



PRESS RELEASE – NO EMBARGO

Dear Editor,

Patients rebel against NICE Guideline

Lyme disease patients are protesting about the way that the National Institute for Clinical and Care Excellence (NICE) are producing their guideline for this potentially devastating infection, which is usually caught from bite of a tick.

The final NICE guideline is expected on April 4th 2018. The draft version for Stakeholder review was published on September 25th 2017. VIRAS are registered stakeholders for the Lyme disease guideline.

The patient group *VIRAS* have complained to Sir Andrew Dillon, Chief Executive of NICE, raising concerns about the quality and objectivity of the guideline they are preparing, and numerous breaches of NICE protocols and standards. *VIRAS* are calling for publication of the guideline to be cancelled.

(http://counsellingme.com/VIRAS/VIRAS_complaint_to_NICE.pdf)

Patients are petitioning the Secretary of State for Health, with over four thousand signatures, calling for postponement of the guideline and for NICE to engage with patients and experienced doctors to ensure that all Lyme disease patients are covered by the guideline and their rights respected.

(<https://www.change.org/p/secretary-of-state-for-health-of-the-united-kingdom-petition-to-the-secretary-of-state-for-health-uk-re-nice-guidelines-on-lyme-disease?>)

In January an All Party Parliamentary Group (APPG) for Lyme disease, co-chaired by the Rt Hon Simon Hoare, MP and the Rt Hon Michelle Donelon, MP, heard statements from ten UK Lyme disease patient groups summarising their concerns about Lyme disease. These included calls for better awareness, testing and treatment of the illness. *VIRAS* pointed out that meetings held by the WHO and NATO in 1993 warned of serious problems with diagnostic testing which have never been addressed. The NICE draft guideline ignores these issues and does not warn doctors about the serious flaws in Lyme disease testing.

(<https://publications.parliament.uk/pa/cm/cmllparty/170502/lyme-disease.htm>)

Please see below for: Patient's experiences and what the draft NICE guideline means to them

The main complaints the groups are raising are:

1/ NICE abandon science, for spin.

Six months before the guideline was due to be complete or published, NICE broke numerous rules including their own 'Golden rules', governing the guideline development process, by running an orchestrated media campaign,

misrepresenting the draft guideline, disenfranchising registered Stakeholders and breaching accepted standards of academic and scientific publishing.

2/ Junk in, junk out

The draft guideline makes treatment recommendations based on only 3 clinical trials which were all found to provide 'low' or 'very low' quality evidence, much of which is irrelevant to thousands of UK patients. Therefore the guideline is not 'evidence based'. There is no good quality data to produce a reliable NICE guideline for UK patients. NICE acknowledge this lack of evidence and have even detailed a whole raft of 'research recommendations'. These focus on the most basic factors relating to Lyme disease in the UK. Yet even with only poor evidence, NICE still went ahead with producing a guideline which VIRAS consider substandard. This might explain why NICE thought it necessary to stoop to employing an extraordinary degree of spin, in an attempt to pass-off a second-rate guideline to patients and doctors even though it does not remotely meet NICE's own usual critical standards.

3/ Discrimination

The draft guideline does not provide guidance for managing patients:

- misdiagnosed with other illnesses, e.g., M.E., MS, Parkinson's, etc.
- patients with chronic infection who might need more than 6 weeks treatment
- patients who do not have a positive lab test even though NHS tests are known to miss up to 60% of infected patients
- patients with common Lyme disease co-infections, which can greatly complicate the illness and its treatment.

NICE have actively discriminated against Lyme disease cases that meet these criteria, which could amount to tens of thousands of patients.

4/ Misleading doctors about laboratory tests

The draft makes unjustifiable recommendations for serology tests, and misleads patients and doctors about their accuracy. NICE claim that Sensitivity of 41% is 'high sensitivity' when any doctor or scientist would consider this 'very low sensitivity'. E.g., serology tests for HIV have sensitivity = >99%. The misleading claims and irrational recommendations help to keep Public Health England in full control of testing for Lyme disease in England, leaving patients and doctors with no practical alternative choices.

For complete documentary evidence of the main issues and numerous other failings of the NICE procedures, please see:

http://counsellingme.com/VIRAS/VIRAS_complaint_to_NICE.pdf

<https://www.change.org/p/secretary-of-state-for-health-of-the-united-kingdom-petition-to-the-secretary-of-state-for-health-uk-re-nice-guidelines-on-lyme-disease>

1/ NICE ABANDON SCIENCE FOR SPIN –brief details

- On September 25th 2017 the National Institute for Clinical and Care Excellence (NICE) published their draft guideline for Lyme disease and at the same time conducted a coordinated media campaign promoting the guideline, breaking NICE's own 'Golden Rules' as well as accepted standards for academic

publication. The final version of the guideline will not be ready until April 4th 2018.

