAATS should be used are not defined well enough to allow measurement to be undertaken. It is problematic to attribute the outcome measures to the statement as they are multifactorial.
- The specific criteria described are sufficiently flexible.
- The specific criteria need to be more tightly defined in order to allow standardised data collection between TB services and to avoid inappropriate use of NAATs.
- The planned roll-out of TB whole genome sequencing (WGS) is likely to impact on the use of NAATs in the future.
- An audit of laboratory provision of TB microbiology coordinated by Public Health England (Colindale) is planned for the autumn. Until the results are available from this it is difficult to say if it will be possible to provide the testing service required by this standard.
- To collect the proposed data effectively and accurately, additional systems would need to be implemented. It would be reasonable to suggest that the best place to collect this data would be at the interface between Clinical TB Services and the Laboratory.
- The statement should be more specific about the specimens to which it refers. NAATs have only been validated for use in specimens from the respiratory tract.
- There is a concern that performing NAATs on specimens in which there is a low pre-test probability of being positive, and in smear negative respiratory samples, the diagnostic accuracy will be compromised.

- The outcomes within this statement on short-term and long-term morbidity in adults and children with pulmonary TB will be difficult to quantify. It is not clear how morbidity is defined or what are the definitions of short term and long term.
- There is a lack of clarity about why some of the specific groups have been selected.

Consultation question 6: Should the statement focus on a specific group?

Stakeholders made the following comments in relation to consultation question 6:

- This standard seems to subgroup already and there is no clear requirement to focus on specific groups further. The identified groups in the quality standards are appropriate and aligned with the tuberculosis NICE guideline. Given the cost of NAATs, they should be reserved for these high-risk groups.
- Suspected pulmonary TB although this may be hard to achieve.
- This should apply if there is clear evidence to focus on a group. If the patient meets clinical criteria, then focusing on specific groups may miss individuals.
- The 4 subgroups identified are valid and appropriate for ensuring they have access to NAATs. However, in terms of measurability, most services would struggle to identify when rapid information about mycobacterial species would alter the person's care sub-group and hence maybe this one should be dropped.

5.3 Draft statement 3

People who have imaging features suggestive of active TB are assessed within 1 working day by the TB service.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- The timescale stated in the statement is not achievable or necessary for a number of reasons. In some cases it is not only difficult but beyond the control of the clinical team. A 7 day service would be more appropriate. It was also highlighted that rapid review in a TB service will be difficult to achieve without substantial investment. It may require a greater flexibility in working practice for TB nurses and teams, in particular in smaller services.
- The suggested timescale differs from the National TB Service Specification which recommends two working days for pulmonary or laryngeal TB.
- Clarification is required about whether this is just for pulmonary TB and if it should focus on those with an infection risk.
- A clearer definition of what 'assessment' means and who undertakes it is required.
- The issue with this statement is that it restricts rapid assessment of suspected TB to those with radiology imaging features. However, patients may be referred e.g. by primary care services with symptoms/signs suggestive of TB without imaging (or before imaging available). The definition of "imaging features suggestive of active tuberculosis" should be changed to read "active pulmonary tuberculosis".
- A more useful statement would be: systems should be in place to ensure that all imaging suggestive of active pulmonary tuberculosis is referred directly to the TB multidisciplinary team.
- The statement should be explicit that this refers only to pulmonary/laryngeal TB.
- Further clarity is required around 'assessed within one working day'. This needs clarification as the implications for service strengthening will be different depending on the decision made. "Within one working day of imaging report reaching the requesting clinician" would be more correct and would assist measurement.

- With regards to the outcome measures treatment delay, morbidity and mortality are multifactorial.
- Stakeholders requested clarity on how the figures for the measures would be obtained.
- The onus on local data collection in this section is potentially onerous. Much of this data is part of cohort review and we suggest using cohort review process.

5.4 Draft statement 4

People with TB from under-served groups are offered directly observed therapy as part of enhanced case management.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Expressions of support for the statement.
- Focussing on the underserved group is too narrow. All patients who are assessed by the TB Service to be at risk of non-compliance with treatment should be considered for DOT (Directly Observed Therapy).
- While it should be considered for all such persons, in fact it is appropriate for only a small proportion to receive this. The decision is for the TB team not the patient.
- Clarification is needed regarding what the measures mean. Treatment completion overall for MDR patients, mortality and loss to follow up are multifactorial and cannot be taken as absolute monitoring measures for this quality statement.
- Treatment completion overall for multidrug-resistant patients, mortality and loss to follow up are multifactorial and in themselves cannot be taken as absolute monitoring measure for this quality standard. Also, denominator data for 'vulnerable migrants' is not currently uniformly available and not recorded on ETS.
- Data on treatment completion is collected in enhanced TB and latent TB surveillance and can be analysed for those with 4 social risk factors (history of drug or alcohol use, homelessness or imprisonment), so local data collection for this is not required. However, local data collection would be needed for additional underserved populations.

5.5 Draft statement 5

People with active TB who are homeless are offered accommodation for the duration of their treatment.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- Suggest adding 'regardless of the patient's immigration status or recourse to public funds'.
- This is desirable. Whilst homeless people with TB often spend long periods in hospital this is not desirable. They do require secure accommodation in single rooms to avoid cross infection.
- Social services should have responsibility for this aspect of the quality standard.
- It was suggested that unless it is specified who holds the legal responsibility to offer accommodation, it is unlikely to happen.
- The outcomes on TB prevalence and incidence are not clearly described. They should be defined by cohort.
- The definition of homelessness is broad, which is difficult to use as a key performance indicator.

Consultation question 7: Would this statement be achievable by local services given the potential resource impact of providing accommodation?

Stakeholders made the following comments in relation to consultation question 7:

- Providing accommodation for vulnerable groups is undoubtedly difficult due to resource impact but is essential from both an individual and public health perspective.
- This is achievable by most local services and not unrealistic in terms of resource impact given the relatively low volume of people the statement is concerned with.
- This is certainly an ideal but it is difficult to understand how this would be achievable in urban areas with a high incidence of TB unless specific funds were available for this.
- The statement has no validity unless responsibilities (NHS, local authorities) are clearly defined.

- Success of this statement relies on government funding for TB-specific social care in the community.
- The statement would not be achievable. Suggest, in a financially constrained system that priority is given to those who have infectious TB and are occupying an acute hospital bed even though fit for discharge.
- The issue arises of what happens once anti-TB treatment is completed. Is there a mechanism to ensure that there is long term accommodation in place?
- A query was raised about what organisations working with homeless people think about this statement and in particular if they think this is something homeless people are likely to comply with.

Consultation question 8: How would you describe suitable living accommodation for people with active TB?

Stakeholders made the following comments in relation to consultation question 8:

- Suitable living accommodation for people with active TB should not be a hostel or temporary in nature but could include shared areas once the infectious period has passed. In addition, in particular cases such as poor compliance with treatment or persistently smear positive TB suitable accommodation would be isolated (i.e. no sharing with others of bedroom, kitchen or bathroom) and supervised heavily.
- A safe, secure, self-contained single room environment per person or family that is adequately heated and has facilities for washing and preparing food. If needed, this should be furnished with appropriate furniture, bedding and cutlery/crockery.
- Accommodation should be located within a reasonable distance of the relevant TB clinic – with consideration given to transport and transport costs.
- Security of accommodation i.e. tenure for duration of TB treatment. This does require caveats i.e. contract with patient that tenure is reliant on treatment compliance, patient may be asked to pay or contribute to cost of accommodation depending on benefits/personal financial situation.

5.6 Draft statement 6

Multidisciplinary TB teams take part in cohort review at least quarterly.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

- This is an important statement but it should be noted that in many areas with few TB cases cohort review are held 6 monthly or 4 monthly. It may not be viable or practical to increase frequency in these areas. Furthermore, experience in low prevalence areas suggests quarterly cohort review may not be meaningful – frequency should be determined by local epidemiology.
- This statement is fully supported though some centres with a high incidence of TB will require more frequent meetings.
- This is not measurable without more detail on who from the TB multidisciplinary team needs to attend and how often. The statement will also be hard to measure because the multi-disciplinary team does not have a standing constitution or structure. The range of people in the team varies according to the location and the complexity of the case being managed.
- The statement should focus on ensuring all notified TB cases should be discussed at cohort review (rather than just that teams take part in cohort review) to ensure all cases in all areas are considered and standards are met.
- Questioned why the statement advocates people with TB having their treatment outcomes reviewed at cohort review, 6 to 9 months after starting treatment when the outcome measures look at treatment completion rates within 12 months.
- Suggestion to state a minimum of 5 close contacts within the process measure on contact screening.

Consultation question 9: Is there a specific action relating to cohort review that the statement could focus on, rather than having a broad statement on this area?

Stakeholders made the following comments in relation to consultation question 9:

- The issue of what is the aim of cohort review appears relevant. It should be a vehicle that ensures high-quality care is delivered to an individual, though mainly it

serves to check that the public health duties associated with TB are being adequately performed. This needs to be done in a setting which is more than just a single service reviewing its own data.

- Suggestion to emphasise the aims of cohort review.
- The audit of treatment outcomes and contact investigations of all people with TB and their contacts.
- This should focus on challenges – e.g. treatment compliance/completion; population movement/contact tracing/immigration status versus ensuring completion of course of treatment.
- It may not be possible to be too prescriptive about the nature of the cohort reviews. This will need to be discussed within Board areas and local solutions developed. Hence defining a specific action in relation to cohort reviews is probably not the way forward.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- As the quality standard relates to TB in the broader sense and not just screening there should be a statement relating to contact tracing/active case finding standards.
- The quality standard should cover delayed diagnosis of TB because it has not been suspected.
- An area that is missing from the quality standards is that of obtaining samples to confirm the suspected TB diagnosis.
- The culture and sensitivity of the TB organism and the need to test routinely for this in all specimens to ensure that treatment resistance is detected earlier needs consideration.
- TB in HIV needs discussion, that any HIV detected patient be screened for TB and be considered for prophylactic isoniazid.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Section	Comments
1	British Thoracic Society	Question 1	**Does this draft quality standard accurately reflect the key areas for quality improvement?** Yes. Sputum smear examination within 24 h is an essential for limiting transmission
2	Joint Yorkshire and Humber and North East TB Control Board	Question 1	Broadly, yes it does.
3	Leeds Teaching Hospitals NHS Trust	Question 1	***Q1: Does this draft quality standard accurately reflect the key areas for quality improvement?*** [For statement 4] Yes.
4	Leeds Teaching Hospitals NHS Trust	Question 1	***Q1: Does this draft quality standard accurately reflect the key areas for quality improvement?*** [For statement 5] Yes.
5	Leeds Teaching Hospitals NHS Trust	Question 1	***Q1: Does this draft quality standard accurately reflect the key areas for quality improvement?*** [For statement 6] Yes.
6	North West TB Control Board	Question 1	Yes, this draft quality standard does accurately reflect the key areas for quality improvement.
7	Royal College of Physicians and Surgeons of Glasgow	Question 1	*Does this draft quality standard accurately reflect the key areas for quality improvement?* Yes, as an overall Standard/ set of Quality Statements. I am slightly dubious about Quality Statement 3 - why focus so much on the (difficult) 1 day time period for assessment based on a CXR abnormality? It is also unclear what is meant by '1 working day' in the context of an NHS that is rapidly moving towards 7-day service models: is this Mon-Friday, or 7 days/ week? The more important – and more achievable – quality measure is surely b) - to ensure that all people with pulmonary TB are started on treatment within 2 months of symptoms onset - and this could/ should be the main quality statement in my view. I am delighted to see Statement 5 included, relating to the crucial issue of accommodation needs.
8	Public Health England	Question 1	No.
9	Joint Yorkshire and Humber and North East TB Control Board	General	The TBCB agrees that safety and experience of care is an important consideration; There are issues regarding provision of/access to high quality diagnostics as well as clinical services, especially in areas of low/ very low incidence that are not captured by these standards.
10	NHS England	General	NHS England welcomes these quality standards for Tuberculosis. They are in line with the joint NHSE/PHE national Strategy on Tuberculosis and reflect key areas for improvement.

