

Vector-Borne Infection Research- Analysis-Strategy



Summary of the VIRAS stakeholder comments on the NICE Draft Short Guideline

November 6th, 2017

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INTRODUCTION

Apologies for the length of this summary, the reasons for this will become apparent. Headings have been added to help readers to find the issues that interest them. The short version of the draft guideline which this document refers to and the Scope documents can be downloaded here: <https://www.nice.org.uk/guidance/gid-ng10007/documents/>

MAJOR OMISSIONS OF THE NICE DRAFT GUIDELINE

1/ Blood Donation

The Short Draft omits to inform doctors that patients should not donate blood or organs.

2/ Excluded cases of Lyme disease

The draft guideline has excluded tens of thousands of UK Lyme disease patients that the health authorities have failed to detect through decades of mismanagement. The Centers for Disease Control and Prevention (CDC) have stated that the true incidence of Lyme disease in the USA is probably 10 to 12 times higher than the 30,000 cases recorded each year. It is ridiculous for the HPA and PHE to claim that the true UK incidence is only 2 to 3 times higher than reported cases (~1,000 per annum). See 'Recovery, Incidence and Prevalence' below.

3/ Common Lyme disease co-infections, opportunistic infection

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 coinfections and opportunistic infections and recommend that these must also be addressed.

4/ Immune Suppression

Singh and Girschick (2004) state: "Long-term exposure of the host immune system to spirochaetes and/or borrelial compounds may induce chronic autoimmune disease. The study of bacterium-host interactions has revealed a variety of proinflammatory and also immunomodulatory-immunosuppressive features caused by the pathogen."

SECTIONS

EM Rash

"Diagnose Lyme disease in people with erythema migrans, that is:"

Add to this list or make it absolutely clear elsewhere, that an Erythema Migrans rash is an uncommon presenting symptom. E.g., occurring in only one fifth to one quarter of patients. Doctors must be informed that **the majority of Lyme disease cases will have to be diagnosed without any visible signs.**

Smith et al, (2000) state in: 'Lyme disease surveillance in England and Wales, 1986 – 1998', "**Erythema migrans was reported in 41% of patients**".

(<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2640888/> doi: [10.3201/eid0604.000416](https://doi.org/10.3201/eid0604.000416))

Knudtzen et al (March 2017) analysed 431 confirmed cases of Lyme neuroborreliosis of which 37% reported a tick bite and **only 20% had an Erythema Migrans rash.**

(<https://doi.org/10.1093/cid/cix568>)

Of the 51 patients studied in the outbreak of Lyme disease in the town of Old Lyme, Connecticut, "**One quarter of the patients had an unusual skin lesion before the onset of joint symptoms**". (http://www.ct.gov/dph/lib/dph/infectious_diseases/lyme/1976_circular_letter.pdf).

As a discrete event representing an 'outbreak' which was studied by the CDC, the latter was completely objective. This is very important statistical evidence and represents data from a real-world 'experiment' that is unlikely to be replicated. Virtually all epidemiological data following this event has been skewed by the recognition of an EM rash as not only indicative of Lyme, but often the only sign.

Failure to make it explicit that most cases will not report an EM rash will predictably put patients at risk of not being diagnosed and treated.

Symptoms

The list of symptoms or signs states: "Consider the possibility of Lyme disease in people presenting with". The list omits the following presentations:

Cerebral vasculitis:

(<https://www.ncbi.nlm.nih.gov/pubmed/?term=cerebral+vasculitis+borreliosis>)

Ischaemic strokes:

(<https://www.ncbi.nlm.nih.gov/pubmed/?term=ischaemic+borreliosis>)

Demyelinating disease:

(<https://www.ncbi.nlm.nih.gov/pubmed/?term=demyelinating+borreliosis>)

Parkinsonian presentations:

(<https://www.ncbi.nlm.nih.gov/pubmed/12946221>)

Dementias:

(www.ncbi.nlm.nih.gov/pmc/articles/PMC2831066/)

(<https://www.ncbi.nlm.nih.gov/pubmed/15894409/>)

(<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3171359/>)

(<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4981904/>)

Laboratory Testing

The draft tells doctors to, "Discuss with the person the accuracy and limitations of the different tests for diagnosing Lyme disease", but it does not provide figures, ranges or estimates.

The draft guideline persistently seeks to downplay or even evade the fact that Lyme serology as used by the NHS is insensitive. **This evasion is dangerous and will predictably lead to patients not being diagnosed and treated.**

The first tier test (ELISA) is an aid to confirming diagnosis in around 50% of POSITIVE cases according to independent research. Of the thousands of tests deemed 'negative' at RIPL, an additional number are actually positive. Even more can be added to this because the species of borrelia is not detected (e.g., myamotoi), the initial level of infection was low or the infection results from low immunogenic round-bodies and the slow reproducing borrelia have not evoked a significant immune response, e.g., **Kurtenbach states: "the onset of the disease might be up to a year later"**. All these add-up to possibly thousands of false-negative tests, and that does not include those who were not tested because their doctor was ill-informed, those who did not go to the doctor or who were misdiagnosed with something else.

"1.2.21 Carry out tests for Lyme disease only at NHS-accredited laboratories"

The Rare and Imported Pathogens Laboratory (RIPL), Porton Down, is not listed as a UKAS accredited laboratory meeting ISO 15189. (<https://www.ukas.com/search-accredited-organisations/>).

Where will the NHS source testing for UK patients? What steps will be taken to retest patients whose Lyme serology was provided by this unaccredited laboratory in order to meet the requirement at Page 8 Line 5?: "When tests have been done in laboratories that do not fulfil the criteria in recommendation 1.2.21, do not diagnose Lyme disease, but carry out testing again using an NHS-accredited laboratory"

The draft requirements appear to be contrived to give RIPL automatic 'validation' by NICE, so that they can keep their virtual monopoly on testing in England. The Health Protection Agency (HPA, now part of Public Health England) 'validated' the VIRAMED tests themselves by comparing them

with the test kits they formerly used. If one poor test is compared with another poor test which uses the same or similar methodology, the outcome might 'validate' that the new is similar to the old, but it does not show that either are accurate or useful. **The ELISA/Western Blot combination has consistently been shown to have low sensitivity that is so poor that it would be unacceptable in many other serious infections demanding urgent diagnosis and treatment.** Furthermore, these tests have never been validated for the UK population and strains of borrelia. It may be cheap and convenient to pick a testing product off the shelf, but if it leaves thousands of patients undiagnosed, that is not convenient for them.

