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# AMA submission to the Standing Committee on Community Affairs: Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients

The presence of Lyme disease in Australia and a potential Lyme-like illness are issues of concern to the AMA. Discussion of legitimate questions around these issues has not been assisted by some of the public commentary that ignores a number of the facts established to date. Specifically, much of the public commentary ignores the advice of the Department of Health's medical advisers, including the Chief Medical Officer, and the facts being established by the Royal College of Pathologists of Australasia, the Australian Society for Microbiology, Australasian Society for Infectious Diseases, the Australian Rickettsial Reference Laboratory and the Royal Australasian College of Physicians. The Department of Health and representatives of the relevant specialist colleges, associations and societies have the AMA's ongoing support as our understanding of Lyme disease and a potential Lyme-like illness in Australia continues to mature.

Medical practitioners do their utmost to accurately diagnose the cause of an illness and provide an appropriate treatment. Doctors support the patient in understanding their condition and what they might expect, define circumstances when patients' symptoms could have several causes, identify and advise on appropriate treatment or preventive options.[1] A doctor's duty of care is to make an accurate diagnosis or state that there is insufficient evidence for a specific diagnosis. Specifically, in the absence of clear presence of a causative organism and definitive diagnosis, a doctor's duty of care is to exclude an alternative evidence based diagnosis or condition.

To date there has been no evidence to support the existence of *Borrelia burgdorferi* (Borrelia) in Australia. It is known to be found endemically in North America, parts of Europe and parts of Asia. In the absence of a conclusive aetiology of an indigenous vector for Lyme disease or a Lyme-like disease, diagnosis remains difficult and patients are frustrated when their illness is not easily diagnosed or treated. The AMA understands that this sentiment is genuine and that a failure to reach a conclusive diagnosis can be stressful, however the medical profession's role is to make clinically appropriate treatment recommendations based on the best available evidence. It is ethically and legally appropriate for doctors to refuse demands by patients, patients' family members or other third parties for tests, treatments or procedures that are not clinically appropriate.

[1] AMA 2011 Position statement: *Role of the Doctor*

The AMA has observed the significant effort by the Department of Health to work and communicate with patients, researchers, clinicians and medical groups regarding concerns around borreliosis and to locate evidence of a species of bacteria causing Lyme-like illness in Australia. The AMA supports the efforts made by the Department of Health to find, share and understand the evidence associated with this and its public communication to date.

**The adequacy of domestic testing facilities**

There has been some public criticism of the capacity of Australian laboratories to accurately diagnose Lyme disease. The AMA agrees that accredited Australian diagnostic laboratories can diagnose classical Lyme disease in Australia in patients who have returned from endemic areas overseas. To support accurate testing, the Royal College of Pathologists of Australasia has issued a protocol to be followed for patients who present with Lyme-like illnesses. It comprises of a mixture of culture of Borrelia, molecular testing and serology that is most likely to detect classical Lyme disease. The Australian system of medical testing accreditation is sound, and uses the international standard ISO 15189.

Research in Australia has shown that the prevalence of true classical Lyme disease amongst people who have travelled to an endemic country is low. Where the prevalence of a disease is low, if the test has a high specificity, a negative test here is highly likely to predict true negativity, whereas a positive test is likely to be a false positive.

The AMA is aware that there have been some concerns about the discordance of test results associated with Lyme disease testing in Australia between the accredited medical testing laboratories and overseas laboratories. The AMA is aware of patients who have had a test in Australia with a negative result who then seek a test from an overseas laboratory which may return as positive.

The other important factor is interpretation. It is important that the results are interpreted correctly. The results need to be interpreted in line with the standardised criteria that are established by large agencies, like the *Centers for Disease Control and Prevention* (CDC), in the United States, as well as other centres in Europe for communicable diseases.[2]

We note that the debilitating symptoms may be caused by a yet to be identified bacterial species, or group of bacterial species. The continued search for a causative organism to remove diagnostic uncertainty is therefore important. This would then allow for the development of a test for that particular causative agent. The AMA supports further research into infectious diseases, including tick transmitted pathogens in Australia by an independent researcher supported by a respected funder such as the National Health and Medical Research Council or the Australian Research Council. This should be supported by the ongoing work of the Department of Health's medical advisers and relevant specialist colleges, associations and societies.

