Breaches of Guideline development rules by NICE and members of the Guideline Development Committee for NG10007, Lyme disease

For convenience and reference, some quotes from relevant sections of the NICE rules for a Guideline Development Committee (GDC) and NICE officers and affiliates are reproduced below:

(Please note that emphases within quoted sections should be presumed - added)

Core principles for developing all NICE guidance
- Independent advisory committees
- Comprehensive evidence base
- Expert input
- Public involvement
- Genuine consultation
- Regular review
- Open and transparent process
- Social values and equity considerations

Quotes from the NICE Standards of Business Code of Conduct

Scope
2. This policy applies to all NICE staff (including those on secondment to other organisations) and the following groups of people who work for or on behalf of NICE. This document describes these (non-staff) groups collectively as 'affiliates':
   - committee chairs and members, and remunerated expert advisers

General
5. NICE staff and affiliates should conduct themselves with integrity, impartiality and honesty and in accordance with the values of the public sector, set out below. They should not deceive or knowingly mislead the Board, the Department of Health, Ministers, Parliament or the public.

Personal Conduct
9. NICE staff and affiliates should be impartial and honest in the conduct of their official business, use public funds entrusted to them to the best advantage of NICE and do nothing that is deliberately intended to damage the confidence of the public or stakeholders in NICE.
10. NICE staff and affiliates should not do anything likely to damage the reputation of NICE or bring it into disrepute. This includes using social media for inappropriate postings about NICE or the people who work at NICE.

Quotes from Developing NICE guidelines: the manual

Involving people affected by the guideline
When developing guidelines, NICE involves people who might be affected by the guideline recommendations in a collaborative and transparent way

1.4 Key principles for developing guidelines
- Guidance is developed by independent and unbiased Committees of experts.

Quotes from The guidelines manual: appendix A – agreements and advice for Guideline Development Group members
(https://www.nice.org.uk/…/the-guidelines-manual-appendix-a-…)

NICE believes that its guidance will be enhanced if those who are intended to benefit from it and those who have the responsibility for implementing it have had the opportunity to be involved in its development.

In order to provide the environment described above, NICE expects GDG members:
To be aware that the Guidance Executive and Senior Management Team at NICE will not comment on the development of a guideline in progress, other than in the context of the formal consultation exercises

Including NICE’s ‘Golden Rules’

A3.2 Golden rules
- Don’t speculate on the content of the guideline before it is finally published
- Draft versions are just that: draft, not final; the content may change after consultation.
- Individuals and organisations can influence the outcome of the guideline only by submitting evidence that supports their point of view as part of the formal consultation process.

Notwithstanding NICE’s own rules for production of a guideline, coinciding with publication of the DRAFT Guideline for Lyme disease on 25th September 2017, numerous media articles appeared in newspapers, magazines and online. These included media specifically targeting health professionals such as Pulse and the Nursing Times. The media reports, which include those from the Royal College of General Practitioners (RGCP) and NICE itself, reported on and interpreted the contents of the draft, sometimes portrayed the draft as ready for use, and were almost entirely of a promotional nature, providing no alternative views or balanced discussion.
This propaganda coup must have been planned for days or weeks in advance of the draft publication, before most Stakeholder groups had even seen the draft let alone had a chance to study the 9,000 word ‘short version’ and its 30+ associated documents. We say ‘most Stakeholder groups’ because it appears that not only were journalists and selected people given privileged access to the draft, but some registered Stakeholder groups were also afforded this privileged access. The Royal College of General Practitioners (RGCP), are a registered NICE Stakeholder Group for the Lyme disease guideline. Yet they were evidently given prior access to the draft and published their comments about it on the same day that it was released:

The Royal College of General Practitioners  
Publication date: 25 September 2017  

Guidance for healthcare professionals on Lyme disease welcome, says RCGP

In response to new NICE guidelines on treating Lyme disease, Professor Helen Stokes-Lampard, Chair of the Royal College of GPs, said:

“This new guidance is an important step forward in giving health professionals clear advice on how to identify and treat Lyme disease – a potentially debilitating disease that is carried and spread by ticks.”

“Lyme disease has previously been regarded as an issue largely confined to rural areas, but we are seeing more and more cases in urban areas – so it is important we work together to raise awareness amongst the public, as well as clinicians.

It is hardly feasible that the Chair of the Royal College of GPs evaluated the 9,000 word short-version draft and its 30+ associated documents, then prepared an analysis for publication on the same day that the draft was released. Therefore this Stakeholder Group must have had prior, privileged access, pre-empting other Stakeholder Groups whose views were effectively marginalised.

NICE break their own rules

On September 25th 2017, in a betrayal of public trust and in breach of their own official rules, NICE pre-emptively published comments about the draft Lyme disease guideline, which the public and medical professionals would reasonably believe to be reliable and authoritative. Whereas the draft was not ready for use, contains serious errors and omissions, was based on a minimal amount of poor quality evidence and was entirely unfit for purpose.

The Chairman of the Guideline Development Committee (GDC) for Lyme disease, Professor Saul Faust, is quoted in numerous articles in newspapers, journals and online - including Twitter, misrepresenting the draft version, as though it is valid, authoritative and ready for use by doctors and patients.
Furthermore, Professor Gillian Leng, Deputy Chief Executive Officer at NICE, has participated in this breach of protocol by adding her official opinions and endorsement to these incomplete guidelines.

The expected publication date for the guidelines is April 4th, 2018. The purpose of publishing the draft was supposedly to allow a 6 week period for Stakeholders to evaluate the document and provide comments and evidence to be considered by NICE before producing the final version for use. This is what NICE wrote to VIRAS on September 25th 2017:

RE: Draft guideline on Lyme disease

This draft guideline and its supporting evidence are now out for consultation.

We hope that your organisation will submit comments on the draft guideline; it is a valuable opportunity to ensure that the guideline considers issues important to your members. The consultation page has all the information and documents you need to comment.