ID	Stakeholder	Section	Comments
11	Public Health England	General	For these quality statements to be of value to TB service providers and commissioners, fewer quality statements are required. The terminology should be recommendations rather than definitive statements.
12	Public Health England	General	The focus on under-served groups throughout this draft document is not supported by fact. The larger group (at least 85%) of people who have TB are not in this group and this risks distorting priorities away from the 85% with TB by relevant statutory agencies, community and voluntary organisations. There is a need to ensure that the relevant organisations focus on all of those affected by TB.
13	Public Health England	General	The standards are repetitive, for example the comments made for 'treatment completion rates' would apply each time. The comment has only been made the first time they are mentioned.
14	RCGP	General	A sensible approach to a medical/social problem. It would be helpful to discuss the epidemiology in more detail and the estimated size of the problem with late diagnosis and secondary cases resulting. The specificity and sensitivity of the Mantoux and antibody test should be considered-separately and in combination. The role of MMR for certain high risk communities needs consideration.
15	Royal College of Physicians and Surgeons of Glasgow	General	This document comes from an almost exclusively Public Health England/NHS England policy context (see references on page 34). This is understandable given the remit of NICE, but given that Health is a devolved issue it does create difficulties for us in Scotland when deciding on whether or not to adopt NICE guidance and/or NICE Standards here. In Scotland, key policy context would include the TB Action Plan for Scotland (2011), currently in the process of being refreshed, along with various policy documents from Health Protection Scotland (HPS) and NHS Scotland. Our National TB Multi-Disciplinary Network (TB-MDN), which sits under the Scottish Health Protection Network (SHPN) and links closely with HPS and Scottish Government, is now central to formulating TB policy for Scotland. The Scottish TB-MDN has absolutely no desire to 're-invent the wheel' in Scotland or to develop separate TB guidelines and standards just for the sake of it. The excellence of the evidence-based work undertaken by NICE is also recognised. With this in mind the Scottish TB-MDN recently recommended to SHPN that the 2016 NICE guideline on Tuberculosis (NG33) should be adopted in Scotland, subject to a few caveats to ensure coherence with existing Scottish policy. A similar review would need to take place when the final NICE TB Standards are published, with no guarantee at this point in time that the Standards will be adopted in Scotland (in their totality at least), as there is a significant potential for conflicts and contradictions with a refreshed TB Action Plan for Scotland.
16	British Society for Antimicrobial Chemotherapy (BSAC)	General	Members of the British Society for Antimicrobial Chemotherapy (BSAC) have no comments to this draft Tuberculosis quality standard.
17	Department of Health	General	The Department of Health has no substantive comments to make, regarding this consultation.

ID	Stakeholder	Section	Comments
18	Joint Yorkshire and Humber and North East TB Control Board	General	There are some issues with language which are addressed in the comments below and which need clarification/to be made more explicit.
19	Joint Yorkshire and Humber and North East TB Control Board	General	The comments below refer to ensuring the document is specific and meets its purpose.
20	Royal College of Nursing	General	Is there any scope to furnish arrivals from high incidence countries with information or card that informs them that they must present to healthcare professional for a check within five years of residency/arrival so they can assist in the screening process - warning cards could be a more accepted way of receiving information…the same for malaria and leishmaniasis?
21	Royal College of Paediatrics and Child Health	General	From an education and training perspective, we would suggest that adequate exposure to training opportunities in Paediatric TB may not always be available in routine paediatric placements (both for doctors of all grades and other HCP including nurses). We would therefore recommend that suitable training environments are identified locally and regionally to ensure adequate experience is gained. This may involve attendance at clinics in tertiary centres, or at regional network hubs where significant volumes of cases are managed. We would recommend the inclusion of this paragraph directly in the text of the standard.
22	Royal College of Physicians	General	The RCP is grateful for the opportunity to respond to the above consultation. We would like to formally endorse the response submitted by the British Thoracic Society.
23	Joint Yorkshire and Humber and North East TB Control Board	Introduction	[P2, 2nd paragraph] Suggestion. Restructure the sentence to recognise that there is a difference between the activities of Public Health England and the local Health Protection Teams.
24	Joint Yorkshire and Humber and North East TB Control Board	Introduction	[P2, 3rd paragraph] Suggestion. Change 'burden' to incidence. Burden usually refers to active disease and the strategy refers to and has action re active and latent TB disease. We are interested in latent TB cases who convert to active TB disease.
25	Joint Yorkshire and Humber and North East TB Control Board	Introduction	[P2, 3rd paragraph] Suggestion. Last sentence refers to homelessness and infers that it is an issue for people born in countries with a high incidence of TB whereas it isn't meant to
26	Joint Yorkshire and Humber and North East TB Control Board	Introduction	[P2, 4th paragraph] Suggestion. The word 'relevant' is non-specific – could the sentence be more specific?

ID	Stakeholder	Section	Comments
27	Joint Yorkshire and Humber and North East TB Control Board	Introduction	[P3, bullet point 7] Suggest amending this to be more specific – either 'premature mortality' or 'mortality attributable to TB'
28	Portsmouth Hospital Trust	Introduction	[Paragraph 2] The wording in the second paragraph could be misleading regarding definition of latent and active TB. 'Latent TB' cannot spread. The organisms multiply and overwhelm the immune defences resulting in active TB disease presenting with symptoms.
29	Public Health England	Introduction	**Correction** ' latent TB can spread in the lung (pulmonary TB) or develop' should read ' latent TB can develop into active TB in the lung (pulmonary TB)
30	Public Health England	Introduction	**Correction** ' or develop in the other' – delete 'develop'
31	Public Health England	Introduction	**Correction** – first sentence incorrect as 'public health measures' cannot prevent reactivation of latent TB infection. 75% of TB disease is identified in people born overseas and is likely to be reactivation of latent TB infection.
32	Public Health England	Introduction	[Page 2, Paragraph 2] Correction – paragraph headed Collaborative tuberculosis strategy for England. The most recent reports on TB incidence and cases show a small decline in MDRTB. Therefore suggest the second sentence deletes 'The increasing numbers of 'and starts with 'Drug resistant cases…'Please check statement and quote the newest annual report (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/492431/TB_Annual_Report_v2.6_07012016.pdf) p43. The proportion of drug resistant TB is stable; MDR has even been slightly decreasing most recently. For all surveillance figures – please use newest annual report (third paragraph p2).
33	Public Health England	Introduction	[Page 2, Paragraph 3] Correction – first sentence – 2016 changed to 2014 which is the year for which data is available. TB figures for 2015 not yet available.
34	Public Health England	Introduction	[Page 2, Paragraph 4] Correction – add in 'and alcohol' to last sentence
35	Joint Yorkshire and Humber and North East TB Control Board	Coordinated services	This is woolly. What forms part of the pathway? Does this include e.g. Border Force / Immigration work? Legal / Magisterial parts of pathway for those detained under Part 2A? Not reasonable to assume that this part of the pathway could / should / would be commissioned by the same organisation as acute healthcare.
36	Joint Yorkshire and Humber and North East TB Control Board	Outcomes frameworks	Question. Is preventing infant mortality rational in this context?
37	Joint Yorkshire and Humber and North East TB Control Board	Outcomes frameworks	Question. Ensuring that people have a positive experience of care – can people with TB, subject to part 2A orders; have a positive experience of care?

ID	Stakeholder	Section	Comments
38	British HIV Association (BHIVA)	Question 2	Local data capture is likely to be very patchy across sites. For some areas this should be relatively easy e.g. anything which involves lab information as this is usually electronically stored (though from personal experience it can be incredibly difficult to extract negative results routinely from systems, for example if one wanted to check that the relevant samples had been sent and were culture negative). For other data measures (e.g. abnormal chest radiographs requiring rapid patient review by TB services, new systems will have to be introduced to flag up and record information on the images in the first place).
39	North West TB Control Board	Question 2	For the majority of these quality measures, local systems and data collection systems are in development. Exceptions are detailed in the remainder of this response. However, overall, additional funding/administrative staff may be required.
40	British Thoracic Society	Question 2	**Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?** Partially. Some additional administration staff / funding may be required to deliver the required data.
41	Joint Yorkshire and Humber and North East TB Control Board	Question 2	A huge amount of work is underway to address this, overseen by TBCB. Considerable work is being undertaken to look at local provision against the national service specification and to bring this to the attention of commissioners with the support of TBCB to improve commissioning and define pathways of care. The work has demonstrated issues with gaps in routine data collection along the entirety of the pathway as currently defined (which differs between areas).
42	Public Health England	Question 2	No. Some data collection can be accomplished through participation in cohort review.
43	Leeds Teaching Hospitals NHS Trust	Question 2	***Q2. Are local systems in place to collect data?*** [For statement 4] Yes. Information collected for Enhanced tuberculosis surveillance (ETS) reporting (or London Tuberculosis register LTBR).
44	Leeds Teaching Hospitals NHS Trust	Question 2	***Q2. Are local systems in place to collect data?*** [For statement 5] Yes (ETS / LTBR).
45	Leeds Teaching Hospitals NHS Trust	Question 2	**Q2. Are local systems in place to collect data?** [Statement 2] Children under 16, HIV, and risk factors for MDR TB fairly easy to collect data for. “People for whom rapid information about mycobacterial species would alter care” is much harder to define. This could be argued to apply to anyone with a positive smear or culture for AAFB, in that if we know it is or is not TB we would give different drugs. How much does care have to be affected? In practice I suspect most clinicians would start TB treatment, and change later if found to be Non tuberculous mycobacteria, unless strong grounds to think NTM more likely. This becomes an issue only if get adverse reaction to a drug that wouldn’t have been used for NTM (e.g. Pyrazinamide), or if starting large scale contact tracing.