Negative Tests

The draft states:

"Explain [...] that the accuracy of blood tests may be reduced if:

"testing is carried out too early (before antibodies have developed)

"the person has reduced immunity, which might affect the development of antibodies, for example people on immunosuppressant treatments."

The draft omits:

1/ "the infecting species of borrelia might not be detected by NHS tests"

2/ "testing is carried out too late and the infection is now hidden from the immune system" E.g., Berndtson, (2013): **"This review describes known and suspected mechanisms by which spirochetes of the Borrelia genus evade host immune defenses and survive antibiotic challenge."** (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3636972/>)

And Citera et al (2017) remark: **"Identifying Borrelia has proven challenging because it has the ability to evade the immune system"** and "the bacteria is able to traverse the blood brain barrier, endothelial tissue, and imbed itself in joints, entering certain cells intercellularly and invaginating itself in a manner that reduces the potential exposure of antigens, enabling it to avoid immune recognition". (<https://www.dovepress.com/empirical-validation-of-the-horowitz-multiple-systemic-infectious-dise-peer-reviewed-fulltext-article-IJGM> DOI <https://doi.org/10.2147/IJGM.S140224>)

3/ "testing is carried out too late and the infection has itself become immunosuppressant" E.g., Jarfores et al, 2007 state: "Furthermore, we showed that chronic LB had higher amounts of *Borrelia*-specific FoxP3 mRNA than healthy controls, **which might imply that chronic LB patients have an immunosuppression** caused by the increased T_{reg} population." (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1810439/>)

Alternative Laboratory Tests

The draft states: "Advise people that tests available privately (including from overseas) may not have been fully evaluated or meet the standards needed to diagnose Lyme disease"

If this statement is included then it is essential to also state that NHS/RIPL tests have NOT "been fully evaluated or meet the standards needed to diagnose Lyme disease". Otherwise this statement is prejudicial against non-NHS laboratories which it lumps together. The purpose of this appears to be in order deprive patients of choice and to maintain RIPL's monopoly on testing for England. The tests used by RIPL have not been 'fully evaluated' – for UK patients, ever, and RIPL and its tests do not "meet the required standards needed to diagnose Lyme disease". No test ever marketed has met all the requirements to "diagnose Lyme disease". Implying that RIPL are capable of this feat using a methodology that is hardly better than flipping a coin is dangerously misleading. If the guidelines fail to make this fundamental element of serology testing absolutely explicit, and cease the ploy of 'implying', 'suggesting', 'hinting' or prompting readers to 'draw conclusions' from muddled and misleading information, it is going to cause serious harm to patients and threaten their doctor's careers.

Treatment

“offer antibiotic treatment according to their symptoms as described in table 1”

These guidelines stick patients in boxes and doctors in other boxes. It is convenient, neat and unethical. Straightforward treatment of a complex illness is a lovely dream, but for those patients that end-up in a living nightmare because their skilled physician felt constrained by what was ‘described in table 1’ is not by any stretch, the practice of medicine.

The consequences to the patient are potentially catastrophic. Halting treatment before the infection is eradicated could allow the remaining infection to re-establish. The infection could become worse than it was before treatment and result in serious injury – especially if necessary further treatment is withheld because the patient’s continued and/or relapsing symptoms are explained away as E.g.:

“1.3.11 Explain to people with persisting symptoms following antibiotic treatment that:

“symptoms of Lyme disease may take months to resolve even after treatment

“continuing symptoms does not necessarily mean they still have an active infection”

“1.3.12 Support people who have a slow recovery from Lyme disease by:

“encouraging and helping them to access additional services, including

“referring to adult social care for a care and support needs assessment, if they would benefit from these

“communicating with social services, educational services and employers about the person’s need for “gradual return to activities, if relevant”

In the context of these draft guidelines and its illogical restrictions for treatment, the meaning of these statements is obvious – ‘patients should not get any more treatment even if they remain ill (infected), or relapse or deteriorate.’ This would be unacceptable in any other infectious disease and is a disgraceful abandonment of basic medical ethics. There is NO evidence to support depriving a patient of treatment when their symptoms indicate a progressive infection.

If treatment fails to eradicate the infection, this may also increase the risk of antimicrobial resistance, not only of the Lyme spirochaetes, but of other infections transmitted by the tick bite, as well as opportunistic infections that take advantage of the immune suppression caused by the Lyme bacteria.

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. These guidelines 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.

This NICE guidance is dangerous and will result in entirely foreseeable iatrogenic harm to patients. It will result in large numbers suffering avoidable illness and injury and justifiably seeking compensation.

Jarisch-Herxheimer reaction

“If symptoms worsen within the first day of antibiotic treatment, assess the person for Jarisch-Herxheimer reaction.”

In the treatment of Lyme disease, a 'herx' or significant 'die-off' of the bacteria can occur at any time during treatment before the infection burden is substantially reduced. **Giving doctors and patients a false sense of security once the 'first day of antibiotic treatment' is passed, is dangerously misleading.** Some doctors experienced in treating Lyme patients recommend pausing treatment if a severe worsening of symptoms occurs at any time.

Patients receiving antibiotic treatment should be routinely provided with information about 'herxes' as they occur and manifest in Lyme, including what to do if they experience a severe worsening of symptoms or new symptoms.

Withdrawing treatment

"Do not routinely offer further antibiotics if a person has persisting symptoms following 2 courses of antibiotics. Consider discussion with or referral to a specialist as outlined in recommendation 1.2.19."

This advice is dangerous and has no clinical basis. Where and who are these 'specialists' that the draft refers to? VIRAS are aware of numerous incidents where patients have attended Consultants, most of whom deny the existence of chronic Lyme, and who are indoctrinated by PHE, IDSA and BIA propaganda to serve the interests of medical re-insurance companies by promulgating the belief that Lyme is rare, easy to detect and straightforward to treat with a short course of antibiotics. Complicated and chronic Lyme is far outside their knowledge or expertise. It is entirely predictable that this advice will result in harm to patients if their treatment is interrupted or halted altogether. **This recommendation represents nothing other than part of a non-medical 'disengagement' strategy to dismiss patients who remain symptomatic due to continuing infection following 6 weeks of antimicrobial treatment.** These patients do, and will continue to exist, and in their current form these draft NICE guidelines will perpetuate and compound this entirely foreseeable threat to patient safety. Doctors that follow this NICE guidance in good faith will inevitably face Fitness to Practice complaints. No wonder NICE include such a comprehensive Disclaimer with their guidelines if this is an example of their cavalier approach to patient care.

