

**NATIONAL INSTITUTE FOR HEALTH AND  
CARE EXCELLENCE**

**HEALTH AND SOCIAL CARE DIRECTORATE**

**QUALITY STANDARD CONSULTATION**

**SUMMARY REPORT**

**1 Quality standard title**

Lyme disease

Date of quality standards advisory committee post-consultation meeting:  
4 April 2019.

**2 Introduction**

The draft quality standard for Lyme disease was made available on the NICE website for a 4-week public consultation period between 12 February and 12 March 2019. 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 16 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 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:

4. For draft quality statement 4: Should this statement be aimed at local authorities? If not, who should be organising health promotion activities to raise public awareness about how to prevent Lyme disease?
5. 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 General comments

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

- General support for the quality standard and the areas identified, especially early diagnosis and treatment, and raising awareness.
- Raising awareness of tick bite prevention, and of Lyme disease diagnosis and treatment among both the general public and healthcare professionals is likely to have the greatest impact.
- Stakeholders felt that the standard:
  - does not emphasise the importance of clinical diagnosis for all cases; many people do not recall a tick bite
- Potential barriers to implementing the standard were identified:
  - limited awareness of Lyme disease in healthcare professionals (GPs, community pharmacists, allied health professionals are examples) and 'at risk groups' such as farmers and outward-bound leaders
  - poor understanding in primary care clinicians of the limitations of serological testing and overreliance on testing
  - the potential for long-term symptoms to arise as healthcare practitioners' may not be willing to prescribe a long course of antibiotics when there is uncertainty about diagnosis
  - general lack of clinical experience of Lyme disease in non-specialists, such as in GPs
  - limited awareness of the NICE guideline among many clinicians.
- The RCGP has a spotlight project on Lyme disease which includes a toolkit for GPs and the public. An e-learning module to support improving awareness among healthcare professionals has also been developed.

### Consultation comments on data collection

- Stakeholders felt it would be difficult to collect the data for all the measures because:
  - the number of clinically diagnosed cases are not recorded nationally

- Lyme disease is not a notifiable disease
- patients present in different settings including primary and secondary care
- it would be difficult to collect the required data. Patients may present in primary or secondary care. Stakeholders felt it may be difficult to identify cases of people who had been tested or retested for Lyme disease.
- Limitations and variability of coding practices could reduce the feasibility and value of auditing patient records:
  - GP records may not contain the required information. The relevant details may be available within the free-text part of the record; there may be inconsistent or missing Read codes
  - inconsistent coding across primary and secondary care. Lack of coding in hospital records needed to identify children under the age of 16 who attended outpatient appointments for suspected Lyme disease was also highlighted.
- Improved awareness of Lyme disease could improve the quality of Read coding as well as diagnosis.

### **Consultation comments on resource impact**

- There was a mixed response:
- No clear cost savings could be achieved, as time and resources are required to:
  - repeat ELISA tests in microbiology laboratories
  - educate healthcare professionals to raise their awareness
  - raise the public's awareness of tick bite prevention and preventing Lyme disease
  - support increased antibiotic prescribing
  - identify cases due to limitations and variability of Read coding.
- Stakeholders felt that the quality standard may support cost savings:
  - early recognition and reducing cases of misdiagnosis and undertreatment help prevent people with acute cases of Lyme disease avoid severe and long-term illness, which also incur NHS and social care costs
  - testing only when appropriate could save money and resources
  - running a successful campaign to raise awareness about Lyme disease and how to prevent infection / remove ticks could ultimately save money.

## **5 Summary of consultation feedback by draft statement**

### **5.1 Draft statement 1**

People presenting with erythema migrans are diagnosed with Lyme disease by clinical assessment alone, without laboratory testing.

#### **Consultation comments**

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

- Statement is an important area as tests for Lyme disease are often initially false and so treatment is delayed, which adversely affects patient outcomes.
- Barriers to implementing the statement were identified:
  - primary care professionals (such as GPs) may be unaware EM is diagnostic of Lyme disease.
  - lack of confidence among GPs because:
    - skin presentation may be variable, and may change over time
    - atypical rashes may not be recognised as EM
    - referring people with rashes to specialists may delay diagnosis.
- Statement should refer to treatment starting on recognition of EM rash.
- To reduce risk of misdiagnosis the statement should refer to EM being a distinctive sign of Lyme disease.
- Provide a more precise definition of EM.
- Highlight that EM may be missed in people from black, Asian and minority ethnic groups.

Structure measure a)

- unlikely that local arrangements are in place to support this measure
- lack of existing systems to trigger immediate treatment following diagnosis and suggested local protocols and adaptations to laboratory request forms.
- Structure measure b)
  - audit numbers of people who complete the Lyme disease e-learning module and access the Lyme Disease Tool Kit

- should be aimed at all first responders (such as A&E departments)
- provide supporting resources to aid the diagnostic process.
- Process measure
  - diagnosis depends on accurate recognition of EM
  - query about whether the numerator included people who did not have a diagnosis of Lyme disease because the GP did not believe the rash to be EM
  - a definitive diagnosis of Lyme disease may not be recorded; this group is not 'measurable'.
- Outcome
  - query about whether the outcome is in fact another process measure
  - queried whether the numerator includes people diagnosed with Lyme disease through laboratory testing.

### **Consultation comments on data collection**

- Stakeholders highlighted potential barriers to accurate data collection for process and outcome measures:
  - cases may not be recorded as cases of Lyme disease or EM, but as cases of (for example) insect bite or allergy especially in out-of-hours services
  - the characteristics of the rash may be recorded in the free-text sections only, photographic evidence would support a more complete clinical record
  - lack of reliable alternative strategies to identify cases.
- Suggestion to collect data on GPs' confidence in diagnosing EM.

### **Consultation comments on resource impact**

- The e-learning module is freely available, but time is needed to complete it.

## **5.2      *Draft statement 2***

People with an initial negative enzyme-linked immunosorbent assay (ELISA) test result for Lyme disease who were tested within 4 weeks of onset of symptoms, and who continue to have symptoms have a repeat ELISA test at 4 to 6 weeks after the first test.

### **Consultation comments**

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

- There was a mixed response to this statement.
- The statement is a helpful reminder to repeat the ELISA test but may encourage inaction meanwhile.
- People in high risk occupations may have started antibiotic treatment after removing ticks; a repeat ELISA test would therefore have little value. The statement may encourage ongoing reliance on serology tests which have known limitations.
- The statement does not accurately reflect clinical priorities and would be difficult to implement:
  - if there is high clinical suspicion of Lyme disease treatment should not be delayed - a negative test cannot exclude a diagnosis of Lyme disease
  - follow-up checks are time-intensive and the mechanism supporting recalls requires clarification: it was queried whether the follow-up/recall is initiated by the clinician, or by people re-presenting due to ongoing symptoms. If people aren't recalled, they would risk missing treatment, or being undertreated, for Lyme disease
  - people may not have a repeat blood test: they did not re-present to the GP, are already being treated for Lyme disease, or had an alternative diagnosis
  - people with a negative initial ELISA result and with ongoing symptoms 4-6 weeks later may seek treatment elsewhere.
- Stakeholders felt that the statement's target population is probably relatively small.
- Suggestions to include the following in the statement:
  - immunoblots ordered if people have ongoing symptoms after 12 weeks
    - no further testing should be done if the follow-up ELISA result is negative.

- The definition and rationale should acknowledge the limitations of testing, the importance of clinical diagnosis, additional possible causes of negative results, and clarify which symptoms are relevant to this stage of care.
- GP education should be emphasised rather than follow-up appointments in the process measures.
- Structure measures:
  - systems are in place to support clinicians ordering repeat ELISA tests, suggested that laboratory advice about additional testing needs to be communicated to patients, such as changes to reporting protocols to achieve this
  - systems could trigger a reminder at the appropriate time so that people are offered a repeat test if it is required.
- Uncertainty as to how cases are ascertained, with stakeholders suggesting that potential cases could be identified from records of people who had testing for Lyme disease, but that this has limited benefit and that the process would be time-consuming and expensive.



### **5.3      *Draft statement 3***

People with Lyme disease have antibiotic treatment, with the choice of antibiotic, dosage and duration determined by their symptoms and clinical presentation.

#### **Consultation comments**

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

- There was general support for this statement.
- Stakeholders agree it is an important area, with reports that low doses and short courses are being prescribed to children.
- Statement achievable if local formularies reflect NICE guidance.
- Reviewing people and providing a second course of antibiotics for ongoing symptoms is more important.
- Resource impact would be associated with follow-up appointments (time) and auditing patient records collection (time and money) to support data collection.
- Barriers to implementation were raised:
  - reluctance to prescribe relatively long courses of antibiotics without a confirmed diagnosis, although stakeholders reported that antibiotics may be prescribed on a 'just-in-case' basis for some groups
  - may need to extend treatment beyond the recommended duration for patients experiencing ongoing symptoms
  - active and intensive follow-up after treatment required to collect the data
  - patients may not report for follow-up for example: if they feel well, or, if they feel unwell and have sought treatment elsewhere
  - severity of side-effects, and whether people should wait until symptoms are more apparent and they have had a positive ELISA result, before starting treatment.
  - microbiologist advice about prescribing may override clinical assessment.
- Rationale
  - query about how symptoms and clinical presentation can be used to determine the correct antibiotic treatment for specific forms of Lyme disease
  - include the importance of review following initial treatment and follow-up appointments after antibiotic treatment

- Process measures could be applied separately or combined with the extra factor each time (so that c) measures all 3 elements together.
- Outcome measure
  - link to the process measure was queried
  - symptom improvement and symptom resolution should be separate outcomes
  - follow-up of people treated on the basis of EM would be more useful.