ID	Stakeholder	Section	Comments
46	Joint Yorkshire and Humber and North East TB Control Board	Question 2	Lack of clarity in the definitions is challenging.
47	British Thoracic Society	Question 2	With reference to each specific quality statement: 1. No – not for GPs yet (to be funded by PHE).
48	Leeds Teaching Hospitals NHS Trust	Question 2	***Q2. Are local systems in place to collect data?*** Flag 4 data can be used to estimate number of new arrivals registering with primary health care. No systems in place to count those who do not.
49	British Thoracic Society	Question 2	2. Insufficient funding for on-site PCR.
50	British Thoracic Society	Question 2	3. Yes.
51	Leeds Teaching Hospitals NHS Trust	Question 2	***Q2. Are local systems in place to collect data?*** At present no system to collect data for number of imaging reports suggestive of tuberculosis.
52	British Thoracic Society	Question 2	4. Yes.
53	British Thoracic Society	Question 2	5. Dependent on local authorities and out of remit of the NHS.
54	Portsmouth Hospital Trust	Question 2	TB Nurses collect data for active TB for ETS. No national system for data relating to LTBI treatment. Local data is collected but a national resource would be useful if admin support can be resourced for TB services.
55	British Thoracic Society	Question 2	6. Yes.
56	Leeds Teaching Hospitals NHS Trust	Question 2	***Q2. Are local systems in place to collect data?*** [For statement 6] Yes.
57	Royal College of Physicians and Surgeons of Glasgow	Question 2	*Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?* I suspect the honest answer is that for many/ most of the quality measures Scottish Boards would not currently be in a position to provide the required data. For a number of the quality measures it would be feasible to do so without too much difficulty, but others look more problematic (see later comments).

ID	Stakeholder	Section	Comments
58	British Thoracic Society	Question 3	**Do you have an example from practice of implementing the NICE guidelines that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.** There are a number of examples which can be submitted including: - patients that have been housed for the duration of their treatment by the local authority. - Refugees in multi-occupancy hostels - good practice examples from Westminster and Hackney where there is a dedicated funding scheme to house TB patients without recourse to public funds.
59	Joint Yorkshire and Humber and North East TB Control Board	Question 3	The joint Yorkshire and Humber and North East England TBCB has a wealth of examples and can provide as required.
60	North West TB Control Board	Question 3	Yes. A comprehensive system of cohort review has been established in the North West since 2012 covering all our notified TB cases and TB Services. The latest Annual Report will be available after sign off from the North West TB Control Board later in 2016. Cheshire and Merseyside are working on a framework pathway to provide accommodation for homeless TB patients to be shared with the NW TB Control Board once finalised. Greater Manchester are developing a pathway for those patients with No Recourse to Public Funds to enable them to be accommodated for the duration of treatment. Both could be shared with NICE later in 2016. East Lancashire (secondary care) new entrant LTBI screening programme
61	Royal College of Physicians and Surgeons of Glasgow	Question 3	*Do you have an example from practice of implementing the NICE guidelines that underpins this quality standard?* I have no particular examples (the 2016 NICE guidelines also only very recently adopted in Scotland)
62	British HIV Association (BHIVA)	Question 4	Extra resource is likely to be needed for the introduction of Quality standards 2 (use of NAAT in primary samples), 4 (DOT in underserved), and 5 (accommodation for homeless). Some of the costs in 2 might be offset by moving away from performing AFB smears on samples and replacing this with NAAT. However, consideration needs to be then given to technical issues (is NAAT adequate if the sample is pus and contains potential amplification inhibitors?) and what are the public health implications of a positive NAAT in terms of isolation and de-isolation on treatment?
63	British Thoracic Society	Question 4	For lab diagnostics more testing equipment may be needed.
64	British Thoracic Society	Question 4	For all patients to be seen within one day extra TB team capacity may be needed. Additional robust data collection will also require administrative support.

ID	Stakeholder	Section	Comments
65	British Thoracic Society	Question 4	Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment. For DOT more staff of a different grade may be needed.
66	British Thoracic Society	Question 4	Housing will require extra funds.
67	Joint Yorkshire and Humber and North East TB Control Board	Question 4	Uncertain re LTBI screening. Only some areas have funding for programmatic screening; if this quality standard expects increased screening across the board, then may not be deliverable within current resources. Similarly, possible increase in DOTS as a result of Statement 4 may not be deliverable without extra resources, especially in low TB incidence areas with very small TB workforces.
68	Leeds Teaching Hospitals NHS Trust	Question 4	***Q4. Would this statement be achievable?*** [For statement 5] Would need additional resources including agreement from local authority housing dept. But would potentially be cost saving to the overall public spending budget as some of these patients end up with prolonged hospital stays. Needs to clearly specify that applies even to those otherwise not entitled to public housing or funding e.g. undocumented migrants, failed asylum seekers, etc.
69	Leeds Teaching Hospitals NHS Trust	Question 4	***Q4. Would this statement be achievable?*** [For statement 3] NO. In high incidence areas, workload demand may make it impossible to assess a patient within 1 working day. In low incidence areas, the TB service may have one consultant and a part time nurse with other duties or a large geographical area to cover. The consultant may have a ward round and a bronchoscopy list tomorrow, the nurse may be on a day off, or visiting a patient miles away, or doing an asthma clinic. A 1 week standard should be achievable.
70	Leeds Teaching Hospitals NHS Trust	Question 4	***Q4. Would this statement be achievable?*** [For statement 4] Yes, but may need additional resources in numbers of TB nurses or others to deliver DOT in some areas.
71	Leeds Teaching Hospitals NHS Trust	Question 4	***Q4. Would this statement be achievable?*** [For statement 6] Yes.
72	North West TB Control Board	Question 4	Quality Statement 1 – A key resource requirement to achieve this statement is a systematic and reliable system to identify eligible new entrants. Previously Flag 4 data has been used to identify new entrants for screening, but there are no current sustainable formalised local arrangements in place for this to be provided for new entrant screening as the national contract for this is now held by Capita.
73	North West TB Control Board	Question 4	Quality Statement 2 – This will require NAAT equipment to be routinely available to all TB services. This is not currently the case.

ID	Stakeholder	Section	Comments
74	North West TB Control Board	Question 4	Quality Statement 3 – This is likely to require additional capacity within a TB team.
75	North West TB Control Board	Question 4	Quality Statement 4 – Again, this may require additional capacity within a TB team – including increased TB Physician numbers/PAs and TB Nurses.
76	North West TB Control Board	Question 4	Quality Statement 5 – This will require additional funding by the organisation deemed responsible for providing the accommodation. In the North West, two areas are currently exploring pathway options for provision that would ensure patients could be housed without delay, preventing unnecessary bed blocking and freeing up clinicians and TB nurses from protracted negotiations. Many patients in this category may have no recourse to public funds which adds to issues of procurement. Overall, additional robust data collection will require additional administrative support.
77	Royal College of Physicians and Surgeons of Glasgow	Question 4	*Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.* Statement 1: Very challenging area, but it is probably achievable to set systems up in primary care. However, given that many arrivals from high incidence countries may be migrants of uncertain/ tenuous immigration status, who may not engage well with (or indeed be eligible to register with) primary care teams, it is not clear how robust any such system would be.
78	Royal College of Physicians and Surgeons of Glasgow	Question 4	Statement 3. As previously indicated, what is meant by '1 working day' is unclear. Few, if any, dedicated TB services would have the manpower resources to deliver what is being requested on a 7-day basis – and even a 5-day basis would be a stretch. Linking TB services in with an on-call generic Infectious Diseases or Resp Medicine services, where available on a 24/7 basis, might work.
79	Royal College of Physicians and Surgeons of Glasgow	Question 4	Statement 4: The TB nursing resource varies between Boards, but most would have the capacity to deliver DOT to under-served groups I think – especially when linking in with community based volunteers etc. for medication supervision. Defining and formally recording who represents a patient from an underserved group, to calculate the standard, would require additional data collection - but is certainly achievable.
80	Royal College of Physicians and Surgeons of Glasgow	Question 4	Statement 6. This would be achievable by local services, although clearly requires time to both establish and to run effectively. Provision of some dedicated administrative time would be vital for success. Busy clinicians, who face a myriad of other pressures, also need to have this formally recognised in their job plans to ensure sustainable engagement.

ID	Stakeholder	Section	Comments
81	Royal College of Physicians and Surgeons of Glasgow	Question 4	Statement 2. There needs to be a further expansion of NAAT availability and its use in TB diagnosis – as for other areas of microbiological diagnosis. This is achievable, but will require additional resources. Unfortunately, we will need to retain culture-based diagnostic services as well – as the 'gold standard' for TB diagnosis and also for full/ extended sensitivities. However, some cost-savings may be possible in terms of rationalising existing TB diagnostic services.
82	Joint Yorkshire and Humber and North East TB Control Board	Question 4	This is a work in progress but it is evident that this is a poorly resourced area for commissioning in both low and high incidence areas. The expectations of the strategy have not been matched by any increase in investment and in many areas TB is not seen as a priority for commissioning. At this stage – with TBCB undertaking gap analysis against the national specification – it is not possible to quantify the resource requirements and it is unlikely that this information will be made available in any meaningful way for several months.
83	Public Health England	Question 4	No.
84	Leeds Teaching Hospitals NHS Trust	Question 4	***Q4. Would this statement be achievable?*** [For statement 1] At threshold of 40/100,000 in country of origin not achievable without huge increase in resources including qualified health professionals. This would not be a sensible use of health care resources.
85	Leeds Teaching Hospitals NHS Trust	Question 4	***Q4. Would this statement be achievable?*** [For statement 2] Yes. Even if NAAT not available locally, should be available via reference laboratories.
86	Leeds Teaching Hospitals NHS Trust	Question 4	***Q4. Would this statement be achievable?*** [For statement 6] Yes.
87	Portsmouth Hospital Trust	Question 4	The standards would be achievable if services are adequately resourced. Currently funding is allocated on number of TB notifications. It would be useful to have resources allocated based on areas that have high risk factors for TB such as high levels of deprivation, migrant populations etc. This would allow resource to be used to focus on screening and prevention in these areas.
88	Royal College of Physicians and Surgeons of Glasgow	Question 4	Statement 5. See answer to Question 7 below.
Statement 1			
89	Joint Yorkshire and Humber and North East TB Control Board	Statement 1	Implementation of this statement would require: • Require massive increase in resources. • Much additional workload for minimal additional yield of screening. • Not cost effective (Pareek et al, Lancet Inf Dis 2011) • Illogical - should screen all immigrants to Yorkshire from London.