- Professor Gillian Leng, Deputy Chief Executive of NICE and Professor Saul Faust, Chairman of the Guideline Development Committee, were quoted in numerous newspapers, online journals, Twitter and Facebook, including NICE's own web site (<https://www.nice.org.uk/news/article/nice-sets-out-how-to-diagnose-and-treat-lyme-disease>), implying that the draft was final and ready for use while making false claims about its contents.
- NICE state: "A3.2 Golden rules", "Don't speculate on the content of the guideline before it is finally published", "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." (<https://www.nice.org.uk/process/pmg6/resources/the-guidelines-manual-appendix-a-agreements-and-advice-for-guideline-development-group-members-pdf-3304370657221>)
- NICE further state: "In order to provide the environment described above, NICE expects GDG [Guideline development group] 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".
- Before Stakeholder Groups (which NICE describe as 'peer-reviewers') had even had a chance to read the draft version, any comments, criticisms or corrections they might have provided, had been effectively pre-empted and marginalised by NICE's propaganda coup.
- Sage Publications state that: "Peer Review is the most valid form of research evaluation and it is a cornerstone of the process of bringing academic research to publication", and that it, "ensures the integrity of the publishing process and the scholarly record". (<https://uk.sagepub.com/en-gb/eur/purpose-of-peer-review>)
- NICE have side-stepped the peer-review process in breach of their own rules, and have misled the media, doctors, patients, the public and the government as to the contents and accuracy of their advice about Lyme disease.
- In breach of their own rules and procedures, NICE have degraded Stakeholders (peer-reviewers) and have tampered with a sitting NICE Guideline Committee, in a manner likely to exert undue influence in contravention of their own Charter.

2/ Junk in, junk out – brief details

If a clinical guideline is based on junk research then the guideline itself is going to be junk. When NICE realised the dearth of evidence available, and the low quality of that which they included, they could have stopped the development of the guideline. Alternatively, they could have called for alternative sources of evidence, i.e., the clinical experience of USA doctors who have treated many thousands of patients. Or they could have produced an open-ended guideline, with clearly tentative 'suggestions', allowing doctors to use their skills and exercise discretion. They did not. They produced a draft with unjustifiable restrictions on treatment and false claims about laboratory tests. For substantiation of this assertion, please see the VIRAS letter to Sir Andrew Dillon: (http://counsellingme.com/VIRAS/VIRAS_complaint_to_NICE.pdf)

3/ Discrimination – brief details

The CDC have admitted that the true incidence of Lyme disease in the USA is probably 10 to 12 times higher than 'official' figures. This is in a country where doctors and the public are much more aware of Lyme than in the UK. It is ridiculous for Public Health England to claim that the true UK incidence is only 2 to 3 times higher than officially reported cases

(<http://counsellingme.com/VIRAS/UKLymeIncidence2.pdf>). Therefore it is logical to conclude that for decades the UK has been accumulating thousands of undiagnosed and untreated patients per year, with an unknown proportion of these patients becoming chronically and severely ill. These patients must have been (mis)diagnosed with something, and many will have been misdiagnosed with M.E or CFS which can have very similar complex and varied symptoms. Yet M.E. patients whose symptoms and history strongly suggest Lyme, have been specifically excluded by the draft guideline. This is active discrimination against Lyme disease patients who have never been properly investigated and are misdiagnosed.

A tick bite carries the risk of transmitting at least 10 serious infections to humans. Some doctors in the USA are finding that treatment of Lyme disease is hampered by common co-infections and recommend that these must also be addressed in Lyme disease patients but the NICE draft guideline discriminates against these patients.