### **Consultation comments on data collection**

- There was a mixed response:
  - antibiotic prescribing data should be available if people with a diagnosis of Lyme disease can be identified in primary and secondary care records
  - data on antibiotic usage, dosage and duration would be very difficult to collect.
- Objectivity of the audit process was questioned, in reference to complex cases of Lyme disease.

## **5.4      *Draft statement 4***

Local authorities organise health promotion activities to raise public awareness about how to prevent Lyme disease.

### **Consultation comments**

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

- There was general support for this statement.
- Raising awareness should be organised on a large-scale footing, with national and local involvement. Stakeholders suggested ways to raise awareness, such as media channels, national adverts and displaying information in outdoor recreational areas, GP surgeries, and pharmacies.
- Information should be made visible/available so that it does not have to be 'sought out'.
- The following barriers were identified:
  - many important public health issues are competing for government funding. Stakeholders felt however that some activities could be delivered with a limited budget, such as including tick awareness information in existing campaigns
  - increased public awareness may be negated by healthcare professionals providing inadequate care due to lack of awareness or confidence. It may also affect their willingness to display tick awareness information for patients in their practices.
- Outcome
  - does not measure public awareness adequately, it should measure this more directly as the supporting data could be affected by many variables.
  - Stakeholders suggested alternatives:
    - criteria for action by the relevant bodies and checking adherence to them
    - early detection of Lyme disease
    - prevention of Lyme disease
    - reduction in the number of people with continuing symptoms.
  - Questionnaires could assess the public as knowledge before and after events.

### **Consultation comments on data collection**

- Local authorities may request local data such as Lyme disease cases in a specific area that isn't currently available.
- Collecting local data and engaging with local stakeholders would build an evidence base of risk for Lyme disease.

### **Consultation question 4**

Stakeholders made the following comments in relation to consultation question 4:

- It would be appropriate for local authorities to raise awareness of Lyme disease
- They are in a good position to work with other local stakeholders, such as schools.
- Local authorities have an important role in disseminating awareness information.
- Stakeholders reported that relatively few local authorities provide links to national (PHE) information about tick awareness on their websites.
- Engagement of all local authorities is essential to ensure awareness is developed in all areas. People may travel to endemic areas but live in a 'low risk' area; stakeholders felt urban areas may be overlooked, for example.
- A wide range of other organisations should be involved:
  - activities should be coordinated with NHS providers
  - schools, organisations with responsibility for public safety (including those in the private sector), veterinary practices, and national and local organisations associated with outdoor activities, were highlighted as being important.

## 6 Suggestions for additional statements

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

- Diagnosing Lyme disease using clinical presentation and laboratory testing (based on recommendation 1.2.12).
- Choice of treatment based on clinical presentation and laboratory testing (based on recommendation 1.2.13).
- Care of people with Lyme disease and coinfections.
- Care of people with continuing symptoms of Lyme disease.
- Measuring follow-up data on longer-term outcomes, including the effects of outcomes of antibiotic treatment.

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## Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments <sup>1</sup>
01	British Society for Antimicrobial Chemotherapy	General	No further comments to make for the quality standard on Lyme disease
02	NHS England – Clinical Programmes Team	General	<ul style="list-style-type: none"> <li>To the best of your knowledge, how widely adopted is this quality standard in the NHS currently. E.g. a small number of early adopters/fairly widespread etc. <i>I would say a small number aware, often prompted by patient and public awareness rather than the GP looking at a rash and saying 'oh, you've got Lyme Disease'. There was an article in the BMJ about 15-20 years ago that raised awareness really well but most of us who read it are probably retired now.</i></li> <li>To the best of your knowledge, what would you consider to be the biggest barrier/s to commissioning and/or adoption of this quality standard. <i>Education and raising awareness among professionals (doctors/nurses/ANP/all health professions) and patients (especially 'at risk groups' such as walkers/dog walkers/farmers/agricultural workers/outward bound leaders etc.)</i></li> </ul> <p>To the best of your knowledge, and broadly speaking, which (if any) of the recommendations might require additional funding or workforce to deliver, and why. <i>More testing requires microbiology resource (gold standard is follow up test after 4-6 weeks if initial test negative) and I would recommend that this is highlighted by the microbiologist in the lab report, educational resource/time for health care professionals, increased antibiotic prescribing</i></p>
03	Royal College of General Practitioners	General	<p>The RCGP has a Spotlight Project on Lyme Disease.</p> <p>The Lyme Spotlight project is funded by charitable donations and managed by the RCGP Clinical Innovation and Research Centre (CIRC). It has been developed in line with the NICE guideline objectives of raising awareness and improving patient care, by a group of GPs and infectious diseases consultants. An easily accessible Lyme disease toolkit will allow GPs and patients to access information on all aspects of Lyme disease.</p>

<sup>1</sup>PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement number	Comments <sup>1</sup>
			<p>The RCGP/Lyme Disease Action e-learning module is linked to the website. Links are also provided to numerous sources of information including NICE and patient support groups. CIRC can provide data on the use of both the e-learning module and the toolkit.</p> <p>The project is currently due to finish in June 2019, however increased funding would enable the project to be extended. With additional funding, the RCGP Lyme Disease Spotlight project will be able to provide GP educational workshops throughout the UK.</p> <p><a href="https://www.rcgp.org.uk/clinical-and-research/our-programmes/clinical-priorities/spotlight-projects-2018-to-2019/lyme-disease.aspx">https://www.rcgp.org.uk/clinical-and-research/our-programmes/clinical-priorities/spotlight-projects-2018-to-2019/lyme-disease.aspx</a></p>
04	Royal College of Physicians	General	<p>The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our Joint Specialty Committee for Infectious Disease and would like to make the following comments. Our experts believe that the quality standard addresses the main issues but would like to make the following points: <b>See RCP comments about the statements.</b></p>
05	Vis-a-Vis Symposiums	General	<p>As stakeholders, we take the stance of no confidence in the National Institute for Health and Care Excellence and its inherent bias and ownership of Lyme Disease treatment and advice. Their fundamental lack of understanding and ability to successfully deal with the Lyme Disease situation is of utmost concern. We feel patients and their physicians will be placed at dangerous and unnecessary long-term risks by these poor efforts of Guidelines and Quality Standards.</p> <p>For these reasons we are unwilling to endorse the Lyme Quality Standards.</p> <p>See below comments which outline just two statements arising from numerous concerns.</p>
06	British Infection Association	Question 1	<p>QS2-4 are correct, QS1 the priority is to raise awareness but the QS would not clearly achieve this as currently written as the proposal as written is entirely dependent on the correct recognition of an evolving rash by a range of non-specialists. It is unlikely to be possible to produce data from QS1 as it is currently worded</p>
07	Lyme Disease Action	Question 1	<p>This quality standard addresses some of the key areas. However, it does not address the lack of specialist knowledge in secondary care. LDA is aware that consultants are unaware of some key facts about Lyme disease and as a result, complex cases (eg. Cases of Lyme disease with negative or inconclusive serology, relapses and partial treatment failures) are not receiving the consideration and care they need. Is there any evidence that doctors in A&amp;E, neurology and infectious diseases are trained to recognise Lyme disease or do they all rely on positive serology? Do any have Lyme disease included in their continuing professional development? Records of this could be monitored in the same way as for GPs mentioned in quality statement 1.</p>
08	Lyme Disease UK	Question 1	<p>The draft covers some key areas for quality improvement, but the statements need to include the unreliability of current testing rather than encouraging an ongoing, over-reliance on serology. The need for an Immunoblot test if</p>

ID	Stakeholder	Statement number	Comments <sup>1</sup>
			<p>a second ELISA test is negative but someone is symptomatic for 12 weeks or more also needs to be stressed along with this test's limitations.</p> <p>Additionally, the fact that antibiotic treatment should be started immediately following an erythema migrans rash needs to be included in the short statements. The importance of clinical diagnosis also needs to be stressed, not just in the case of someone who experiences a rash, but for all cases due to flawed testing at every stage of the illness.</p> <p>One key area which is missing from the draft is the importance of following up with patients who have had 6 weeks of antibiotic treatment, in order to find out if they have truly been cured and how effective the NICE guideline actually is.</p>
09	Royal College of Paediatrics and Child Health (on behalf of the British Society for Paediatric and Adolescent Rheumatology)	Question 1	This standard accurately reflects key areas
10	VIRAS	Question 1	It is a self-serving contradiction that the Guideline for which NICE are preparing a 'Quality Standard' – Lyme disease, is an opinion-based guideline, with almost no supporting evidence. This means that the only scope for "quality improvement" lies in a more inclusive evidence base and guidance which is declared to be qualitative, as opposed to pretending to be quantitative and which emphasises that doctors must exercise their discretion, rather than following some non-evidence based rote.
11	VIRAS	Question 1	<p>Cruikshank, O'Flynn and Faust (Chairman of the NICE Guideline Committee for Lyme disease), published their "Lyme disease: summary of NICE guidance" in the British Medical Journal in April 2018. (Cruikshank Maria, O'Flynn Norma, Faust Saul N. Lyme disease: summary of NICE guidance BMJ2018;361:k1261. Online: <a href="https://www.bmj.com/content/361/bmj.k1261.full">https://www.bmj.com/content/361/bmj.k1261.full</a>)</p> <p>The summary in the BMJ covers all the key information and advice of the guideline and usefully states the nature and quality of the 'evidence' used to inform each section. When reviewing the complete list of sources of 'evidence' provided below, please remember that NICE claim to produce "evidence-based guidelines", e.g: the NICE homepage states: "Improving health and social care through evidence-based guidance" (<a href="https://www.nice.org.uk/">https://www.nice.org.uk/</a>).</p>