ID	Stakeholder	Section	Comments
90	Janssen	Statement 1	Success of this measure relies on the ability to link the data for "people who have arrived in the country within the past 5 years from countries with high incidence of TB" to their first presentation at a health service. At present, it is unclear how practitioners (GPs, nurses, dentists) will be privy to such information and thus refer patients for TB testing appropriately.
91	Joint Yorkshire and Humber and North East TB Control Board	Statement 1	Comment 3. 'First present to healthcare services' When? This needs more definition to be useful and measureable.
92	North West TB Control Board	Statement 1	It may not be practical or realistic to expect all dentists/nurses/all healthcare providers to be responsible for identifying and referring new entrants for LTBI testing. Primarily this currently happens via new GP registrations. Therefore we would suggest the statement should be amended to read "….first register with a primary care provider".
93	RCGP	Statement 1	Patients often first present to the GP. There are 20 high prevalence Tuberculosis countries including Brazil, Zimbabwe, China and Pakistan. The test for latent Tuberculosis is the tuberculin test or a blood test. This would involve GP practices in routinely doing tuberculin tests on newly registering patients from these countries. Few practices would have the expertise or experience. The RCGP suggests locally enhanced services or screening on arrival in this country? (Both require considerable investment and organisation which would be worth it but require a change in usual practice). The RCGP wonders if it would be worth it to screen for HIV to those patients too. (JA)
94	Leeds Teaching Hospitals NHS Trust	Statement 1	***Q1: Does this draft quality standard accurately reflect the key areas for quality improvement?*** In many areas there is limited or no new entrant screening. This is therefore an area for quality improvement. However, by trying to reach too large a group for screening, the risk is that the priority for screening the highest risk group will be missed.
95	British Thoracic Society	Statement 1	**People who have arrived in the country within the past 5 years, from countries with a high incidence of tuberculosis (TB), are tested for latent TB infection when they first present to healthcare services.** This is a good indicator however the following points should be noted: The statement should include children, ideally as a "family unit". The draft NICE quality standards define a high incidence country as >40:100,000. The LTBI new entrant screening screens people from countries with >150:100,000 incidence based on cost effectiveness analysis. Do the two numbers need to be consistent in relation to who should be screened? Not so useful to indicate a time limit (i.e. arrivals within the past 5 years), as travel is an important cause of further exposure. Suggested revision: *Those who have come from or visited relatives in a country with a high incidence of tuberculosis should be screened for symptoms of active disease and latent infection*.

ID	Stakeholder	Section	Comments
96	Joint Yorkshire and Humber and North East TB Control Board	Statement 1	Comment. Different to LTBI strategy - extremely confusing to those in primary care. Secondly the age range needs deciding upon.
97	Leeds Teaching Hospitals NHS Trust	Statement 1	Definition: A high-incidence country has more than 40 cases of TB per 100,000 people per year. This cut off is arbitrary and not evidence based. The NHSE/PHE collaborative national strategy has set a threshold of 150/100,000 as the TB incidence in country of origin for new entrant screening. There is evidence that this threshold TB incidence for screening is cost effective (Pareek et al, Lancet Inf Dis, 2011) but 40/100,000 is not. It is worth noting that a proposal using the higher 150/100,000 threshold was rejected by National Screening Programme as they felt there was not sufficient evidence for effectiveness/cost effectiveness. Extending new entrant screening to this much wider range of countries would require large increase in resources and workload, with limited additional yield from screening. It is therefore more appropriate to focus resources on the higher incidence countries as recommended by collaborative strategy. The number of cases of active TB in UK diagnosed in people born in countries with incidence between 40 and 150000 is relatively low, and a significant proportion of those have drug resistant TB for whom chemoprophylaxis would be ineffective, so the impact on TB case numbers in UK would be minor. Logically, if screening new entrants from a country with TB incidence of 40/100,000, we should also screen new arrivals in Yorkshire from London (and immigrant from e.g. Libya arriving in e.g. Newham should be screened even though they have moved to a much higher TB incidence area than where they came from). The priority must be to establish effective screening for LTBI in new entrants from the highest risk countries.
98	North West TB Control Board	Statement 1	The quality standard defines a high incidence country as >40:100,000. The Board do not feel that this would be achievable and would support using the threshold used by the funded Latent TB infection new entrant screening programme (>150/100,000).
99	Portsmouth Hospital Trust	Statement 1	This statement is at odds with the Roll out strategy for latent TB. The national strategy screening criteria is for those who have arrived from countries with an incidence of 150/100,000 and only those up to the age of 65. Making a quality statement that is at odds with the national strategy will only lead to confusion regarding commissioning of services, resource allocation etc. While it is optimal to aim to screen everyone arriving from a high incidence country using >40/100,000 this will be unachievable currently and receives no support from the national strategy.

ID	Stakeholder	Section	Comments
100	Public Health England	Statement 1	Data collections for the national programme are being collected centrally through PHE Colindale and GPs/ CCGs should support the process – see http://www.hscic.gov.uk/media/20098/2108982015isn/pdf/2108982015isn.pdfIt would also be preferable if processes and indicators are aligned with ours, see https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/442192/030615_LTBI_testing_and_treatment_for_migrants_1.pdfand https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/501736/LTBI_GP_templates_user_guide.pdf
101	Joint Yorkshire and Humber and North East TB Control Board	Statement 1	Structure measure (a). Comment. This time period needs closer definition to be measurable. For example, a dentist would not screen for TB - may refer to GP. Would this meet quality standard?
102	Joint Yorkshire and Humber and North East TB Control Board	Statement 1	Process measure. Comment. This figure is going to be very hard to ascertain.
103	RCGP	Statement 1	Patients starting cytotoxic drugs and long term steroids may also need screening for latent Tuberculosis. Tuberculosis latent in bone, kidney, etc. also needs to be considered and managed.(PS)
104	British Infection Association	Statement 1	What is the process where the existing incidence in an area is >40 per 100 000 such as in Brent?
105	Janssen	Statement 1	Please specify the “systems in place” that are capable of identifying people that have arrived in the country in the past 5 years from high incidence countries and meet the criteria for latent TB testing? At present this is ambiguous.
106	Joint Yorkshire and Humber and North East TB Control Board	Statement 1	Comment 1. Is it reasonable to test people who are unlikely to be offered LTBI treatment i.e. elderly, patients with liver failure?
107	Joint Yorkshire and Humber and North East TB Control Board	Statement 1	Comment. This statement should be re-word to be clear that it is latent, not active, TB.
108	Joint Yorkshire and Humber and North East TB Control Board	Statement 1	Comment. This is not the case in patients who would not be treated.
109	Joint Yorkshire and Humber and North East TB Control Board	Statement 1	Comment 2. How – there is no suggestion of how the testing for LTBI might be done.

ID	Stakeholder	Section	Comments
110	Joint Yorkshire and Humber and North East TB Control Board	Statement 1	Overall need to clarify expectation to ensure it happens
111	NHS England	Statement 1	Currently the National Strategy recommends LTBI screening on registration at a GP practice. Perhaps in future this could be conducted in country of origin? The current National Strategy recommends LTBI screening for new migrants between the ages 15-35. The latest NICE guideline suggests 65 as the upper age limit for LTBI treatment in other circumstances. The migrant programme would struggle if the age range was similarly expanded.
112	British Infection Association	Question 5	Yes- it would be sensible to focus the question more or health services will be overwhelmed e.g. in London and many of those who test positive will in fact not receive treatment subsequently.
113	Joint Yorkshire and Humber and North East TB Control Board	Question 5	The eligibility age group 16-35 as per programmatic screening only refers to the funded programme so this needs to be thought through carefully, especially with regards to screening children and families
114	Public Health England	Question 5	Yes
115	Public Health England	Question 5	Definition – commissioners may wish to evaluate the cost effectiveness of local programmes through the establishment of criteria that narrow the definitions of who should be tested. The current NHSE funded national LTBI testing and treatment programme is evidence based and targeted at those aged 16 – 35 years, from countries with TB rates ≥150/100,000 population etc. This programme has been funded using those criteria as having the most significant impact on TB in England and most cost effective. The cost of funding beyond 35 years would require further financial assessment.
116	Public Health Wales	Question 5	In response to question 5 'Is there a need to focus on the population more for this statement by specifying age range?' Although no age range is specified in the NICE guidance, latent TB testing is generally only recommended for individuals aged 65 or under. Separate to the NICE guidance the document 'Latent TB Testing and Treatment for Migrants' prioritises those within primary care aged 16-35.
117	Leeds Teaching Hospitals NHS Trust	Question 5	***Additional question: Is there a need to focus the population more for this statement by specifying an age range?*** As LTBI treatment not offered to those over 65, could suggest limit standard to age under 65. However in practice the number of new immigrants over this age is likely to be small.
118	Joint Yorkshire and Humber and North East TB Control Board	Question 5	Comment. There is a need to focus the population, but not just by age. I would suggest only testing those who might reasonably receive treatment, but I can see that there is a reasonable counterargument to this (i.e. awareness of LTBI diagnosis might increase presentation if symptomatic)

ID	Stakeholder	Section	Comments
119	North West TB Control Board	Question 5	The statement should focus on the 0-65 age range. The Board felt it was very important to include screening of children (which the body of NICE guidance supports).
120	British Thoracic Society	Question 5	**Is there a need to focus the population more for this statement by specifying an age range?** The statement should include children, ideally as a "family unit".
121	British HIV Association (BHIVA)	Question 5	There is an argument for offering latent TB testing to children aged <18. It is not clear from the statement whether they are or aren't included. They are generally at an increased risk of progression to active TB compared to adults, have longer to live with latent TB and in a country with a relatively low risk of local transmission, effectively treating previous infection acquired abroad is likely to be a useful means of reducing active TB at a personal and public health level.
122	Royal College of Physicians and Surgeons of Glasgow	Question 5	*For draft quality statement 1: Is there a need to focus the population more for this statement by specifying an age range?* I am not sure that it makes clinical sense to specify an age range. The highest prevalence of active TB in people originating from high incidence countries is in young adults, so this age range should be captured. However, children are clearly also a risk group that we would not wish to ignore – and TB reactivation in older adults is also a well-described clinical issue.
123	Royal College of Nursing	Question 5	Page 7: Age range may not necessarily be reflective of level of exposure. Unless there is clear evidence then, this would be 'No'.
Statement 2			
124	British Thoracic Society	Statement 2	**People who are referred to a TB service, who meet specific criteria, have rapid diagnostic nucleic acid amplification tests (NAATs) for the M. tuberculosis complex on primary specimens.** This is an important standard but is too vague to be useful: Suggested revision: *Rapid nucleic acid amplification tests on primary specimens should be routine for all those who might have active TB (preferably with a test for rifampicin resistance mutations).* This would then align with WHO policy, include CSF, pericardial effusions etc. and reduce use of side rooms for those with NTMs or other illnesses which are not infectious.
125	Leeds Teaching Hospitals NHS Trust	Question 1	***Q1: Does this draft quality standard accurately reflect the key areas for quality improvement?*** Yes, but wording is inappropriate. For each criterion, quality statement is expressed as "proportion of people referred to TB services…" This will include a significant number of people in whom the TB specialist team are confident that TB is unlikely and therefore such testing is irrelevant. Would be better to say "proportion of people suspected to have tuberculosis..."