NICE state in:
“11 The consultation process and dealing with stakeholder comments”

Consultation with stakeholders, which lasts 6 weeks for standard clinical guidelines, is an integral part of the NICE clinical guideline development process. Comments received from stakeholders are a vital part of the quality-assurance and peer-review processes, and it is important that they are addressed appropriately. This chapter advises staff in National Collaborating Centres (NCCs) and the NICE Internal Clinical Guidelines Programme[16] on responding to stakeholder comments following consultation.

There are 134 organisations registered as Stakeholders for the NICE Lyme disease guidelines, which were invited to submit comments which according to NICE is: “a vital part of the quality-assurance and peer-review processes” and, “a valuable opportunity to ensure that the guideline considers issues important to your members”.

This promise to consider issues raised by stakeholders has led to members of some of those groups devoting considerable time and effort to analysing the draft guideline and its associated documents. This occurred to our certain knowledge, with some Stakeholder Groups devoting many hours of work to producing valid and valuable comment and criticism. Some Stakeholders had also invited their members to provide their comments (SEE APPENDIX B). This effort - undertaken in good faith, has been rendered useless by corruption of the guideline development process including multiple breaches of NICE’s own rules.
Professor Gillian Leng - Deputy Chief Executive of NICE

A small selection of statements appearing in the media and NICE’s own website quoting Professor Leng, published on the same day that the DRAFT guideline was released for stakeholder review:

NICE sets out how to diagnose and treat Lyme disease | News and ...
25 Sep 2017 - Professor Gillian Leng, director of health and social care and deputy chief executive, said: “Lyme disease is easy to treat. However, if left undiagnosed, it can lead to more serious symptoms. This can include heart problems, arthritis and problems affecting the nervous system, for example, weakness on one ...

NICE provides advice on diagnosing Lyme disease | GPontline
https://www.gponline.com/nice-provides-advice...lyme-disease/infections.../1445536
25 Sep 2017 - 'Our draft guidance will give GPs and hospital doctors clear advice on how to diagnose if they think Lyme disease is a possibility.' Professor Gillian Leng, deputy chief executive of NICE, said: 'Lyme disease is easy to treat. However, if left undiagnosed, it can lead to more serious symptoms. This can include ...

New guidance to diagnose and treat Lyme disease | Health Business
www.healthbusinessuk.net › News
25 Sep 2017 - New guidance, published by NICE, will help UK health professionals spot a potential diagnosis of Lyme disease, without the need for tests. ... Gillian Leng, deputy chief executive, said: ‘Lyme disease is easy to treat. However, if left undiagnosed, it can lead to more serious symptoms. This can include heart ...

Draft guidance drawn up to 'spot and treat' Lyme disease | News ...
https://www.nursingtimes.net/news/primary-care/...lyme-disease/7021404.article
25 Sep 2017 - Gillian Leng. The draft guidance said Lyme disease should be diagnosed in patients who presented with a circular red rash, known as erythema migraines, after a tick bite without the need for further tests. In addition, NICE said clinicians should not rule out Lyme disease if a patient had symptoms consistent ...

We are unaware of any information that Professor Leng is an expert on Lyme disease, and question the appropriateness of her unqualified public statement that, “Lyme disease is easy to treat”. The draft guideline shows clearly that there was a minimal amount of evidence available for making treatment recommendations, none of which was UK based and all of which was of ‘low’ or ‘very low quality’. Professor Leng must therefore have access to some privileged and undisclosed source of knowledge about the treatment of Lyme disease, enabling her to supersede the actual content of the draft guideline. This is not “transparency”.

Due to pre-emptive and exclusive media exposure, Professor Leng’s comment now constitutes an official opinion and assurance by a NICE senior officer, pre-empting alternative views and evidence which could be provided by Stakeholders, individual members of the NICE GDC, etc. The general public,
patients, medical professionals and even Stakeholder Groups could hardly be blamed for accepting and trusting information provided by the NICE Deputy Chief Executive. Yet Professor Leng’s unqualified statements could result in foreseeable and serious harm to those patients whose Lyme disease is not ‘easy to treat’.

**Professor Saul Faust - Chairman of the NICE Guideline Development Committee for Lyme disease**

A small selection of statements in national newspapers, health related magazines and online, quoting Professor Saul Faust, published on the same day that the DRAFT guideline was published for stakeholder review:


  ‘Our draft guidance will give GPs and hospital doctors clear advice on how to diagnose if they think Lyme disease is a possibility.
  ‘We also recommend tests used for this illness meet certain laboratory criteria. This is to make sure a potential diagnosis is based on clinically relevant and robust test results.’

- [Health body warns many UK areas have high Lyme disease risk | New ...](https://www.newscientist.com/.../2148357-health-body-warns-many-uk-areas-have-hi...)

  25 Sep 2017 - Antibiotic treatment. “Lyme disease may be difficult to diagnose as people can have common and unspecific symptoms, like a headache or fever, and they may not notice or remember a tick bite,” says Saul Faust, of the University of Southampton, UK, who worked on Nice’s new guideline.

- [GPs issued guidance on lyme disease | News | The Times & The ...](https://www.thetimes.co.uk/article/gps-told-to-be-tough-with-lyme-disease-57jtrl5w6)

  26 Sep 2017 - Public Health England estimates that about 2,000 to 3,000 people a year contract lyme disease but patient groups believe that the true figure could be much higher because doctors do not diagnose the condition. Saul Faust, who led the development of the advice, said a key aim was to avoid the ...

- [Parts of UK identified as high risk areas for Lyme disease | Science ...](https://www.theguardian.com/.../parts-of-uk-identified-as-high-risk-areas-for-lyme-disea...)

  25 Sep 2017 - “Lyme disease may be difficult to diagnose as people can have common and unspecific symptoms, like a headache or fever, and they may not notice or remember a tick bite,” said Saul Faust, professor of paediatric immunology and infectious diseases at the University of Southampton. “Our draft guidance ...

- [Highlands listed as a 'high risk area' for Lyme disease | The National](https://www.thenational.scot/.../15557261.Highlands_listed_as_a___high_risk_area___for...)

