

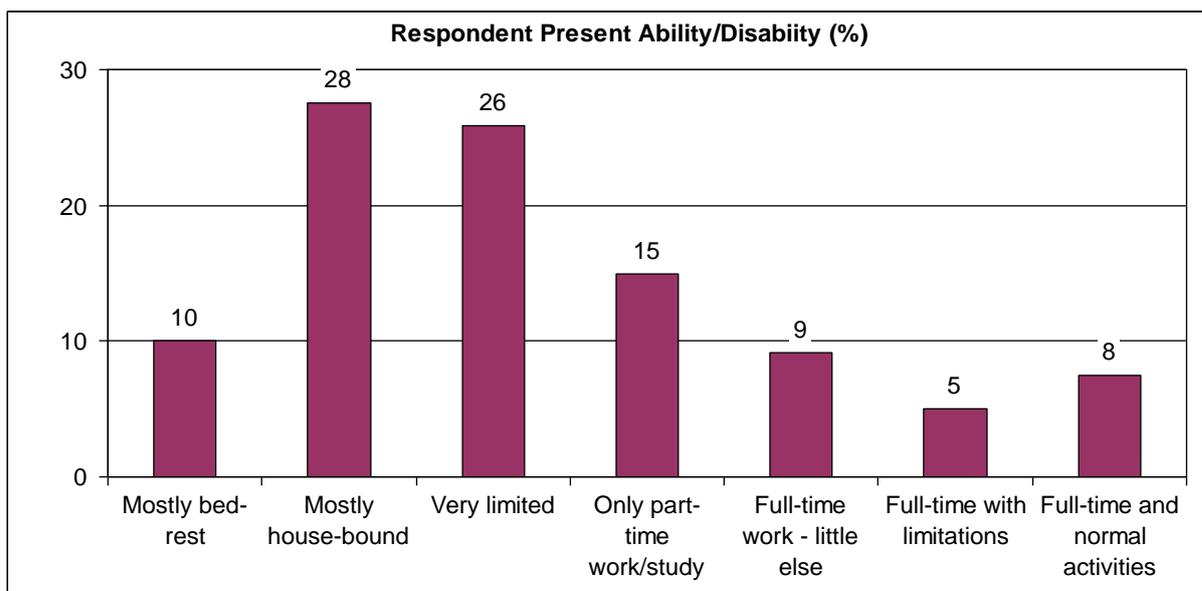
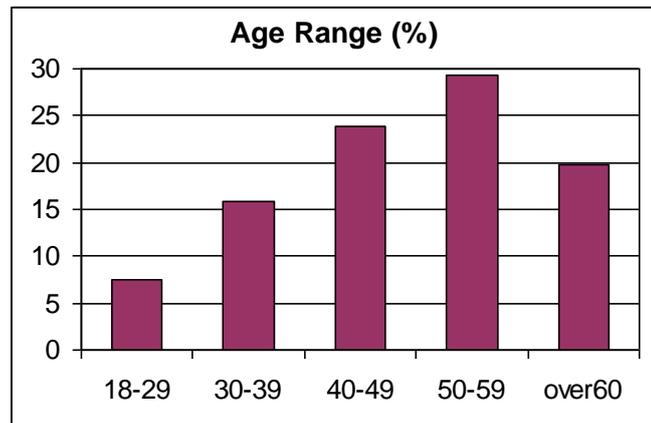
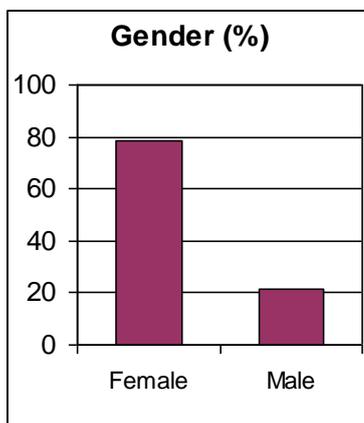


**NHS Testing and Investigation of
Lyme Borreliosis – Patient Experiences Survey**

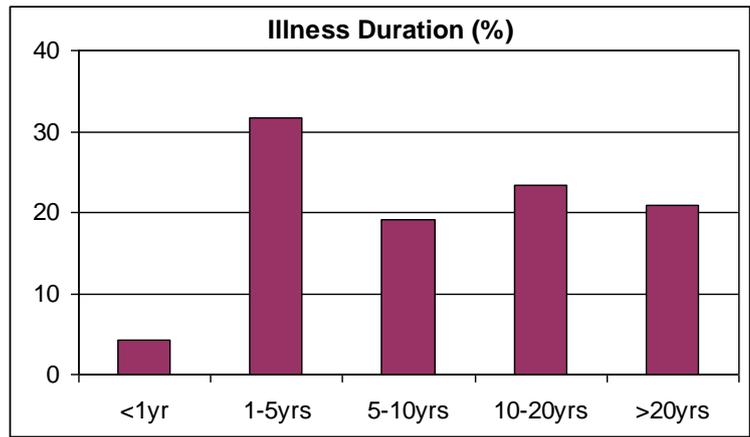
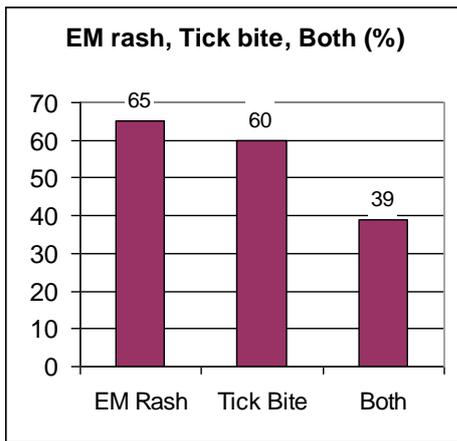
120 people from online patient support groups completed a survey with questions about their symptoms, tests and experiences of medical investigations for Lyme borreliosis (LB) carried out by the National Health Service (NHS).

