

## **VIRAS response to: Who is the Focus? And excluded groups placed at risk by the Draft Scope**

30 1.1 Who is the focus?

49 Areas that will not be covered

51 Managing chronic fatigue syndrome. This is covered by the NICE 51 guideline: Chronic fatigue syndrome/myalgic encephalomyelitis (or 52 encephalopathy) (CG53)

### **Abbreviations**

AIDS, Acquired Immune Deficiency Syndrome

BIA, British Infection Association

CDC, Centres for Disease Control and Prevention, (USA)

CFS, Chronic Fatigue Syndrome

CRD, Centre for Reviews and Dissemination

DoH, Department of Health (UK)

FDA, Food and Drug Administration, (USA)

IDSA, Infectious Disease Society of America

LB, Lyme borreliosis

M.E., Myalgic Encephalomyelitis

HPA, Health Protection Agency

NATO, North Atlantic Treaty Organization

PCR, Polymerase Chain Reaction

PHE, Public Health England

WHO, World Health Organization

### **The following groups are at risk of being neglected by the NICE Guideline:**

Infected in the past and presently ill due to:

- never investigated for LB
- not investigated properly for LB
- misdiagnosed with something other than LB

Since the Lyme disease spirochaete *Borrelia burgdorferi* was discovered in 1982 by Dr Willy Burgdorfer, multiple species of Lyme Borreliosis-causing spirochaetes have been found in Europe. In the decades following these discoveries, UK doctors have probably encountered many thousands of patients with symptoms highly suggestive of LB, just as doctors have in all the other countries of north-western Europe.

Yet many of those doctors never considered Lyme borreliosis (LB) as a cause of their patient's illness - let alone conducted a careful evaluation or ordered tests, because:

- they had no experience of LB and little, if any, knowledge about the infection
- UK reported incidence figures made LB appear rare (and therefore unlikely)
- the doctor believed Lyme is only present in certain areas of the country
- if they did order tests and the results were negative they wrongly believed this excluded LB (and may even have been told by the test laboratory staff that this was so)

In England and Wales, in the 15 years from 1997 to 2011 there were a total of 7,903 cases of LB reported at an average of 527 cases per annum giving an average annual incidence of ~0.93 per 100k population. (Public Health England. 2013.) This apparent rarity has meant that in past decades, many doctors were not alert to the risk of the disease, except perhaps for some of those practising in LB 'hot-spots'. Yet significant risk to UK residents has been present and known to some, for decades.

In 1993, Nuttall et al (1993) submitted data to NATO's Second European Symposium on Lyme Borreliosis on the Ecology of Lyme borreliosis in the United Kingdom: showing that *Ixodes ricinus* (principal vector of LB in Europe) could be found throughout "Most of the UK" and that around 40% of unfed nymph and adult ticks "collected in Lyme disease foci" carried *Borrelia burgdorferi*, as shown by PCR.

In 2007, the late Professor Klaus Kurtenbach of Bath University told the BBC, "In France they have diagnosed 10 times as many cases as here; yet we've found the same number of ticks here carrying the disease." (BBC. 2007)

Dr Darrel Ho-Yen, who was head of the Scottish Lyme Reference Laboratory at Inverness, was quoted in The Field (2005) magazine: "He believes that the known number of proven cases should be multiplied by ten "to take account of wrongly-diagnosed cases, tests giving false results, sufferers who weren't tested, people who are infected but not showing symptoms, failures to notify and infected individuals who don't consult a doctor"."

Bruce Alexander (2012) wrote in the Scotsman, "A recent audit of patients at a Perthshire Medical Practice found a ratio of confirmed cases equivalent to 125 per 100,000 people. Applying this ratio across Scotland, there could be around 6,500 people contracting Lyme disease each year, the vast majority going undiagnosed and untreated." This computes to 30 times the reported incidence for Scotland, a country which has 3 times more recorded LB than England and Wales; and where more doctors are aware of the risks and symptoms of LB.

Some of the tens of thousands of 'the vast majority going undiagnosed and untreated' who had symptoms, have probably recovered. But without doubt, some of those who became chronically ill, were misdiagnosed with Myalgic Encephalomyelitis (M.E.) or Chronic Fatigue Syndrome (CFS); illnesses with very poor recovery rates and symptoms highly suggestive of chronic Lyme borreliosis.