(<https://www.nytimes.com/roomfordebate/2013/08/11/deconstructing-lyme-disease/to-treat-lyme-disease-focus-on-the-co-infections>). Nicolson remarks "Lyme Disease patients are at risk for a variety of opportunistic infections, including other bacterial infections, viral and fungal infections. These can complicate diagnosis and treatment, but they may be principally a problem in the late persistent phase of the disease. Late stage patients with neurological manifestations, meningitis, encephalitis, peripheral neuropathy and other signs and symptoms may have complicated co-infections that are neither recognized nor treated by their physicians." (<http://www.prohealth.com/library/showarticle.cfm?libid=8026>)

The draft guideline imposes irrational restrictions on the treatment of Lyme disease. This is not supported by research or the clinical recommendations of the doctors most experienced in treating Lyme disease. All Infectious disease doctors treat chronic infections with individualised care. Bone infections need 6 weeks of intravenous antibiotics, but if the patient is a diabetic this can sometimes increase to 12 weeks followed by oral doxycycline plus co-trimoxazole for months, based on the patient's clinical response. The NICE draft guideline should state that treating Lyme disease needs a similar approach. This could start with a three month trial of doxycycline or co-trimoxazole, extended as necessary according to the patient's clinical response. Clinical guidance for dermatology is to treat for a 3 to 6 month period for 'bad acne' with doxycycline or sometimes co trimoxazole, as precedent to considering the more toxic and more expensive acne drugs like roaccutane. Recommended treatment for Tuberculosis is for 6 or 9 months with high dose combination antibiotics. If a 14 day or longer break in treatment occurs, the whole treatment regime must start again from scratch. Patients that are re-infected can repeat this treatment and patients that relapse or do not respond can have alternative combinations and repeated and/or extended phases of treatment. Chronic Q fever is difficult to

treat and can require up to four years of treatment with doxycycline and [quinolones](#) or doxycycline with hydroxychloroquine.

The International Lyme and Associated Diseases Society (ILADS) have compiled a list of over 700 peer reviewed articles that support the evidence of persistence of Lyme and other tick-borne diseases. (http://www.ilads.org/ilads_news/wp-content/uploads/2015/09/EvidenceofPersistence-V2.pdf)

4/ Misleading doctors about laboratory tests – brief details

(taken from http://counsellingme.com/VIRAS/VIRAS_complaint_to_NICE.pdf)

The draft NICE guideline makes the following false claim: “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”

In contradiction of this false and misleading claim, suppliers of the *Immunetics* C6 Lyme ELISA IgM/IgG ELISA test kit, (as used by the NHS and PHE), provide Sensitivity figures for various criteria:

(http://www.oxfordimmunotec.com/international/wp-content/uploads/sites/3/CF-E601-807_Manual.pdf)

“The C6 Lyme ELISA™ Kit was evaluated in comparison with the Two-Tier protocol on the “All Lyme disease”, patient group. Overall, the C6 Lyme ELISA™ (NOTE: this is the ‘screening test’) detected 74.9% of the Lyme patients, compared with 55.3% found positive by the Two-Tier protocol” When tested against patients who were positive for Lyme disease by Culture methods, The ELISA detected only 65% of cases and the two-tier test only 41% of cases.

By any rational measure, these sensitivity figures are terrible. A screening-test has one very simple requirement, it MUST detect 100% of cases. The test manufacturer’s own figures show that the NHS screening test misses 35% of cases and combined with the 2nd tier Western Blot, 6 out of every ten cases of Lyme disease are missed. That figure does not even include negative results due to low antibodies following antibiotics, immune suppression – known to be caused by Lyme disease and species/strains not detected by the tests.

NICE have misled doctors and patients about testing.

Patient’s experiences and what the draft NICE guideline means to them

(For patient’s contact details, photos etc, please get in touch with VIRAS)

Alice Reeve of Cheltenham, has a degree in Australian Studies and a Masters in Business Administration, which she says she cannot use due to being ill since her early twenties. Alice wrote:

“I got bitten by a tick in my own garden in 1999 and became ill afterwards. I was misdiagnosed with M.E. and Fibromyalgia and ran support groups for people with those illnesses. I think the NICE guidelines should do something to help

patients who have been misdiagnosed. By the time I heard about Lyme disease and got a positive test from a lab in Germany, I had gone for 17 years without treatment. Because I have inflammatory arthritis, I got eight weeks of antibiotics which is more than most people get for Lyme, and though the treatment helped a lot, I still have very bad symptoms. I need surgery but the hospital have refused because they are worried about infection. The NICE guideline does not recommend anything for patients with complicated illness like mine."

