



Analysis of the NICE Lyme disease draft Guideline Research Recommendations

Introduction

The number and nature of NICE's recommendations for "high priority" research can lead to only one conclusion: attempting to produce a guideline with so much missing evidence, was an exercise in futility which should not have been undertaken. NICE have wasted thousands of pounds of public money in the production of advice which at best will cause confusion and at worst will harm patients and doctors. NICE have chosen to ignore the clinical evidence of doctors who have treated thousands of patients, but have included some biased and low quality clinical trials as 'evidence'.

NICE do not fund research and they can call for any and every investigation they can think of, and none of it will ever have to be delivered. Aside from the sheer scale of the research that they have recommended, some of the projects conceal hidden agendas. When analysed critically, some of these projects would predictably harm patients and obstruct their proper medical care, and some would be either pointless or even impossible to complete.

When reading the NICE research recommendations, please remember that all of these are supposedly "high priority" for England and Wales. Combined, these two countries have around 1,000 officially reported cases of Lyme disease per year. This equates to an incidence of 1.75 cases per 100,000 population. It is notable that much of the research that NICE recommend has not been done by nearby countries, even though they have incidence rates up to 170 times higher than England and Wales. Yet NICE believe that UK scientists are going to spend millions, researching a disease which Dr Matthew Dryden of Public Health England claims has a 100% cure rate with a short course of antibiotics, and where ['recurrence or relapse' is 'extremely unusual'](#).

Country	Incidence (new cases per year) per 100k population.	Number of times more cases than England and Wales
England, Wales	1.75	
France	49	28
Belgium	114	65
Netherlands	149	84
Germany	261	148
Austria	300	170

Research Recommendation 1

1/ Core outcome set for studies of management of Lyme disease

"Can a core outcome set be developed for clinical trials of management of Lyme disease?"

"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."

Producing a Core Outcome Set and expecting multiple Clinical Trials to adopt those criteria, is in contradiction to other contents of the draft guideline. The NICE draft includes treatment recommendations which have predetermined that most patients will be cured with 3 weeks of a single antibiotic and the remainder will be cured with a further 3 weeks treatment. Therefore, a "core outcome set" is superfluous and the call to establish one is questionable.

"Meta-analysis" is a research method which combines data from multiple clinical trials to effectively make one big trial. E.g., the data from 10 trials with 20 participants each, could be combined to make a virtual trial with 200 participants. As the UK does not have one clinical trial, and most of our neighbouring countries with up to 170 times more cases than us, have not found it necessary to produce a 'core outcome set', worrying about 'meta-analysis' when even the basic research has not been done, is nonsensical.

A possible explanation for this research proposal which would otherwise appear ridiculous, appears to be in order to provide justification for stopping treatment of patients who remain ill following so-called, 'adequate treatment', regardless of whether or not they are still infected. E.g., a core outcome set for Lyme patients might show what Dr Dryden claims for his own research, that Lyme is cured with a short course of

antibiotics. According to this principle, if a patient remains symptomatic or relapses after treatment, then they cannot have Lyme disease and can be re-diagnosed with something else, even if that requires making-up a new illness. As a way to guarantee 100% treatment success this would be a Catch-22 that patients with persistent infection could not escape from, even though it is completely illogical.

There is a theory known as '[Test of Treatment](#)' in which an uncertain diagnosis is treated experimentally to help confirm or disconfirm a diagnosis. For this to work, it requires that the treatment can produce a predictable effect. In the case of long-term infection with Lyme bacteria the effect of antibiotics depends on numerous variables and can be further confounded by co-infections and opportunistic infections. The *Borrelia* family bacteria which cause Lyme, contain some very toxic and immunogenic proteins which can be released when the bacteria is killed, so an immediate worsening of symptoms with antibiotic treatment could be an indicator. However, the effects of the treatment will also depend on the locations and morphological stages of the bacteria. E.g., a patient whose infection is mostly comprised of dormant [propagule](#) forms of borrelia, might have a negligible response to doxycycline or penicillin unless the treatment is maintained for months. Factoring-in these and other complexities mean that a Test of Treatment would often require evaluation by an experienced physician specialising in Lyme disease. The same complexities described above, would apply to a core outcome set, rendering a one-size-fits-all criteria, impractical and undesirable if individualised patient care was ever a consideration.