Persistent symptoms and infection

The guideline refers to "persistent symptoms" however they do not recognise the existence of persistent infection. Borrelia can evade the immune system and the bacteria can tolerate antibiotics and there are numerous articles that demonstrate this. **The possibility that persistent infection may require more than 6 weeks of antibiotics is not considered, but should be communicated to clinicians.** TB, leprosy and acne patients can all benefit from long courses of antibiotics. The following citations are from works by recognised Lyme experts that demonstrate persistent infection after antibiotics:

* Sleeper cells: the stringent response and persistence in the Borrelia (Borrelia) burgdorferi enzootic cycle. 2017. Cabello FC, Godfrey HP, Bugrysheva JV, Newman SA. The metabolic and morphologic changes resulting from activation of the stringent response in B. burgdorferi may also be involved in the recently described non-genetic phenotypic phenomenon of tolerance to otherwise lethal doses of antimicrobials and to other antimicrobial activities. It may thus constitute a linchpin in multiple aspects of infections with Lyme disease borrelia, providing a link between the micro-ecological challenges of its enzootic life-cycle and long-term residence in the tissues of its animal reservoirs, with the evolutionary side effect of potential persistence in incidental human hosts.
(<https://www.ncbi.nlm.nih.gov/pubmed/28836724> doi: 10.1111/1462-2920.13897)

* These results extended previous studies with ceftriaxone, indicating that antibiotic treatment is unable to clear persisting spirochetes, which remain viable and infectious, but are nondividing or slowly dividing

From <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2812145/?tool=pmcentrez>> Barthold, Stephen W. et al. 2010. "Ineffectiveness of Tigecycline against Persistent *Borrelia burgdorferi*." *Antimicrobial Agents and Chemotherapy* 54(2):643-51. Retrieved (<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2812145&tool=pmcentrez&rendertype=abstract>).

* The agent of Lyme borreliosis, *Borrelia burgdorferi*, evades host immunity and establishes persistent infections in its varied mammalian hosts. Hodzic, Emir, Denise Imai, Sunlian Feng, and Stephen W. Barthold. 2014. "Resurgence of Persisting Non-Cultivable *Borrelia burgdorferi* Following Antibiotic Treatment in Mice" edited by R. M. Wooten. *PLoS ONE* 9(1):e86907. Retrieved January 24, 2014 (<http://dx.plos.org/10.1371/journal.pone.0086907>).

* We demonstrated that *B. burgdorferi* treated in the stationary phase has a higher probability of regrowth following removal of antibiotic. Caskey, John R. and Monica E. Embers. 2015. "Persister Development by *Borrelia burgdorferi* Populations In Vitro." *Antimicrobial agents and chemotherapy* 59(10):6288-95. Retrieved January 18, 2016 (<http://aac.asm.org/content/early/2015/07/21/AAC.00883-15>).

* Results indicated that following antibiotic treatment, mice remained infected with nondividing but infectious spirochetes, particularly when antibiotic treatment was commenced during the chronic stage of infection. Hodzic, Emir, Sunlian Feng, Kevin Holden, Kimberly J. Freet, and Stephen W. Barthold. 2008. "Persistence of *Borrelia burgdorferi* Following Antibiotic Treatment in Mice." *Antimicrobial agents and chemotherapy* 52(5):1728-36. Retrieved November 7, 2010 (<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2346637&tool=pmcentrez&rendertype=abstract>).

* Our study substantiates borrelial persistence in some EM patients at the site of the infectious lesion despite antibiotic treatment over a reasonable time period. Hunfeld KP et al 2005 In Vitro Susceptibility Testing of *Borrelia burgdorferi* Sensu Lato Isolates Cultured from Patients with Erythema Migrans before and after Antimicrobial Chemotherapy. (<http://aac.asm.org/content/49/4/1294.full>)

Lyme disease during and after pregnancy

The manifestation of Lyme disease symptoms can be delayed for months or years. It is essential that both mother and baby are monitored for an extended period. Given the time that it takes most patients to get a diagnosis and treatment after the initial infection, the unreliability of tests and failure of treatment, it can be expected that a significant number of women give birth whilst infected with Lyme bacteria. Some of these will be identified cases, some will not. Where the infection has been identified and treated, an absence of symptoms should not lead to the assumption that the infection has been eradicated. **Of all Lyme disease patients, babies and children have the greatest number of years to suffer the consequences of bad clinical judgement.** Mother and child must be monitored long-term specifically for Lyme disease relapse.

Recovery, Incidence and Prevalence

The draft states: "most people recover completely". This claim is meaningless without data or an evidence based estimate. If NICE claim to have a number or range, then state it: e.g., "90% to 95% recover completely". If you do not have authoritative figures or a range then this statement is an outright lie. It is unsubstantiated and dangerously creates a false sense of security. The surveillance of Lyme in the UK is wholly inadequate to make this claim.

The authorities responsible for public health in the UK have no idea how many people in the UK get Lyme, nor what happens to them, because the vast majority never even get diagnosed let alone treated for the infection. Define 'recover completely'. Are NICE claiming that this means that the infection is eradicated? Also explain how you know that this occurs in 'most people'.

Also explain why, if 'most people recover completely', the draft also claims: "The development of a core outcome set was identified as a high priority"? If most patients recover completely, then the development of a 'core outcome set' would be a ridiculous waste of resources. (see: 'Research, core outcome set', below)

The Centres for Disease Control and Prevention in the USA admit that the true incidence of Lyme is 10 to 12 times higher than the number of reported cases. That is in a country where 14 states have an officially recorded average incidence of 43 per 100k compared to England and Wales measly 1.7 per 100k. **Public Health England are deluded if they believe that UK surveillance for Lyme is 4 times more efficient than that of the USA.**

Therefore it is a logical deduction that as an absolute minimum, 9,000 cases of Lyme disease in the UK go unrecorded every year. That could be ~160,000 missed cases since the turn of the century. The NICE guidelines imply that they know what has happened to these tens of thousands of undiagnosed and untreated patients when that is impossible. **Stop making ludicrous claims based on nothing more concrete than wishful thinking and wilful ignorance.** These attempts at diverting patients are propaganda and they have no scientific validity. If NICE are so bent on manipulating doctor's into accepting false information, then one must assume that the pretence of having a public consultation and gathering different viewpoints – is primarily for the purpose of producing more effective and acceptable propaganda. **There appears to be an underlying agenda in the guideline's constant use of insupportable statements.** As these mostly seem intended to create a false sense of security, and thereby justification for dismissing patient's concerns, it can be concluded that these deceptions reveal an underlying contempt for patients and patient rights.