  25 Sep 2017 - “Lyme disease may be difficult to diagnose as people can have common and unspecific symptoms, like a headache or fever, and they may not notice or remember a tick bite,” said Professor Saul Faust, who chairs Nice’s guideline committee. “Our draft guidance will give GPs and hospital doctors clear ..
Higher risk of Lyme disease for the South of England | Daily Mail Online
25 Sep 2017 - 'Lyme disease may be difficult to diagnose as people can have common and unspecific symptoms, like a headache or fever, and they may not notice or remember a tick bite,' said Professor Saul Faust. 'Our draft guidance will give GPs and hospital doctors clear advice on how to diagnose if they think Lyme ...

On Tuesday September 26th 2017, the Times reported:
(https://www.thetimes.co.uk/article/gps-told-to-be-tough-with-lyme-disease-57jtrl5w6)

Nice has now issued its first advice on the condition [...] Saul Faust, who led the development of the advice, said a key aim was to avoid the "confrontational politics" between scientists and patients that are seen in the US, where many believe that they suffer chronic symptoms for years despite negative blood tests. "There are unscrupulous private providers in the UK and abroad who are willing to take your money and tell you you've got - lyme disease even if you've got something else that's undiagnosed,"

If Professor Faust wished to avoid 'confrontational politics' it would have made more sense for him not to make misleading remarks on a subject he clearly does not understand. Firstly, the numerous points of argument around Lyme disease, are not disagreements between 'scientists and patients', that is misleading and is in fact, indulging in 'confrontational politics'.

The disagreements are between on the one hand; scientists and doctors, and on the other hand; other scientists and doctors. Patients, some of whom have already lost everything to Lyme disease, have every right to participate in these debates that directly impact on their health and wellbeing – just as they have the right to participate in the development of the Lyme disease guideline produced by NICE.

Professor Faust’s statement implies that some patients are in conflict with scientists per se. This indicates bias against the credibility of patients and patient campaign groups, whose views he evidently considers to be inferior with the implication that they must be irrational. He also considers patients to be too stupid to be able to discriminate between ‘unscrupulous private providers’ and legitimate practitioners. Exactly how Professor Faust formed this derogatory view of patients and patient campaigners is unknown to us, as he does not appear to have any dealings with Lyme disease patients. Therefore it appears that the Chairman of the GDC has been influenced by some ‘unscrupulous private provider’ of misleading information about patients, and is now prejudiced against a very large number of the very patients who are supposed to be helped by the NICE guideline.

This back-door psychologisation of patients and campaigners may have originated from Public Health England (PHE). In a document prepared by PHE of which Dr Tim Brooks was a co-author and who is currently a NICE GDC member, and submitted to the Health and Safety Executive (HSE), are these remarks: (http://www.hse.gov.uk/aboutus/meetings/committees/acdp/161012/acdp_99_p62.pdf)
“As a significant proportion of self-acclaimed Lyme sufferers are self diagnosed, with no objective evidence of infection, it is essential to develop protocols that identify true cases, and refer those with other conditions sympathetically but firmly to appropriate practitioners for their problems.” (p.3)

“RIPL and HPA staff will discuss with Simon Wesseley’s [sic] group and other interested parties the development of guidance for clinicians on dealing with the disaffected group with unprovable Lyme disease. This will cover the therapeutic approach, investigation of cases and “disengagement” strategies when further investigation is counter-productive.” (p.24)

There are in fact, a minimal number of “self diagnosed” patients. The vast majority of chronically ill Lyme disease patients that VIRAS are aware of, have been diagnosed by qualified physicians possessing excellent knowledge and experience of the disease. Many of these patients have had EM rashes which are objective evidence of the disease, and contrary to the assertions of PHE, most do have other evidence of being infected, including positive NHS tests. Others have confirmation provided by top-class laboratories in Europe and the USA, some of which have accreditation far superior to PHE’s Lyme reference laboratory at Porton Down which is not even UKAS accredited. Aside from an EM rash, the only reliable objective evidence of the infection, is direct detection of the infective organism, something which PHE do not generally offer and are mostly incapable of achieving.

Public Health England’s derogatory preconceptions about patients and their plan to ‘disengage’ chronic Lyme disease patients from their ‘clinicians’, have been fully incorporated and actualised in the NICE draft guideline. This shows that NICE have been either manipulated or willingly collaborated in producing a policy enforcement stratagem of PHE.

To those familiar with the ‘confrontational politics’ of Lyme disease, it is self-evident how the enforcement of this policy will work. Simple cases of Lyme disease will follow the normal route of testing, diagnosis, treatment and discharge. Complicated cases will follow the same routine, but when the patients is re-tested at three months, and/or following their full allotment of 6 weeks of antibiotics, they will be referred to a ‘specialist’ who can then determine that they have had ‘adequate treatment’. The next step is simply to decide whether the patient has some evidence of injury, like arthritis, carditis, obvious neurological deficits, etc. If they do, then these and any other remaining symptoms can be diagnosed as, ‘Post Lyme Disease Syndrome’. Patients that don’t have any obvious signs can simply be diagnosed with Chronic Fatigue Syndrome. It is convenient. It is cheap.

For the policy to be successful, it will of course, be necessary to try and discourage these patients from seeking further investigation for a persistent Lyme disease infection. This is simply dealt with by denigrating those that could provide this service, as “unscrupulous private providers”, and psychologising the
behaviour of patients as neurotic and hypochondriac, aka, “negative blood tests”. Any objections that patients have about their NHS treatment can be branded “confrontational politics”.