The source of respondents means that many are patients who have not recovered from their illness following NHS investigations, have been ill for some time and are likely to be relatively well-informed regarding testing and diagnosis of Lyme borreliosis.

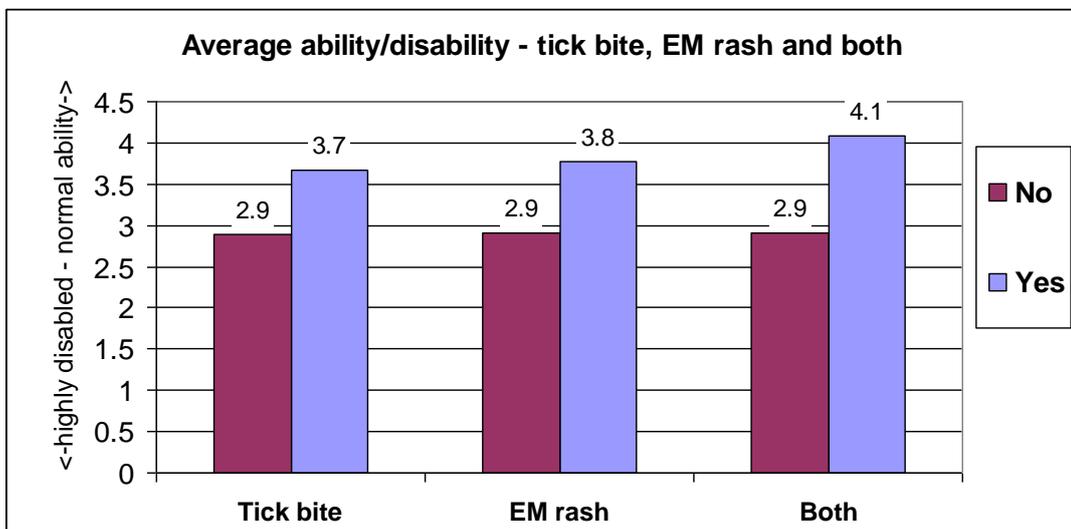
Respondent Details



- Only 22% of respondents are well enough for full-time work



- A tick-bite is a risk factor for LB. Some patients do not recall being bitten by a tick.
- An Erythema Migrans rash (EM rash) is diagnostic. However, the rash may be absent, overlooked (faint, atypical or hidden) or forgotten.