VIRAS will argue that those patients, some of whom by now have been infected for decades, deserve proper investigation and a correct diagnosis. Even if some believe that patients with chronic LB infections may suffer the same fate as Tertiary Syphilis patients, who can have intractable infection and symptoms, it would be unethical to leave these patients misdiagnosed with CFS. Excluding these patients would be negligence reminiscent of the Tuskegee Syphilis Experiment (Wikipedia 2016).

The symptoms of some patients diagnosed with long-term M.E. or CFS should lead a well-informed doctor to suspect LB and duly investigate. We are not aware of a single case where this has happened. Instead, it has been left to patients to find out about Lyme borreliosis by sheer chance. Then, when they do consider their symptoms, risk factors and the course of their illness and consult their doctor; they are all too often dismissed or misled by an unreliable blood test which they are told definitively excludes LB.

With UK 'CFS' prevalence estimated at 256,000 (NICE 2007), and full recovery occurring in only ~10% (CRD 2002), if just 10% of M.E. or CFS patients were actually misdiagnosed cases of chronic LB, that could be 25,000 cases in the UK whose illness might respond to treatment. That will not happen while they are misdiagnosed.

Far from leading the way in recognising and addressing the silent epidemic of LB, PHE (and the former HPA) have been effective in suppressing the problem, in the worst traditions of national medical authorities who made a complete mess of dealing with the early years of AIDS. Patients who remain ill with every indication of chronic LB, frequently with laboratory confirmation, and who do not accept PHE's simplistic notions about a complex disease, have been branded "disaffected" and described as coming from a "parallel universe". It is an old political strategy to denigrate those whose views you wish to suppress and is a resort of those who have power and influence but no scientific evidence to back-up their arguments.

M.E. and CFS patients and campaigners have been subject to years of the same, with orchestrated efforts in the media to portray them as neurotic, hypochondriac and anti-science. And for whose benefit have chronically sick people been made the target of denigrating propaganda? Not the patients. Not their doctors. The winners are the medical insurance companies that avoid paying for the sustained treatment and management that chronically ill patients require; and those that have been negligent in protecting the Nation's health.

Schwarzwalder et al (2010) found that 14% of Lyme disease infection was misdiagnosed by patients and 20% misdiagnosed by physicians. This review was in Maryland, a USA state where many counties were classed by the CDC as 'high incidence' by the early 2000's (Kiersten et al. 2015).

If that is what happens where LB is common and well-known to doctors, what chance do UK patients have? Quite simply, the UK has a low incidence rate because PHE produce low incidence rates, making the disease appear rare, obscuring the risk, and misleading doctors and the public. In the UK, Lyme is not rare, but it is rarely diagnosed.

Dr Hugh Derham (2014) in Australia tested 300 of his ME, CFS and FM patients and found that 95% were positive for Lyme.

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*."

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.

### **Chronic LB and Post Treatment Lyme Disease Syndrome**

VIRAS consider the term 'chronic Lyme' legitimate. The infection can be persistent just as Syphilis, Leptospirosis and other bacterial infections such as TB can be persistent. There is no medical or scientific basis for rejecting the term 'chronic Lyme'. Whilst this invidious reservation may serve the purposes of those that have motives to portray Lyme as a simple, acute illness – it denies the complexity of the infection and flies in the face of common sense and a wealth of published evidence.

Dr Willy Burgdorfer, who discovered the Lyme spirochaete, *Borrelia burgdorferi*, in 1982, told investigators for *Under Our Skin* (2007): "I am a believer in persistent infections because people suffering with Lyme disease, ten or fifteen or twenty years later, get sick [again]. Because it appears that this organism has the ability to be sequestered in tissues and [it] is possible that it could reappear, bringing back the clinical manifestations it caused in the first place." (Square brackets as published)

VIRAS consider the term 'post treatment Lyme disease syndrome' (PTLDS) misleading, though this depends to an extent on what is meant by 'post treatment'. The term is loaded and intentionally or not, implies that the 'treatment' aspect must have been sufficient and effective. The term suggests that if a patient remains ill after treatment it is not because their treatment was ineffective and the infection remained and relapsed. If this was not the intention of those who use the term, we might also have the term 'Failed Treatment Lyme Disease Syndrome', which would accurately indicate failure to cure a patient who had received some treatment. Unfortunately, in some people's minds the responsibility for the latter might fall on physicians rather than the bacteria or patient. So it may lack a certain appeal to those who coin these terms and foist them on unsuspecting patients.