The draft states: "Explain to people who are starting antibiotic treatment for Lyme disease that some people may experience a worsening of symptoms early in treatment." [...] "Tell them to contact their doctor if this happens and not to stop their antibiotic treatment".

NO! It is evident that for years PHE have portrayed Lyme disease as rare and not very serious and patients, especially those who do not respond to treatment as PHE dictate, as hypochondriacs and neurotics. This contemptuous attitude also appears to have pervaded NICE and its GDC so thoroughly, that they seem to forget that a lot of people are actually, stoical. As patients, these people don't like making a fuss, and even if they are able to 'contact their doctor' may not give adequate information to receive appropriate advice. **If you tell people that they might feel worse on treatment but not to stop their treatment, then you are going to have some very seriously ill patients.** This is foreseeable due to the wrong advice the guideline gives on Jarisch-Herxheimer reactions. If the NICE GDC possessed a basic knowledge of Lyme, or had taken advantage of the wealth of published information about Lyme disease then they would recognise how stupid and dangerous this advice is.

If a person is experiencing a herx but they put it down to, 'the doctor told me I might feel worse', and they continue treatment they could have a crisis that will land them in A&E. Some experienced doctors are concerned that a severe herx can result in permanent injury. NICE have to break this down and give better advice. A good first step towards achieving this would be to show some respect for patients. The second step would be familiarity with the borrelia pathogen that causes Lyme disease and the antigens and bio-toxins exposed when it is killed.

RESEARCH RECOMMENDATIONS

Research, a core outcome set

"The development of a core outcome set was identified as a high priority because it would allow comparison across trials and allow appropriate meta-analysis to strengthen results."

NICE affect to recognise the weakness of the available evidence and acknowledge that better is required. Yet notwithstanding this lack of evidence meeting their requirements, the draft guideline makes treatment recommendations with such authority and confidence that they consider it appropriate to set definite limits on treatment and make the unsubstantiated claim that 'most people recover completely'. If this were true, then there would be little point in spending hundreds of thousands of pounds developing a 'core outcome set'.

NICE appear willing to substitute quality evidence with assumptions and opinions when it suits them, but have been selective in the opinions that they chose to upgrade to 'evidence'. This shows that bias is involved. **That bias is in favour of those who hold the opinion that a Lyme infection at any stage is easily eradicated with a few weeks treatment.** The opinion of those who hold that a Lyme infection could take longer to eradicate is ignored. No balance, no evidence and no science, just opinions, prejudiced against patients who need longer treatment for a disseminated and persisting infection.

Producing a Core Outcome Set and calling for multiple Clinical Trials adopting those criteria, is a contradiction in the context of the draft guideline. The draft treatment recommendations have determined that most patients will be cured with 3 weeks of antibiotics and all of the remainder will be cured with a further 3 weeks of treatment. Therefore, a "core outcome set" would be superfluous and the call to establish a set is contradictory and suspect.

VIRAS and others are well aware that the draft treatment regimen would leave substantial numbers of patients infected. Following treatment some patients will continue to have symptoms due to an ongoing infection and others will relapse later. This is exactly what happens with inadequately treated tuberculosis and other difficult infections.

The contradiction makes sense when one understands that a 'core outcome set' will provide 'evidence' to facilitate the re-diagnosis of patients with persisting or relapsing symptoms, which in any other resistant infection would probably be interpreted as 'treatment failure'.

Once a 'core outcome set' has determined that 'adequately treated' patients can have persisting, relapsing or even deteriorating symptoms, the patient can nevertheless be classed as 'adequately treated'. Patient's ongoing disease and symptoms can be attributed to tissue damage or acquired autoimmune disease, and they can be re-diagnosed as having post-treatment Lyme disease syndrome (PTLDS). This will mean that they require no further investigations or treatment beyond symptom management. Alternatively, some could be re-diagnosed with CFS or any other convenient label that gets rid of them with less expense to the NHS. Informed patients have been aware of PHE's plans to realise this outcome for chronic Lyme patients for some years (see below).

Evidence that a 'core outcome set' is impractical

without reliable tests and that antibody tests are inapplicable in chronic Lyme disease

J Infect Dis. 1992 Aug;166(2):440-4.

Fibroblasts protect the Lyme disease spirochete, *Borrelia burgdorferi*, from ceftriaxone in vitro. Georgilis K1, Peacocke M, Klempner MS.

Abstract

The Lyme disease spirochete, *Borrelia burgdorferi*, can be recovered long after initial infection, even from antibiotic-treated patients, indicating that it resists eradication by host defense mechanisms and antibiotics. (<https://www.ncbi.nlm.nih.gov/pubmed/1634816>)

N Engl J Med. 1988 Dec 1;319(22):1441-6.

Seronegative Lyme disease. Dissociation of specific T- and B-lymphocyte responses to *Borrelia burgdorferi*.

Dattwyler RJ1, Volkman DJ, Luft BJ, Halperin JJ, Thomas J, Golightly MG.

Abstract

[...] We studied 17 patients who had presented with acute Lyme disease and received prompt treatment with oral antibiotics, but in whom chronic Lyme disease subsequently developed. Although these patients had clinically active disease, none had diagnostic levels of antibodies to *B. burgdorferi* on either a standard enzyme-linked immunosorbent assay or immunofluorescence assay. On Western blot analysis, the level of immunoglobulin reactivity against *B. burgdorferi* in serum from these patients was no greater than that in serum from normal controls. [...] We conclude that the presence of chronic Lyme disease cannot be excluded by the absence of antibodies against *B. burgdorferi* and that a specific T-cell blastogenic response to *B. burgdorferi* is evidence of infection in seronegative patients with clinical indications of chronic Lyme disease.

HOW ARE NICE GOING TO PROVE THAT PATIENTS ARE NO LONGER INFECTED? Without a validated method to show this, the whole 'research recommendation' section is nonsense as far as patient care is concerned.

Ignoring this requirement shows that a 'core outcome set' would simply be a means of establishing arbitrary thresholds beyond which patients can be denied further treatment. Many of the patients formerly misdiagnosed with M.E., but who later discovered that they have borreliosis are aware of this stratagem, because it has already been used to marginalise those patients. PHE intend to use the same strategy on Lyme patients.