ID	Stakeholder	Statement number	Comments <sup>1</sup>
12	VIRAS	Question 1	<p>Please also note that where “the experience and opinion of the Guideline Committee” is used in place of actual evidence, the committee did not appear to include any doctor experienced in treating Lyme disease. Two of the committee members appear to have some knowledge of testing, but they had to leave the committee meetings when recommendations were discussed because of Conflicting Interests, casting serious doubts over the competence and impartiality of recommendations for tests (See Appendix 5, pp 15 to 18 which highlights some of the problems). Therefore the ‘opinion and experience of the committee’ is not evidence, it is not even credible opinion and is doubtful that it is based on experience.</p> <p>Sources and Quality of the 'Evidence' used in the NICE Guideline for Lyme disease. (BMJ 2018; 361 doi: <a href="https://doi.org/10.1136/bmj.k1261">https://doi.org/10.1136/bmj.k1261</a>)</p> <ol style="list-style-type: none"> <li>1. Incidence and distribution of ticks: <b>Based on the experience and opinion of the Guideline Committee (GC) and informed by an evidence review on Lyme disease incidence in the UK</b></li> <li>2. Infection rates of ticks: <b>Based on the experience and opinion of the GC</b></li> <li>3. Prevention advice: <b>Based on the experience and opinion of the GC</b></li> <li>4. EM rash: <b>Based on the experience and opinion of the GC</b></li> <li>5. Non-focal presenting symptoms: <b>Based on the experience and opinion of the GC</b></li> <li>6. Focal presenting symptoms: <b>Based on very low-quality evidence from observational studies and the experience and opinion of the GC</b></li> <li>7. Other risk factors for getting the infection: <b>Based on the experience and opinion of the GC</b></li> <li>8. Diagnosing: <b>Based on very low-quality evidence from observational studies and the experience and opinion of the GC</b></li> <li>9. Laboratory testing: <b>Based on the experience and opinion of the GC</b></li> <li>10. Treatment: <b>Based on the experience and opinion of the GC</b></li> <li>11. Second treatment: <b>Based on the experience and opinion of the GC</b></li> <li>12. Cease treatment and referral for patients who do not recover: <b>Based on moderate to very low-quality evidence from randomised controlled trials and the experience and opinion of the GC</b></li> <li>13. Explain to patients uncertainties about testing: <b>Based on very low-quality evidence from observational studies and the experience and opinion of the GC</b></li> <li>14. Explain why test results might be wrong: <b>Based on the experience and opinion of the GC</b></li> <li>15. Explain to patients that they should ignore ongoing symptoms: <b>Based on the experience and opinion of the GC.</b></li> </ol> <p>Conducting a Quality Standard for an opinion-based guideline is counter to science or evidence-based practice. Therefore the Quality Standard appears to be an economic and political action, which is rather ironic. NICE want</p>

ID	Stakeholder	Statement number	Comments <sup>1</sup>
			evidence to demonstrate the implementation of the recommendations in their guideline – which have no evidence to support them. Good one!
13	Vis-à-Vis Symposiums	Question 1	No, this draft quality standard fails all patients with long standing Lyme disease and accompanying co-infections. It is well known that there are no suitably qualified UK tick-borne illness Infectious Disease consultants in place to advise or treat patients with Lyme Disease. It is reprehensible to pretend or claim that there is UK expertise.
14	Lyme Disease UK	Question 2	We are unaware of whether local authorities have the structures in place to collect data for the proposed quality measures.
15	Royal College of Paediatrics and Child Health (on behalf of the British Society for Paediatric and Adolescent Rheumatology)	Question 2	In reference to the local systems in place, identifying under 16yrs referred to paediatric departments with possible Lyme disease may be difficult as there is no hospital diagnostic coding for outpatient attendances. Thus, outpatient attenders do not have diagnostic coding attached to their attendance. They would only be identified from coding if GP coded as Lyme disease, or if they had an inpatient stay and therefore were coded on an inpatient diagnostic coding system
16	Royal College of Physicians	Question 2	Collecting data will be difficult as this is not a notifiable disease and patients might present only to GPs or only to hospitals. It will be difficult to trawl through notes of those tested to see who has been retested and who has not, for example.
17	VIRAS	Question 2	<p>We are not aware that intruding into the affairs of patients and doctors is a power bestowed by the NICE charter. What we are aware of, is that NICE guidelines are not obligatory and that NICE accept no responsibility or liability for the use or misuse of their guidelines.</p> <p>It is one thing for a quasi-academic body to conduct its business with impunity, but when it threatens to breach Article 8 of the Declaration of Human Rights, and deny doctors and patients their privacy and dignity, NICE are going too far.</p> <p>Who appointed NICE the right to access private and personal information that even doctors are not permitted to share without some demonstrable medical or legal need, or without express permission from their patient? If researchers wish to access patient records for their medical investigations, they are required to go through a lengthy process to ensure that their conduct is ethical and secure – have NICE made such an application and what was the result? Are patients who are HIV positive or who have hepatitis B, syphilis, depression, anxiety, TB, acne and all the conditions that NICE have produced recommendations for, requiring medication - to be subjected to the same intrusion into their personal affairs?</p> <p>Doctors already tread a fine line between protecting their patient's privacy and acting in their best interests. They may do this by i.e., discussing their care with family members or recommending non-medical sources of help.</p>

ID	Stakeholder	Statement number	Comments <sup>1</sup>
			<p>Such decisions are made on a case by case basis and are informed by the demands and experience of working in the real-world with real patients. Do NICE claim to possess these qualities and capabilities, and if so, how many patients have NICE examined, diagnosed and treated in the past year?</p> <p>The information about patients contained within their medical records is the property of the patient, which is why all patients have the legal right to access their medical records even though the physical documents are the property of the recording physician. What measures have NICE taken to honour these proprieties?</p> <p>What measures have NICE taken to ensure the security of the private information it intends to collect? Have all NICE staff been adequately vetted and its systems tested to prevent the theft of sensitive information?</p> <p>It seems that NICE are acting with assumed authority but with no accountability. Intrusion into the business of doctors' and patients' to check-up on adherence to its guidelines, is one thing, but it is a very small step to using such activities to enforce adherence. Do NICE see any problem with assuming these powers?</p>
18	Vis-a-Vis Symposiums	Question 2	Not if this question implies monitoring physicians and pharmacists for antibiotic compliance, and not if guideline usage is to be monitored for the purpose of mandatory compliance, rules and regulations.
19	British Infection Association	Question 3	There are no clear cost savings from the proposal. The quality standards suggest would require time input and therefore resources.
20	Lyme Disease UK	Question 3	<p>We are unaware of local authorities' budgets and what is financially feasible. However, the first 3 statements should be achievable in order to give people with acute cases of Lyme disease a chance to avoid debilitating, chronic illness. The key is for GPs to be made aware of the RCGP course and the NICE guideline and for better training and education to take place to raise the profile of the disease amongst the medical profession.</p> <p>In terms of Quality Statement 4, Lyme Disease UK has had a positive response from local councils wanting to display our charity's awareness information but we feel it is important that local authorities are also motivated by Public Health England to spread awareness. Lyme Disease UK rolls out a national, annual awareness campaign but on a shoestring budget with a team of volunteers afflicted with Lyme disease. The government needs to be supporting charity awareness campaigns with their own large-scale initiatives.</p> <p>Every undiagnosed, misdiagnosed and under-treated patient is a burden to the NHS and to the benefit system in the UK. Awareness and prevention are key and will lead to savings for the government if they invest money in rolling out a successful campaign.</p>

ID	Stakeholder	Statement number	Comments <sup>1</sup>
21	Oxford Health NHS Foundation Trust - Urgent & Ambulatory Care	Question 3	<p>Resource requirements and savings</p> <p>The most cost-effective way to achieve all of these quality statements would be via improved medical education - particularly focused on primary care clinicians, OOH, pharmacists A&amp;E,</p> <p>Advice on lab request forms regarding EM rashes may reduce the number of requests for Lyme serology and increase cost saving.</p> <p>Encouraging correct read coding - eg in general practice &amp; OOH would mean that auditing of the incidence of Lyme disease, in the future, would be more accurate - which would allow better long-term planning.</p> <p>NICE should encourage investment in education - eg by supporting the RCGP Lyme disease spotlight project and the RCGP/LDA e-learning module.</p>
22	Royal College of General Practitioners	Question 3	<p>Improved medical education may help with achieving the quality statements- this could be particularly aimed at primary care clinicians, A&amp;E departments and medical students.</p> <p>Emphasis on testing only when appropriate will potentially save money and resources. A more detailed request form would allow more selectivity of testing - particularly for cases of Lyme disease contracted outside the UK.</p> <p>Development of patient follow up forms over the following 1-2 years would allow follow up of a percentage of laboratory confirmed cases and provide feedback on antibiotic prescribing and long-term outcomes.</p> <p>Encouraging correct read coding (e.g. Lyme disease, suspected Lyme disease, EM rash and suspected EM rash) would ensure that subsequent auditing of the incidence of Lyme disease would be more accurate. Various methods of accessing GP data are available but some NHS financing would be required. Improved data would allow a more informed estimate of the incidence of Lyme disease in the UK and better focusing of resources.</p> <p>Resources also need to be targeted at raising public awareness of tick bite prevention and prevention of Lyme disease through national/government campaigns.</p> <p>Whilst local services may be required to instigate the required awareness campaigns, this is a national problem which requires national leadership.</p>
23	Royal College of Paediatrics and Child Health (on behalf of the British Society for	Question 3	Identifying patients may be difficult for the reasons provided above ( <b>see comment 15</b> )

