

## **VIRAS response to NICE request for comments on 6 month 'phase' (including observations on why this might have been suggested):**

- "1) Is the time period of '< 6 months since tick bite or first symptoms or signs' an acceptable interpretation for 'early Lyme borreliosis'?
  - 2) Is the time period of '> 6 months since tick bite or first symptoms or signs' or an acceptable interpretation for 'late Lyme borreliosis'?"
- Pertains to Draft Scope document Page 3. Lines 74 to 77

### **Abbreviations**

CFS, Chronic Fatigue Syndrome  
GDG Guideline Development Group  
HPA, Health Protection Agency (now part of PHE)  
IDSA, Infectious Disease Society of America  
ILADS, International Lyme and Associated Diseases Society  
LB, Lyme Borreliosis  
NHS, UK National Health Service  
PHE, Public Health England  
M.E., Myalgic Encephalomyelitis  
NICE, National Institute for Health and Care Excellence

An arbitrary time limit deemed to be a transformation point from one Lyme borreliosis phase to another has no medical or scientific logic.

Miklossy (2012) states in The Open Neurology Journal:

"Late Lyme neuroborreliosis is accepted by all existing guidelines in Europe, US and Canada. The terms chronic and late are synonymous and both define tertiary neurosyphilis or tertiary Lyme neuroborreliosis. The use of chronic and late Lyme neuroborreliosis as different entities is inaccurate and can be confusing. Further pathological investigations and the detection of spirochetes in infected tissues and body fluids are strongly needed."

In Lyme borreliosis, the time between infection (or re-infection) and the appearance of symptoms/signs which a patient or physician might associate with LB is highly variable and could be months or years. The U.S. Library of Medicine, MedlinePlus (2015) states:

"Symptoms of early disseminated Lyme disease (stage 2) may occur weeks to months after the tick bite, and may include ..."

"Symptoms of late disseminated Lyme disease (stage 3) can occur months or years after the infection. The most common symptoms are muscle and joint pain..."

Clearly the stages of LB infection do not conform to a predetermined timescale. Different stages depend upon variables impossible to compute and more rationally deduced by careful evaluation of each individual patient's symptoms and laboratory tests, if indeed a physician considers determination of a 'stage' or 'phase' to be a worthwhile exercise.

What purpose is served by attempting to define the progression of a disease by a fixed time period and how would it help doctors in making their clinical decisions?

It seems unlikely that re-labelling patients at 6 months is considered a useful way to suggest the best tests for a patient's infection. According to Public Health England (2014), the weaknesses they acknowledge for their tests relate to cross reactivity with other infections and "antibody tests in the first few weeks of infection may be negative". These problems would not be improved by a 6 month deadline.

Once a patient has been diagnosed and treated, further standard NHS two-tier testing is rendered useless because as West (2014) states: "Both IgM and especially IgG antibodies can remain positive for years after successful therapy with antibiotics." So the determination of treatment success or failure by standard testing would not be helped by a 6 month time limit.

There are no tests for LB at any stage which can reliably exclude infection or confirm that treatment or time has eradicated an infection. If such a test (or combination of tests) existed, it is certain that PHE, the CDC, the IDSA and others would have used the test in support of their opinion that persistent infection does not occur beyond what they claim is 'adequate' treatment. In contrast, the scientists and doctors of ILADS (2012) who declare that persistent LB infection does occur, provide a list of 700 peer-reviewed scientific papers indicating persistence, in 'Peer Reviewed Evidence of Persistence of Lyme Disease Spirochete *Borrelia burgdorferi* and Tick-Borne Diseases'.

Furthermore, treatment considerations are guided by disease manifestations and sometimes supported by laboratory test results. E.g., neuroborreliosis is a diagnosis of the spread of LB spirochaetes to the central nervous system (CNS). It is suspected by symptoms, supported by examination and testing of cerebrospinal fluid (CSF) and treated by intravenous antibiotics. Neuroborreliosis can occur at any time in infected individuals because it relates to the spread of the infection. If the bacteria's 6 month 'VISA' runs out, that would not prevent it crossing the barrier into the CNS.

Therefore determining the choice of tests or treatment cannot be the motive for trying to determine the phase of a patient's infection according to a calendar.