If any of this seems unlikely then please consider the contents of the draft guideline itself. With the guideline advice, it is possible to follow the course of an imaginary patient roughly as follows:

Patient presents with Tick bite and/or risk factors + symptoms. Order ELISA blood test. ELISA negative but symptoms persist. Wait 12 weeks then order another ELISA and a Western Blot. Negative but symptoms persist. Then, according to the draft guideline:

Because of the limitations of tests for Lyme disease the committee also agreed that people with negative test results who continue to have symptoms might be discussed with or referred to an infectious disease specialist or a specialist appropriate for the person’s symptoms to review whether further tests are needed or to consider alternative diagnoses

And as the Loony Tunes cartoons conclude: “That’s all Folks”. Because after this, there is nothing. No more guidance, no more advice. NICE are all out of ideas and still have an awkward patient on their hands that they need to get rid of. This patient now has a history of several months of symptoms and a full set of negative blood tests which only looked for selective antibodies. The only thing that NICE suggest is to refer the patient to a ‘specialist’ - and that is the end of their involvement in what happens to this patient. The consultant will probably order standard blood tests which, if the patient has Lyme disease – will almost certainly show nothing significantly abnormal. The consultant will exclude a number of other possible diagnoses, then diagnose the patient with Chronic Fatigue Syndrome (CFS) and discharge them, perhaps with a prescription for a course of CBT or Graded Exercise Therapy. The healthcare system has washed its hands of this patient, who is now somebody-else’s-problem, even though statistically, the blood tests for Lyme disease they were given, and which have obstructed their diagnosis and treatment, only detect a maximum 41% of true-cases (see section: Laboratory Investigations below).

It does not matter that there are numerous published papers demonstrating the unreliability of blood tests for Lyme disease and dozens more showing chronic infection. The policy that NICE have sanctioned and embodied in their draft guideline means that doctors, under the auspices of a ‘NICE Guideline’, can cheaply and conveniently dismiss chronically ill Lyme disease patients in good conscience and with little fear of a successful malpractice complaint. The evidence shows that Public Health England laid plans for this strategem in 2012. In 2018, NICE will make this an official policy.

Many patients do not have the luxury of avoiding “confrontational politics”, because their very lives may depend on getting a proper diagnosis and treatment. These patients are victims of the competing interests of insurance companies, vaccine developers and holders of the many hundreds of patents on
diverse aspects of Lyme disease. Those who have the money and power to control the perception of the illness have used every resource to promote a simple version of Lyme disease: ‘it is difficult to catch, straightforward to detect and easy to treat’. This is the version of Lyme disease for which NICE have produced a draft guideline. Evading all difficulties or complications and thereby condemning chronically infected, late-diagnosed and misdiagnosed into a medical black-hole.

Professor Faust’s conduct and the contents of the NICE draft guideline suggest that far from avoiding ‘confrontational politics’, he was completely won-over by Public Health England’s political ideas and stratagems before he even took-up his appointment as chairman of the GDC. For those who prefer a mincing approach to dealing with the realities of controversy, it may be worth considering a statement made by Dr Willy Burgdorfer (1925 – 2014), the discoverer of the Borrelia burgdorferi spirochaete which causes Lyme disease and author of over 200 scientific papers, when he said:

The controversy in Lyme disease research is a shameful affair. And I say that because the whole thing is politically tainted. Money goes to people who have, for the past 30 years, produced the same thing - nothing.

And in 2010, Dr Kenneth B. Liegner, M.D. remarked: (https://www.lymedisease.org/554/)

In the fullness of time, the mainstream handling of chronic Lyme disease will be viewed as one of the most shameful episodes in the history of medicine because elements of academic medicine, elements of government and virtually the entire insurance industry have colluded to deny a disease.

This has resulted in needless suffering of many individuals who deteriorate and sometimes die for lack of timely application of treatment or denial of treatment beyond some arbitrary duration.

At least six Stakeholder Groups for the NICE guideline are comprised of Lyme disease patients and patient carers. It appears that any opinions or comments from these Stakeholder Groups that Professor Faust does not care for, are liable to be branded, “confrontational politics”, by him. Professor Faust’s claims are in contradiction to the draft guideline which he helped to produce, given that they identify numerous valid grounds for disagreement. The draft is unequivocal about the range and degree of uncertainties on matters which directly impact proper patient care, especially its remarks regarding the poor quality of ‘evidence’ available. These provide every reason for vigorous argument against a one-size-fits-all approach to the complexities of Lyme disease.
Quotes from the NICE draft Guideline for Lyme disease:

There is currently insufficient quality evidence on the most effective drug and dose, and the effectiveness of extended treatment or retreatment regimens in those with continuing symptoms remains uncertain (p.17)

The evidence on the effectiveness of antimicrobial treatment regimens used in different presentations of Lyme diseases is of poor quality, out-dated and often based on small studies. Most studies are not UK based. (p.17)

Current literature suggests that a combined IgG/IgM ELISA based on the C6 peptide and immunoblot are useful but published evidence is of either low or very low quality and is not UK based. (pp.17-18)

In particular, further research into the value of CXCL13 and other biomarkers including, ELISPOT testing and lymphocyte transformation tests may be helpful to support the current low quality evidence. (p.18)

There is uncertainty over which test or combination of tests are most helpful in diagnosing Lyme disease. (p.20)

A number of studies examined antibiotic treatment of Lyme disease with erythema migrans using different antibiotics, doses and durations of treatment. The evidence was all of poor quality. (p.23)

There was a lack of evidence identified on the information needs of people with suspected or confirmed Lyme disease, or specific Lyme disease presentations. (p.31)

There is a lack of robust epidemiological data on Lyme disease in the UK (p.16)

Furthermore, the draft guideline makes extensive research recommendations which demonstrate a shocking absence of the most basic information on which to base reliable recommendations, making differences of opinion inevitable. (pp.15-18)

**Recommendations for research**

1. Core outcome set for studies of management of Lyme disease
2. Seroprevalence of Lyme disease-specific antibodies (and other tick-borne infections in the UK population)
3. Clinical epidemiology of Lyme disease in the UK
4. Antimicrobial management of Lyme disease
5. What are the best laboratory tests to diagnose initial and ongoing infection and determine re-infection in the different presentations of Lyme disease in the UK

Secondly, Professor Faust’s remark that, “many believe that they suffer chronic symptoms for years despite negative blood tests” is, if possible, even more misleading and derogatory to patients.
Patients whose lives have been destroyed by Lyme disease deserve better than to have their suffering and losses portrayed as a mere belief - “that they suffer chronic symptoms for years despite negative blood tests”. Given his position as Chairman of the GDC for Lyme disease, Professor Faust should be aware that the validity of ‘blood tests’ in Lyme disease are dependent on numerous factors, with antimicrobial treatment and timing being highly significant, especially in regard to the re-testing of previously treated patients by serological methods (see section Laboratory Investigations below). Even test manufacturers and laboratory services always qualify their test results by stating that their tests cannot exclude a diagnosis. The Chairman of the GDC appears to be ill-informed to make reference to ‘blood tests’ or to make denigrating judgements about patients.