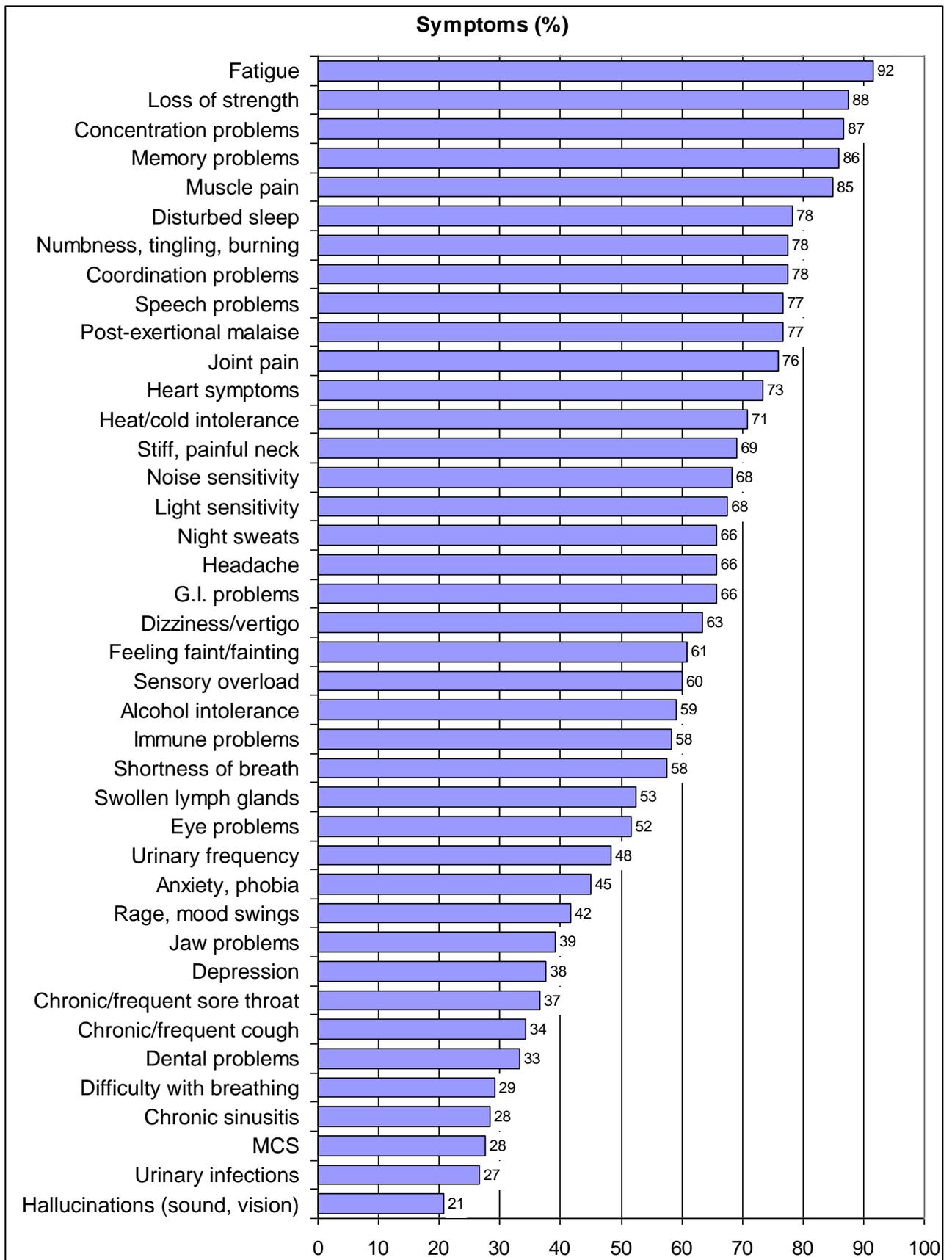


On average, respondents that reported either a tick-bite or an EM rash were less restricted in activities. Respondents that reported both were on average, an entire point more able-bodied on the scale of ability/disability. This could mean the difference between being bed-bound or housebound; or able to work part-time or full-time, as well as the corresponding improvement to quality of life.

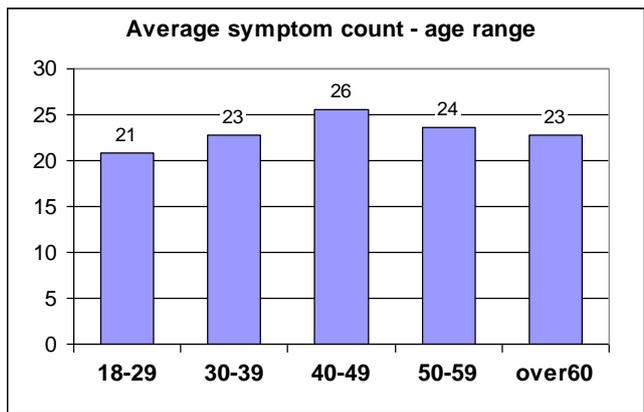
Respondent's Symptoms

- The average number of symptoms reported by respondents is 24
- 92% have had 10 or more of the symptoms listed
- 70% have had 20 or more
- 33% have had 30 or more

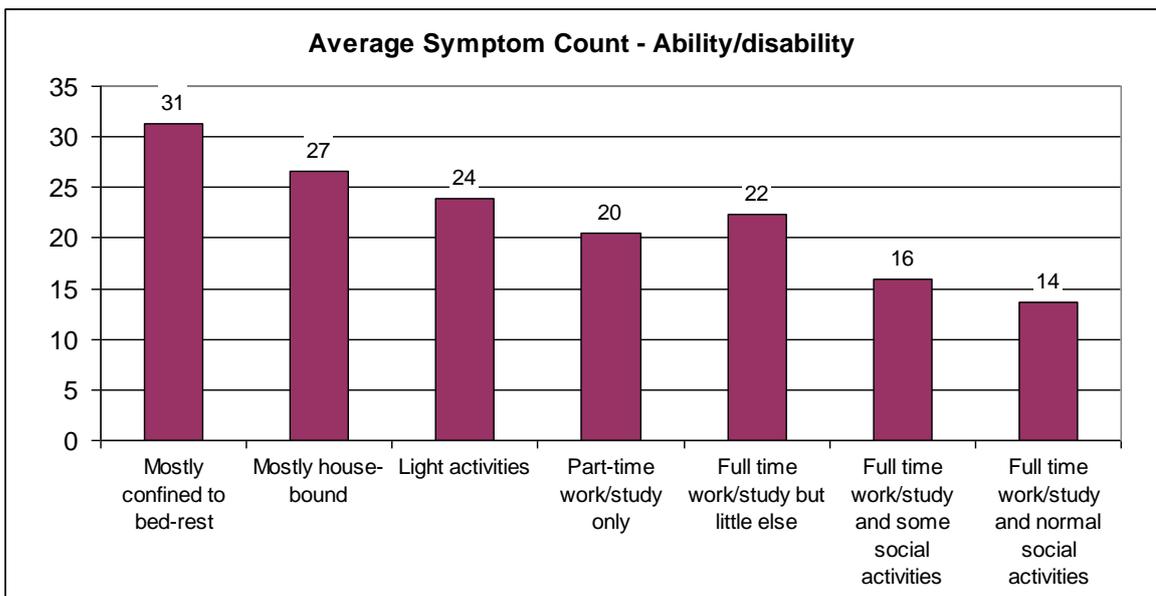
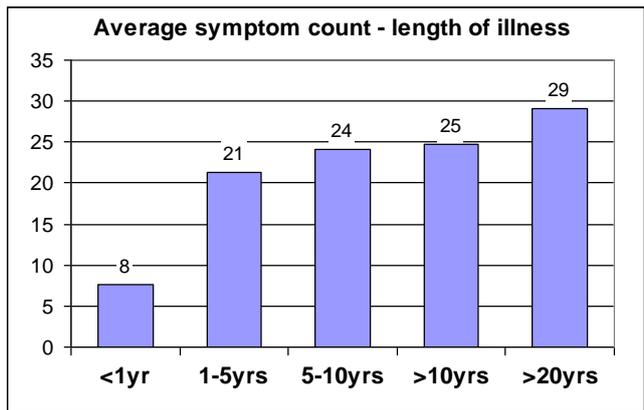
The chart below shows the percentage of respondents having symptoms that were significantly disturbing and which were present for a month or longer and of new onset and which they associate with their illness. Therefore some symptoms may have occurred in an acute or relapse phase or as progression of chronic disease. These symptoms can all correlate with Lyme borreliosis.