**Overseas acquired Lyme disease**

There are patients in Australia who have been diagnosed and treated for overseas acquired Lyme disease.[3]

The Australian guidelines on overseas acquired Lyme disease, issued by the Department of Health, advise that Lyme disease should be considered in patients presenting with a history of a

[2] Dr Lum, Senate Community Affairs Committee: Senate Estimates, Wednesday, 21 October 2015, p 20
[3] Shradha Subedi, David J Dickeson and James M Branley. *First report of Lyme neuroborreliosis in a returned Australian traveller, Medical Journal of Australia 2015,* 203 (1): 39-40

tick bite from one of these endemic areas along with a fever and mild influenza-like symptoms.[4] The guidelines are supported by the position statement from the Royal College of Pathologists of Australasia which provides specific guidance on testing procedures for Borreliosis.[5]

The acute illness of tick-borne Lyme disease, which is seen overseas and can be present when people return to Australia from endemic areas, is relatively straightforward to manage. It is a clinical diagnosis with the characteristic (pathognomonic) rash supported by pathology tests. Medical testing laboratories in Australia that test patients who have acquired classical Lyme disease in endemic areas are able to readily diagnose the disease using standard serological tests.[6] This is then followed by a short course treatment of antibiotics that is effective in the majority of cases.

The question regarding ongoing 'chronic Lyme disease' is more vexed. In the United States it is referred to as Post-treatment Lyme Disease Syndrome (PTLDS). The exact cause of PTLDS is not yet known. Most medical experts believe that the lingering symptoms are the result of residual damage to tissues and the immune system that occurred during the infection. Similar complications and 'auto–immune' responses are known to occur following other infections, including Campylobacter (Guillain-Barre syndrome), Chlamydia (Reiter's syndrome), and Strep throat (rheumatic heart disease).[7]

The prevalence of PTLDS is rare. This was exemplified by the great difficulty three investigative teams had in recruiting subjects for clinical trials investigating this condition. The dominant reason for this is that very few of the screened patients had documentation of prior Lyme disease. This, the researchers posit, suggests that the attribution of chronic symptoms to Lyme disease is grossly out of proportion to its actual occurrence.[8] Interestingly, in most longitudinal studies of Lyme disease, the prevalence of chronic post-treatment symptoms is no higher than their prevalence in the population at large.

Regardless of the cause or veracity of PTLDS, the use of long-term antibiotics for patients with persistent symptoms of fatigue, musculoskeletal pains and neurocognitive dysfunction has been scrutinised using the highest level of scientific evidence. Four placebo-controlled randomised trials have been conducted and the results do not support the use of long-term antibiotics as an appropriate treatment for Lyme disease.[9, 10]

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[4] Department of Health (2015) *An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis*, p 1.

[5] Royal College of Pathologists of Australiasia (2014) Position Statement: *Diagnostic Laboratory testing for Boreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand*

[6] Dr Lum, Senate Community Affairs Committee: Senate Estimates, Wednesday, 21 October 2015, p 20

[7] Centre for Disease Control and Prevention *Post-Treatment Lyme Disease Syndrome* http://www.cdc.gov/lyme/postlds/

[8] Lantos, P. Chronic Lyme Disease: The Controversies and the Science, *Expert Rev Anti Infect Ther*. 9 (7): 787-797, 2011

[9] Infectious Diseases Society of America (2012) Statement for the House Foreign Affairs Committee Africa, Global Health and Human Rights Subcommittee's Hearing on Global Challenges in Diagnosing and Managing Lyme Disease — Closing Knowledge Gaps http://www.idsociety.org/uploadedFiles/IDSA/Topics_of_Interest/Lyme_Disease/Policy_Documents/Lyme%20Disease%20Testimony-Global%20Health%20Subcommittee.pdf

[10] Klempner MS, Hu LT, Evans J, Schmid CH, Johnson GM, Trevino RP, Norton D, Levy L, Wall D, McCall J, Kosinski M, Weinstein A. Two controlled trials of antibiotic treatment in patients with persistent symptoms and a history of Lyme disease. *New Eng. J. Med*. 345: 85-92, 2001

Krupp LB, Hyman LG, Grimson R, Coyle PK, Melville P, Ahnn S, Dattwyler R, Chandler B. Study and treatment of post Lyme disease (STOP-LD): a randomized double masked clinical trial. *Neurology*. Jun 24;60(12): 1923-30, 2003

Furthermore, long-term antibiotic treatment for Lyme disease has been associated with serious complications, discussed below.

**Syndromes resembling Lyme disease in Australia**

The AMA is aware of questions about the existence of an indigenous form of Lyme disease in Australia. To date there is no conclusive evidence of a causative agent in Australia leading to problems with the accurate diagnosis of Lyme disease or an Australian Lyme disease like syndrome.[11] The lack of a causative agent causes problems with the accurate diagnosis of Lyme disease or an Australian Lyme disease like syndrome.

'Lyme-like' illness is a term that has been used in the Australian context; however, the particular range of clinical manifestations it is being used to describe is unclear. Patients present with varying concerns, ranging from fever and mild influenza-like symptoms, tiredness, history of worsening motor instability, confusion and headaches, arthralgia and myalgia. There are a plethora of conditions that might account for these symptoms.