Professor Faust’s apparent view that chronic Lyme disease patients and campaigners are ‘anti-scientist’ (and must therefore be irrational), and whose opinions and wishes are therefore of no credibility or value, are extremely disturbing. By his own words and actions, Professor Faust’s bias show that he should never have been a member of the GDC, let alone its Chairman. Providing and maintaining such a position of influence for someone whom the evidence suggests is contemptuous of patients and their views is a gross breach of public trust and their own guidelines by NICE.

On September 27th, 2017, VIRAS emailed NICE to complain about the premature statements in the media:

Dear xxxxxxxxxxxx,

re: Nursing Times article
Draft guidance drawn up to ‘spot and treat’ Lyme disease
25 SEPTEMBER, 2017 BY STEVE FORD

"Guidelines have been drawn up to provide “clear advice” to support clinicians in diagnosing and treating patients with Lyme disease, which is spread by ticks."

Whilst we appreciate that the draft guideline documentation is in the public domain and free for anyone to access and comment on, the ‘consultation’ is still in progress and the expected publication date of the official guideline is not until April 2018.

We think it is unethical that the Chair of the GDG, Dr Saul Faust is quoted in the above article.

“Professor Saul Faust, an expert in paediatric immunology and infectious diseases at Southampton University, who helped draw up the guidance, noted that Lyme disease can be difficult to diagnose.

“People can have common and unspecific symptoms, like a headache or fever, and they may not notice or remember a tick bite,” he said.
He added that the draft guidance would give health professionals “clear advice on how to diagnose if they think Lyme disease is a possibility”.

“We also recommend tests used for this illness meet certain laboratory criteria,” he said. “This is to make sure a potential diagnosis is based on clinically relevant and robust test results.”

There is no question that this article intends that the draft guidelines (or quoted opinions about what the guidelines include) should be implemented immediately by readers of the Nursing Times.

I would be grateful if you would confirm in writing at your earliest convenience, that the NICE Guidelines for Lyme disease are complete and that no significant changes will be made to the Final Guideline regardless of the substance or gravity of any matters raised in this pretence of a ‘consultation’ process.

The sooner that this ‘consultation’ exercise is exposed as a façade, the sooner we can get on with the challenge of instigating an anti-trust initiative.

Most of the members of VIRAS are severely ill and struggle to even take care of themselves. Yet they sacrifice what little time and energy they have to try and make things better for the tens of thousands of others who have and will, suffer for years and decades from Lyme disease.

I take a dim view of those that waste the time and energy of those who have already been failed so disgracefully by the UK medical establishment. Kindly do not waste any more of our time.

Peter Kemp MA
VIRAS

The reply which VIRAS received to this complaint is simply incredible:

Dear Peter,

Thanks for getting in touch about this.

I am sorry that you have been given the impression through the Nursing Times article that the recommendations on our website are final and not draft. As you might appreciate, we have limited influence over how organisations outside of NICE publicise our consultations; however, I can confirm that the guideline recommendations are in draft form and I would encourage your organisation to submit comments on the consultation if you feel it is appropriate to do so.

Following the end of consultation, the committee will review all stakeholder comments: comments received from registered stakeholders will be responded to and published on our website when the guideline is finalised. As an example, here is a link to a recent example of how stakeholder responses are addressed in a published guideline on faltering growth: https://www.nice.org.uk/guidance/ng75/documents/consultation-comments-and-responses
I hope this goes some way to addressing your concerns; but, if you have further comments or queries, please feel free to contact me directly.

Kind regards,
xxxxxx
xxxxxxx
Guidelines Commissioning Manager - Centre for Guidelines

The claim that, “we have limited influence over how organisations outside of NICE publicise our consultations”, beggars belief. The same statements about the guideline, which cannot do other than bias public and professional opinion as well as that of stakeholders, were published by NICE on its own website:

NICE sets out how to diagnose and treat Lyme disease | News and ...
25 Sep 2017 - Saul Faust, Professor of paediatric immunology and infectious diseases at the University of Southampton and chair of the guideline committee, said: “Lyme disease may be ... “Our draft guidance will give GPs and hospital doctors clear advice on how to diagnose if they think Lyme disease is a possibility”.

Furthermore, compounding this breach of public trust and NICE’s own rules are Professor Gillian Leng, Deputy Chief Executive Officer at NICE, and Professor Saul Faust, Chairman of the NICE Lyme disease GDC. In view of which, the claim of ‘limited influence’ is ludicrous because it suggests that neither of these NICE officers know or understand NICE’s own rules, and implies that their conduct could not be curtailed by NICE.

There can be little doubt that somebody at NICE authorised Professors Faust and Leng to participate in the propaganda campaign, promoting an unfinished guideline that Stakeholders had not even had a chance to read. The statements made in the media by Professors Faust and Leng pre-empted a farcical ‘consultation process’ which was rendered meaningless by these officers’ ill-considered, misleading and official endorsements of the draft guideline.
WE REPEAT: NICE's own 'Golden Rules':


"A3.2 Golden rules
"Don't speculate on the content of the guideline before it is finally published.
"Draft versions are just that: draft, not final; the content may change after consultation.
"Individuals and organisations can influence the outcome of the guideline only by submitting evidence that supports their point of view as part of the formal consultation process."

It is our opinion, that the large numbers of professionals, patients, public and stakeholders exposed to the misinformation which flooded the media, before stakeholders had even had the opportunity to read-through all the documents, as a "vital part of the quality-assurance and peer-review processes" has invalidated the entire process.

