ADVANCING LYME SCIENCE

LDAA & GLOBAL EXPERTS RESPOND TO THE DSCATT CLINICAL PATHWAY

"I pray for the Australian people that this clinical pathway is not instituted. It is incomplete and misleading and requires major revisions before undergoing a clinical trial. This document if instituted, is likely to contribute to ongoing patient suffering and potentially death in Australia."

Dr Richard Horowitz, Eminent Lyme Specialist, Consultant to the Department of Health, LDAA Patron

"I read in March of this year, you published a clinical pathway which basically states family practitioners can't diagnose or treat tick bites / Tick-Borne Diseases and need to refer these cases to Infectious Disease Specialists, where there is an inordinately long wait of several months to be seen.

Inadequately diagnosed, inadequately treated and delayed treatment of Lyme/Tick-Borne Diseases can result in serious mental illness and deaths from suicide. Although there is already a large amount of peer-reviewed evidence of Lyme/Tick-Borne Diseases causing psychiatric symptoms https://www.mdpi.com/2227-9032/7/3/105/s1 *[Bransfield RC, Cook MJ, Bransfield DR. Proposed Lyme Disease Guidelines and Psychiatric Illnesses. Healthcare. 2019; 7(3):105.* https://doi.org/10.3390/healthcare7030105], *a recent study unequivocally proves the causal association to the most extreme sceptics and negates the validity of the highly restrictive IDSA Lyme Disease guidelines that are based upon a failure to recognize this significant and serious causal association:*

Psych News Alert: Lyme Disease Heightens Risk of Mental Disorders, Suicidality, Study Finds
https://alert.psychnews.org/2021/07/lyme-disease-heightens-risk-of-mental.html
Lyme Borreliosis and Associations With Mental Disorders and Suicidal Behavior: A Nationwide Danish Cohort Study | American Journal of Psychiatry

I have previously lectured on Tick-Borne Diseases in Australia. By restricting access to treatment for tick-borne patients you are fully responsible for an otherwise preventable epidemic of mental illness. I shall save this correspondence and be available to provide future testimony against you for committing this crime against humanity if you do not change this irresponsible policy."

Clinical Associate Professor Robert C. Bransfield MD, DLFAPA, Eminent Lyme Psychiatrist, past President ILADS

ADVANCING LYME SCIENCE

2nd August 2021

To Whom It May Concern:

Key points that justify urgent remedial action:

- The Lyme Disease Association of Australia (LDAA) and global expert doctors assert that the Australian Government's 'DSCATT Clinical Pathway' (hereafter 'the Pathway') provides dangerously ignorant advice to Australian physicians that may result in injury or death to patients.
- The Pathway purports to be a tool to help physicians with patient assessment and management, rather than an instructive guideline. The restrictive and constrictive nature of its contents informally permits physicians to place complex Lyme and associated disease patients in the medically obsolete category of 'medically unexplained symptoms' (MUS). Resurrecting this now disused medical category derails investigation and treatment for infection, potentially causing harm to patients, and blocking possible return to health. Further, comparisons with other vector-borne illnesses demonstrate that the pathway creates unequal and discriminatory access to diagnosis and treatment for borreliosis patients/tick-borne disease patients. The Pathway also ignores WHO's documentation of pathogenic borreliosis in every region of the world and its recommendation of early diagnosis and treatment.
- The Australian Government has contracted educational materials for the public and physicians based on the Pathway. The forthcoming educational materials increase the parameters of harm that may be caused to patients by the Pathway, by reinforcing its dangerous, government-sanctioned advice to Australian physicians.