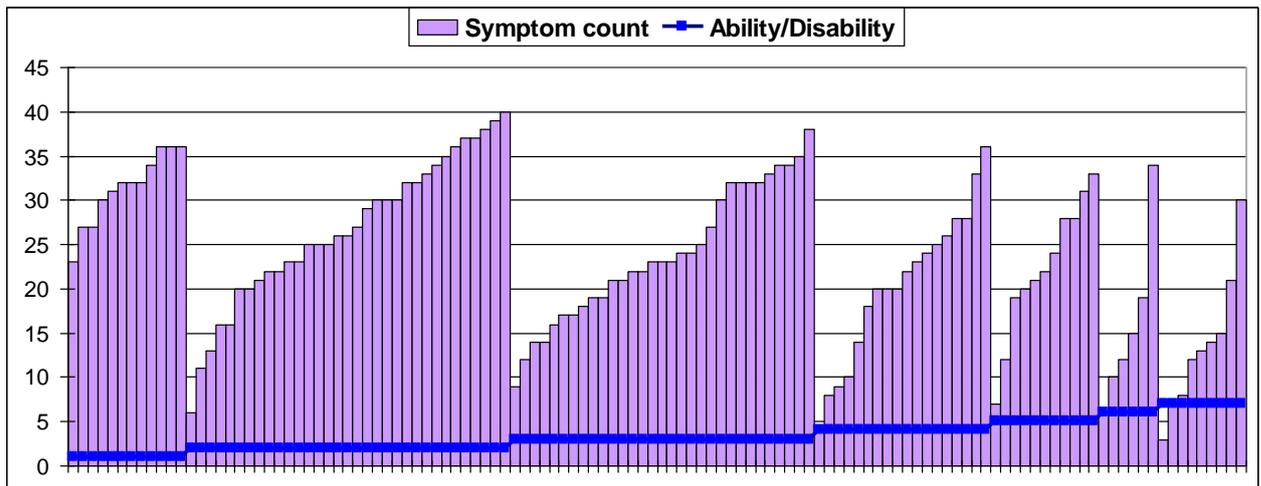
- Symptom Count – Age Range. The data shows no correlation between the average of respondent’s Symptom Count and their Age Range.



- Symptom Count – Length of Illness. Respondents that have been ill for over 1 year can experience many symptoms that correlate with LB.



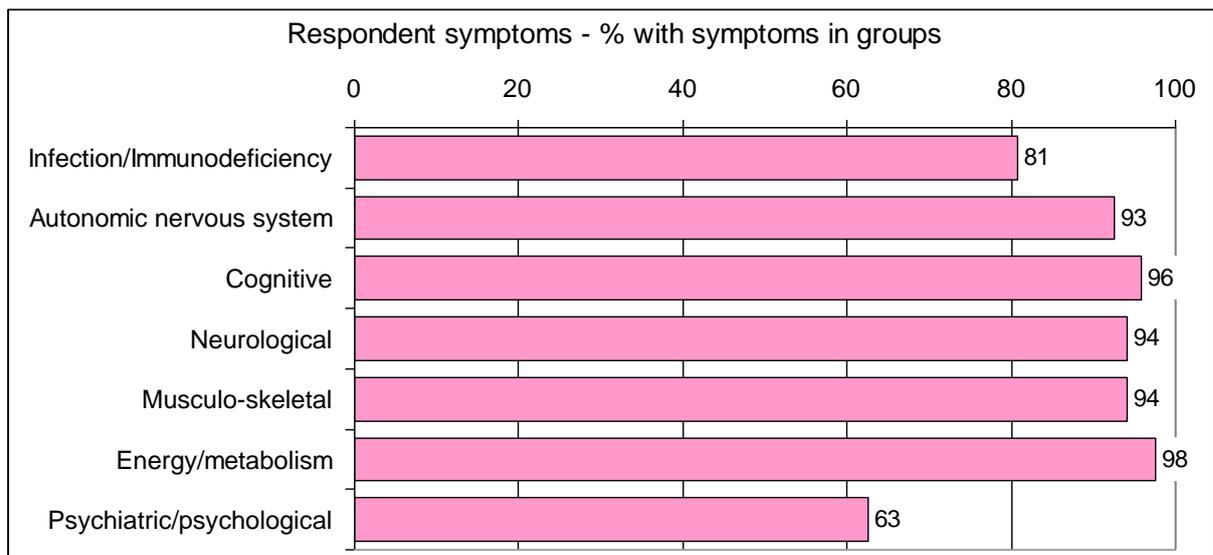
A trend is seen which suggests that the *average* number of symptoms in a group might be associated with the level of ability/disability. However, the following chart illustrates an important factor and one that was found with all measures and experimental cross-correlations in this survey: the data invariably shows a wide range of values. The data has shown some trends, but in individual cases these trends could be misleading. E.g., the chart below shows that respondents who are currently housebound have had from 6 and up to 40 symptoms; and that those in full-time work sometimes reported 30 or more symptoms.