ID	Stakeholder	Section	Comments
126	Leeds Teaching Hospitals NHS Trust	Statement 2	Yes, but wording is inappropriate. For each criterion, quality statement is expressed as “proportion of people referred to TB services…” This will include a significant number of people in whom the TB specialist team are confident that TB is unlikely and therefore such testing is irrelevant. Would be better to say “proportion of people suspected to have tuberculosis..”
127	Public Health England	Statement 2	Whilst generally supportive of the use of NAATS, the situations where it should be used are not well enough defined to allow measurement (for example how to count ‘people for whom rapid information about mycobacterial species would alter care) – clinically this can probably be defined and justified, usually on a case by case basis – but almost impossible to measure…. Also – whilst it is possible that NAATs would contribute to reducing treatment delay, these delays are multifactorial and it cannot be deduced that introducing NAATs will directly impact on this. Equally – NAATs may or not have a measurable effect on PTB morbidity and mortality overall as these are also multifactorial. .
128	NHS England	Statement 2	The “specific” criteria are sufficiently flexible.
129	Joint Yorkshire and Humber and North East TB Control Board	Statement 2	Comment. Not clear how morbidity data would be collected (short or long term).
130	North West TB Control Board	Statement 2	Most of the criteria are clear (Age 15 or younger; HIV positive; Multi Drug Resistant risk factors) but it is difficult to define when “rapid information about mycobacterial species would alter the person's care”. Without a clear definition, it is not possible to measure this consistently. ETS does not collect data on HIV status and thus it is not possible to measure that part of the standard using ETS and there are issues in collecting data on HIV status.
131	Public Health England	Statement 2	In addition, the planned roll-out of TB WGS is likely to impact on the use of NAATs in the future.

ID	Stakeholder	Section	Comments
132	North West TB Control Board	Statement 2	An audit of laboratory provision of TB microbiology coordinated by Public Health England (Colindale) is planned for the Autumn. Until the results are available from this it is difficult to say if it will be possible to provide the testing service required by this standard. Locally, the Board has been advised that our laboratories would not be able to collect data on proposed quality measures with current laboratory information systems. To collect the proposed data effectively and accurately, additional systems would need to be implemented. It would be reasonable to suggest that the best place to collect this data would be at the interface between Clinical TB Services and the Laboratory (as the laboratory does not have easy access to clinical information such as risk factors for Multi Drug Resistant TB or for samples referred from satellite laboratories). There is concern that it would be difficult to collect data regarding the "proportion of people referred to TB services, for whom a rapid information about mycobacterial species would alter care…" We feel this needs to be a tighter definition in order to allow standardised data collection between TB services and to avoid inappropriate use of NAATs (for example it is not appropriate to use our current NAAT as a screening tool). We would suggest considering revising this definition – for example defining these patients as in-patients with evidence of significant respiratory or systemic compromise?
133	North West TB Control Board	Statement 2	The statement should be more specific about the specimens to which it refers. It is our understanding that NAATs have only been validated for use in specimens from the respiratory tract. Therefore the Statement should be explicit that NAAT tests are restricted to respiratory samples.
134	North West TB Control Board	Statement 2	The rationale states: "Diagnostic test accuracy and time to diagnosis or treatment initiation are critical for decision making". There is a concern that performing NAATs on specimens in which there is a low pre-test probability of being positive, and in smear negative respiratory samples, the diagnostic accuracy will be compromised. The sensitivity of current NAAT used locally is significantly reduced when performed on specimens that are smear negative, thus a negative result would not be able to exclude a diagnosis of TB. We are concerned that indiscriminately offering NAATs direct on primary specimens may offer false reassurance and should be co-ordinated through a Multi-Disciplinary Team setting involving Clinicians and Microbiologists in order to identify those whom performing NAAT directly on the primary specimen would be of benefit.
135	North West TB Control Board	Statement 2	The outcomes within this statement on short-term and long-term morbidity in adults and children with pulmonary TB will be difficult to quantify. It is not clear how morbidity is defined nor what are the definitions of short term and long term. Following completion of treatment, TB patients are not routinely followed up, so long term morbidity will be particularly difficult to document.
136	British HIV Association (BHIVA)	Question 6	Not clear why NAAT has been selected for people aged <15. There is less pulmonary disease – so are you implying that you would be seeking to diagnose/confirm more extra-pulmonary TB?

ID	Stakeholder	Section	Comments
137	British HIV Association (BHIVA)	Question 6	Not clear why HIV infected population has been specifically selected. Also, not sure what the measurements in the numerator and denominator will indicate as “primary specimen” is a very broad concept (e.g. does this include urine, bone marrow and blood? – which are often cultured in suspected HIV/TB). The denominator may need some rewording as it is assumed that you are interested in patients with active TB who have HIV, rather than e.g. latent TB requiring treatment.
138	Public Health England	Statement 2	Question – why has the age group ‘aged 15 years or younger’ been defined?
139	Public Health England	Statement 2	Question – why is ‘aged 15 years or younger‘ a specific criteria? Rapid information about mycobacterial species would alter the person’s care, suggest add ‘or associated public health action’.
140	British HIV Association (BHIVA)	Statement 2	One of the measures selected for local data collection is “the proportion of with pulmonary TB starting treatment within 2 months of symptom onset”. We would be interested to know how this timeframe was chosen. Is there good evidence that it is a useful measure of transmission risk to others? (presumed reason for choosing this measure)
141	British Infection Association	Statement 2	The number in the denominator who start treatment within 2 months of symptom onset.- should the numerator not be timed from presentation to health services of any kind- is the aim to prevent missed opportunities?
142	Cepheid UK Ltd	Statement 2	"The use of NAATs reduces the time for identification of M. tuberculosis to just 3 to 6 hours after the specimen is ~~processed~~ collected.” Alternately, "The use of NAATs reduces the time for identification of M. tuberculosis to just 3 to 6 hours after the specimen is ~~processed~~ received by the laboratory.”
143	Cepheid UK Ltd	Statement 2	Define “Rapid” or “Rapid diagnostic nucleic acid amplification tests” as, a test with ability to report the result within 6 (six) hours from individual sample collection. Alternately, a test with ability to report the result within 6 (six) hours from individual sample receipt by the laboratory.
144	Cepheid UK Ltd	Statement 2	Quality standard discusses the importance of time to diagnosis and treatment initiation, but nowhere in this document recommends the measurement of time to result reporting to ensure results are reported back to clinicians in a timely manner. Thus, following measurements should be considered:x) Proportion of people referred to TB services, for whom rapid NAATs for the *M. tuberculosis* complex on primary specimens are conducted and result reported within defined rapid timeframe. Numerator – the number in the denominator who have diagnostic NAATs for the *M. tuberculosis* complex on primary specimens and result reported within defined rapid timeframe. Denominator – the number of people who are referred to TB services for whom rapid information about mycobacterial species would alter care. ***Data source:*** Local data collection.

ID	Stakeholder	Section	Comments
145	Janssen	Statement 2	The rationale for rapid NAATs should include the necessity of reducing the risk of TB transmission and societal impact (i.e. the health burden and cost associated with further infection).
146	North West TB Control Board	Statement 2	TB Nurses often find it difficult to establish a precise date of symptom onset. Locally through cohort audit we measure treatment within 4 months (not 2) of symptom onset (where date of symptom onset is known).
147	Public Health England	Statement 2	Suggest add in somewhere 'and other samples'.
148	Royal College of Nursing	Statement 2	The term '***specific criteria'*** is used seven times between page 6 and 15 in the document; before one gets to the definition of the term. Consider putting the definition upfront or hyperlinking for ease of reference.
149	Royal College of Paediatrics and Child Health	Statement 2	If rapid diagnosis needed for those with HIV, it should include those with immune compromise or live in household with someone with immune compromise or child under age 2 years.
150	British Infection Association	Question 6	This standard seems to subgroup already and there is no clear requirement to focus on specific groups further
151	Janssen	Question 6	Answer to Question – The identified groups in the Quality Standards are appropriate and aligned with NICE clinical guideline [NG33]. Given the cost of NAATs, they should be reserved for these high-risk groups. People with "risk factors for multidrug resistance" pose a societal threat due to the risk of transmitting strains of TB that carry the greatest disease burden and require arduous and costly treatment regimens. Groups where "rapid information about mycobacterial species would alter the person's care" are also a priority for rapid testing given their risk of being prescribed inappropriate treatment regimens which may lead to the development of resistance and further infections.

ID	Stakeholder	Section	Comments
152	Public Health England	Question 6	No
153	Public Health Wales	Question 6	In response to question 6 'Should the statement focus on a specific group? 'No – all these groups represent instances when a rapid diagnosis is vital.
154	British Thoracic Society	Question 6	**Should the statement focus on a specific group?** Suspected pulmonary TB although this may be hard to achieve.
155	Royal College of Nursing	Question 6	Page 7: This should apply if there is clear evidence to focus on a group. If the patient meets clinical criteria, then focusing on specific groups may miss individuals. The 5 year, high incidence criteria is broad enough to capture most TB cases if it can be applied.
156	Royal College of Physicians and Surgeons of Glasgow	Question 6	*For draft quality statement 2: Should the statement focus on a specific group?* The first 4 subgroups identified (a-d) are valid and appropriate for ensuring that they have access to NAATs. However, in terms of measurability, I think most services would struggle to identify sub-group c) and hence maybe this one should be dropped whilst retaining a, b and d. I am confused about subgroup e) Is this in the wrong place? Or is this supposed to be an outcome, but has not been labelled as such in the draft document? Doesn't seem to make sense as it stands!
157	Joint Yorkshire and Humber and North East TB Control Board	Question 6	The answer to this is in part dependent on diagnostic availability and will be informed by the outcomes of the local lab audit and any ongoing investment in reference laboratories. Criteria would be helpful.
Statement 3			
158	British Thoracic Society	Statement 3	**People who have imaging features suggestive of active TB are assessed within 1 working day by the TB service.** The Society supports this statement. Many services do not a TB nurse available 7 days a week. Doctors with paediatric TB expertise are in even shorter supply. In reality this should be in individuals who have a chest x-ray suggesting active pulmonary tuberculosis should be seen within 24 h by the TB team or their proxies for sputum collection and smear examination.
159	British Thoracic Society	Statement 3	A 7 day service would be hard to achieve with current staffing, but is ideal rather than next working day.