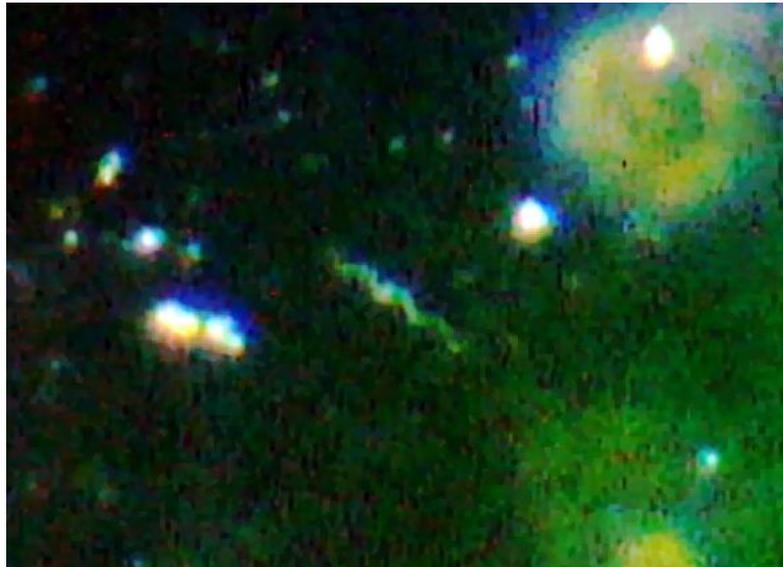
[>VIRAS comment on Alice's experience: UK prevalence of M.E. or CFS is estimated at 256,000, and full recovery occurs in only ~10%. (<https://www.nice.org.uk/guidance/cg53/evidence>). If just 20% of M.E. or CFS patients were actually misdiagnosed cases of Lyme disease, as happened to Alice, that could be 50,000 cases of Lyme disease in the UK requiring diagnosis and treatment.

>Dr Hugh Derham (2014) in Australia tested 300 of his ME, CFS and FM patients and found that 95% were positive for Lyme. (<http://www.perthnow.com.au/news/western-australia/lyme-disease-a-ticking-timebomb-that-health-authorities-say-does-not-exist/story-fnhocxo3-1226886911487>)

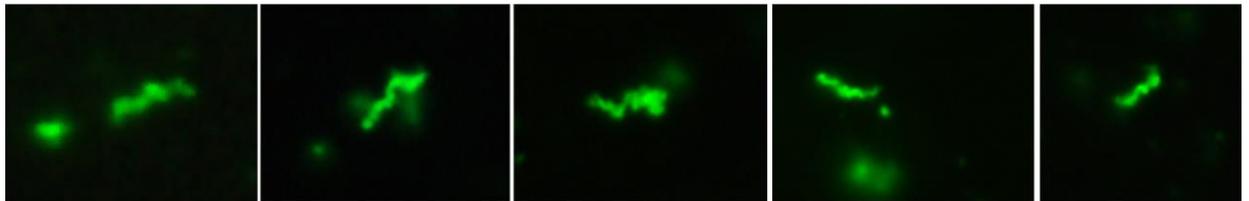
>Dr Samuel Shor (2011) in the USA reviewed 210 patients and found that a, "potentially substantial proportion of patients with what would otherwise be consistent with internationally case defined CFS [...] actually have a perpetuation of their symptoms driven by a persistent infection by *Borrelia burgdorferi*." (<http://iacfsme.org/ME-CFS-Primer-Education/Bulletins/BulletinRelatedPages3/RETROSPECTIVE-ANALYSIS-OF-A-COHORT-OF-INTERNATIONALA.aspx>)

>Dr. Kenny De Meirleir (2014) in a presentation to the Belgium Senate, observed that 95% of Chronic Fatigue Syndrome and ME (Fukuda & Canadian criteria) were cases of Late Stage Lyme Disease. 95% having had positive *Borrelia burgdorferi* LTT tests. (http://nelelijnen.be/images/nele_afbeeldingen/laatste_nieuws/2014/Presentatie_De_Meirleir.ppt) The NICE draft guideline actively discriminates against Lyme disease patients misdiagnosed with M.E. or CFS by specifically excluding them from the Scope of the guideline.

Richard Brooke-Powell aged 70, of Royston, Herts, became ill after a tick bite in 1984. Following an appointment with an Infectious Disease consultant in 2013 he writes, "I tested negative for Lyme but positive for Bartonella and Brucellosis, which are co-infections of Lyme disease. The hospital asked my GP to refer me to a Neurologist but the GP, who I had never seen before, sent me to psychiatrist. The NICE guidelines won't help me get treated for Lyme or the co-infections even though my symptoms are beyond terrible."