A 6 month phase could not apply to an infant born infected or an infant with an immature immune system that becomes infected. How would 6 months apply to a child which is quite simply, a much smaller mammal than an adult human? Would the transformation from 'early' to 'late' infection happen at the same time in a person initially infected with a few spirochaetes compared to someone infected via multiple heavily infected tick bites which also transmitted ehrlichia and bartonella? In some regions, 10% to 20% of healthy blood donors are seropositive for Lyme antibodies. If they become ill in the future, will that be 'early' or 'late' Lyme? (Mygland, Skarpaas and Ljøstad, 2006; Hjetland et al 2014)

Dr Willy Burgdorfer, who discovered the *Borrelia burgdorferi* spirochaete in 1982, stated (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."

When asked about the similarities between *Borrelia burgdorferi* and syphilis, Dr. Burgdorfer stated: "The similarities that I know of are associated with the infection of the brain, the nervous system. The syphilis spirochete, *Treponema pallidum* has an affinity for nerve tissues. The *Borrelia burgdorferi* spirochete very likely has that too. Children are especially sensitive to *Borrelia burgdorferi*. The Lyme disease spirochete is far more virulent than syphilis." (Under Our Skin, 2007).

Since early and late stages for Lyme borreliosis reflect similarities with syphilis, they must recognise that stages are determined by the spread and manifestation of the infection and not by a calendar. NHS Choices, (2014) remarks on Syphilis:

Primary syphilis: "The initial symptoms of syphilis can appear any time from 10 days to three months after you have been exposed to the infection."

Secondary syphilis: "The symptoms of secondary syphilis will begin a few weeks after the disappearance of the sore."

Latent phase: "The latent stage can continue for many years (even decades) after you first become infected."

Tertiary syphilis: "The symptoms of tertiary syphilis can begin years or even decades after initial infection."

Specifying a 6 month or other arbitrary time-point between phases is so illogical, that one could be excused for questioning the motives behind even contemplating such a notion.

Perhaps it is a coincidence that the CDC/Fukuda (1994) criteria for a diagnosis of Chronic Fatigue Syndrome requires 6 months of symptoms with fatigue criteria (which is common in LB). There is evidence which suggests that Public Health England intend that chronic LB patients should be re-diagnosed as having CFS or some other contrived 'syndrome', e.g., 'chronic arthropod neuropathy syndrome'. The HPA (now part of PHE) informed the Health and Safety Executive (2012) of their plans:

"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 un-provable Lyme disease. This will cover the therapeutic approach, investigation of cases and disengagement strategies when further investigation is counter-productive."

In view of their plans for 'development of guidance for clinicians', one may speculate that PHE will attempt to steer the NICE GDG process to meet their predetermined agenda. That agenda appears to include a 6 month period after which they deem it acceptable for doctors to 'disengage' from patients if the

patient cannot 'prove' that they have Lyme borreliosis. This agenda could deprive patients of medical care and deny them treatment and could be attractive to some who are more concerned about financial costs than patient welfare.

The strategy might also be favourable to medical re-insurance companies who have saved a lot of money thanks to a few psychiatrists who compounded the neurological disease, Myalgic Encephalomyelitis with 'CFS' and then classified CFS as a Functional Somatic Disorder. This has meant that policy claims can be limited to 2 years for a notoriously chronic and severely debilitating neurological disease. Are people with chronic Lyme borreliosis destined for the same?

'Professor Sir Simon Wessely's group' are psychiatrists, and it seems that PHE would like them to take control of the fate of patients who do not recover in an allotted time. They have some history with NICE, as observed by Professor Malcolm Hooper (2007) in his written evidence to the Parliamentary Select Committee on Health regarding the NICE GDG for 'CFS/ME':

"14. The advisors upon whom NICE relies have been shown to have undeclared vested interests: These psychiatrists and their adherents are heavily involved with the medical insurance industry, including UNUM Provident, Swiss Life, Canada Life, Norwich Union, Allied Dunbar, Sun Alliance, Skandia, Zurich Life and Permanent Insurance, as well as the re-insurers Swiss Re..."

Dr Darrel Ho-Yen (1990), who became the head of the Lyme Reference Laboratory at Inverness, commented on the Wessely group's ideas in the Journal of the Royal College of General Practitioners: "...it has been suggested that a new approach to the treatment of patients with postviral fatigue syndrome would be the adoption of a cognitive behavioural model (Wessely S, David A, Butler S, Chalder T: Management of chronic (postviral) fatigue syndrome. JRCGP 1989;39:26-29). Those who are chronically ill have recognised the folly of the approach and, far from being maladaptive, their behaviour shows that they have insight into their illness".

VIRAS rejects the concept of a 6 month period for the transformation of a patient's LB infection from one stage to another as inaccurate, negligent and unethical. We are curious to know where this idea originated and what scientific justification was provided for this notion of an infectious disease progressing according to a calendar.

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