E.g., in the PACE Trial (2011) of treatments for M.E. and CFS, the treatments failed to reach the reach the Primary Outcome Thresholds for 'recovery' and 'improved'. But after all the data had been collected, the Primary Outcome Measures were discarded, and new ones were designed with much lower thresholds, which created the appearance of a Treatment Effect.

The same people that pulled this stunt are in collaboration with PHE with the intention of using the same stratagem on Lyme patients. Therefore the call for research to establish a 'core outcome set' has no validity but is a stratagem which would allow chronically ill and chronically infected Lyme patients to be deemed 'successfully treated'.

More false claims about treatment

The draft states: "Antibiotic treatment is the mainstay of management for Lyme disease."

This statement is false and without understanding why, it is impossible to recognise that what follows the statement is meaningless. The actual 'mainstay of management for Lyme disease' in the UK, which has been applied to the vast majority of Lyme disease patients (i.e., >90%) is:

- 1/ do not recognise the disease
- 2/ diagnose the patient with something else, probably M.E. or CFS.
- 3/ try to get rid of them.

Therefore the 'mainstay' of Lyme disease management in the UK is to misdiagnose the patient and thereby deprive them of the treatment that they need. This is the 'management' that has been given to tens of thousands of patients, who were often previously fit and successful, but were then left to rot in their homes among the shattered remnants of their former life. Thanks to PHE (and the HPA), the NHS has been providing this mainstay service for 30 years.

The outcome of this 'mainstay' of Lyme disease management in the UK is fairly well established for patients who became and remained symptomatic for longer than 6 months. Few patients recover (<10%). The majority improve somewhat over a course of years and decades with a fluctuating course of remission and relapse, around 25% remain very severely ill and a proportion of these have progressively worsening disease. A substantial proportion of patients with M.E. remain more chronically ill and disabled and with a lower quality of life, than patients with almost all other diseases*. A patient's risk of being among the 25% of severely ill is increased if in the course of their illness they had a period of extreme illness and incapacity, especially if this was

prolonged. However, even some of the 25% can improve substantially with long-term treatment targeting Lyme disease and co-infections.

***Quality of life and functional status in M.E. and CFS**

The following papers show greater incapacity and worse quality of life in ME/CFS than virtually all other diseases

<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0132421>

<https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-11-402>

[http://www.amjmed.com/article/S0002-9343\(96\)00174-X/pdf](http://www.amjmed.com/article/S0002-9343(96)00174-X/pdf)

The draft NICE guideline shows no concern for, and does not even acknowledge the existence of the tens of thousands of Lyme disease patients that are chronically ill because they were never diagnosed or treated. For those who were misdiagnosed with M.E. or 'CFS', their plight was specifically excluded from the NICE guideline Scope, and their situation is permanently compounded by getting a 'waste-basket' diagnosis that obstructs further investigation or treatment. That is all the evidence that VIRAS or any reasonable person needs in order to recognise that from the outset, the NICE guideline was never about helping patients with Lyme disease. It was only ever about protecting PHE and covering-up a shameful medical scandal representing decades of incompetence.

Research, a clinico-epidemiological study

The draft states: "A large clinico-epidemiological study to collect data on incidence [...] would generate population-based statistics".

This claim is misleading. An epidemiological study is not possible without an accurate method for identifying cases and one does not exist. The exercise as it is described would predictably maintain the current gross underestimation of incidence and ignore prevalence altogether. It may be acceptable to PHE who appear to enjoy ridiculous Lyme disease statistics but will do nothing for patients, doctors or the population at risk.

Research, seroprevalence

The draft states: "What is the current seroprevalence of Lyme disease-specific antibodies and other tick-borne infections"

For the reasons outlined above (16,2, 16,3 to 6) this exercise would produce predictably misleading information, especially in view of the proviso for using the PHE approved test method of serology which has been shown to be inaccurate. This statement appears to show a willingness to make concessions to the concerns of patients. However, when read in the context of the remainder of this draft guideline and the historical claims of PHE and the HPA, it can be recognised as just another ruse to protect those responsible for the incompetent management of Lyme disease. Furthermore, it facilitates those who wish to enforce antimicrobial stewardship on doctors and an unsuspecting patient population, and maintain the illusion that regarding Lyme in the UK – everything is under control.

Research, Lyme and coinfection seroprevalence

The draft states: "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)?" And: "This information is not currently available and is of high priority".

It is of higher priority to recognise the deceptive nature of these grandiose calls for research and the specific meaning and consequences of this particular recommendation,

i.e., for somebody else to spend hundreds of thousands, if not millions of pounds on projects that will not help doctors or patients.

All that anyone needs to recognise at the present time, is the patent fact that Lyme disease in the UK has not been, and is not being monitored or handled effectively. Acquiring evidence about seroprevalence in the population is of LOW priority and in fact, has no practical application to protect the nation's health from the threat of Lyme disease. **Claiming that this is 'high priority' appears to be in order to create an impression that Lyme disease is being taken seriously. Whereas the predictable result of this stratagem would be to show that healthy people are seropositive in substantial numbers** – just as has been found in other countries. This would aid RIPL and the former Reference Laboratory at Southampton to defend their disgraceful record of obstructing the diagnosis of patients requiring treatment, but would do nothing for doctors or their patients who suffer serious and chronic illness due to infection with Lyme bacteria.

E.g.: "Screening of IgG antibodies against *B. burgdorferi* in blood donors as a proxy for the presence in the healthy population showed seroprevalences of 2.7% both in Hamburg and Bavaria [16], [17]. In France (3.2%) [18], Italy (4.9%) [19] and Romania (4.3%) [20], similar proportions of seropositive individuals among blood donors were assessed. In population-based surveys, higher seroprevalences were seen in Germany (Berlin: 8%, n = 3,736 [21]; Bavaria: 15%, n = 4,896 [22]; Baden-Württemberg: 16.9%, n = 1,228 [5]) and Finland (19.3%, n = 3,248 [23]). In individuals with higher risk of exposure to ticks such as forestry and agricultural workers seroprevalences between 8% and 52% have been described [15], [18], [19], [24]–[26].", etc., etc. (<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0041321> <https://doi.org/10.1371/journal.pone.0041321>)

Research, seroprevalence

The draft states: "What is the current seroprevalence of Lyme disease-specific antibodies [...] in people in the UK when performed using UK-accredited assays (ELISA based on C6 antigen and immunoblot)?"

There is no such thing as a "UK-accredited assay" for Lyme disease. **This research recommendation is nonsense and is simply a ploy to show that some healthy people have borrelia antibodies.** This is intended to justify the dismissal of patients with positive NHS test results because their borrelia antibodies are merely lingering 'from a past infection'.