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	Paediatric and Adolescent Rheumatology)		
<b>Statement 1</b>			
24	Association of British Neurologists	S1 - General	<p>Auditing the number of patients with erythema migrans who get treatment without Lyme disease testing should be measurable and auditable, provided primary care practices could search through coding diagnoses to ascertain cases to perform an audit.</p> <p>Achievability could be increased by laboratories rejecting testing of patients in whom the clinical details are erythema migrans only and suggesting treatment with antibiotics to increase early treatment and false reassurance of negative tests. This may take extra resources but would save money on unnecessary testing for the laboratories.</p>
25	British Association of Dermatologists	S1 - General	The clinical diagnosis of erythema migrans can be difficult. Experienced GPs are often uncertain about the diagnosis and require support from secondary care. It can sometimes be difficult to distinguish from urticaria, urticarial vasculitis and partially treatment tinea corporis. Erythema annulare centrifugum looks similar sometimes. Erythema multiforme and fixed drug eruptions have also been misdiagnosed as Lyme disease. The guideline and quality standard should say something about getting dermatology advice if there is diagnostic uncertainty.
26	British Association of Dermatologists	S1 - General	The MRCGP eLearning package that is linked to the document goes to a page that requires a login. The educational package should be accessible.
27	British Association of Dermatologists	S1 - General	Acrodermatitis Chronica Atrophicans is very rare in the UK. There have been few cases reported since 1994.
28	Cauldwell LymeCo Charity	S1 - General	We think over- and under-diagnosis happens because there's too much emphasis on red rings, and we think GPs order blood tests because they're just not sure. Doctors appear not to know what other indicators to look for and question. Could information be provided on how to differentiate similar ringed rashes and on recognising less typical EM rashes? (Source: online patient groups).
29	Forestry Commission England	S1 - General	No comment was submitted for this statement
30	Lyme Disease Action	S1 - General	Lyme Disease Action is aware of evidence that UK GPs may lack the necessary clinical experience and may not feel confident in making a definite diagnosis of Lyme disease by accurate identification of the erythema migrans rash. As well as inappropriate testing at the erythema migrans rash stage, there is evidence of a tendency to refer people with such rashes to secondary care for a specialist opinion which involves further unnecessary delay. Resource requirements would include increasing awareness and education in primary care, for example by promotion of the RCGP elearning module together with the RCGP Spotlight project on Lyme disease which are available free of charge for healthcare professionals. The draft quality standard does not include any statements

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			on improved awareness and education in secondary care, despite the expectation of availability and provision of specialist care in the NICE guideline (NG 95).
31	Lyme Disease UK	S1 - General	This statement needs to include that treatment must be started immediately when an erythema migrans (EM) rash is discovered in case people do not read the entire Quality Standard document. If this Quality Standard is implemented, it is important to consider that the number of cases diagnosed by EM rash should go up, which is positive as it means cases are being picked up promptly. Conversely, diagnosis by serology may reduce as doctors become more confident in recognising and treating Lyme disease when they see patients presenting with an EM rash. At present, only those cases diagnosed by serological testing are recorded and used to ascertain the incidence of Lyme disease in the UK. Therefore, when implementing this Quality Standard, it should be discussed with relevant authorities whether all forms of Lyme diagnoses should be recorded in the future so that it is possible to assess infection incidence in the UK with more accuracy.
32	NHS England – Clinical Programmes Team	S1 - General	Patients with symptoms of Lyme Disease are treated without waiting for laboratory tests Tests are often falsely negative on initial presentation and patients may end up having delayed treatment and worse outcomes. There needs to be some data collected on the confidence of GPs in diagnosing erythema migrans. The skin presentation can be variable (as evidenced on the NICE resource library of images.) As there is no single consistent appearance, GPs may not be confident on diagnosing unusual appearances of erythema migrans.
33	Cauldwell LymeCo Charity	S1 - Statement	“People presenting with erythema migrans” is not clear. Is this people presenting with a true erythema migrans? Or people presenting with what they think is an erythema migrans? Or people presenting with what the doctor decides, rightly or wrongly, is an erythema migrans? This group appear as denominator in algorithms so definition must be clear.
34	Cauldwell LymeCo Charity	S1 - Rationale	An erythema migrans must be identified correctly for the rationale to hold. Atypical rashes may be dismissed. (Source: online patient groups)
35	British Infection Association	S1 - Structure measure a)	This is not possible to measure as those in whom erythema migrans is detected are usually diagnosed with Lyme disease. It is those in whom it is missed who will be diagnosed with alternative conditions such as cellulitis. How does NICE propose this is therefore measured?
36	British Infection Association	S1 - Structure measure b)	This seems sensible but needs to include A & E departments and other first responders not only GPs. Please include pictures of erythema migrans on non-Caucasian skin within the reference photo resource document to aid recognition.
37	Cauldwell LymeCo Charity	S1 - Structure measure b)	Healthcare professionals need better training to recognise the erythema migrans rash on which this statement depends. Resources using flowcharts or tick-lists of information to seek from the patient could be formed from the information given in the guideline (eg time between bite and rash development, how the rash has expanded over time) (Source: online patient groups)

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38	Cauldwell LymeCo Charity	S1 - Structure measure b) – data source	It might be useful to look for GP surgeries where NO doctor has completed the RCGP e-learning course.
39	Cauldwell LymeCo Charity	S1 – Process and outcome measures	Outcome does not appear to be the answer from the algorithm in the Process, expressed more simply in words. The Outcome here appears to be a different Process algorithm, with the same denominator but different numerator. Should these be two Process statements, each identifying the two parts of the Quality Statement ie diagnosed with Lyme disease and without laboratory testing?
40	Cauldwell LymeCo Charity	S1 - Process and outcome measures	Calculations depend on the count of the number of people who present with erythema migrans. The definition of this is unclear and the diagnosis of doctors not dependable.
41	Cauldwell LymeCo Charity	S1 - Process measure	Does the numerator here include people who were not given a diagnosis of Lyme because the GP believed the rash was not an erythema migrans?
42	Cauldwell LymeCo Charity	S1 - Outcome	Does the numerator here include people who did have laboratory testing but were given a diagnosis of Lyme disease?
43	Cauldwell LymeCo Charity	S1 - Outcome	How are the algorithms combined to give the number of people who are clinically diagnosed without testing AND given a diagnosis of Lyme disease? The Process and Outcome and the use of the algorithms for this Quality Statement are not clear.
44	Cauldwell LymeCo Charity	S1 - Definitions (erythema migrans)	The definition itself demonstrates the very real diagnostic challenge presented by a possible erythema migrans. Note multiple inclusion of words such as may, sometimes, usually, not usually, around.
45	Cauldwell LymeCo Charity	S1 - Equality & diversity considerations	Anecdotal evidence from membership of patient groups suggests that erythema migrans is more likely to be unnoticed on darker skin.
46	Oxford Health NHS Health Foundation Trust – Urgent & Ambulatory Care	S1 - Question 1	People presenting with erythema migrans are diagnosed with Lyme disease by clinical assessment alone, without laboratory testing.  This is a vital area for quality improvement. However the majority of GPs and other primary care clinicians are not aware that an EM rash alone is diagnostic of Lyme disease. EM rash cannot always be diagnosed by clinical assessment. Many GPs are not aware that serological tests are not required with an EM rash or that a negative test DOES NOT exclude the diagnosis. The focus should be on education of primary care clinicians, OOH clinicians, pharmacies, paramedics, general public. Focus on this issue also ignores the fact that only approx two thirds of Lyme cases report an EM rash.
47	Royal College of General Practitioners	S1 - Question 1	This is a potential area for quality improvement as it can towards facilitating the quality of care of patients with Lyme disease. There is currently an over-reliance on testing and poor understanding of its limitations amongst

ID	Stakeholder	Statement number	Comments <sup>1</sup>
			<p>primary care clinicians. The avoidance of treatment delays and barriers is likely to result in more effective elimination of <i>Borrelia</i> and fewer longer term sequelae for patients.</p> <p>However, there is a lack of awareness amongst clinicians that Erythema Migrans (EM) is pathognomonic of Lyme and that it can be diagnosed in primary care. To remove ambiguity, NICE could consider adding a statement such as: 'People presenting with erythema migrans are diagnosed with Lyme disease by clinical assessment alone, without laboratory testing (<i>as presence of the rash is diagnostic of this infection</i>)'.</p> <p>The inclusion of a slightly more specific definition of erythema migrans would assist in recognition of the rash. E.g. 'Erythema migrans is a red rash, specific to Lyme disease, that increases in size and may be uniform in colour or may sometimes have a central clearing. It is not usually itchy, hot or painful. It usually becomes visible from 1 to 4 weeks (but can appear from 3 days to 3 months) after a tick bite and lasts for several weeks. It is usually at the site of a tick bite, though may appear distant from the original bite in disseminated disease and appears in around two-thirds of cases.'</p> <p>There is likely to be a lack of confidence in diagnosis of EM in primary care, which can be misdiagnosed as cellulitis or ringworm. There may be a reluctance to prescribe the relatively prolonged 3 week course of antibiotics when there is uncertainty, especially when the potential for long term sequelae in Lyme disease is not fully recognised by the clinician. There needs to be education and emphasis of the importance of early diagnosis of a centrifugally spreading, relatively asymptomatic rash in the context of known or possible tick bite. Where there is genuine diagnostic doubt, early liaison with dermatology departments who may be able to assist (including with urgent biopsy) would be key. Awareness of the unreliability of serology at this stage is critical.</p> <p>Photographic recording of confirmed or suspected EM rashes should be encouraged and potentially filed within the patient's medical records to ensure a more complete clinical record. This may prove to be particularly useful if the diagnosis is uncertain or should the patient develop disseminated disease some months later when further treatment may be required.</p> <p>Whilst acknowledging the significance of the EM rash, it is essential for clinicians to be aware that 30% of cases do not report an EM rash. (Public Health England statement which the NICE guidelines do not specifically mention.) Patients presenting with symptoms of late undiagnosed Lyme disease are unlikely to recall an EM rash. The RCGP Lyme disease Spotlight project has been developed with the aim of raising awareness in Primary Care as education amongst primary care professionals is important for the quality standard to be met.</p>
48	British Infection Association	S1 - Question 2	<p>For QS1 recognition of erythema migrans is likely to also lead to diagnosis of Lyme disease so coding could be used but would not provide a robust means of measuring due the reliance on recognition in the denominator.</p>