ID	Stakeholder	Section	Comments
160	British HIV Association (BHIVA)	Statement 3	Rapid review in a TB service may require a greater flexibility in working practice for TB nurses and teams, in particular in smaller services which do not run as a service separate service from e.g. general respiratory specialist nursing for airways disease.
161	Janssen	Statement 3	This measure relies on the rapid reporting of imaging and the ability to return the patient to the hospital/health service quickly. Patients likely to have active TB in the community are often from poor socioeconomic backgrounds and such rapid turnaround may be difficult.
162	Joint Yorkshire and Humber and North East TB Control Board	Statement 3	1 working day is not practical 'imaging features could include possible lymphadenopathy - the next consultant clinic would be fine. Even for probable pulmonary TB, 3 working days would be OK.
163	Joint Yorkshire and Humber and North East TB Control Board	Statement 3	Unnecessary. Even assuming that there is an X-ray with cavities and the diagnosis of TB is correct - the patient has probably been infectious for some time, a few more days won't make much difference. The delays in presentation are usually being measured in weeks or months. Early diagnosis and treatment important but there are other things which would have a much bigger impact. A 7 day target would still be quicker than e.g. cancer targets.
164	Joint Yorkshire and Humber and North East TB Control Board	Statement 3	Process measures. Unachievable. In low incidence areas the TB service may have a consultant and a part time nurse covering a large geographical area. A nurse who covers TB as part of a respiratory nurse specialist role might be doing an asthma clinic on the day after the X-ray report is received. The consultant may have a ward round and a bronchoscopy list. A 7 day target allows the patient to be booked into the next clinic, or a nurse to arrange a visit around his/her other duties. Clarification. Within 1 working day of what? The X-ray or the report or the transmission of the report to the requesting clinician? Clarification required - see further comments below - states pulmonary cavitatory/likely smear positive etc. is that is what is meant here?
165	NHS England	Statement 3	This is an ambitious statement. The implication is that the patient is seen by the clinical team within 24 hrs. This may be difficult or beyond the control of the clinical team. It is reasonable however, to at least have had a triage plan and make contact with the patient to arrange an urgent appointment. Many radiology reports will say things like “active TB cannot be excluded” which may create unpredictable demand if a common sense step is not inserted.

ID	Stakeholder	Section	Comments
166	North West TB Control Board	Statement 3	What is meant by a 'working day'? Is this Monday to Friday? If we assume the NHS provides a 7 day service, and assessment is required within 1 day this could have significant workforce implications. The assessment definition on page 19 implies a physical face to face assessment (as opposed to a telephone consultation). Many services do not have a TB nurse available 7 days a week and/or provision of a daily 'triage' service for TB. Doctors with paediatric TB expertise for example, are in even shorter supply. Aspiration is good but practicalities will require substantial investment.
167	Royal College of Paediatrics and Child Health	Statement 3	Seeing someone suspected of having TB within one working day we expect will be difficult for providers. Good practice is that they are not waiting where/when other patients are waiting for risk of passing on infection. This urgency is at contrast with Statement 2 where, for majority, patients will await routine diagnosis (a few weeks) on culture, possibly not treated till diagnosis confirmed. Suggest standard should be 'seen within 5 working days'.
168	Public Health England	Statement 3	Comment - This suggestion is at odds with the National TB Service Specification which recommends two working days for pulmonary or laryngeal TB and two weeks for? TB. All TB services are expected to see patients who self-refer.
169	British Thoracic Society	Statement 3	The following specific points should be address: Is this just for pulmonary TB, clarity is required, should it be those who are an infection risk?
170	British Thoracic Society	Statement 3	Clearer definition of what "assessment" means: Is this a telephone consultation or physical face to face assessment.
171	Public Health England	Statement 3	Addition – this statement should say ' This type of assessment is done by a clinical member (doctor or TB nurse specialist) …'

ID	Stakeholder	Section	Comments
172	Leeds Teaching Hospitals NHS Trust	Statement 3	***Q1: Does this draft quality standard accurately reflect the key areas for quality improvement?*** Partially. Aim to get early investigation, diagnosis and treatment is important, but this statement is misguided for the following reasons: Restricts standard for rapid assessment of suspected TB to those with radiology imaging features. However patients may be referred e.g. by primary care services with symptoms/signs suggestive of TB without imaging (or before imaging available). In our clinic, for example we would do a chest X-ray on arrival for patients who have not had one recently - the GP arranging an X-ray and then awaiting a report would actually DELAY the patient being seen. The definition of "imaging features suggestive of active tuberculosis" should be changed to read "active pulmonary tuberculosis". An ultrasound of a cervical node showing enlargement and central necrosis is" imaging features suggestive of active tuberculosis", but infection control and urgent treatment are rarely significant issues for uncomplicated cervical lymph node TB. The standard to see within 1 working day is too tight and unnecessary. While the rationale of early infection control and prompt treatment is welcome, there are many factors contributing to delays before the patient gets an X-ray report. These include delayed presentation to health care, often a reasonable decision by GP to treat for standard infection before requesting a CXR, and delays in X-ray reporting. In practice if the patient is at home their family will have been exposed for some weeks and an extra few days will make little difference in most cases. If a CXR suggests active pulmonary TB, it would be more useful for the referring team (including GP) to arrange urgent sputum examination for AAFB before patient seen by TB team. A more useful statement would be: Systems should be in place to ensure that all imaging suggestive of active pulmonary tuberculosis is referred directly to the TB multidisciplinary team. All patients referred to the TB service, including those referred by radiology reports, should be assessed by the TB service within 1 week for suspected active pulmonary TB and within 2 weeks for suspected active extrapulmonary TB. This would address the problem in some centres of prolonged waiting times for clinic appointments, would be achievable (in line with cancer 2 week wait targets), would ensure that suspected TB on X-rays was not overlooked, and would avoid the distinction between referrals with and without X-ray reports.
173	Public Health England	Statement 3	Change – either adding 'pulmonary to read 'active pulmonary TB' or replace active with 'pulmonary' in this section.
174	Joint Yorkshire and Humber and North East TB Control Board	Statement 3	Process measures. Unachievable. In low incidence areas the TB service may have a consultant and a part time nurse covering a large geographical area. A nurse who covers TB as part of a respiratory nurse specialist role might be doing an asthma clinic on the day after the X-ray report is received. The consultant may have a ward round and a bronchoscopy list. A 7 day target allows the patient to be booked into the next clinic, or a nurse to arrange a visit around his/her other duties. Clarification. Within 1 working day of what? The X-ray or the report or the transmission of the report to the requesting clinician? Clarification required - see further comments below - states pulmonary cavitatory/likely smear positive etc. is that is what is meant here?

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175	Leeds Teaching Hospitals NHS Trust	Statement 3	***Q1: Does this draft quality standard accurately reflect the key areas for quality improvement?*** Partially. Aim to get early investigation, diagnosis and treatment is important, but this statement is misguided for the following reasons: Restricts standard for rapid assessment of suspected TB to those with radiology imaging features. However patients may be referred e.g. by primary care services with symptoms/signs suggestive of TB without imaging (or before imaging available). In our clinic, for example we would do a chest X-ray on arrival for patients who have not had one recently - the GP arranging an X-ray and then awaiting a report would actually DELAY the patient being seen. The definition of "imaging features suggestive of active tuberculosis" should be changed to read "active pulmonary tuberculosis". An ultrasound of a cervical node showing enlargement and central necrosis is" imaging features suggestive of active tuberculosis", but infection control and urgent treatment are rarely significant issues for uncomplicated cervical lymph node TB. The standard to see within 1 working day is too tight and unnecessary. While the rationale of early infection control and prompt treatment is welcome, there are many factors contributing to delays before the patient gets an X-ray report. These include delayed presentation to health care, often a reasonable decision by GP to treat for standard infection before requesting a CXR, and delays in X-ray reporting. In practice if the patient is at home their family will have been exposed for some weeks and an extra few days will make little difference in most cases. If a CXR suggests active pulmonary TB, it would be more useful for the referring team (including GP) to arrange urgent sputum examination for AAFB before patient seen by TB team. A more useful statement would be: Systems should be in place to ensure that all imaging suggestive of active pulmonary tuberculosis is referred directly to the TB multidisciplinary team. All patients referred to the TB service, including those referred by radiology reports, should be assessed by the TB service within 1 week for suspected active pulmonary TB and within 2 weeks for suspected active extrapulmonary TB. This would address the problem in some centres of prolonged waiting times for clinic appointments, would be achievable (in line with cancer 2 week wait targets), would ensure that suspected TB on X-rays was not overlooked, and would avoid the distinction between referrals with and without X-ray reports.
176	North West TB Control Board	Statement 3	The statement should be explicit that this refers only to pulmonary/laryngeal TB.
177	Joint Yorkshire and Humber and North East TB Control Board	Statement 3	Process measures. Clarification. How would these figures be obtained?

ID	Stakeholder	Section	Comments
178	North West TB Control Board	Statement 3	Further clarity is required around 'assessed within one working day': Is it the day that the imaging was undertaken, or the day that it was reported, or the day that the report was received by the professional requesting the image? These can all be different. This needs clarification as the implications for service strengthening will be different depending on the decision made. "Within one working day of imaging report reaching the requesting clinician" would be more correct and would assist measurement. However, it should require that a direct referral is made from radiology to the TB Service where TB is suspected (and the requesting physician is not part of the TB service – e.g. a GP).
179	Royal College of Paediatrics and Child Health	Statement 3	TB services having local arrangements in place to ensure that people who have imaging features suggestive of active TB have an assessment within 1 working day. The question is, what does 1 working day mean? Does this include the weekend or not? Who will fund weekend assessments- healthcare or commissioners or social care? https://www.england.nhs.uk/ourwork/qual-clin-lead/7-day-week/ New BCG VACCINEhttp://www.ncbi.nlm.nih.gov/pmc/articles/PMC4238842/ and http://rstb.royalsocietypublishing.org/content/royptb/366/1579/2782.full.pdf
180	Public Health England	Statement 3	Treatment delay, morbidity and mortality are multifactorial.
181	Joint Yorkshire and Humber and North East TB Control Board	Statement 3	Clarification. What are "the results"? Images or reports?
182	Joint Yorkshire and Humber and North East TB Control Board	Statement 3	Clarification. Received by whom? The secondary care provider, the referring physician, the patient, or someone else?
183	Joint Yorkshire and Humber and North East TB Control Board	Statement 3	Comment. This implies the patient getting the result - may or may not be consistent with measure above, depending on when the clock starts.
184	Public Health England	Statement 3	Comment - The onus on local data collection in this section is potentially onerous. Much of this data is part of cohort review and suggest using cohort review process.
185	Public Health England	Statement 3	Suggest – include 'pathways in place to ensure local imaging services and providers appropriately refer people with imaging features suggestive of active pulmonary TB disease directly to TB services within two working days'
186	Janssen	Statement 3	Utilising community care/homecare visits as "members of the TB service" may benefit this measure.
187	North West TB Control Board	Statement 3	Whilst the quality statement refers to 'imaging', at the top of page 19 it refers only to X-rays. This should be amended to include CT scans.