We are not aware of any scientific evidence that 'post treatment Lyme disease syndrome' even exists; or that anyone deemed to have the syndrome has ever been repeatedly tested to the full extent of available methods. An experiment like that could provide convincing evidence that the infection really had been eliminated and make PTLDS a plausible explanation for their ongoing symptoms. Whereas the contrary is true. When chronically ill UK patients are thoroughly investigated the infection is often found to remain present long after they received 'adequate treatment'.

It is widely recognised that LB infection even in the quite short-term, can cause serious damage to almost any parts and systems of the body. It seems reasonable to believe that the injury could be long lasting or permanent. But that does not mean that it is the only cause in patients whose symptoms persist. The fact that patients continue to experience exacerbations and relapses, sometimes decline and are afflicted with new, debilitating and distressing symptoms, suggests an ongoing disease process for which persistent infection is a strong candidate supported by scientific evidence. (See: ILADS. 2012. Peer Reviewed Evidence of Persistence of Lyme Disease Spirochete *Borrelia burgdorferi* and Tick-Borne diseases. And Moyer. 2015. Scientific American. Lyme Disease May Linger for 1 in 5 Because of "Persisters")

Without evidence meeting scientific standards of thoroughness, reliability and reproducibility, 'post treatment Lyme disease syndrome' is simply an opinion based upon a one-size-fits-all notion of 'treatment' and is in our experience, used by those with biased opinions and conflicting interests.

When patients with chronic LB research the field to try and find out how science could help them, what they find is that 'science' has been usurped by 'opinions'. It is not the patients and campaigners that are anti-science; our views are almost invariably supported by scientific research. But examine the IDSA or BIA or PHE Guidelines for LB and where there is controversy, those guidelines are based on mere opinion with no scientific evidence to support them. These opinions might look good, thanks to 'paper-pile' publishing and 'circular-referencing' and quoting (and misquoting!) of each others opinions creating an appearance of authority. Challenges to anything that threatens their views are slipped under the door of peer review as "a quibble, couched in the language of an exposé" (Earp. 2015). Critical examination reveals nothing more substantial than repetition of opinions lacking objective evidence.

Ioannidis, (2005) stated in Plos Medicine, "Empirical evidence on expert opinion shows that it is extremely unreliable". Yet much of the information about LB supplied by the DoH, NHS, PHE and BIA is nothing more than 'expert opinion' imported from the American IDSA and parroted to patients and physicians as though it is scientific fact. These opinions (which happen to serve the interests of medical insurance and re-insurance companies) portray Lyme borreliosis as a simple, self-limiting, acute infection, easily detected and diagnosed and eradicated with a few weeks of antibiotics.

Professor Charlton (2008) remarks: "And when a branch of science based on phoney theories serves a useful but non-scientific purpose, it may be kept-going indefinitely by continuous transfusions of cash from those whose interests it serves. If this happens, real science expires and a 'zombie science' evolves."

The converse is true. When the research needed to identify, understand and treat UK borreliosis is not being undertaken (because according to those charged with the protection of the nation's health, it is so rare in the UK), it is little wonder that many LB patients have been misdiagnosed with M.E. or CFS. Yet UK authorities

continue to rely on either non-UK sources, or UK sources which are simply repeating opinions which actually originate from the IDSA.

We hope that NICE Guidelines for LB will recognise a duty to the thousands of LB patients who have never been properly evaluated or diagnosed and treated. These patients have been failed by the authorities appointed to protect them and too often have been misdiagnosed with 'CFS'.

Notwithstanding NICE guidelines for that illness, these patients have been subject to prejudice and abuse by all and sundry; portrayed as neurotic, blamed for their illness and marginalised, whilst their lives have been ruined by a chronic infectious disease.

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