VIRAS consider these recommendations for 'Priority' research, to be nothing more than a subterfuge intended to deceive patients and patient groups. They are structured in such a way that even if they were actually carried out, they will not change UK Lyme statistics and will not improve patient care. However, they would help to protect PHE and RIPL from the legitimate charge that their management of Lyme disease is unacceptable.

Co-infections

The draft states: "Many patients are concerned about the possible presence of co-infections transmitted by ticks".

As this concern was specifically excluded from the Scope and has not been properly addressed in the draft guideline and is represented only as a concern of 'many patients', it is safe to assume that this is not a concern of PHE or of NICE. This statement is just another stratagem to try and mollify patients. It in no way addresses the evidence, including that provided in the stakeholder responses to the Scope. E.g., Lyme Disease UK: page 53, 54, 72. Lyme Research UK: page 95, 176, 285. VIRAS: page 159, 327. Caudwell LymeCo: page 2, Lyme Disease Action: page 33 and many other references to Lyme coinfections which can cause serious complications in the effective treatment of Lyme disease and some of which represent serious diseases in their own right.

Research, Treatment

The draft states: “A series of prospective multicentre studies is needed to compare the clinical and cost-effectiveness of different dosages and length of treatment”.

The draft NICE guideline provides restrictive treatment recommendations, which VIRAS consider to be unfounded, unethical and dangerous. This proposal for ‘multicentre studies’ appears to support our view. **NICE admit that the clinical effect of “different dosages and length of treatment” are unknown, yet they nevertheless make insupportable and restrictive treatment recommendations which cannot be ‘Evidence Based’.**

The only rationale for an expensive ‘multicentre’ study would be if various borrelia species produce different responses to treatment and these are expected to vary according to different regions of the UK. ‘Multicentre’ studies are not generally required for ‘prospective’ studies, they are only required for such time as a full-scale Clinical Trial is designed. That is, unless wide variations are actually anticipated – in which case, explain why they are expected. This research proposition is wildly excessive and as such, it does not appear to be authentic.

It is notable that in the past 16 years the Medical Research Council has not allocated funding for a single study into Lyme disease. In the past 16 years, of the 7 billion pounds allocated to around 20,000 research projects of medically related research by the Wellcome Trust, only 2 projects were vaguely relevant to Lyme disease patients and doctors. One was a study of pathogens found in ticks in Europe led by the late Professor Klaus Kurtenbach which included investigation of borrelia species in ticks in the UK. The second was a study of borrelia spirochaetes in ticks in the Baltic region of Europe, led by Dr Sarah Randolph. The Cochrane library list one systematic review of Lyme disease treatment, relating to treatment of neurological complications but not focussed on the UK. The National Institute for Health Research (NIHR) list no projects for Lyme disease. However, the University of Liverpool is getting some funding from NIHR for Health Protection Research and indicate that zoonoses including Lyme: “will explore new ways of detecting and characterising pathogens”. This is a drop in the ocean and cannot be expected to translate into benefit for patients or doctors in the foreseeable future. Where do NICE imagine that the millions of pounds needed to make their research recommendations a reality, are going to come from?

At first glance the Research Recommendations appear encouraging. Further evaluation suggests that they are disingenuous. **NICE do not conduct or fund research and neither they nor anyone else will ever have to deliver on their recommendations.** The gaping holes in Lyme research for UK patients have remained exactly the same for 30 years and in all that time the need for research has gone unanswered.

PHE have been telling doctors and patients for years that the UK is different from the USA and the rest of Europe. That Lyme is different here and that is why France and Holland record >10 times as many cases. Yet they are prepared to import tests, diagnostic criteria and treatment protocols from all and sundry without a shred of UK research to show whether these are applicable – even after telling us that they are not.

Research, persisting symptoms

The draft states: “However, we know little about the evolution of antibody titres over time in those who have been treated successfully and in those who have persisting symptoms.” [emphasis added]

This loaded statement implies that there are only two possible outcomes to treatment: 1/ successful treatment, or 2/ “persisting symptoms”. As already noted, the latter are explained as NOT treatment failure (p12 lines 1 – 10). Even though “treatment failure” is mentioned in the draft, it is not addressed. There are no good medical or scientific justifications for this omission. The draft guideline evasion of treatment failure discriminates against patients.

'Reinfection' is mentioned but failed-treatment and delayed-relapse due to failed-treatment are not. Perhaps NICE do not want these patients to have a valid test, which could be interpreted as a strategy to discriminate against and marginalise those patients, deny them treatment and permit their ongoing infection to progress. This stratagem would permit PHE to claim that all cases of proven 'post-treatment' Lyme must represent 'reinfection'. That would give PHE a useful get-out for their years of failures. They can evade blame for harms due to inadequate treatment because the patient 'must have got reinfected'. Therefore this serves the interests of PHE whilst discriminating against patients and their medical needs.

Testing and common symptoms

The draft states: "Many symptoms associated with Lyme disease have more common causes, so testing is helpful to ensure accurate diagnosis and appropriate treatment"

This bizarre sentence appears to be contrived to mislead with assumptions. A test with ~50% accuracy cannot possibly be "helpful to ensure accurate diagnosis" – it is impossible. In all cases, diagnosis is based on a physician's evaluation of the evidence. Laboratory testing as used by the NHS is already known to be unreliable. Just HOW unreliable remains to be seen and will only ever become clear when those tests can be compared with better tests, which have been demonstrated to have sufficient accuracy to authentically provide a reliable diagnosis, e.g., with sensitivity and specificity equivalent to tests for HIV.

How to get rid of patients – a guide for physicians

The draft states: "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."

This statement appears innocent enough even though it actually makes no sense. But for those who are aware that PHE have formulated cynical plans to marginalise chronically ill Lyme patients, it appears that this statement is part of that agenda.

EVERY patient with ongoing symptoms gets further investigation when initial investigations do not find the cause of their symptoms. This is routine practice, which makes the draft guideline statement bizarre. The claim that the referral of patients to a specialist is: "Because of the limitations of tests for Lyme disease", appears disingenuous and evidence is provided below to support this view.

The NICE draft guideline statement appears to be just one stage of a planned DISENGAGEMENT STRATEGY to get rid of problem patients, who have negative Lyme serology but remain ill with symptoms correlating to Lyme. This criteria will predictably apply to the vast majority of UK patients with chronic Lyme disease.