It is currently not clear if the 'Lyme-like illness' is one single condition or a collection of different illnesses that have overlapping clinical symptoms. This is a significant issue for treating practitioners as many patients present with symptoms that are similar to other chronic conditions. For example, some patients present with symptoms similar to motor neurone disease, multiple sclerosis, fibromyalgia, complex neurodegenerative disorders or psychiatric illnesses. Doctors who make a diagnosis of Lyme-like disease or Lyme disease occurring in Australia must be able to demonstrate that alternative causes of the symptoms have been excluded in a documented and evidence based record.

Practitioners are required to treat patients in a manner that meets the Medical Board of Australia's *Code of Conduct* which requires doctors to 'Provid[e] treatment options based on the best available information'.[12] Currently the best available information from the Australian infectious diseases specialists, who manage all infectious disease in Australia is that more evidence is required than we have now to be assured that what they are being asked to treat is in fact Lyme disease. Their opinions on infectious diseases are highly regarded within Australia's very good health care system and there is no reason to doubt their advice for this one disease.

Research suggests that some patients have received a firm diagnosis ruling out Lyme disease that they are unwilling to accept, instead seeking an alternate diagnosis of Lyme disease from another medical practitioner.[13] Whilst it is a patient's right to choose their doctor freely, to accept or reject advice and to make their own decisions about treatment or procedures, the ability for consumers to find the small minority of practitioners who make a diagnosis without appropriate evidence is an issue of concern to the AMA.[14]

Fallon BA, Keilp JG, Corbera KM, Petkova E, Britton CB, Dwyer E, Slavov I, Cheng J, Dobkin J, Nelson DR, Sackeim HA. A randomized, placebo-controlled trial of repeated IV antibiotic therapy for Lyme encephalopathy. *Neurology*. 2008 Mar 25;70(13):992-1003. *Epub* 2007 Oct 10.

[11] Gofton A, Doggert S, Ratchford A, Oskam C, Paparini A, Ryan U, Irwin P. Bacterial Profiling Reveals Novel 'Ca.Neoehrlichia, Ehrlichia, and Anaplasma species in Australian Human Biting Ticks. *PLOS one* 28 : 1-16, 2015

[12] Medical Board, 2014, Good Medical Practice: A Code of Conduct for Doctors in Australia p 6

[13] Feder et al. A Critical Appraisal of 'Chronic Lyme Disease', *N Engl J Med*, 357:1422-1430, 2007

[14] Australian Medical Association *Code of Ethics* 2006

**Australian Health Practitioner Regulation Agency and the Medical Board of Australia**

The Australian Health Practitioner Regulation Agency (AHPRA) and the Medical Board of Australia (MBA) have a combined role to implement the National Registration and Accreditation Scheme ensuring Australians have access to safe, high quality health practitioners. Part of the role incorporates a compliance function in order to address concerns about registered health practitioners.

AHPRA has publicly stated that it does not have an official position on Lyme disease in Australia. At the Community Affairs Senate Estimates hearing on 21 October 2015, Prof Chris Baggoley provided evidence that neither AHPRA nor the Medical Board are 'targeting' doctors who are treating Lyme disease. He stated that "the Medical Board of Australia does not set clinical standards or adjudicate on the treatment of specific conditions. The board does not have a position on Lyme disease in Australia or any disease or treatment regime".[15]

Patients trust doctors to make a diagnosis, to be up to date and be ready to seek out the most appropriate treatment, to be capable of responding to the patient's needs and to be ready to take responsibility for the patient's care. If they cannot fulfil these roles they are expected to refer the patient to a colleague who may.[16] For diseases where the symptoms are similar to other diseases, using the correct process to make a diagnosis is essential. In this regard, the diagnosis of Lyme disease is the presence of the pathognomonic rash with support of a pathology test. The importance of an accurate diagnosis cannot be understated as pathology results for Lyme disease have a high false positive rate.

The AMA is aware of some media commentary suggesting that the use of long-term microbial treatment provides a benefit for chronic Lyme disease, and asks "why not supply antibiotics on a long term basis?". Year on year microbial treatment should not be provided for illnesses where the cause is not conclusive. The use of long term antibiotics is not recommended because it can cause potentially fatal complications and lead to the development of drug-resistant infections. Potential side effects range from liver failure, acute psychosis and other neuropsychiatric reactions, severe diarrhea and phlebitis.[17]

There is an onus on the doctor to demonstrate that the patient has given informed consent as to the basis of the diagnosis and treatment proposed. AMA members report that patients come to them complaining about two issues: they did not understand that the diagnosis was not accepted by the majority of the profession; and, the previous doctor did not diagnose their condition correctly. Unfortunately there are doctors who fail to adequately document their process of diagnosis, but rather base their diagnoses on assertions rather than evidence.