- The data shows a trend for more symptoms to be associated with greater disability but this could be misleading in individual cases

Categorised Symptoms grouped as:

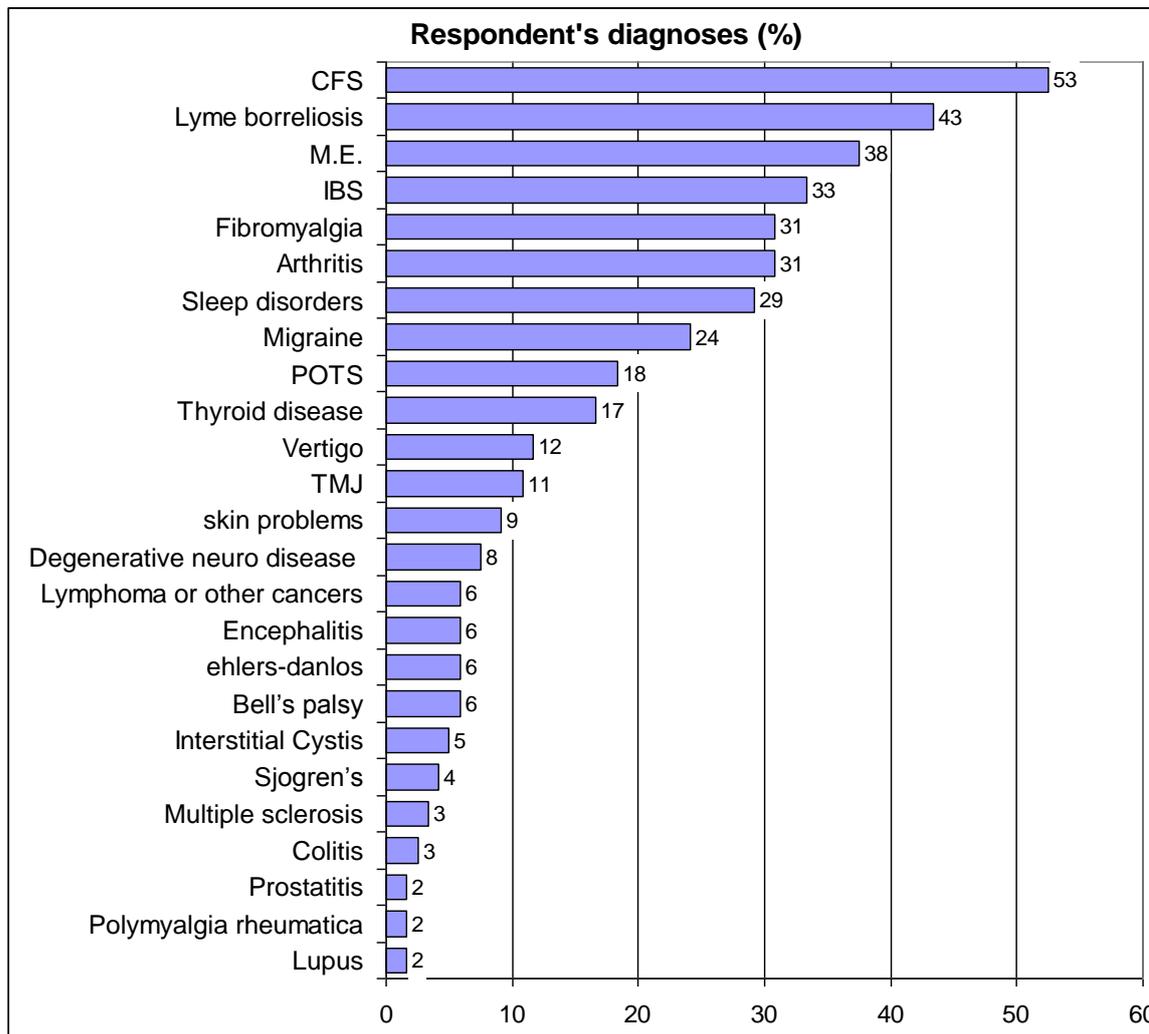
Infection/Immuno-deficiency	Cognitive	Energy/metabolism
Immune problems	Concentration problems	Fatigue
Swollen lymph glands	Memory problems	Post-exertional malaise
Chronic/frequent cough	Speech problems	Loss of strength
Chronic/frequent sinusitis	Sensory overload	Psychiatric/psychological
Chronic/frequent sore throat	Neurological	Anxiety, phobia
Urinary infections	Coordination problems	Depression
Autonomic nervous system	Light sensitivity	Rage, mood swings
Difficulty with breathing	Noise sensitivity	
Shortness of breath	Numbness, tingling, burning	
Urinary frequency	Musculo-skeletal	
Feeling faint/fainting	Stiff, painful neck	
Heat/cold intolerance	Muscle pain	
Heart symptoms	Joint pain	