However, if the objective was to get rid of patients and deny them proper medical care, then a core outcome set could be the perfect solution. The criteria would probably show that patients can remain symptomatic for weeks or months and make it possible to claim that it is acceptable and common for patients to remain ill following 'adequate treatment', but that they no longer have Lyme disease and therefore no longer require treatment or care for the infection.

This makes sense when one understands that a core outcome set would support the re-diagnosis of patients with persisting or relapsing symptoms, which in most other persistent infections would be interpreted as inadequate treatment. Re-diagnosing Lyme disease patients with PTLDS, CFS or CANS, would support Dr Dryden's construction of a [new illness](#) which he believes is [not Lyme disease](#) and would provide justification to deprive patients of treatment, as well as maintaining Dr Dryden's claims of 100% treatment success.

As a strategy to help save insurance companies a fortune by denying support and treatment for chronically ill Lyme patients and protecting shareholder dividends, this NICE recommendation makes perfect sense. Most wonderful of all (from a profit perspective) is that NICE can recommend this 'high priority' project without it costing a penny to them or the insurance companies who would probably be the main beneficiaries, whilst Lyme disease patients and/or the UK public are expected to fund an enterprise that would predictably deprive many patients of NHS or insurance funded healthcare and support.

Patients that remain ill, or who relapse following 'adequate treatment', can be re-diagnosed with a made-up illness that has no World Health Organisation (WHO), International Classification of Diseases (ICD) coding. This can result in violation of the Human Rights of patients if they are denied care and treatment. The latter issue is part of an [investigation](#) by a Special Rapporteur of the United Nations Human Rights Council. One of those providing testimony is Jenna Luché-Thayer, a Human Rights expert with 32 years experience. Jenna states:

"Borreliosis infections are pandemic – these include relapsing fever and Lyme borreliosis. The WHO diagnostic codes do not recognize many of the disabling conditions caused by these infections. Across the globe, medical systems use these codes to diagnose illness and determine treatments. The outdated codes result in very sick people being denied treatment—even when treatment options meet the internationally accepted gold standard for guidelines set by the Institute of Medicine (IOM)."

In an ongoing [lawsuit](#) being pursued in the USA against the Infectious Diseases Society of America (IDSA), multiple medical insurance companies and some of their named employees who were responsible for the IDSA Guidelines for Lyme disease (much of which appears to have found its way into the NICE guidelines), the plaintiffs complaints include:

"46....Lyme doctors know that if Lyme patients are undiagnosed, or are misdiagnosed with another ailment, the Lyme disease can become so severe that without longterm antibiotic treatment the disease will spread to their joints, their heart, and their nervous system causing crippling muscle and joint pain, disabling fatigue, arthritis, neurological disorders, cardiac disorders, depression, memory loss, bladder loss, bowel dysfunction, visual loss, and death.

47. Initially, the Insurance Defendants provided coverage for Lyme disease patients, covered long-term antibiotic treatment, and even paid for extended hospital stays to treat patients with Lyme disease who did not respond to short-term antibiotic treatment. This allowed doctors to properly assess and treat patients with chronic Lyme disease and prevented the suffering and death of many thousands of Lyme disease patients.

48. In the 1990's the Insurance Defendants decided that treatment of Lyme disease was too expensive and "red-flagged" Lyme disease. The health insurance industry made a concerted effort to deny coverage for treatment of Lyme disease. The Insurance Defendants enlisted the help of doctors who were researching, not treating, Lyme disease. The Insurance Defendants paid these IDSA Panelists large fees and together they developed arbitrary guidelines for testing Lyme disease.

49. Once these arbitrary guidelines were decided, the Insurance Defendants could, and did, deny coverage for patients if they did not meet their new stringent Lyme testing protocols. Since most Lyme patients would not test positive under the new protocols, the Insurance Defendants could deny coverage for many people suffering from Lyme disease.

50. Additionally, the Insurance Defendants, with the help of the paid IDSA Panelists, decided that long term antibiotic treatment was not necessary and all Lyme disease patients could be cured in less than a month. By August of 1992, the Insurance Defendants had imposed an intravenous antibiotic limit of twenty-eight days."

(With thanks to [Dr. Steven Phillips & Dana Parish](#) for identifying these important excerpts.)

At the present time a core outcome set is not needed and is certainly not any sort of priority for doctors or patients. However, it might be desirable to those who against all evidence, deny that chronic Lyme disease exists and might serve the purposes of those who do not want chronic Lyme disease patients to be treated in a similar way to patients with other chronic infections.