A spirochaete cultured from Richard's blood.
Video of same, available at: <https://youtu.be/BgIRmw0Zo9s>



Spirochaetes cultured from Richard's blood and stained with fluorescent antibody for *Borrelia burgdorferi* (Lyme) spirochaetes. Micrographs by Peter Kemp

"My name is Claire Sidwell. I was fit and healthy and studying accounting prior to a tick bite in Worcester in April 2015. The bullseye rash was misdiagnosed as eczema, dermatitis, psoriasis. I had to get a second opinion/locum to agree to do a test for Lyme disease as, "we don't have ticks in Worcester". The NHS C6 ELISA test was positive, NHS western blot negative.

"I was Referred to rheumatology, neurology, gynecology, had two operations and multiple infections. I got a grant for a private test at an accredited lab in Germany, result positive but not accepted by the NHS. Result, I must have fibromyalgia take sleeping tablets and pain killers. Followed by another test positive for Lyme from an accredited lab in the USA - also not accepted by the NHS.

"I've been told it's all in my head and referred to mental health. Result of that referral: I do not have a mental health problem! But I got a dustbin diagnosis of 'CFS/ME'.

"Unable to study. Unable to work. Unable to raise my family. Unable to afford private treatment. Left to rot."

[>VIRAS comment: Claire's experience is not unusual but in one respect at least, the draft NICE guideline might have prevented her being misdiagnosed and "left to rot". The draft states: "infected ticks are found

throughout the UK and Ireland". This might stop GP's from making silly claims like, "we don't have ticks in Worcester". The draft also reaffirms what has been established for decades: that an EM rash is diagnostic for Lyme disease and should be immediately treated with antibiotics.

>Unfortunately, Claire's EM (bullseye) rash was not recognised and in fact 75% of cases do not have any documented rash at all. So even with the draft NICE guideline, Claire's situation could be exactly the same as it is today, not diagnosed or treated, but misdiagnosed and 'left to rot'.

>This is because without a diagnosable EM rash, the guideline ONLY recommends diagnosis and treatment with a positive NHS blood test, even though these tests are only positive in as few as 4 out of ten infected patients. The draft guideline does not warn about the appalling inaccuracy of NHS laboratory tests – in fact the draft guideline actually misleads doctors or patients about it, by claiming that their tests have "high sensitivity".

>Because the draft NICE guideline only recommends and accepts NHS tests, Claire's positive tests from accredited laboratories in Germany and the USA would also be dismissed.

>Even if Claire's EM rash had been treated at the earliest opportunity, there is abundant evidence that treatment of EM rash fails in a substantial number of patients. When this happens, the NICE guideline steers patients like Claire towards one inevitable outcome: denial of prolonged treatment and management for their complicated Lyme disease, and misdiagnosis with M.E. or 'CFS', or as Claire describes it: "a dustbin diagnosis".]

Karen Caldwell writes:

"Prior to tick bite in July 2015, I was a fit active 39yr old. I found a tick embedded in my stomach and my husband removed it with a tweezer. About 2/3 weeks later I started to develop flu like symptoms, stiff sore neck and general aches and pains. After weeks of going back and forth to my Dr, I realised that all my symptoms were since my tick bite and were all classic lyme disease symptoms. I told my GP that I had lyme disease. They did a lyme disease test but it came back negative. **I was told by my GP that I definitely didnt have lyme disease as the test was negative. I have since found out that there is a actual disclaimer on the test about that they shouldnt rule out lyme disease as the test is not very accurate in early lyme as it can take several weeks for the body to produce enough antibodies to create a positive result.** I have no idea why my Dr told me I definitely didn't have Lyme disease when there is a disclaimer telling them not to do that.

"At the end of September 2015 my symptoms worsened as the disease spread throughout my body including my brain and spine. I was unable to eat, sleep, lots of twitching and had weakness in my limbs, my brain and spine was

inflamed and I had a lot of pain. I was also unable to work for 6 months. I contacted the Lyme disease clinic in Winchester run by Dr Dryden. They had a 8 week wait but the female Dr working under Dr Dryden(an amazing brilliant Dr). She was so concerned about the progression of my symptoms that she contacted my GP to get them to immediately start me on medication. My GP didn't immediately start medication and did not follow the Dr recommendation. They only started treatment after speaking to the local microbiologist (who is not a Lyme Specialist). I saw the Female Dr (Dr C) in December 2015, she was a 100% certain that I had Lyme disease and wrote to my GP to start a antibiotic treatment protocol. I was initially put on a 6/8 week course of antibiotics and improved. I recieved one further 6 week treatment. **Dr C wanted to continue treatment long term as I had improved. My GP spoke to Dr Dryden and he said I had enough treatment and that I shouldn't have anymore. Bypassing the advise of Dr C.**