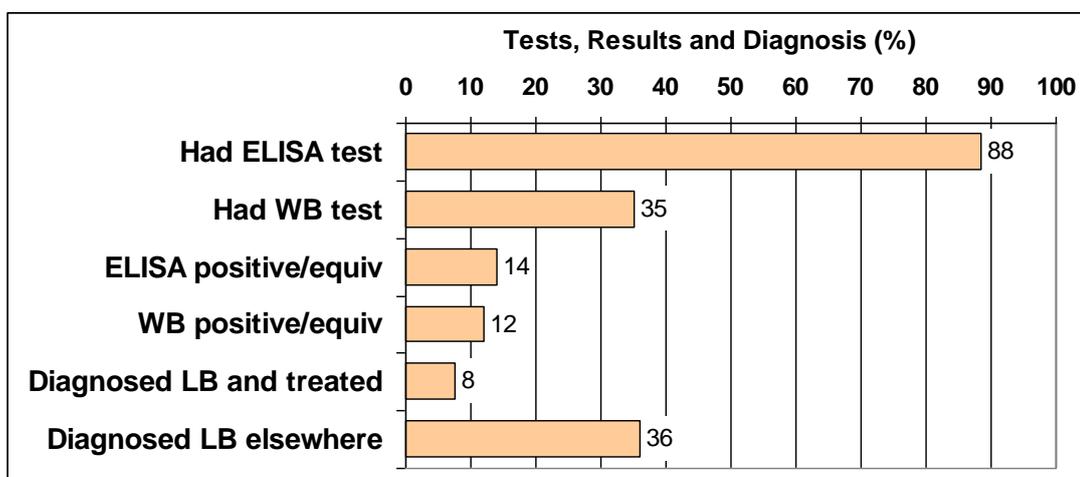
- 53% reported a symptom in all 7 categories and 30% have a symptom in 6 categories.

Respondent's Diagnoses

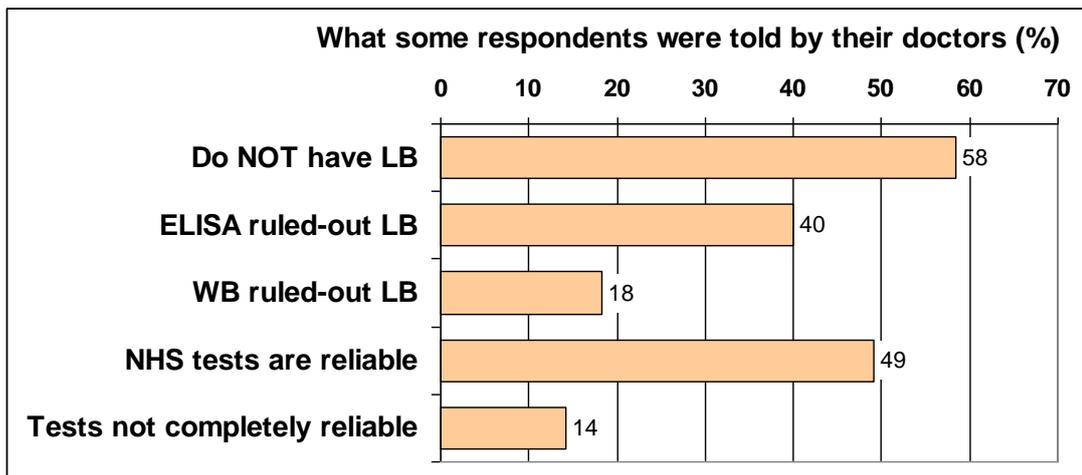
A considerable number of diseases and conditions can be co-diagnoses or misdiagnoses of Lyme borreliosis. Lyme is sometimes called 'the new great imitator' because it can manifest with diverse symptoms and illness.