This damage cannot be undone. The guideline development committee must be dismissed in its entirety and the publication cancelled. We trust that these actions to follow promptly as the only legitimate course to avert harm to patients and their doctors, due to the wilful misconduct of NICE and affiliates.

**Laboratory investigations**

The NICE draft guideline states:

**Laboratory investigations**
1.2.12 Offer testing if there is a clinical suspicion of Lyme disease, using an enzyme-linked immunosorbent assay (ELISA) for Lyme disease that tests for both IgM and IgG antibodies and is based on C6 peptide or an equivalent purified or synthetic ViSE antigen.

It is serendipitous for PHE that the very detailed criteria specified in the NICE draft guideline for laboratory investigations, describe the exact same screening-test offered by PHE’s Lyme reference laboratory within the Rare and Imported Pathogens Laboratory (RIPL) at Porton Down, of which Dr Tim Brooks is Director. Dr Brooks is also a member of the NICE GDC.

A Lyme disease first-tier ELISA screening-test can be carried out at many suitable laboratories local to hospitals and GP surgeries. However, those that source testing at laboratories that use kits not meeting NICE specifications, will have to change their procedures if they wish to comply with NICE recommendations. As this change could prove costly, it might be expected that some will simply start sending all their test samples to RIPL. Samples requiring the more complex and expensive second-tier Western Blot tests are already sent to RIPL.
The minutes of the NICE committee meeting #4, held on 24/01/2017 states: (please note that the date on this document is wrong)

The Chair and a senior member of the Developer’s team noted that the following members would not participate in a part of the meeting:

Nick Beeching and Tim Brooks both have previously declared interests in diagnostic method; therefore, they were asked to act as experts to the group and to withdraw from the group for the discussion of recommendations.

Doctors Beeching and Brooks, were asked to act as experts to the group, but then withdrew from the group when it came to discussing recommendations on the ‘diagnostic method’. Whether this was sufficient to prevent competing interests influencing the GDC is unclear. PHE and its laboratory at RIPL, appear to have complete control over Lyme disease testing in England. Considering this, and the fact that the draft guideline maintains and perpetuates that control, practically guaranteeing PHE a virtual monopoly, there is a potential anti-trust issue involved. This hardly seems to be adequately addressed by the experts withdrawing from discussions on the topic for which their expertise was required.

Furthermore, the draft NICE guideline ‘Research Recommendation #3’ includes:

What is the current seroprevalence of Lyme disease-specific antibodies and other tick-borne infections (such as babesiosis, ehrlichiosis, anaplasmosis, bartonellosis or Q fever) in people in the UK when performed using UK-accredited assays (ELISA based on C6 antigen and immunoblot)?
This information is not currently available and is of high priority. (page 16)

More serendipity for PHE. Instead of recommending a valid study of disease incidence or prevalence which might be of actual value, NICE recommend a study of ‘seroprevalence’ - again specifying the exact serology provided by PHE at their laboratory at Porton Down. They even call this proposal ‘high priority’.

The information that NICE have called for is not in fact, ‘high priority’ at all. Compared to the urgent need for improvements in diverse aspects of direct patient care and public safety, this project is of relatively low priority. All the epidemiology that is actually required at the present time, is recognition of the fact that Lyme disease in the UK is not being monitored or managed effectively. Seroprevalence cannot provide information about either incidence or prevalence of Lyme disease, it can only provide information about ‘antibodies’ in the population. In Lyme disease, research has repeatedly shown that the presence of antibodies is minimally related to either infection status or disease. E.g., in a study of 90 patients, Tylewska-Wierzbanowska and Chmielewski concluded that:

There is no correlation between the level of antibodies (ELISA), the number of protein bands (Western blot) and the presence of spirochetes in body fluids (culture and PCR), indicating that in addition to serological testing the use of PCR and cultivation in the diagnosis of Lyme borreliosis should be recommended.

Therefore, other than complying to maintain PHE’s complete control with this ‘seroprevalence’ project, the information it would provide is of no practical use or value to anyone other than Oxford Immunotec, who provide the C6 test to PHE.

There is no question that PHE have firm control over testing for Lyme disease in England. That control means that the vast majority of patients and doctors have no choices. PHE’s virtual monopoly on testing is secure and NICE have made highly specific recommendations which virtually guarantee that this lack of choice for customers is maintained.

Of equal concern is that the draft guideline contains egregiously misleading information about the tests it specifies. This must raise questions regarding the credibility of including ‘experts’ in the GDC, for consulting on diagnostic methods, when the draft guideline does not even provide valid figures for Sensitivity and Specificity. This is information which physicians require to inform their clinical judgements. Instead of providing this information, the draft guideline actually misleads doctors on the subject. Page 20 of the draft guideline states:

**Laboratory investigations**
12 Why the committee made recommendations 1.2.11 to 1.2.22
If the initial ELISA test is positive or equivocal, the committee agreed that an immunoblot test should be offered to confirm diagnosis. The evidence suggested that the combination of initial IgM and IgG ELISA and confirmatory IgM and IgG immunoblot testing had a high sensitivity and specificity, particularly for Lyme arthritis, Lyme carditis and acrodermatitis chronica atrophicans.

**PLEASE NOTE:**
- **Lyme arthritis** is rare with European strains of Lyme borreliosis and presents in less than 1% of cases, according to a PHE colleague of Dr Brooks – Dr Matthew Dryden.
- **Lyme carditis** is rare and presents in only 1% of UK Lyme cases according to Dr Dryden
- **Acrodermatitis chronica atrophicans** is rare in the UK, and occurs in less than 1% according to Dr Dryden
(Dr Dryden data: [https://www.rcplondon.ac.uk/file/5902/download?token=7RdaXVeP](https://www.rcplondon.ac.uk/file/5902/download?token=7RdaXVeP))

Although important to the small minority of Lyme disease patients who develop these conditions, more relevant to the vast majority (>97%), are test data for those that do not present with these conditions. The sophistry of amalgamating sensitivity data from common presentations affecting more than 97%, with the rare conditions affecting less than 3% in the UK, appears to have been done for...
the purpose of making false and misleading claims of ‘high sensitivity and specificity’.