The very small number of doctors who come before the MBA often have a history of complaints made about them from the public and the profession. The conditions imposed on the registration of any individual medical practitioner are always specific to that practitioner. They do not reflect the Board's view about any disease state or treatment regime.[18] The AMA continues to support the role of AHPRA and the MBA in this respect.

**Politicisation of medical practice overseas**

The Infectious Diseases Society of America (IDSA) issued updated clinical practice guidelines in 2006 for the diagnosis and treatment of Lyme disease. Within days, the Connecticut attorney

[15] Prof Baggoley, Senate Community Affairs Committee: Senate Estimates, Wednesday, 21 October 2015 p 19
[16] AMA 2011 Position Statement: *The Role of the Doctor*
[17] Mulhall JP, Bergmann LS. Ciprofloxacin-induced acute psychosis. *Urology* 46:102-103, 1995
[18] Prof Baggoley, Senate Community Affairs Committee: Senate Estimates, Wednesday, 21 October 2015 p 21

general launched an investigation, alleging IDSA had violated state antitrust law by recommending against the use of long-term antibiotics to treat 'chronic Lyme disease'. This type of investigation exemplified the politicisation of medical practice and research.[19]

Against the research and the advice of the CDC, the state of Connecticut went on to enact a law on June 18, 2009, to allow a licensed physician to prescribe, administer or dispense long-term antibiotics for a therapeutic purpose to a patient clinically diagnosed with Lyme disease.[20]

Whilst it is understandably frustrating to wait for results from research into an agreed vector, a set of tests to diagnose the disease and agreed treatment options, ignoring the processes that have supported the Australian health system for so long may shortchange patients, particularly if they are incorrectly administered drugs to treat the wrong disease.

**Supporting ongoing research**

Research published by Prof. Peter Irwin at Murdoch University in Perth describes new bacteria in ticks collected from animals in Australia. Whether these bacteria can cause chronic debilitating symptoms, and the implications for human health, have yet to be determined. Further research by Prof Irwin found that all 460 ticks tested negative for the bacterium which causes Lyme disease.

Whilst this research did not find the *Borrelia burgdorferi* species, several newly discovered organisms (bacteria) were identified.[21] Discovery of new microorganisms is only part of the story. Attributing disease causation to any one of them requires more research and epidemiological studies and determining whether these newly discovered organisms cause disease in humans and animals is of public health importance and requires further investigation. To this end, the AMA supports the Royal College of Pathologists of Australasia's view that "only a genuine case in a non-travelling Australian patient would confirm the disease as being present in Australia".[22]

The Department of Health has contracted with the National Serology Reference Laboratory to undertake an evaluation of the serology assays currently used for the diagnosis of Lyme disease in some specialist Lyme disease laboratories as well as accredited pathology laboratories in Australia. The results will hopefully provide insight as to why test results from one patient can be positive in one laboratory and negative in another.[23]

Given the progress made to date in identifying new bacteria and the Department's ongoing efforts to eradicate problems with pathology outcomes, the AMA supports further scientifically rigorous research into this issue. Any research in this area would need to be competitively funded by reputable funding organisations such as the National Health and Medical Research Council or the Australian Research Council.

[19] John D. Kraemer, JD, MPH; Lawrence O. Gostin, JD, The Politicization of Professional Practice Guidelines *JAMA*. 2009; 301(6):665-667
[20] Novella, S, Connecticut Legislature Intrudes on Debate Over Chronic Lymes Disease, Science Based Medicine (2009) https://www.sciencebasedmedicine.org/connecticut-legislature-intrudes-on-debate-over-chronic-lyme-disease/ viewed 8 March 2016
[21] Gofton A, Doggert S, Ratchford A, Oskam C, Paparini A, Ryan U, Irwin P. Bacterial Profiling Reveals Novel 'Ca.Neoehrlichia, Ehrlichia, and Anaplasma species in Australian Human Biting Ticks. *PLOS one* 2015:28 pp 1-16
[22] The Royal College of Pathologists of Australia (RCPA) (2014) Position Statement: Diagnostic Laboratory Testing *for Borreliosis ('Lyme Disease ' or similar syndromes) in Australia and New Zealand.* Available online: https://www.rcpa.edu.au/Library/College-Policies/Position-Statements/Diagnostic-Laboratory-testing-for-Borreliosis-Lyme [last accessed 23/02/16]
[23] Department of Health (2015) Progress Report on Lyme Disease in Australia, p 1

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