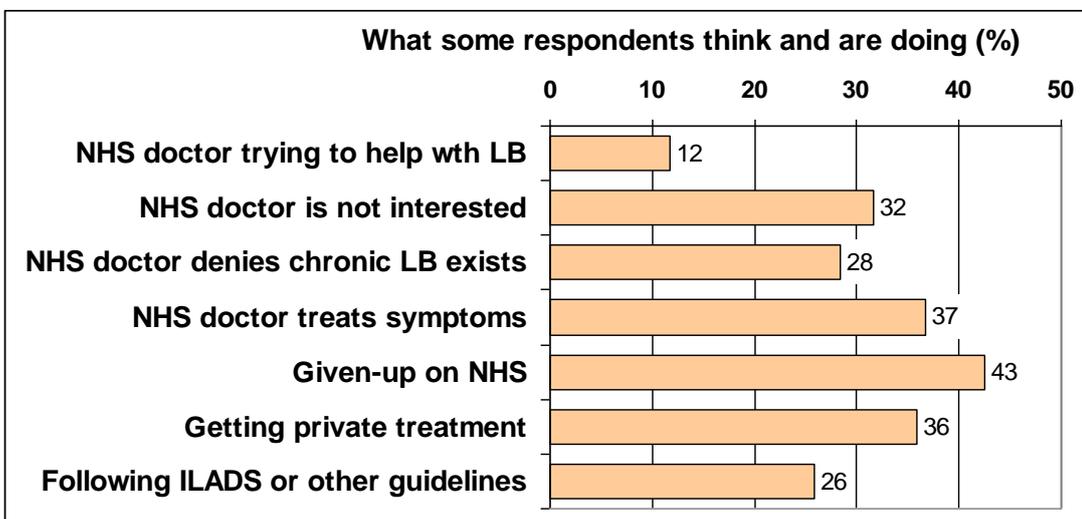
Tests, Results, Diagnosis and More



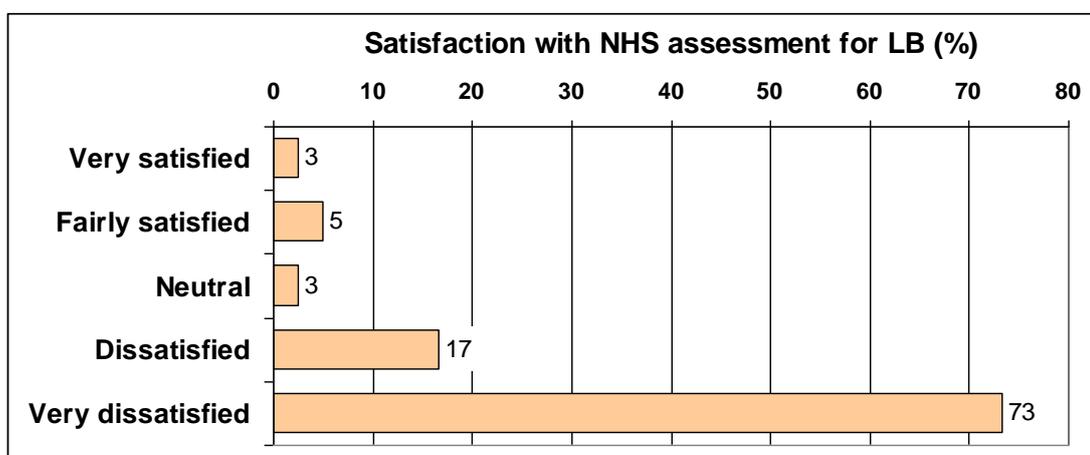
- Only 6% of respondents had a positive ELISA *and* a positive Western Blot (not shown). This is the NHS 2-tier indirect test which attempts to support a Lyme diagnosis by detecting the presence of antibodies to a borrelia infection.



- 53% of respondents were told that an ELISA and/or a Western Blot test ruled-out Lyme borreliosis. There is no laboratory test that can rule-out a Lyme diagnosis.



- 55% of respondents are not receiving NHS or private treatment and must therefore be self-managing their illness. This group's average symptom count is 22. 60% of these have very limited ability and 30% are housebound by their illness.



- 90% of respondents are dissatisfied with their NHS assessment for LB.

Discussion

Misinformation

The NHS 2-tier test for Lyme borreliosis attempts to detect the presence of antibodies to a borrelia infection. The first-tier or screening test is the ELISA which if positive or equivocal, may be followed by the second-tier test which is a Western Blot. 53% of respondents were misinformed by their doctor that a negative ELISA and/or a negative Western Blot test ruled-out Lyme. Ruling-out Lyme with these tests is scientifically impossible. These indirect tests are incapable of confirming the presence or absence of infection with any of the borrelia genus spirochaetes. Doctors should not mislead patients by making false claims about Lyme disease testing. This apparently common occurrence is in breach of General Medical Council (GMC) Guidelines for Good Medical Practice and shows a shocking level of ignorance of the most basic facts about Lyme testing.

Utility of a Symptom List

The indicative symptoms that respondents have reported in this survey could be a clue for their doctors to consider further investigations and/or a tentative diagnosis of Lyme borreliosis. But there are a number of reasons why these clues could be overlooked. Firstly, patients often cannot recall all the symptoms that they have without help (e.g. with a list – as was presented with this survey). It seems likely that the symptoms that they do report to their doctor are those which cause them most restrictions and/or pain and are therefore foremost in their mind.

Secondly, with a complex and variable illness like Lyme, only experienced specialists could be expected to know how to examine and interview a patient for its numerous possible symptoms; including making allowance for the commonly observed cognitive problems which 96% of respondents reported experiencing. Therefore General Practitioners might benefit from having a symptom list to refer to – as would their patients. A comprehensive list and additional guidance is available in ***Advanced Topics in Lyme Disease*** by Dr Joseph Burruscano which is available here: http://www.ilads.org/lyme/B_guidelines_12_17_08.pdf

A reference list of symptoms might prove valuable in evaluating patients with long-term illness of unknown aetiology such as M.E., Chronic Fatigue Syndrome, IBS, Arthritis, Fibromyalgia etc. In this survey 62% of respondents had been diagnosed with either M.E. or CFS. The National Institute for Health and Care Excellence (NICE) Guidelines for ME/CFS specifically require excluding Lyme before making a diagnosis. Doctors that rely upon serology to exclude Lyme have not been thorough enough.