The procedure for this particular 'stage' of disengagement is that a 'Consultant physician' will have examined the case or discussed it with a GP, and when they cannot find anything wrong and based-on-all-the-evidence, they can declare that they are certain that it is not Lyme disease. This is to be followed by the Penultimate Stage when the 'Specialist' says, "I am sorry that you have these subjective symptoms, but we cannot find any cause for them, perhaps you should see a psychiatrist".

The Final Stage is for the GP to provide a diagnosis of Chronic Fatigue Syndrome (CFS) and offer a course of CBT or Graded Exercise. Whatever the patient does or says, their symptoms have been investigated to the fullest extent necessary to pre-empt a successful complaint and the patient is now officially, on a medical rubbish-heap where they can be refused any further investigations or treatment. If they don't like it, they can take themselves and their illness elsewhere. If they do not get a label of 'CFS', alternatives might include Post-Treatment Lyme

Disease Syndrome (if they had any treatment for Lyme) Somatic Symptom Disorder, Bodily Distress Disorder, Malingering or Being a Nuisance, or any other convenient waste-basket label which all amount to the same thing.

This is PHE's plan for the 'disengagement' of chronically ill Lyme patients from their healthcare provider. PHE must be delighted with the contribution that the draft guidelines makes towards realising this goal.

Evidence of plans to disenfranchise patients with chronic Lyme disease

In a document prepared by PHE and submitted to the Health and Safety Executive (HSE) (http://www.hse.gov.uk/aboutus/meetings/committees/acdp/161012/acdp_99_p62.pdf) are the following remarks:

"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)

According to these draft NICE Guidelines, and in fact, most other guidelines for Lyme disease, the only objective sign of the infection is an EM rash which occurs in less than 50% of cases in the UK. If PHE took the trouble to actually communicate with patients, they would find that some of these so-called "self diagnosed" patients, have in fact had EM rashes. Aside from an EM rash, the only practical currently available 'objective evidence' is direct detection of the infective organism, or as a second best - indirect detection by the presence of immune markers.

Contrary to the assertions of PHE, many of the patients that they have denigrated and intend to marginalise, do actually have 'objective evidence' of infection with Lyme bacteria, identified by top-class laboratories, some of which have accreditation superior to that of RIPL.

Furthermore, in those patients that did not have or do not recall having a rash and whose only serology was provided by the inaccurate tests supplied at RIPL, it is often found that they have (or had) high risk occupations and/or leisure and sporting activities. It is also often found that they live in or have visited highly endemic areas called 'hot spots'. Also, investigation of the so-called "self diagnosed" patients would frequently show that prior to becoming ill, many of these patients were very fit and active with no history of significant physical or mental illness, and that they have an illness which has devastated their health and deprived them of their social roles and careers. They also have symptom complexes which strongly correlate to Lyme disease.

These observations about common features of patients are based on VIRAS member's years of participation in support groups. We now witness almost daily occurrences of patients joining groups because they have illness following a tick bite, some with EM rashes, and too many of these have been dismissed by their doctor without even a test for Lyme disease. Some are told that 'there is no Lyme disease in this area', or incredibly that, 'there is no Lyme disease in the UK'. People with symptom profiles highly indicative of Lyme who do get tested are told by their doctor that 'your test results were negative so you do not have Lyme', without informing the patient that negative serology cannot exclude Lyme (rather suggesting that the doctor may be unaware of this basic fact). Many patients who had been misdiagnosed with 'Chronic Fatigue Syndrome' and M.E. and who learn about Lyme disease, share a history which strongly suggests that Lyme disease has been the cause of their illness, yet they have never been investigated. We now frequently witness patients who had been diagnosed with an EM rash or NHS positive serology, who were treated with 2 or 3 weeks of antibiotics, but weeks, months or even years later

their symptoms are not just relapsing, but are worse than they were before they were originally treated.

The mismanagement of Lyme disease has caused untold suffering. But instead of admitting its failings, PHE are arranging matters so that the very patients that it has so egregiously failed, will take the blame for their illness and suffer even more. The denigrating remarks in the document sent to the HSE are an insult to these patients who would be entirely justified in laying the blame for the chronic and devastating nature of their illness squarely at the door of PHE. But instead of honesty and an apology, these often terribly ill patients, they get more insults and stratagems to 'disengage' them from their healthcare providers.

No ELISA, Western blot or combination of these two has ever been validated for UK patients or the UK strains of borrelia causing disease. In addition to its disturbing misrepresentation of sensitivity figures, the HPA then shockingly state that "A negative ELISA does not require a confirmatory western blot and is recorded as negative". Whilst the HPA claim that this practice will result in a tiny percentage of false negatives, the reality is that it has, and will continue to result in a foreseeable and substantial percentage of false negatives:

In a study of 90 patients, Tylewska-Wierzbanowska and Chmielewski concluded that (<https://www.ncbi.nlm.nih.gov/pubmed/12422608>):

"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."

The implications of this are important. This study was a rare example of the type of study needed to quantify the comparative efficiency of different testing methods. This type of investigation is almost completely absent from Lyme disease literature and with good reason. It must cause serious consternation to test kit manufacturers and anyone who has made exaggerated claims for these tests and whose credibility could depend on those same kits being reliable. Yet the research showed unequivocally that whenever a single testing methodology is used, its sensitivity is unacceptable. Please remember, that even with 2 tier testing, diagnosis is by two SINGLE tests. This DOUBLES the chances for low sensitivity to exclude patients from a diagnosis and treatment.

RIPL omitted to apply this basic scientific discipline when they chose the VIRAMED tests for UK patients. They 'validated' the new test against the two-tier test they had previously been using, and which relied on virtually identical methodology.

What Tylewska-Wierzbanowska and Chmielewski showed, is that the presence of borrelia antibodies has no reliable correlation to the presence of Lyme spirochaetes infecting a patient. The implications of this finding has been continuously evaded by test kit manufacturers and testing laboratories such as RIPL. There can be only one interpretation of this anti-evidence, anti-science conduct, and that is that the intention is to NOT diagnose and not treat Lyme disease.

So, whilst we do not know exactly how many false negative ELISA's RIPL produce, according to the optimistic literature it will be a bare minimum of 30% and would probably be shown to be double that amount if alternative methods were used, and increase again if UK isolates were included. In two-tier testing (as required by PHE for Lyme serology) the number of false negatives would render the method entirely useless except perhaps in helping to confirm a small percentage of TRUE POSITIVES, whilst at the same time producing numbers of FALSE NEGATIVES that would be unacceptable in any other serious infectious disease.