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49	Lyme Disease Action	S1 - Question 2	Improved education within healthcare about the diagnosis of Lyme disease is essential to ensure valid data collection and that this correctly recorded. Service providers (both primary care and A&E) will need to have in place an agreed code for recording erythema migrans. Monitoring will be very expensive if it has to rely on free text searches. Service providers should be encouraged to use the right code if they provide treatment on the basis of the rash even if they are not 100% sure that a rash is erythema migrans.
50	Oxford Health NHS Foundation Trust – Urgent & Ambulatory Care	S1 - Question 2	<p>1) It's unlikely that there are local arrangements in place, across the entire UK, to ensure that patients presenting with an EM rash are diagnosed and treated for Lyme disease.</p> <p>2) Raising awareness of the NICE guideline amongst primary care clinicians, OOH clinicians, pharmacies, paramedics, general public. With a relatively asymptomatic rash, patient may be more likely to report to a pharmacist or practice nurse rather than a GP. OOH clinicians see high numbers of local reactions to insect bites and must be able to distinguish between infection, allergy and an EMrash.</p> <p>3) Local laboratories could advise doctors that a Lyme Elisa is not required if an erythema migrans rash has been identified.</p> <p>Read coding for EM rashes is unlikely to be reliable in primary care or OOH. Since it is not possible to accurately record total numbers of EM rashes diagnosed in the UK then it would be impossible to calculate what percentage had serology testing.</p> <p>Therefore auditing patient records will be of limited value at the present time. Local pilot studies might be useful if combined with GP education.</p>
51	Royal College of General Practitioners	S1 – Question 2 (structure measures)	<p>It is unlikely that there are any existing arrangements to ensure that EM recognition triggers immediate treatment for Lyme disease. However, it may be possible to adapt local and national systems and structures in order to improve clinical management.</p> <p>The following methods could be considered:</p> <p>1) Development of a national EMIS protocol (with equivalents in other clinical systems, e.g. System 1 and OOH provider systems) which would trigger an alert if EM is coded. Coding is likely to be erratic however.</p> <p>2) Raising awareness of the NICE guideline, the RCGP Lyme disease Spotlight project and the RCGP/LDA e-learning module would improve the knowledge of primary care physicians. Notification of these resources could be cascaded via practice managers/LMCs.</p>

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			<p>Evidence of clinicians' training in Lyme disease could be collected through audit of numbers completing the RCGP/LDA e-learning module or accessing the RCGP Lyme disease toolkit. This could be carried out via RCGP Clinical Innovation and Research Centre (CIRC).</p> <p>3) Local laboratories could consider adding a note to their electronic test request forms advising doctors that a Lyme Elisa is not required if an erythema migrans rash has been identified.</p> <p>4) The RIPL request form could be altered (in line with the Scottish request form) to include a tick box list of potential Lyme disease symptoms and a statement that testing is not required if an EM rash has been identified.</p>
52	Royal College of General Practitioners	S1 - Question 2 (process measures)	<p>At the present time there is no system in place to reliably record total numbers of EM rashes diagnosed within primary care. Ongoing (unpublished) research has indicated that a definite diagnosis of EM rash may not always be recorded and clinicians may in fact record "suspected EM rash" or "suspected Lyme disease" or "insect bite" with characteristics of the rash and suspicion of Lyme disease recorded in free text.</p> <p>Therefore attempting to determine what percentage of this 'unmeasurable' group had undergone laboratory testing would be inaccurate and of limited value at the present time.</p> <p>One could potentially search for the antibiotic courses of a 3 week duration and in appropriate doses to identify retrospectively patients without tests who had a clinical diagnosis of Lyme disease (and compare it to those patients who had serology) It does depend though on the appropriate doses and durations being prescribed (as these are relatively specific to Lyme disease) and this is a potential pitfall.</p>
53	Royal College of General Practitioners	S1 - Question 2 (outcome)	<p>Raising awareness amongst health care professionals is important for improving diagnosis rates and read-coding. At the present time, an audit of patient records will be of limited value as well as being both time consuming and expensive because of the limitations and variability of coding practices.</p>
<b>Statement 2</b>			
54	Association of British Neurologists	S2 - General	<p>This statement may be difficult to be fully measurable because it is difficult to see how systems could identify the patients to whom this Quality Statement is relevant. Possibly this may be achievable if case notes of patients who had Lyme disease testing sent could be reviewed to identify potential cases.</p> <p>The quality standard could be achieved by implementing measures such as those below:</p> <ol style="list-style-type: none"> <li>1. To look at laboratory result reporting to check that there is advice given on negative reports for the need for repeat testing if symptom onset was within 4 weeks.</li> <li>2. Increasing the coverage of retesting could be achieved by microbiological laboratories copying the negative results directly to the patients (as well as the GPs), informing them of their potential need for repeat testing. The</li> </ol>

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			result information would have to be worded carefully, would require minimal additional resource but could potentially save money on undiagnosed Lyme disease and the health implications of this.
55	British Infection Association	S2 - General	The denominator is those with a negative test who still have symptoms 4 weeks later but how is this to be ascertained? Are patients with an initial negative test to be recalled at 4 weeks and asked if they have symptoms? Or is the expectation that those with symptoms will return to seek further medical input. Please can this be clarified.
56	Cauldwell LymeCo Charity	S2 - General	Concentration on this possible source of false negatives from tests may suggest that this is the only reason for false negatives. It should be included that false negatives may arise for other reasons and that clinicians should not automatically rule out Lyme disease even if results are negative. (Source NICE Lyme guideline: visual summary.)
57	Cauldwell LymeCo Charity	S2 - General	Is there a way that IT systems could trigger a reminder for repeat testing at the appropriate time after a negative ELISA test, making sure that patients do not slip through the net?
58	Forestry Commission England	S2 - General	When people present themselves at a GP, it has been reported within my organisation that generally the GP will prescribe antibiotics without a conclusive diagnosis, based on the patient stating that they have removed ticks from their body and working in a high-risk environment (forestry). Therefore a second ELISA test may be of no significant use as the antibiotics should have cured the condition/symptoms. Any initial testing carried out may also be invalid as patients may present before 4 weeks.
59	Lyme Disease UK	S2 - General	This statement needs to include the fact that even at 6-8 weeks, a false negative result may occur due to inadequacy of current Lyme disease testing. People who have had a negative ELISA test but who have been experiencing symptoms for 12 weeks or more should have an Immunoblot test carried out. Again, a false negative with this test could be a possibility due to the limitations of current tests. Encouraging ELISA testing only in this statement whilst failing to mention limitations will lead to the continuation of an over-reliance on flawed serology.
60	NHS England – Clinical Programmes Team	S2 - General	Key area for quality improvement 2 Patients with a negative test for Lyme disease are recalled for a repeat test in 4-6 weeks as the test can often become positive.  Patients may be under treated or not treated if not recalled for a follow up Lyme Disease test.
61	Royal College of Physicians	S2 - General	There should be something in statement 2 that if the follow-up ELISA is also negative, no further testing should be done
62	Lyme Disease Action	S2 - Rationale	General comment: There appears to be a speculative message in the Rationale for Quality Statement 2, that current Lyme serology test kits with acknowledged limitations (NICE CG 95 1.2.24 and 1.2.25) will “ensure an accurate diagnosis”, despite an extensive body of well-documented evidence to the contrary in the peer-reviewed scientific literature. Lyme Disease Action is concerned about over-reliance on Lyme serology test results given the limited clinical experience of UK healthcare professionals.

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63	Lyme Disease UK	S2 - Rationale	<p>This statement is problematic in the rationale section: 'Repeating the test at 4 to 6 weeks after the first test helps to ensure an accurate diagnosis.' Lyme disease testing is flawed and whilst repeating an ELISA test at 4-6 weeks may pick up some cases of Lyme disease, an 'accurate' diagnosis cannot be ensured. This statement is misleading and encourages an over-reliance on unreliable serology.</p> <p>Clinical diagnosis of Lyme disease must remain an option in the absence of a positive test and there is also no mention of carrying out an Immunoblot test if someone has a negative ELISA test but is symptomatic for 12 weeks or longer. Although this test also has its limitations, it may pick up the illness.</p>
64	Oxford Health NHS Health Foundation Trust – Urgent & Ambulatory Care	S2 - Measures	<p>STRUCTURE</p> <p>It is usual for local laboratories and RIPL to provide this information on the laboratory reports. So systems are required to ensure that GPs inform patients of this information .</p> <p>PROCESS</p> <p>Assessing the proportion of patients who have repeat Elisa tests if symptoms persist is not feasible. There may be numerous reasons why a further blood test is not repeated - eg patient already on treatment for Lyme disease, alternative diagnosis, patient did not re-present to GP,</p> <p>GP records are unlikely to provide the necessary information. An audit of GP records would be time consuming, costly and of little benefit.</p> <p>Emphasis on this statement neglects other equally important advice from NICE - ie “ that a negative test does not exclude the diagnosis” and that” clinicians can initiate treatment based on clinical suspicion”.</p>
65	Royal College of General Practitioners	S2 - Structure measure	<p>It is usually standard for local laboratories and RIPL to provide this information on the laboratory report i.e. protocols should already be in place. GP practices must ensure that this advice is conveyed to the patient.</p>
66	Lyme Disease UK	S2 - Audience Descriptors (commissioners)	<p>This statement is misleading, “People who had a negative blood test for Lyme disease in the 4 weeks after their symptoms began but continue to have symptoms have another blood test 4 to 6 weeks after their first test when they return to their doctor. This helps to ensure that the person gets the correct diagnosis and treatment.” The test could still be falsely negative at 4-6 weeks meaning that a Lyme disease diagnosis is missed, and treatment is not administered. Limitations of the tests need to be emphasised as well as the importance of clinical diagnosis.</p>
67	Lyme Disease UK	S2 - Definitions – initial ELISA test for Lyme disease	<p>This statement is misleading as an antibody response may never develop in immunosuppressed patients, “Repeating serological testing at a later point allows time for antibody response.” Again, this encourages an over-reliance on serology without emphasising the importance of clinical diagnosis.</p>