Therefore the following pertains to the contribution of NICE on the ‘diagnostic method’ for the vast majority of patients, and the claim that:

“The evidence suggested that the combination of initial IgM and IgG ELISA and confirmatory IgM and IgG immunoblot testing had a high sensitivity and specificity”


“The C6 Lyme ELISA™ Kit was evaluated in comparison with the Two-Tier protocol on the Lyme patient group. Overall, the C6 Lyme ELISA™ detected 74.9% of the Lyme patients, compared with 55.3% found positive by the Two-Tier protocol”

<table>
<thead>
<tr>
<th>Table 3. Sensitivity by Sample Definition Criteria</th>
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<tr>
<td>Immunetics® C6 Lyme ELISA™ Kit</td>
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<tr>
<td>--------------------------------</td>
</tr>
<tr>
<td>74.9%</td>
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<td>Two-tier ELISA + WB Kits</td>
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As shown in the table published by Immunetics, the ELISA test applied to patients who were proved positive for infection by gold-standard testing with culture, the SENSITIVITY was only 65%. This means that 35 out of 100 true cases of Lyme disease would get a false-negative test result with the C6 ELISA, potentially leading to the patient being denied a diagnosis and treatment.

The data also shows that when a screening-test ELISA was followed by a Western Blot, the SENSITIVITY was only 41% for patients who were positive by culture. This means that 59 out of 100 true cases of Lyme disease would predictably get a false-negative result with a 2-tier test.

Furthermore, the NICE draft guideline is absolutely specific that ONLY tests which detect VISE peptide antibodies (e.g., C6) should be used as a screening-test. This automatically precludes test kits which use a Whole Cell Sonicate (WCA) ELISA test. These can detect multiple relevant antibodies for multiple Borrelia burgdorferi proteins compared to the single section of a single protein with the C6 only test.

Whole Cell Sonicate ELISA preparations actually have an average of 7% higher sensitivity compared to the C6 ELISA test recommended by NICE. This is
according to data produced by the same source as other data published by *Immunetics*. This makes the exclusionary recommendation by NICE for using only a C6 based screening-test inexplicable.

All of the Borrelia burgdorferi ELISA tests have such poor sensitivity that in most circumstances, a 7% improved detection rate would be emphasised as a definite advantage. In practice it could help 7 more infected patients per hundred in getting a proper diagnosis of their infection. This makes the NICE recommendation for laboratory investigations using only a VISE peptide inexplicable.

The Embers *et al* data shown in the APPENDIX A, shows that in their experiments with 10 Lyme disease infected macaque monkeys, detection of C6 antibodies could never achieve sensitivity of more than 80% at any given time-point. Furthermore, over time the sensitivity dropped even further. An additional two of the untreated monkeys became seronegative by 28 and 35 weeks post-infection, and four of the antibiotic treated monkeys became seronegative by ~26 to 33 weeks. This is despite the fact that in eight of the ten monkeys, other Borrelia burgdorferi antibodies remained at seropositive levels throughout the trial, and that every single monkey was shown to remain infected at the end of the experiment.

**This suggests that at 40 weeks after infection, the SENSITIVITY of a C6 based SCREENING-TEST could be as low as 40% in untreated patients. In patients that have taken antibiotics between the time of infection and testing, the SENSITIVITY of the C6 at 40 weeks post-infection, could be 0% (ZERO %).**

In 2018 VIRAS conducted a survey which included 117 UK Lyme disease patients. **59% of these patients were not tested until more than a year after the onset of symptoms.** The data for all 330 respondents, which included 116 patients from the USA (where Lyme disease testing and diagnosis is much more common), also showed that 59% of patients were not tested until more than a year after the onset of symptoms. It is also notable that **38% of respondents had taken antibiotics after the onset of symptoms but before getting tested for Lyme disease**, potentially rendering the C6 test completely useless for them. ([http://counsellingme.com/VIRAS/LymeTestDelayFinal.pdf](http://counsellingme.com/VIRAS/LymeTestDelayFinal.pdf))

The *Immunetics* figures for sensitivity show that doctors should not be mislead by NICE making the false claim that “the combination of initial IgM and IgG ELISA and confirmatory IgM and IgG immunoblot testing had a high sensitivity and specificity”. These tests are intended to help doctors in diagnosing an infection that if left untreated can cause serious illness and injury. Instead of NICE providing further useful advice to these doctors and their patients, they have misled them.

The *Immunetics* figures for the C6 for ‘All Lyme disease patients’ may appear reasonable and if they were accurate, in some circumstances they could be, even with sensitivity of only 65%. However, this test is used by PHE as a
SCREENING-TEST. As such it has one very simple requirement: **it must detect \~100% of true cases.**

A screening-test must NOT eliminate any true cases or instead of helping patients and doctors, it increases the risk of a non-diagnosis or delayed diagnosis and deprive the patient of necessary and urgent treatment. When doctors order a screening-test, they might not necessarily believe the result if it is positive – that is why screening-tests have a follow-up test for confirmation. But when a screening-test is negative, a doctor is entitled to be reasonably confident that they have successfully eliminated a potential diagnosis from their investigations of a patient’s illness. This is especially so, when doctors have been assured by NICE that the test which they ordered has, **“high sensitivity and specificity”**. It is unacceptable that instead of providing emphatic warnings to doctors about the poor sensitivity of this test, NICE have instead, misleadingly exaggerated its accuracy.

‘High sensitivity’ for a credible screening-test would be 99%. Even that might not be considered acceptable to the one person in one hundred infected patients who gets a false-negative test result. That person might end-up with a misdiagnosis, or have to wait for three months for further tests while the infection increases exponentially, putting the patient not only at risk of worse illness, but progressing to a point where the infection could become much more difficult to treat.

The test manufacturer’s own data roundly contradicts the claims made by NICE, and that does not even include figures produced within the UK. Applied to UK strains of borrelia, the sensitivity of these tests is unknown, but it could be even worse.