ID	Stakeholder	Section	Comments
Statement 4			
188	NHS England	Statement 4	Fully support.
189	British Thoracic Society	Statement 4	**People with TB from under-served groups are offered directly observed therapy as part of enhanced case management**. The Society strongly supports this standard – the following revision to wording is suggested: *All those who may not be able to take TB medication regularly for whatever reason should be offered directly observed therapy.*
190	Janssen	Statement 4	The Quality Statement implies that DOT is reserved only for those from under-served groups. DOT should be offered to all patients regardless of socioeconomic status to ensure the highest quality of care and infection control. Suggest the Quality Statement be amended to "Patients with TB are offered DOT as part of enhanced case management, particularly to vulnerable or at-risk groups", or similar. Adherence to treatment is paramount to effectively treating TB and DOT is mandatory for all MDR-TB patients. NHS England commissioning policy for bedaquiline and delamanid states that DOT is required for all MDR-TB patients [1].
191	Public Health England	Statement 4	Addition – change to 'People with tuberculosis (TB) who are assessed as likely to be non-compliant or have complex social and/or medical needs or from under-served groups are offered directly observed therapy as part of enhanced case management. This statement should be used throughout this section.
192	North West TB Control Board	Statement 4	The wording of this statement needs clarification: Focussing on the underserved group is too narrow. All patients who are assessed by the TB Service to be at risk of non-compliance with treatment should be considered for DOT (Directly Observed Therapy). The definition of underserved in the Quality Standard is based on ETS social risk factors rather than a needs based approach across all age groups. As stated, it can be interpreted as a decision for the patient about whether to receive this form of treatment or not. In addition while it should be considered for all such persons, in fact it is appropriate for only a small proportion to receive this. The decision is for the TB team not the patient. The recommendation should be to "consider DOT for underserved groups". However worded, while measurable the proportion of patients complying will be small for the above reasons. Providing DOT is only possible where the workforce is adequately resourced to provide it.
193	Public Health England	Statement 4	Is this meant to be 'proportion of patients who completed treatment'? (a proportion, not a rate). Need to define at what time point. At 12 months (for the drug sensitive cohort), 24 months (for MDR/RR TB), or at last recorded outcome? Treatment completion overall for MDR patients, mortality and loss to follow up are multifactorial and in themselves cannot be taken as absolute monitoring measure for this quality standard. Also, denominator data for 'vulnerable migrants' is not currently uniformly available and not recorded on ETS

ID	Stakeholder	Section	Comments
194	Public Health England	Statement 4	Does this really mean mortality rate? There are no good denominator data for underserved populations, so how would this be calculated. Does this instead me “proportion of cases who had died”. Again good to define time point (at 12/24 months, or last reported outcome)?
195	Public Health England	Statement 4	Data on treatment completion is collected in enhanced TB and latent TB surveillance and can be analysed for those with 4 social risk factors (history of drug or alcohol use, homelessness or imprisonment), so local data collection for this is not required. However, local data collection would be needed for additional vulnerable groups/underserved populations. How is “underserved group” being defined?
196	Joint Yorkshire and Humber and North East TB Control Board	Statement 4	Comment. Not sure that this is in line with practice - is it always a specific person? Is it always healthcare worker? Is it always a "meeting" rather than video DOTS?
197	RCGP	Statement 4	The homeless, alcoholic is a particular problem- not least societal attitudes and real problems in providing hostel accommodation and DOTS.
198	British HIV Association (BHIVA)	Statement 4	It is surprising that migrants aren’t classified as an under-served group, given potential issues of access, stigma, associated co-morbidities e.g. HIV, Hepatitis B or C. If one were to do so, then the issue of paternalism may arise if you are suggesting that DOT is routinely offered. A difficult issue but one that needs to be acknowledged more transparently.
Statement 5			
199	British Thoracic Society	Statement 5	**People with active TB who are homeless are offered accommodation for the duration of their treatment.** The Society strongly supports this standard – the following revision addition to wording is suggested: “*regardless of the patient’s immigration status or recourse to public funds”*
200	NHS England	Statement 5	This is desirable. Whilst homeless people with TB often spend long periods in hospital this is not desirable. They do require secure accommodation in single rooms to avoid cross infection.
201	NHS England	Statement 5	The responsibility for this aspect of the quality standard should lie with social services.
202	North West TB Control Board	Statement 5	Unless the statement says explicitly, with whom the legal responsibility lies to offer the accommodation then this unlikely to happen. Recent experience locally is that there is no authority who feels it is their responsibility so negotiating this is difficult and time consuming. Whilst work is underway locally to address those without recourse to public funds, this remains aspirational and difficult to achieve. The definition of homelessness is broad, which is good for guidance but difficult to use as a KPI.

ID	Stakeholder	Section	Comments
203	Public Health England	Statement 5	Outcomes a) see above, presumably % completing treatment rather than completion rates. Outcomes b (TB prevalence) and c (TB incidence) are not sufficiently described. Again need to define by cohort and time point at which this is assessed (as above) b (TB prevalence. How would this be measured? Where would you get denominator data for the homeless population? Prevalent over what time period? and c (TB incidence: again, what would be the source of the denominator for the homeless population? Outcomes b (TB prevalence) and c (TB incidence) are not sufficiently described.
204	North West TB Control Board	Statement 5	The definition of homelessness is broad, which is good for guidance but difficult to use as a KPI.
205	Joint Yorkshire and Humber and North East TB Control Board	Statement 5	Comment. Rates of TB are high compared to what?
206	RCGP	Statement 5	The homeless, alcoholic is a particular problem- not least societal attitudes and real problems in providing hostel accommodation and DOTS.
207	Joint Yorkshire and Humber and North East TB Control Board	Question 7	Comment. Unsure; likely that it would be near impossible to deliver effective treatment without accommodation, so don't think this quality statement should be removed even if current resources are not sufficient.
208	Portsmouth Hospital Trust	Question 7	Providing accommodation for vulnerable groups is undoubtedly difficult due to resource impact but is essential from both an individual and public health perspective.
209	Royal College of Physicians and Surgeons of Glasgow	Question 7	*For draft quality statement 5: Would this statement be achievable by local services given the potential resource impact of providing accommodation?* I am not the budget holder for Social Services/ the Housing Dept and hence this is a difficult question to answer. However, my instinct is that this is achievable by local services and not unrealistic in terms of resource impact, for most Local Authorities at least, given the relatively low volume of people that we are talking about. I think this is an important Quality Statement and I would be very disappointed if it does not make it through to the final Standard due concerns regarding resource impact. This is a BIG issue – and a Standard in this area could drive significant improvement
210	British Infection Association	Question 7	This is certainly an ideal but it is difficult to understand how this would be achievable in urban areas with a high incidence of TB unless specific funds were available for this. The potential resource impact of providing accommodation would be great and may therefore impact significantly on other health services.

ID	Stakeholder	Section	Comments
211	British Thoracic Society	Question 7	**Would this statement be achievable by local services given the potential resource impact of providing accommodation?** We note that this depends on buy in from CCG's and local authorities. Many patients in this category may not have recourse to public funds which can cause local authorities problems when trying to allocate funds. However there are examples of good practice, e.g. Westminster pre-agreed housing agreement that does not require recourse to public funds as long as connection is shown.
212	Joint Yorkshire and Humber and North East TB Control Board	Question 7	The statement has no validity unless responsibilities (NHS, local authorities) are clearly defined.
213	Janssen	Question 7	Answer to Question – Success of this statement relies on government funding for TB-specific social care in the community. Patients with TB cannot be housed in standard homeless shelters due to infection risk, nor can they be communally housed together due risk of reinfection prior to treatment completion. Health services with the appropriate infrastructure would have to be paid for nationally. Establishing a few satellite centres in areas of high risk, e.g. London, would help enforce a higher quality of care and cure rates. Such centres would require isolation units for those infectious or at high risk of reinfection, as well as clean accommodation, good ventilation systems and employed health care staff to monitor treatment adherence and potential adverse drug reactions.
214	Public Health England	Question 7	No
215	Public Health England	Question 7	1 - Would this statement be achievable…? No. Suggest, in a financially constrained system that priority is given to those who have infectious TB and are occupying an acute hospital bed even though 'fit for discharge'2 – see comment 14.
216	British HIV Association (BHIVA)	Question 7	The issue arises of what happens once anti-TB treatment is completed? Is there a mechanism to ensure that there is long term accommodation in place? The costs associated with housing during treatment could be offset by local groups (e.g. the footprint of the TB control boards) undertaking cost-sharing across a region and working in partnership with local housing organisations.
217	Royal College of Nursing	Questions 7 and 8	Page 7: What do organisations (e.g. Shelter, local government authorities) that work with the homeless think? It has to be something the homeless are likely to comply with (e.g. hostel/ sheltered accommodation with support; following an initial inpatient period where applicable).The eligibility for providing a home/ bed space for the individual has to be effectively communicated to reach the target group i.e. has a strong public health message for those in groups fearful of their status (e.g. illegal immigrants). Community liaison officers may also be key to communicating that message.

ID	Stakeholder	Section	Comments
218	British Infection Association	Question 8	Suitable living accommodation for people with active TB should not be hostel or temporary in nature but could include shared areas once the infectious period has passed. In addition, in particular cases such as poor compliance with treatment or persistently smear positive TB suitable accommodation would be isolated (i.e. no sharing with others of bedroom, kitchen or bathroom) and supervised heavily (e.g. a key worker and directly observed therapy). This might create a system of secondary gain however whereby people fail to comply with therapy in order to obtain improved accommodation.
219	British Thoracic Society	Question 8	**How would you describe suitable living accommodation for people with active TB?** A safe, secure, self-contained single room environment that is adequately heated and has facilities for washing and preparing food / refrigeration. Is needed. This should be furnished with appropriate furniture, bedding and cutlery/crockery.
220	North West TB Control Board	Question 8	Suitable living accommodation would include a bedroom, bathroom, and kitchen per family/person. Not shared accommodation. It may be useful to consult with housing experts (e.g. local authority housing team) to help define the quality of housing.
221	Portsmouth Hospital Trust	Question 8	Suitable living accommodation must include: single, self-contained accommodation without shared facilities and needs to be present for the duration of therapy. Communal cooking and hygiene facilities are not suitable for this group.
222	Public Health Wales	Question 8	In response to question 8 'How would you describe suitable living accommodation for people with active TB?' Secure accommodation in which to rest and recuperate in safety and dignity for the full duration of planned treatment.
223	Royal College of Physicians and Surgeons of Glasgow	Question 8	*How would you describe suitable living accommodation for people with active Bat*he accommodation itself does not need to be luxurious, but needs to be in a safe area (both for the sake of the patient and for the safety of visiting TB nurses), clean, dry and reasonably maintained. It should be located within a reasonable distance of the relevant TB clinic – with consideration given to transport and transport costs. As many patients with TB are started on therapy as an outpatient and hence may potentially be infectious to others during the initial period of therapy, single-room accommodation should be planned for – and indeed a single occupancy flat would probably be the best option in most cases.
224	Public Health England	Question 8	Security of accommodation i.e. tenure for duration of TB treatment. This does require caveats i.e. contract with patient that tenure is reliant on treatment compliance, patient may be asked to pay or contribute to cost of accommodation depending on benefits/personal financial situation
225	Joint Yorkshire and Humber and North East TB Control Board	Question 8	Question needs expanding please.