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68	Oxford Health NHS Foundation Trust – Urgent & Ambulatory Care	S2 - Question 1	<p>People with an initial negative enzyme-linked immunosorbent assay (ELISA) test result for Lyme disease who were tested within 4 weeks of onset of symptoms, and who continue to have symptoms have a repeat ELISA test at 4 to 6 weeks after the first test.</p> <p>Whilst this statement is useful it appears to ignore two key statements in the NICE guideline:</p> <p>Do not rule out diagnosis if tests are negative but there is high clinical suspicion of Lyme disease.</p> <p>If there is a clinical suspicion of Lyme disease in people without erythema migrans: offer an (ELISA) <a href="#">test</a> for Lyme disease <b>and</b> consider starting treatment with antibiotics while waiting for the results if there is a high clinical suspicion.</p>
69	Royal College of General Practitioners	S2 - Question 1	<p>The NICE committee will be well aware of the various papers on the meta-analysis of test accuracy as well as the debate over seronegativity.</p> <p><a href="https://www.ncbi.nlm.nih.gov/pubmed/27920571">https://www.ncbi.nlm.nih.gov/pubmed/27920571</a></p> <p><a href="https://www.researchgate.net/publication/299411474">https://www.researchgate.net/publication/299411474</a> <a href="#">The diagnostic accuracy of serological tests for Lyme borreliosis in Europe A systematic review and meta-analysis</a></p> <p>It is important that clinicians do not withhold treatment from patients in whom there is a high clinical suspicion of Lyme disease pending tests. The emphasis on repeating testing at this specific time may be highly counterproductive.</p> <p>The group to which this standard applies is likely to be relatively small since, given the variable presentation, the disease may not be tested for or even considered within 4 weeks of symptoms appearing. This is especially true given the likely delay in obtaining a GP appointment, and further delay in arranging blood testing after that.</p> <p>In summary, this quality statement does not appear to be an accurate reflection of clinical priorities.</p> <p>Perhaps Public Health England could provide data to indicate how often patients do seroconvert by the time of their second test and the long-term health implications caused by any delays in initiating treatment.</p>
70	Royal College of General Practitioners	S2 - Question 1	<p>This statement is ambiguous and seems to encourage an over-reliance on testing compared with clinical acumen. Repeating the test may perhaps allow pick up of extra cases who “seroconvert” in those few extra weeks but does a disservice to those who do not.</p>

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			<p>This phrase “within 4 weeks of onset of symptoms” needs clarification on what the first symptom(s) would include – is this referring to erythema migrans or is it when fever, headaches and fatigue start?</p> <p>Whilst it may be helpful to remind clinicians that a repeat test may be useful in confirming a diagnosis, the statement seems to suggest that a 4-6 week period of ‘inaction’ should follow the first test. It would seem more clinically expedient to prioritise the following NICE statements within this quality standard:</p> <p>1.2.12 Use a combination of clinical presentation and laboratory testing to guide diagnosis and treatment in people without erythema migrans. Do not rule out diagnosis if tests are negative but there is high clinical suspicion of Lyme disease.</p> <p>1.2.13 If there is a clinical suspicion of Lyme disease in people without erythema migrans:</p> <ul style="list-style-type: none"> <li>• offer an enzyme-linked immunosorbent assay (ELISA) test for Lyme disease and consider starting treatment with antibiotics while waiting for the results if there is a high clinical suspicion.</li> </ul> <p>There is no acknowledgement of the possible causes of a false negative result, including early use of antibiotics, use of steroids, lack of antibody response in patients who are unable to mount an antibody response (e.g. immunodeficiency), inaccurate testing.</p>
71	Royal College of General Practitioners	S2 – Question 2	<p>Assessing the proportion of patients who have repeat Elisa tests if symptoms persist is not feasible. This would involve a significant work load for laboratory staff and GPs. There may be numerous reasons why a further blood test is not repeated – e.g. patient already on treatment for Lyme disease, alternative diagnosis, patient did not re-present to GP.</p> <p>GP records are unlikely to provide the necessary information. An audit of GP records would be time consuming, costly and of little benefit. The emphasis should be on GP education not follow up checks.</p> <p>Emphasis on this statement neglects other equally important advice from NICE – i.e. “that a negative test does not exclude the diagnosis” and that “clinicians can initiate treatment based on clinical suspicion”.</p>
<b>Statement 3</b>			
72	Association of British Neurologists	S3 - General	<p>The local formularies can easily be checked to ensure they align with NICE guidance on antibiotic use for Lyme disease and its manifestations.</p> <p>Antibiotic use for patients diagnosed with Lyme disease could be audited through ascertainment of those with a diagnosis of Lyme disease in GP or secondary care records.</p> <p>This quality standard should be achievable with local formularies reflecting the NICE guidance.</p>
73	British Infection Association	S3 - General	We agree with this quality standard.

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74	Cauldwell LymeCo Charity	S3 - General	The quality statement is appropriate and necessary. Many people, especially children, are being given lower doses for shorter durations than is recommended by the guideline. (Source: online patient groups)
75	Forestry Commission England	S3 - General	As above ( <b>see comment 58</b> ) antibiotics tend to be prescribed on a “just in case” basis, as opposed to a definitive diagnosis. Should people be encouraged to wait until symptoms become evident/a more certain result from ELISA testing can be produced or is early pre-emptive treatment better? Bearing in mind that the antibiotics prescribed can have as many side effects as the symptoms of Lyme’s disease and be particularly unpleasant.
76	NHS England – Clinical Programmes Team	S3 - General	Key area for quality improvement 3 Correct use of antibiotics as advised by protocol Patients may receive no antibiotic or the wrong antibiotic resulting in worse outcome
77	Cauldwell LymeCo Charity	S3 - Rationale	There is an issue with how, practically, “symptoms and clinical presentation” are used to determine treatment. For example, to determine CNS involvement, for which IV ceftriaxone is appropriate, clinicians often use only Lumbar Puncture testing to determine neuroborreliosis perhaps because of lack of clinical experience. (Source: online patient groups) This is in spite of the fact that Evidence Review C of the NICE guideline, section 3.7.1.3 says that “The committee discussed the value of diagnostic tests for neuroborreliosis using CSF samples. It was suggested that the decision to perform a lumbar puncture might depend on whether the person lives in an area where Lyme disease is more common, where a positive serology may not necessarily indicate an active infection. However, the evidence was not strong enough to inform a recommendation.”
78	Lyme Disease Action	S3 - Rationale	“Prompt and standardised antibiotic treatment, determined by the person’s symptoms and clinical presentation, also offers reassurance to people who have ongoing symptoms” Source guidance references NG95 recommendation 1.3.11 which deals with repeat treatment. This should be made clear in the quality statement itself. Perhaps by saying “People with Lyme disease have antibiotic treatment, with the choice of antibiotic, dosage and duration determined by their symptoms and clinical presentation <i>and outcome following initial treatment.</i> ”
79	Lyme Disease UK	S3 - Rationale	The importance of follow up appointments after antibiotic therapy has been completed needs to be added here so that data is gathered to reveal how many cases are truly considered cured after the recommended NICE treatment.
80	Cauldwell LymeCo Charity	S3 - Structure measure	Yes, very important to check and align local formularies. Using other sources for prescribing information is a common reason for not following the guideline. (Source: online patient support groups). Over 10 months after guideline publication, even the BNF online information on amoxicillin does not point to which doses should be used for children with Lyme disease, but only the BNFc. (Source: <a href="https://bnf.nice.org.uk/drug/amoxicillin.html#indicationsAndDoses">https://bnf.nice.org.uk/drug/amoxicillin.html#indicationsAndDoses</a> accessed 06/03/19)
81	Oxford Health NHS Health Foundation Trust – Urgent & Ambulatory Care	S3 - Structure measure (data collection)	Evidence that local formularies align with NICE’s recommendations on antibiotic treatment for Lyme disease.  Ensuring that local formularies and the BNF are aligned with NICE recommendations is quite feasible. Direct link to the NICE guideline is also required. However the limited evidence base for these ‘guidelines’ should be acknowledged, particularly in regard to the management of individual patients with ongoing symptoms.