"From my understanding of the Winchester clinic is that Dr Dryden brought in Dr C because of her knowledge and experience of Lyme disease but wouldn't allow her to continue treatment of patients who clearly improved with treatment. Dr Dryden is a microbiologist and does not see and speak to patients on a day to day basis. I wouldnt be happy referring to Dr Dryden as a lyme disease specialist as I don't think he listens to his patients and stops vital treatment. I never once spoke to him, yet he made decisions on my treatment. I spent the following 6 months self treating until I found a specialist based in Dublin. I have been undergoing treatment for over a year and am about 75 % recovered but am struggling to get my complete health back. I tested positive under Armin but negative under NHS. **I am very dissapointed and saddened my the lack of treatment/knowledge of Lyme Disease under the NHS. They insist there test are accurate, when clearly they are not. I was denied vital treatment early on in the illness and I might never recover from this.** I complained about my treatment directly to my GP and wrote a letter. Within weeks of this letter I had been transfered to anothe GP without any explanation. I have been treated like a lepur ever since. I found this very distressing as I hardly ever go to the Dr.

"I am a proud hardworking member of society. I have worked hard all my life and have never been a burden to society. I felt like a number not an individual. It is very isolating not having the support and help of your GP. I would like to see GP improve their knowledge on Lyme disease including completing the free online course available. When I last checked it was only about 5% of all GP completed the course. Also people like infectious disease and Neurologist consultants should also complete the test as they are also involved in the whole process, and it is amazing how little knowledge on Lyme disease they have. Also Dr's who want to continue treating their patients should be allowed to do so and not fear persecution from the GMC. If they do want to continue long term treatment currently they face loosing their licience, so effectively they have their hands tied behind their backs. If a patient is aware of the risks and they want to continue treatment. They should not be denied treatment. Lyme disease is a debilitating illness which hijacks someones life both physically and financially. It is also very lonely and you don't feel supported. The one organisation which you

look for help and guidance, is the one organisation that lets you down namely the NHS.

A very similar thing happened to a patient in the same surgery. He hasn't been able to travel abroad for treatment so he is a lot worse than me. He got bit a year before me but last time I spoke to him he hadn't yet been able to recover enough to return to work, which has put a burden on his family's finances.

[>VIRAS comment on Karen's experience:

Karen recognised that her symptoms developed following a tick bite, which suggested Lyme disease. Her symptoms and risk factor (tick bite) have been recognised for decades by all medical authorities and guidelines as suggestive of Lyme disease. Karen did the right thing, and so did her GP initially, in ordering a blood test – although some GPs familiar with Lyme and aware of what a dangerous infection it can be, might have prescribed antibiotic treatment immediately, without waiting for test results. Where the GP was mistaken, was in telling Karen that she definitely does not have Lyme disease, because the test result was negative.

>This same mistake, which has obstructed the diagnosis and treatment of many Lyme disease patients, is actualised and perpetuated in the draft NICE guideline. The draft claims that NHS tests have 'high sensitivity', when in fact they have very low sensitivity. This means that the majority of INFECTED people will get a negative blood test on the NHS. This is information which doctors absolutely need to make an informed judgement about their patients, but instead of providing physicians with accurate figures the NICE guideline makes false claims for testing accuracy. Karen's GP might make exactly the same mistake with other patients, even after the NICE guideline is published.

>Karen is correct about the test kit manufacturer's providing explicit direction that a negative test result cannot EXCLUDE the possibility of Lyme disease. There is no test manufacturer in the world that makes that claim. In fact the test supplier to the Lyme Reference Laboratory at Porton Down, provides figures showing that their tests only detect around 4 out of every 10 infected patients.

>In Karen's case, based on the draft NICE guideline, she might have been retested again after a few weeks, which could have slightly improved her chances of having a positive result (and getting treatment) but that is by no means certain. What actually happened, is that Karen was denied a diagnosis based on a negative blood test and that will continue to happen based on the draft guideline. Karen's infection was neglected and allowed to spread, causing worse illness and potentially making the infection much more difficult to treat. It is only by paying for private treatment that things have improved for Karen and the draft NICE guideline does nothing to prevent this happening to many other patients, in fact, it ensures that

NHS testing will be misinterpreted by doctors and lead to many more patients being denied a diagnosis and treatment.]

For further information see: <http://counsellingme.com/VIRAS/VIRAS.html>
https://www.facebook.com/pg/WorldwideLymeProtestUk/about/?ref=page_internal

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