ID	Stakeholder	Section	Comments
Statement 6			
226	British Thoracic Society	Statement 6	**Multidisciplinary TB teams take part in cohort review at least quarterly.** The Society supports this standard but notes that in many areas with few TB cases cohort review are held 6 monthly or 4 monthly. It may not be viable or practical to increase frequency in these areas. It may be more pragmatic to state that in low incidence areas the frequency of cohort review may be 6 monthly for practical reasons. The TB teams will of course enter outcome data at the end of treatment.
227	Joint Yorkshire and Humber and North East TB Control Board	Statement 6	Overall experience in low prevalence areas suggests quarterly cohort review may not be meaningful – frequency should be determined by local epidemiology. Based on North East England experience, not sure that quarterly cohort review is necessarily ideal. When conducted quarterly, there are often very small numbers of cases (2-3) which stretch the definition of "cohort" and make pattern recognition challenging.
228	Joint Yorkshire and Humber and North East TB Control Board	Statement 6	Comment. Is this intended to imply that all of these people are supposed to be at the cohort review? This seems unrealistic, particularly if only discussing 2-3 cases as is common with quarterly cohort reviews in low prevalence areas.
229	Joint Yorkshire and Humber and North East TB Control Board	Statement 6	With reference to previous comment –concern re rationale for cohort review in low prevalence areas.
230	British HIV Association (BHIVA)	Question 9	Suggest that the Multidisc TB teams do more than “take part” – perhaps “are responsible for”, as the ownership may encourage more involvement? Also the issue of what is the aim of cohort review appears relevant. It should be a vehicle that ensures high-quality care is delivered to an individual, though mainly it serves to check that the public health duties associated with TB are being adequately performed. This needs to be done in a setting which is more than just a single service reviewing its own data. Hence there is something about the network of TB services (that are contributing to local cohort review) which might be also within the statement.

ID	Stakeholder	Section	Comments
231	British Thoracic Society	Question 9	**Is there a specific action relating to cohort review that the statement could focus on, rather than having a broad statement on this area?** We suggest emphasising the aims of cohort review: a) reducing diagnostic delays; b) managing adverse effects of treatment successfully without inducing drug-resistance; c) ensuring DOT for all those who need help taking their tablets regularly; d) confirmation of cure (especially important in S+PTB and MDRTB, with cultures at 2m and 6m); e) adequate monitoring of MDRTB (e.g. using the TBnet forms published with the ERJ article); f) early recognition of outbreaks/transmission; g) confirmed adherence to contact tracing whereby positive secondary cases result in wider contact tracing. H) highlighting gaps in service provision that can be escalated to appropriate bodies for action. We support the action that: ''The results of the cohort review should be collated locally and agreed by the chair before being fed back to TB control boards, commissioners and health and wellbeing boards regularly and via needs assessment.''
232	Public Health Wales	Question 9	In response to question 9 'Is there a specific action relating to cohort review that the statement could focus on...' The audit of treatment outcomes and contact investigations of all people with TB and their contacts.
233	Royal College of Nursing	Question 9	Page 8: This should focus on challenges – e.g. treatment compliance /completion; population movement/ contact tracing/ immigration status versus ensuring completion of course of treatment
234	Royal College of Physicians and Surgeons of Glasgow	Question 9	*For draft quality statement 6: Is there a specific action relating to cohort review that the statement could focus on, rather than having a broad statement on this area?* I am not sure one can or should be too prescriptive about the nature of the cohort reviews: I would anticipate significantly different arrangements depending on the size on the Board area, TB case-load and local service configuration. This will need to be discussed within Board areas and local solutions developed. Hence defining a specific action in relation to cohort reviews, at this point in time at least, is probably not the way forward. In the Scottish context, it should also be noted that while the refreshed Action Plan has not be published yet, there has been a view expressed that frequent (6-weekly) local TB MDT meetings should take place, but that formal cohort review could/ should take place less often than the 3-monthly period suggested by NICE – perhaps 6-12 monthly.
235	Joint Yorkshire and Humber and North East TB Control Board	Question 9	Comment. This statement needs revision. Quarterly cohort review is inappropriate in low prevalence areas. Perhaps a statement suggesting that quality of treatment should be reviewed through consideration of every patient as a cohort?
236	Public Health England	Question 9	The statement re Cohort Review to be expanded to 'Services, public health, Local Authorities and commissioners participate in cohort review on a quarterly basis to evaluate patient care and outcomes. Exceptionally where TB services and CCGs report 5 cases per year or less then cohort review could be carried out less frequently or those organisations should look to participating in cohort review with TB services with higher numbers of TB cases.

ID	Stakeholder	Section	Comments
237	NHS England	Statement 6	This statement is fully supported though some centres with a high incidence of TB will require more frequent meetings.
238	North West TB Control Board	Statement 6	This is not measurable without more detail on who from the TB multidisciplinary team needs to attend and how often. It may not be necessary for the pharmacist and the microbiologist to attend quarterly, while it is for others. The statement will also be hard to measure because the multi-disciplinary team does not have a standing constitution or structure. The range of people in the team varies according to the location and the complexity of the case being managed. Very few TB cases will be managed with input from all of the following (as stated in the structure of the multi-disciplinary team): social worker, voluntary sector and local housing representatives, TB lead physician and TB nurse, a case manager, a pharmacist, an infectious disease doctor or consultant in communicable disease control or health protection, a peer supporter or advocate and a psychiatrist. So how will a team be deemed to have participated in cohort review? If only one TB specialist nurse participates, will the team be deemed to have participated? In our experience in the North West, where TB Cohort Audit takes place quarterly across large geographic patches, TB nurses participate diligently in cohort audit but participation from the wider TB team is patchy. TB lead physicians regularly attend from some TB Services but others do not attend at all yet their engagement is probably more important. Perhaps a team should be deemed to have participated only if the following criteria are met – both a TB physician and a TB nurse as well as at least two members of the multi-disciplinary team with at least two distinct other professional backgrounds (e.g. pharmacist and social worker) must attend cohort review at least quarterly. It is unlikely to be achievable to require the entire multi-disciplinary team to be present.
239	Portsmouth Hospital Trust	Statement 6	We feel that the statement should focus on ensuring ALL notified TB cases should be discussed at Cohort review (rather than just that teams take part in cohort review) to ensure all cases in all areas are considered and standards are met.
240	Joint Yorkshire and Humber and North East TB Control Board	Statement 6	Clarification. If looking at completion rates within 12 months, why advocate cohort review at 6-9 months?
241	Public Health England	Statement 6	Addition b) Proportion of people with pulmonary or laryngeal TB who have close contacts identified and screened. The national TB service specification, based on international evidence, recommends an average minimum of five contacts identified and checked for every case of pulmonary or laryngeal TB

ID	Stakeholder	Section	Comments
242	Public Health England	Statement 6	Addition – '**People with TB** have their treatment outcomes, contact investigation and management reviewed once at cohort review, 6 to 9 months after starting treatment.' Change to '**People with TB** have their treatment outcomes, contact investigation and management reviewed at least once at cohort review, 6 to 9 months after starting treatment.' This is to ensure people with drug resistant TB are reviewed in a timely manner at cohort review and due to duration of treatment and the complexities that may change over time that there is an opportunity for Tb teams to bring these patients to cohort review more than once if necessary. This maybe because of contact tracing issues.
243	Public Health England	Statement 6	Second sentence should say 'Members can….' not 'Members will….'
244	British HIV Association (BHIVA)	Statement 6	Does there need to be a definition of a Multidisciplinary TB team? It is not terribly clear exactly what this is. It is within NICE guidance but perhaps could be spelt out again - with the aim of encouraging buy in. This would also enable local teams to be clear re what they need to do to achieve effective MDT working and cohort review.
245	Joint Yorkshire and Humber and North East TB Control Board	Statement 6	See previous comment.
246	Joint Yorkshire and Humber and North East TB Control Board	Statement 6	Cohort review should be explained and defined to ensure expectation is met.
247	Joint Yorkshire and Humber and North East TB Control Board	Question 9	The main focus could be on consistency of standards as these have developed organically.
248	Janssen	Question 9	Answer to Question – As well as a broad discussion of case/outcomes, specific action should be undertaken to report resistant TB strains, their geographical location and the action taken to isolate/control onward infection.
Suggestions for additional statements			
249	Portsmouth Hospital Trust	Additional statement	As this standard relates to TB in the broader sense and not just screening there should be a statement relating to contact tracing/active case finding standards.
250	Royal College of Paediatrics and Child Health	Additional statement	What this guidance doesn't cover is delayed diagnosis of TB because it's not suspected. This should be of public health concern. Data on diagnosis date, retrospective symptom start date, and interim consultations with health need to be collected and analysed to see how diagnoses can be made quicker.

ID	Stakeholder	Section	Comments
251	British HIV Association (BHIVA)	Additional statement	An area that is missing from the quality standards is that of obtaining samples to confirm the suspected TB diagnosis. This is touched upon in sections of Quality standard 2, but only mentions pulmonary TB. It is important to ensure that anyone who is thought to have active TB (and hence is likely to start treatment for TB) should have appropriate sampling and diagnostic tests performed. Clinical examples of this would include lymphadenopathy or pleural effusions; with specimens being sent for microbiological diagnosis. This is important as it will help to improve the current relatively low rate of microbiological confirmation, provide information on drug resistance patterns, reduce the number of people started on treatment perhaps unnecessarily and hence decrease the number of adverse events associated with drug therapy.
252	RCGP	Additional statement	The culture and sensitivity of the Tuberculosis organism and the need to test routinely for this in all specimens to ensure that treatment resistance is detected earlier needs consideration.
253	RCGP	Additional statement	Tuberculosis in HIV needs discussion, that any HIV detected patient be screened for Tuberculosis and be considered for prophylactic Isoniazid.

Registered stakeholders who submitted comments at consultation

- British HIV Association
- British Infection Association
- British Society for Antimicrobial Chemotherapy
- British Thoracic Society
- Cepheid UK Ltd
- Department of Health
- Janssen
- Joint Yorkshire and Humber and North East TB Control Board

- Leeds Teaching Hospitals NHS trust
- NHS England
- North West TB Control Board
- Portsmouth Hospital Trust
- Public Health England
- Public Health Wales
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Royal College of Physicians
- Royal College of Physicians and Surgeons of Glasgow