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82	Royal College of General Practitioners	S3 - Structure measure (data collection)	Ensuring that local formularies and the BNF are aligned with NICE recommendations is feasible. Direct link to the NICE guideline is also required. This will also be available via the RCGP Lyme disease Toolkit. However the limited evidence base for these guidelines should be acknowledged and there should be no suggestion of criticism of clinicians who make individual clinical decisions to extend treatment on individual patients with ongoing symptoms
83	Cauldwell LymeCo Charity	S3 - Process measures a), b), c)	Is the numerator for a, b and c meant to include one extra factor each time? In which case, should c include “at the recommended dosage” as well as “recommended duration” and “correct for symptoms”?
84	Cauldwell LymeCo Charity	S3 - Process measures b) and c)	Both of these beg the question of who will decide whether the prescribing was or was not correct for symptoms and clinical presentation. In simple cases eg uncomplicated erythema migrans, the case notes will demonstrate appropriate prescribing, but in more complex cases evidence in the case notes will have been provided by those who have prescribed and will not be objective.
85	Cauldwell LymeCo Charity	S3 - Outcome	“...resolved or improved...” These are different outcomes and should not be conflated or assessed together. Resolution of a serious infection is a very different outcome to improvement in symptoms. The difference between them could be caused by correct or incorrect prescribing.
86	Cauldwell LymeCo Charity	S3 - Outcome	This Outcome is not the answer that can be deduced from the algorithms in the Process, expressed in simpler words, but is a different, important, measure.
87	Lyme Disease Action	S3 - Outcome	The more relevant outcome would be the proportion of people whose symptoms have not resolved completely. Research shows that most people gain either complete resolution or partial resolution of symptoms. So, an outcome figure of, say, 95% simply shows that 5% had no relief at all. It is possible that this would reflect some mis-diagnoses. A more useful relevant outcome would be the proportion of people whose symptoms had not resolved completely, as this would be a better measure of the effectiveness of the treatment.
88	Cauldwell LymeCo Charity	S3 - Audience descriptors	It should be noted that on occasion doctors are deferring to microbiologists in testing laboratories for decisions on prescribing. Only doctors, with the patient in front of them, are able to take fully into account the patient’s clinical presentation. Occasionally, microbiologists have over-ruled doctors’ decisions. (Source: online patient groups) We are worried about this and wonder if it is really acceptable?
89	Oxford Health NHS Health Foundation Trust – Urgent & Ambulatory Care	S3 - Question 1	People with Lyme disease have antibiotic treatment, with the choice of antibiotic, dosage and duration determined by their symptoms and clinical presentation.  This is an important area for quality improvement.
90	Royal College of General Practitioners	S3 - Question 1	There is no international consensus on the dose, duration and choice of antibiotics and this was the subject of a recent motion in the European parliament (15 November 2018). This is confusing as a quality standard when there is little direction about antibiotic treatment and a lack of quality evidence even for the recommendations in the NICE guidelines, especially when a substantial proportion of patients have ongoing symptoms beyond the perceived maximum 6 weeks of treatment. There are some patients who appear to have symptoms that are



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			indeed responsive to longer courses of antibiotics, relapsing when antibiotics are initially discontinued but eventually recovering. This needs recognition. There is no recognition of the use of combination therapy (which is offered in other countries in Europe with significant perceived benefit in some patients)
91	Oxford Health NHS Foundation Trust – Urgent & Ambulatory Care	S3 - Question 2 (process measures)	<p>Proportion of people diagnosed with Lyme disease who are given the correct antibiotic for their symptoms and clinical presentation.</p> <p>There is no accurate system in place for recording the number of Lyme cases at the present time and therefore no way of calculating how many patients were treated with the appropriate antibiotic at the NICE recommended dosage and duration. An audit of patient notes would be expensive, time consuming and of limited use.</p> <p>GP education is more relevant. Particularly ensuring that GPs are aware of the need to review patients and provide a second course of treatment if symptoms persist. Also acknowledgement of the limitations of the evidence for these guidelines.</p>
92	Cauldwell LymeCo Charity	S3 - Question 2 (process measure)	Data source is given as case note review of patient records. Will these not have been written by the doctors who made the observations of symptoms and clinical presentation? The evidence is therefore being produced by the same people whose correct decisions are being assessed.
93	Royal College of General Practitioners	S3 – Question 2 (Data collection – Process measure)	Due to the read coding issues mentioned previously ( <b>comments 51, 52, 53</b> ), there is at no accurate system in place at present for recording the number of Lyme cases, and therefore no feasible way of calculating how many patients were treated with the appropriate antibiotic at the NICE recommended dosage and duration. An audit of patient notes, at this stage, would be expensive, time consuming and of limited use. However, with improved education of primary care clinicians this may prove useful in the future.
94	Oxford Health NHS Foundation Trust – Urgent & Ambulatory care	S3 – Question 2 (outcome)	<p>The proportion of patients whose symptoms have resolved or improved cannot feasibly be measured. Patients will not report for follow up, particularly if they are well or if unwell and have seeking other treatment.</p> <p>The correct diagnosis of EM rash or Lyme disease cannot always be assumed. Therefore the effectiveness of treatment cannot be measured.</p>
95	Royal College of General Practitioners	S3 – Question 2 (outcome)	<p>As per the above comments (<b>see comment 93</b>) the proportion of patients whose symptoms have resolved or improved cannot feasibly be, measured. Patients will not necessarily report for follow up, particularly if they are well or have sought other treatment.</p> <p>The correct diagnosis of EM rash or Lyme disease cannot always be assumed. Therefore the effectiveness of treatment cannot easily be assumed or audited.</p> <p>It is much more likely that those treated at the EM stage have an excellent prognosis and the active follow up of these patients could prove to be an effective use of resources to further our understanding of this disease and emphasise the importance of early treatment</p>

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96	Royal College of Physicians	S3 - Question 2	These data on antibiotic usage, dose and duration will be very difficult to collect
<b>Statement 4</b>			
97	Association of British Neurologists	S4 - General	I am afraid I feel completely unable to comment on this quality standard- I know very little about funding and mechanisms of public health campaigns let alone what makes them effective Can we say unable to comment on this one?
98	Cauldwell LymeCo Charity	S4 - General	Local authorities – see separate comment on Question 4 ( <b>see comment 114</b> ). Public awareness should overtly include public and private organisations responsible for public safety eg schools, clubs, curators of open spaces with public access.
99	Lyme Disease UK	S4 - General	<p>We agree that local authorities have an important role to play in disseminating awareness information. However, the motivation and drive for such a campaign needs to come from Public Health England and on an annual basis. From discussions members of our Online Community have had with their local public health departments, it seems that any campaign needs to be instigated by Public Health England otherwise it is unlikely to be seen as a priority in terms of funding and resources. One of the major issues is the downplaying of the risk and seriousness of this condition. The absence of a nationally funded and coordinated campaign compounds this problem.</p> <p>It has also become apparent in our Online Community of nearly 10,000 people that many doctors are still unaware of the new NICE guideline for Lyme disease which was published in April 2018. Patients are having to go back to their doctors, having consulted with other patients online, in order to make medical professionals aware of the guideline's existence.</p> <p>Currently, Public Health England information on Lyme disease is not visible enough even though excellent resources are available on their website. This information is unlikely to be viewed unless someone is looking for it specifically. Less than 20 local councils have tick bite awareness information on their websites and clinician and public awareness of Lyme disease is low.</p> <p>For public awareness to increase significantly, there needs to be a visible campaign across all media channels and information clearly displayed in outdoor recreational areas, pharmacies and GP surgeries. We appreciate that there are many important public health issues competing for government funding but with some creative thinking, tick bite awareness amongst the general public could be raised with a very limited budget:</p> <p>For example:</p> <ul style="list-style-type: none"> <li>An email from Public Health England to all Local Authority Directors of Public Health stressing that tick bite awareness is an important message for their communities to be informed about each Spring.</li> </ul>

ID	Stakeholder	Statement number	Comments <sup>1</sup>
			<ul style="list-style-type: none"> <li>• Tick bite awareness could be incorporated into other public health campaigns encouraging people to lose weight and to improve mental health by getting outdoors to exercise. The aim is not to deter people from enjoying the outdoors but to make people aware of the importance of checking for ticks and what to do if a bite is detected.</li> <li>• Links to Public Health England (or charity awareness materials) sent to all Clinical Commissioning Groups, schools, A&amp;E departments, youth organisations such as the Scouts and the Duke of Edinburgh Award. Organisations can then print out materials in-house.</li> </ul> <p>As a voluntary sector organisation running a small scale awareness <a href="#">campaign</a> each year including informative <a href="#">materials</a>, it appears that Public Health England are not planning on holding a national awareness campaign at all. In the meantime, members of the public (often children) are being bitten every year and having their lives ruined by a disease which can be prevented with adequate awareness, early symptoms detection and prompt treatment.</p> <p>It is a common myth that there are areas of the UK that are hotspots for Lyme. Most people and clinicians are unaware that Lyme is endemic in the UK and that infected ticks have been found in urban parks and gardens. Therefore, it is likely that local government departments will need to be informed by Public Health England that tick bite awareness is an issue that needs addressing whether they are located in a London borough or in a more rural area.</p> <p>It would be encouraging to see more local authorities adopting a tick bite awareness campaign each year such as the Public Health England /Wiltshire council tick bite awareness <a href="#">campaign</a> in 2015.</p>
100	Forestry Commission, England	S4 - General	No comment submitted for this statement
101	NHS England – Clinical Programmes Team	S4 - General	Raising awareness in professionals and public Professionals may not recognise the signs of Lyme Disease and patients may not be alerted to seek advice
102	Cauldwell LymeCo Charity	S4 – Structure measure	Care must be taken to ensure that measures are not passive, requiring the public to seek out information, but active, providing information that public cannot avoid.
103	Cauldwell LymeCo Charity	S4 - Outcome	With no reliable data on Lyme disease incidence nationally, and even less locally, disease incidence is an inappropriate measure for effectiveness of public awareness activities. Setting criteria for action by the relevant bodies and checking adherence to those criteria is likely to be a better measure.
104	Cauldwell LymeCo Charity	S4 - Outcome (data source)	1 - Note that using incidence figures derived from laboratory testing is in direct conflict with Statement 1 where the aim is to reduce testing of cases presenting with Erythema Migrans, theoretically to zero. If Statement 1 is