We do not know whether RIPL's current virtual monopoly on Lyme disease testing for patients in England represents a conflict of interests for members of the GDC, but the recommendations in the draft guideline would obviously ensure that the monopoly continues. Whilst that monopoly cannot do RIPL's reputation any harm, it is reasonable to speculate that it serves their purposes,

whether those purposes include costs, or control over diagnosis and treatment of Lyme disease in the UK, and control over antibiotic prescriptions for infected patients.

In the production of this draft guideline, it appears that NICE have permitted the GDC to be controlled by those with conflicting interests and questionable conduct, which would predictably compete with the most effective diagnostic methods and treatment of patients, anti-trust issues preventing open competition for laboratories to market their tests on a level-playing-field, preconceived opinions about patients and outright abuse of those patient's rights and needs. The whole thing reeks of a predefined agenda that has been facilitated and promoted by NICE, and which from all appearances will be endorsed and 'validated' by the auspices of NICE.

CONCLUSION TO THE VIRAS STAKEHOLDER COMMENTS

In view of the extraordinary number of opportunities that these NICE guidelines provide for putting doctors and patients at serious risk, it is essential for all interested parties to be aware that NICE take no responsibility for any misleading information or dangerous advice included in their guidelines. Here is a typical NICE Guidance disclaimer:

"Health care providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply guidances. The recommendations cited here are a guide and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by the practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources. The National Clinical Guideline Centre disclaims any responsibility for damages arising out of the use or non-use of this guidance and the literature used in support of this guidance."
(<https://www.nice.org.uk/guidance/cg138/evidence/full-guideline-pdf-185142637>)

Whilst NICE have discarded a wealth of research and evidence as unsuitable in preparing their guidance, that same evidence may nevertheless stand-up in court. **Examples of foreseeable harms to patients are: if and when the restrictive treatment recommendations fail to eradicate a Lyme infection and a patient suffers injury as a result, or, if and when laboratory testing deprives a patient of a necessary diagnosis and treatment, and they suffer injury as a result.** Then the evidence that has been ignored may receive a fair hearing in legal proceedings, especially as much of this information comes from very experienced scientists and physicians. Harms to patients and complaints against doctors are not just predictable, they are inevitable if doctors with Lyme disease patients follow the advice as presented in the draft form. However, none of this is any consolation to doctors who do not want to spend their time dealing with GMC complaints and law suits, but who simply want to help their patients based on a balanced presentation of the available pool of knowledge.

VIRAS and others have provided ample evidence of foreseeable harms resulting from misleading advice about Lyme disease. NICE may wash their hands of any responsibility by claiming that individual doctors are responsible for their clinical decisions, but they can and will be held to account for negligently misleading the public and government agencies, discriminating against sick and disabled patients, and permitting their procedures to be exploited by groups and individuals with competing interests.

Doctors do not have to follow NICE guidelines but they must be able to justify their clinical decisions. The USA Centers for Disease Control and Prevention (CDC) now estimate that they have over 300,000 cases of Lyme disease per year. Some of the most experienced and knowledgeable Lyme disease doctors and scientists in the USA have produced reliable and trustworthy advice on the management of diverse aspects of Lyme disease. For doctors who want a thorough understanding of Lyme disease medicine, including the limitations of current knowledge, VIRAS recommends the authoritative resources listed here:
<http://www.ilads.org/Lyme/treatment-guideline.php>.

VIRAS reject the NICE draft guideline as unfit for purpose. It contains some downright dangerous advice and too many contradictions to even form the basis of a semi-reasonable guideline. It is

biased, discriminatory and appears to be designed to serve undeclared agendas. It implies certainty where there is none. Where it admits uncertainty it omits to provide balanced views to allow doctor's and patients to make informed choices and give informed consent as is required in the practice of medicine in the UK. This makes the draft unethical. It evades awkward and potentially embarrassing issues such as the inaccuracy of testing provided by the NHS, which it misrepresents with false assurances. It evades the serious medical issues of chronic Lyme disease, coinfections, misdiagnosis of Lyme as some other condition, and inadequate treatment. The guideline is not quantitative or qualitative or a rational amalgam of both. It is bereft of scientific discipline or basic humanistic and medical values.

NICE should have halted the process and rejected the task of producing a guideline when it became apparent that the vast majority of research did not meet the threshold for inclusion. Instead, it has produced a draft based on just a tiny and biased proportion of decades of research. The draft guideline is irrelevant to 99% of UK Lyme patients who would be harmed by its publication. The number and nature of the Research Recommendations clearly shows that not enough is known to produce a guideline that could remotely approach the required standards for NICE Guidance. These Research Recommendations relate to absolutely basic medical science concerned with the diagnosis, treatment and management of Lyme disease. Without good data to work with, or a balanced presentation of all the evidence available, the end product could only ever be a self-contradictory and impractical mess.

Thousands of UK Lyme disease patients have been obliged to take matters into their own hands due to the ignorance and incompetence of Public Health England. PHE (incorporating the HPA) have actively obstructed the diagnosis and treatment of Lyme disease patients for decades. The victims of this discrimination have been forced to either accept terrible illness which for many, represents a life-sentence of loss and suffering, or to seek medical help elsewhere. Patients spend their often meagre income and all their savings to get accurate tests and treatment that have been denied to them by the NHS.

The outcome of the treatment that they are forced to pay for, may not always be the cure that they sought. This is partly due to the incompetence that has delayed their diagnosis and treatment for months, years or even decades. Yet for many, their treatment brings great relief. Some of the appalling chronic symptoms improve or resolve completely. Physical and mental functioning which could have been reduced to just a tiny percentage of their pre-Lyme infection levels, are substantially improved and can be maintained with treatment. These patients KNOW what PHE policies have done to them and are doing to others. They will recognise the PHE official position on Lyme disease permeating the NICE draft guideline. They are not paranoid or conspiracy-theorists, they know from their own lived experience that Lyme disease is a national health threat that is being controlled by vested interests that disregard their Human Rights and the fundamental tenets for the practice of medicine. It is in spite of PHE that many of these patients have improved health, and such is the suffering that many have endured, they do not want others to have a similar experience. With the finest motives that grace humanity, even though their health and fitness may still be just a sad remnant of the energy they once enjoyed, they give of that time and energy to help others who will otherwise be doomed by PHE to the living hell of chronic Lyme disease.

The draft guideline shames UK medicine and will bring the good names of the NHS and NICE into disrepute. The danger to patients is obvious. This confused and confusing guide will predictably harm patients and threaten the reputation and values of doctors who place their trust in it.