It appears that PHE has a virtual monopoly on Lyme disease diagnostic testing in England, despite the fact that its Lyme reference laboratory within R IPL, is not a United Kingdom Accreditation Service (UKAS) accredited laboratory. The NICE draft guideline has provided recommendations with curiously specific and unjustifiable criteria, which happen to exactly match the tests provided by PHE. NICE have promoted these tests with false claims about their accuracy. All of which perpetuates the lack of choice for physicians and patients and secures the exclusivity of Lyme disease testing in England for PHE, despite the fact that the service that they offer is hopelessly unreliable.

The NICE recommendations do not show any sense of commitment to identifying infected patients. This is especially evident regarding patients who may have been misdiagnosed with some other illness. There is good reason why Lyme disease is sometimes called ‘The New Great Imitator’, where syphilis was the original ‘Great Imitator’. Like syphilis, Lyme disease can infect and cause pathology in any organ of the body, producing a range of symptoms which can be mistaken for numerous other conditions. The NICE draft guideline makes not one single reference to this long-recognised fact.
The draft only specifies the use of insensitive tests while misrepresenting their reliability – for newly presenting patients. Patients over the past 30+ years who were not investigated and denied a diagnosis and treatment because they never had a blood test, or had a negative blood-test, are not even considered, even though some of those chronically infected patients will have suffered decades of ill health. These patients must have been diagnosed with something. But NICE have evaded this entire issue.

Even for new patients, the insensitive tests will predictably lead to a substantial proportion of infected patients getting a delayed diagnosis and others not getting diagnosed at all. NICE claim to produce ‘evidence-based’ guidelines. In the case of Lyme disease they have proffered a draft guideline based on smoke and mirrors and produced by a committee whose Chair evidently has a negative view of patients, and ‘experts’ who apparently believe that a laboratory test Sensitivity of 41% can be represented as “high sensitivity” with no qualifications.

There is no excuse for deceiving doctors, patients, the public and the government about the unreliability of serological tests for Lyme disease. Objective facts do not require propaganda. Sensitivity figures are stated as a percentage and do not require interpretation or exaggeration. A credible Stakeholder Consultation should not be pre-empted by publication of official endorsements for a draft that is entirely unfit for purpose. A Guideline Development Committee should be unbiased and objective. The Guideline Committee and draft NICE guideline for Lyme disease fails in regard to all these requirements and more.

We request that the publication of the Guidance is cancelled and the GDC discharged.

Peter Kemp MA
for VIRAS

Embers et al experiment with Lyme infected macaque monkeys shows that two of the ten monkeys never registered a C6 antibody response (cyan lines in the chart below). An additional two of the untreated monkeys C6 levels became seronegative by 28 and 35 weeks post-infection. Four of the antibiotic treated monkeys became seronegative by ~26 to 33 weeks. This is despite the fact that in eight of the ten monkeys, other antibodies remained at seropositive levels throughout the trial, and that every single monkey was shown by other detection methods to remain infected at the end of the experiment.

This suggests that at 40 weeks after infection, the SENSITIVITY of a C6 based SCREENING-TEST could be as low as 40% in untreated and still infected patients. In infected patients that have had antibiotics between the time of infection and testing, the SENSITIVITY of the C6 at >40 weeks could be 0%.

In the chart below, the ‘TREATED’ group received four weeks of Doxycycline from week 16 at a dosage producing levels equivalent to that considered effective for treating Lyme disease in humans. Original image available at: http://journals.plos.org/plosone/article/figure/image?download&size=original&id=info:doi/10.1371/journal.pone.0189071.g003

VIRAS analysis of the Embers et al study is available here: http://counsellingme.com/VIRAS/Embers.html
Chart from Embers et al, 2017, showing levels of 5 Lyme disease antibodies measured for up to 70 weeks post infection. The cyan line, which is emphasized for visibility, is the C6 peptide of VISE.
APPENDIX B
Evidence that Stakeholder groups invited their members to provide comments on the Draft NICE Guideline, in good faith that these would form part of a *legitimate and authentic* Guideline development procedure:

Royal College of Nursing:

**NICE Draft Guideline Consultation for Lyme Disease**

**Get Involved/Consultations/**
NICE Draft Guideline Consultation for Lyme Disease
This draft guideline and its supporting evidence are now out for consultation and we hope that you will submit comments on this as it is a valuable opportunity to ensure that the guideline considers issues important to our members.
British Infection Association
(https://www.britishinfection.org/professional-affairs/consultations/ Accessed Feb 1, 2018)

Consultations

This page contains details of ongoing consultations where the opinion and input of BIA members is sought.

If you are commenting on any consultation as an individual or on behalf of another organisation such as RCPPath and you belong to the BIA please do copy your form to BIA@Hartleytaylor.co.uk. Responders will receive a BIA Guideline Review Support Certificate which can be used to self-credit up to 10 CPD points for commenting on a consultation and we will incorporate your individual/other organisation response into the response of the BIA.

Recently published consultations are listed below

- Use of organs from Hepatitis C virusemic donors in Hepatitis C negative recipients. Please respond by Apr 4th, 2nd February 2018
- UK BMI B2: Investigation of specimens for screening for MRSA. Please respond by 5pm, 2nd February 2018
- PRSB survey on document nomenclature. Please respond by 2pm, 2nd February 2018

Recently published consultations are listed below

The following consultations are currently open:

- NICE QI on syphilis test. Consultation closed 19 January 2018. Expected publication: 18 May 2018
- UK NICE consultation: antenatal screening for syphilis
- NICE hepatitis B consultation closed 20/12/21. Review process due to be completed March/April 2018.

Topic engagement exercises: NICE emergency and acute medical care QI. Consultation closed 01/12/17. Click for BIA comments.

- UK NICE consultation: guidance on the development, production and review of information to support screening. Consultation closed 19/11/17. We hope to publish responses and an updated version of the guidance within 12 weeks of the conclusion of the consultation.

NICE draft guideline on Lyme disease. Consultation closed 30/11/17. Expected publication date: Spring 2018. Click for BIA comments.

NICE QI Consultation: Sepsis. Published September 2017. Click for BIA comments on Sepsis QI.