As the current NHS tests cannot rule-out Lyme borreliosis and given the overlap of symptoms, misdiagnosis with M.E. or CFS is inevitable. Exactly how unreliable the 2-tier test is, remains unknown. Objective experiments suggest that 50% sensitivity is probably overly generous. Tests are evaluated against other methods which also suffer from sensitivity limitations; immune response in patients is variable; and it remains to be seen just how many additional borrelia species cannot be detected with current tests. Therefore the number of missed cases which end-up misdiagnosed as ME/CFS or something else that is unknown.

What is known, is that in 2007, the late Professor Klaus Kurtenbach 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." The same disparity in diagnosis between France and the UK remains today, so the UK could have tens of thousands of undiagnosed and untreated cases of borreliosis.

Borrelia genus spirochaetes are related to Treponema Pallidum, the spirochaete which causes syphilis. Syphilis is known as 'The Great Imitator' because of the diversity of illness and symptoms that it can cause. It is also known to cause persistent infection. In 2007 Dr Willy Burgdorfer, who discovered the Lyme disease spirochaete stated: "The Lyme disease spirochete is far more virulent than syphilis", indicating the potential severity of symptoms and debility that can occur with Lyme.

Lyme borreliosis is referred to by some as the 'new great imitator' because like syphilis, it can manifest in diverse ways, affecting multiple organs and systems of the body. Therefore patients with untreated Lyme could be expected to present with diverse symptoms that might seem to make no sense to their doctors. As a result they may get a host of seemingly unrelated diagnoses which would predictably include syndromes with unknown aetiology such as Chronic Fatigue Syndrome.

Missed cases of Lyme in the UK are probably diagnosed with M.E., CFS, arthritis, MS, IBS etc., as well as psychological diagnoses like depression, phobia, bipolar disorder etc. European Lyme epidemiology suggests that in the UK this is likely to have happened to thousands if not tens of thousands of unfortunate patients. The consequences to patients misdiagnosed in this way have sometimes been terrible.

As with syphilis, an unknown number of untreated Lyme cases will not simply resolve but persist, causing symptoms and illness. Thorough investigation of patients with symptoms that could be indicative of Lyme borreliosis is therefore essential; even if some other diagnosis has already been made. The use of a symptom list could help to identify those patients requiring more reliable Lyme investigations than are currently routinely provided.

EM Rash and Tick Bite

The survey data cannot explain why the 33% of respondents that reported both a tick-bite and an EM rash are on average, a full point less disabled on the ability/disability scale, even when those with positive Western Blots (and therefore more likely to have received treatment) were excluded from the calculation. Perhaps some factor(s) made a better outcome more likely which could include:

- The respondent consulted their GP earlier
- The GP or respondent connected the patient's illness with Lyme earlier
- With a clear risk factor and indicative sign, respondents that did not get help from the NHS and who could afford to, consulted a private doctor and/or travelled abroad for diagnosis and treatment

28% of respondents reported neither a tick-bite or EM rash yet have similar symptoms, length of illness and worse disability to those that did report them. Many of these respondents have symptoms that suggest Lyme borreliosis. However, the data shows that a substantial proportion with both a tick bite and an EM rash have

also not been diagnosed and treated by the NHS. This shows that many respondents regardless of prior test results, treatment or diagnosis, require further investigations for borreliosis. More investigations employing the same methods that have failed so many respondents (and according to published research, many thousands of others) might well be useless. Therefore evaluation and testing by alternative methods are required. Alternatives could include use of direct detection methods such as tissue culture; multiple tissue sources where indicated, DNA detection and microscopy. This would provide patients with the best possible chance of detection of a borreliosis infection.

Investigations for Lyme borreliosis by the NHS has left respondents dissatisfied, seemingly inadequately investigated, frequently misinformed by their doctor and remaining ill with no diagnosis and no treatment. Over-reliance on patients noticing and remembering a tick-bite and/or presenting with an EM rash and/or having positive 2-tier serology, any and all of which are merely inconsistent clues in a complex puzzle, is irresponsible in the diagnosis a serious disease.

These tests and criteria are failing many patients. The UK has been left far behind in borreliosis diagnosis, treatment and research, but not as far behind as the patients whose lives are blighted by a treatable infection that the NHS seem incapable of even diagnosing.

Recommendations

VIRAS suggest that a symptom list should be made available to doctors similar to the list designed by Dr Burrascano. This could improve evaluation of suspected Lyme borreliosis cases. It would also assist in investigation of patients with long-term illnesses such as Chronic Fatigue Syndrome.

Doctors should be instructed to provide their patients with accurate information in accordance with GMC Guidelines and to not make false and misleading claims about the capabilities of NHS testing for Lyme.

VIRAS propose that measures should be taken to instigate the routine use of alternatives to 2-tier testing for Lyme borreliosis when patient symptoms are indicative but the current NHS 2-tier test fails to confirm infection. A test similar to the one provided by Advanced Laboratory Services, which combines refined and rapid culture methods with direct detection of borrelia bacteria, would compensate for some of the shortcomings of the present system.