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			<p>successful, and more cases are identified via Erythema Migrans presentation, without testing, then number of cases reported will reduce but this will NOT mean that incidence has fallen.</p> <p>2 - In addition, a successful public awareness campaign could mean more cases identified in the early stages, so that increased incidence would result from a successful campaign.</p> <p>Prevention is the ideal outcome but early detection is also desirable. Use of Public Health England figures is an inadequate measure of incidence.</p>
105	Cauldwell LymeCo Charity	S4 - Outcome (data source)	<p>Using the incidence of Lyme disease as a measure for the effectiveness of awareness activities is inappropriate because there is no direct correlation or causality between them. Attempts should be made to assess public and health professional awareness more directly. How are other public health campaigns, such as 5-a-day and HIV campaigns assessed?</p>
106	Lyme Disease UK	S4 - Outcome	<p>We have noticed that some other Quality Standards don't have measurable outcomes listed such as those for smoking, drug misuse, alcohol misuse.</p> <p>Our concerns regarding measuring Lyme disease incidence as an outcome of success of the Quality Standard are due to the following issues:</p> <ul style="list-style-type: none"> <li>• Cases diagnosed by rash will not be included in figures</li> <li>• Number of cases confirmed through laboratory testing do not provide a true representation of Lyme disease incidence as testing is unreliable. GPs may pick up more patients by EM rash if awareness improves, leading to less testing being carried out in acute cases</li> <li>• There are many variables including tick population and effectiveness of previous awareness campaigns</li> <li>• As public awareness increases, patients with late stage Lyme disease may also be correctly diagnosed, potentially increasing the number of cases identified by serological testing. This will skew the assessment of the effectiveness of tick bite prevention campaigns as old infections may be included in annual cases detected by serology.</li> </ul>
107	Public Health England	S4 - Outcome	<p>A reduction in LD incidence may be difficult to measure, because raising awareness may also lead to the detection of more cases.</p>
108	Oxford Health NHS Health Foundation Trust – Urgent & Ambulatory Care	S4 - Question 1	<p>Local authorities organise health promotion activities to raise public awareness about how to prevent Lyme disease.</p> <p>Raising public awareness on tick bite prevention, tick removal and early recognition of Lyme disease symptoms is a key area for quality improvement. However this task should fall to many different organisations: eg local authorities, primary care, school authorities, tourist boards, forestry commissions, national trust, Duke of Edinburgh organisation, etc.</p> <p>Awareness needs to be raised amongst clinicians as well as the general population.</p>

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109	Royal College of General Practitioners	S4 - Question 1	<p>Raising public awareness of tick bite prevention, tick removal and early recognition of Lyme disease symptoms may be helpful. This task should fall to many different organisations. PHE and local authorities clearly have a key role to play. However, other organisations such as CCGs, school authorities, tourist boards, forestry commissions, national trust, youth organisations such as Duke of Edinburgh, scouting, guiding, pharmacies, veterinary practices, emergency departments, employers, worker's unions can all contribute to this process.</p> <p>National adverts run by public bodies and circulated on social media would be valuable and would reach a wide audience.</p> <p>It is particularly important for the public to realise that ticks are not limited to rural areas but may be present in urban parks and gardens. A significant percentage of the UK population will spend time in Lyme endemic areas, either in the UK or overseas. The engagement of all local authorities is therefore essential.</p> <p>However, as is frequently reported by patients, public awareness is negated when clinicians lack the same knowledge and fail to provide adequate advice or clinical care. Unless GPs feel confident in managing tick bites and Lyme disease they will be reluctant to display patient awareness information within their practices.</p>
110	Oxford Health NHS Foundation Trust – Urgent & Ambulatory Care	S4 - Question 2	<p>Local authorities organise health promotion activities to raise public awareness about how to prevent Lyme disease.</p> <p>Raising awareness amongst the general public and the medical profession, of tick bite prevent and Lyme disease diagnosis and treatment is essential. However "incidence of Lyme disease' cannot be used an outcome measure of success.</p> <p>The incidence of Lyme disease in the UK is unknown. Increased education and awareness amongst the medical profession and patients may result in more cases of EM rashes being diagnosed early and clinically, which may in fact result in a decrease in the number of positive test results reported by the Lyme reference laboratory at Porton Down. Positive serology numbers are the only recordable data on Lyme disease at the present time.</p> <p>The incidence of Lyme disease is NOT a measure of public awareness.</p> <p>Many organisations besides local authorities need to be involved in raising public awareness eg tourist boards, forestry commissions, national trust &amp; English heritage, holiday locations, DofE YHA, Edinburgh Scheme, RCGP, GP surgeries, veterinary practices,</p> <p>NB the 111 system should ensure that they include appropriate advice on EM rashes within their protocols.</p>

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111	Public Health England	S4 - Question 2	LAs often ask for data not currently available such as LD case numbers for their area. PHE regional case data is of interest but may not provide the evidence they require to take action or justify resources for LD/tick awareness work. The importance of local data and talking with local stakeholders to build local evidence of risk could be emphasised here.
112	Royal College of General Practitioners	S4 - Question 2	<p>Raising awareness amongst the general public and the medical profession, of tick bite prevention and Lyme disease diagnosis and treatment is essential, and likely to have the greatest impact. However the outcome measure 'incidence of Lyme disease' is an unsuitable method by which to measure effectiveness of an awareness campaign.</p> <p>The incidence of Lyme disease in the UK is unknown and unrecordable at the present time. Raised awareness may increase the number of cases being diagnosed. Increased education and awareness amongst the medical profession may result in more cases of EM rashes being diagnosed clinically, which may in fact result in a decrease in the number of positive test results reported by the Lyme reference laboratory at Porton Down. Positive serology numbers are the only recordable data on Lyme disease at the present time.</p>
113	British Infection Association	S4 - Question 4	Public Health England are the organisation best placed to organise such an activity though parts of it (e.g. posters in parks) may be delegated to local authorities as appropriate.
114	Cauldwell LymeCo Charity	S4 - Question 4	There is a danger of a "postcode lottery" if awareness is handled locally. Some Local Authorities may be very active (eg where local risk is perceived as high) but others may not, despite the fact that people from lower risk areas may visit and take part in risky activities in high risk areas. Coverage should be under both national (eg strategies to use GP surgeries, school curricula, rules for sports clubs and the media) and local (eg clear signage in areas with exposure risk) control. Strategies should be comparable to other notable public health campaigns such as HIV, smoking, seat belt use and 5-a-day campaigns.
115	Lyme Disease UK	S4 - Question 4	Local authorities should be involved in Lyme disease awareness campaigns but as explained in previous comments, Public Health England need to be the driving force behind local and national awareness campaigns in addition to the valuable work being done by Lyme disease charities.
116	Oxford Health NHS Health Foundation Trust – Urgent & Ambulatory Care	S4 - Question 4	<p>Local authorities and PHE have the responsibility for raising public awareness. However, by encouraging other organisations to work alongside them an awareness campaign would be much more effective.</p> <p>A coordinated effort with NHS providers will be of significant benefit to both primary care services and the general public.</p>
117	Public Health England	S4 - Question 4	LAs are in a good position to coordinate efforts with other local stakeholders (as suggested in PHEs tick toolkit).

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118	Royal College of General Practitioners	S4 - Question 4	<p>The Health and Social Care Act of 2012 resulted in the transfer of public health from the NHS to local government and Public Health England (PHE). It represented a unique opportunity to change the focus from treating sickness to actively promoting health and wellbeing.</p> <p>It is clear therefore that local authorities and PHE have the responsibility for raising public awareness. Their efforts will obviously be enhanced by encouraging other organisations (as previously mentioned) to work alongside them.</p> <p>A coordinated effort with NHS providers will be of significant benefit to both primary care services and the general public.</p>
119	Royal College of Paediatrics and Child Health (on behalf of the British Society for Paediatric and Adolescent Rheumatology)	S4 - Question 4	It seems appropriate for LA to raise public awareness
120	Royal College of Physicians	S4 - Question 4	Statement 4 should be directed to local authorities as that is where public health now sits.
<b>Local practice examples</b>			
121	British Infection Association		Not submitted
122	Lyme Disease UK		N/A
123	Public Health England		We've had a number of LAs use the toolkit to signpost to further information or run campaigns. LAs often evaluate these events by assessing knowledge other public before and after these events (through questionnaires etc).
124	Royal College of General Practitioners		<p>The RCGP Lyme disease Spotlight project is an example of implementing the NICE guideline to raise awareness amongst both the medical profession and the general public.</p> <p>General practitioners are the group of medical professionals who are most likely to diagnose Lyme disease. With appropriate education, they are in a position to provide the early diagnosis and treatment which provides the best opportunity of preventing long term health complications. Apart from individual benefit to the patient, this will impact overall health and social care costs.</p> <p>NICE should encourage NHS financial backing of GP education, with particular emphasis on the RCGP Lyme disease Spotlight Project and the RCGP/LDA e-learning module as a priority.</p>

### ***Registered stakeholders who submitted comments at consultation***

- Association of British Neurologists
- British Association of Dermatologists
- British Infection Association
- British Society for Antimicrobial Chemotherapy
- Cauldwell LymeCo Charity
- Forestry Commission, England
- Lyme Disease Action
- Lyme Disease UK
- NHS England – Clinical Programmes Team
- Oxford Health NHS Foundation Trust – Urgent & Ambulatory care
- Public Health England (regarding the Tick Awareness Toolkit)
- Royal College of General Practitioners
- Royal College of Paediatrics and Child Health (on behalf of the British Society for Paediatric and Adolescent Rheumatology)
- Royal College of Physicians
- VIRAS (Vector-borne Infection - Research, Analysis, Strategy)
- Vis-a-Vis Symposiums