Critical Synopsis

There are no official data that may help to quantify the size of the 'Lyme' problem in Australia and there has been no epidemiological study or surveillance mechanism established, not even a simple tally of positive results for all tick-borne diseases after the formation of the Australian Government's *Clinical Advisory Committee on Lyme Disease* in 2013. Some evidence of the prevalence and geographic distribution of emerging Lyme and associated diseases is reported in scientific literature (525 cases)[1]. These numbers likely underestimate the true incidence of Lyme and associated diseases in Australia, given a lack of appropriately trained medical practitioners and unreliable diagnostics as demonstrated in other countries,[2, 3, 4] together with infrequent and under-testing of patients and disputes in relation to the interpretation of positive results.

Internationally, the incidence of Lyme disease is on the rise. WHO reports showing evidence of Lyme borreliosis and other pathogenic borreliosis across all regions of the world[5-13]. The USA recently updated its surveillance figures by 900%, estimating more than 476,000 new cases per year[3]. The LDAA also tracks and reports on prevalence rates from 39 other countries, tallying a mean global prevalence of 5.8 percent[5]. As such, it seems highly implausible that Australia is the only continent without this disease.

Based on the mean global prevalence, the LDAA estimates that half a million people are suffering from Lyme and associated diseases in Australia[14]. Many of them cannot obtain basic medical care. They are chastised, ridiculed and suffer intolerable discrimination. Medical practitioners admit they cannot or will not test and diagnose patient symptoms, and Lyme and associated disease patients are often told that their symptoms are psychological in origin. The Pathway seeks to entrench this harmful status quo, in its guise of informal guidance, and confuses the now obsolete 'medically **unexplained** symptoms' (MUS) with medically/diagnostically **unexplored** symptoms[15].

The Pathway bows to legacy thinking, dogmatic denial, ignorance of international research, limited and narrow research funded by the Australian Government Department of Health (DoH), and the apathy of policymakers who have failed to investigate the situation proactively and comprehensively.

"LDAA & GLOBAL EXPERT DOCTORS Respond to the DSCATT Clinical Pathway" asserts that the Australian Government's 'Pathway' provides dangerous advice to Australian physicians, ignorant of current evidence-based research and patient clinical presentation, which may result in injury or death to patients.

Specifically:

1. Risk: The World Health Organisation (WHO) has recognized the increasing global health threat of Lyme, greatly expanding the ICD codes in response to its potentially disabling, chronic and fatal complications. Furthermore, WHO has documented pathogenic borreliosis in every region of the world and recommends early diagnosis and treatment. The scientific and medical advancement represented in the ICD11 were ratified by the WHO in 2018. These improvements are reflected in the ICD11 Codes for Lyme borreliosis.

The ICD10 Codes for Lyme borreliosis were limited to[16]:
A69.2 Lyme Disease
M01.2 Arthritis due to Lyme
G01 Meningitis due to Lyme
G63.0 Polyneuropathy due to Lyme

The ICD11 includes[17]:
1C1G Lyme borreliosis
1C1G.0 Early cutaneous Lyme borreliosis
1C1G.1 Disseminated Lyme borreliosis
1C1G.10 Lyme Neuroborreliosis
1C1G.11 Lyme Carditis
1C1G.12 Ophthalmic Lyme borreliosis
1C1G.13 Lyme arthritis
1C1G.14 Late cutaneous Lyme borreliosis
1C1G.1Y Other specified disseminated Lyme borreliosis
1C1G.1Z Disseminated Lyme borreliosis, unspecified
1C1GY Other specified Lyme borreliosis
6D85.Y Dementia due to other specified diseases classified elsewhere; Dementia due to Lyme Disease
9C20.1 Infectious panuveitis; Infectious panuveitis in Lyme disease
9B66.1 Infectious intermediate Chorioditis; Infectious intermediate uveitis in Lyme disease
8A45.0Y Other Specified white matter disorders due to infections; Central Nervous System demyelination due to Lyme borreliosis
ICD11 now recognizes fourteen complications from Lyme borreliosis whereas the ICD10 recognised only three complications from the disease. Six of the fourteen new codes describe infection in the central nervous system.

The ICD11 demonstrates and confirms Lyme has affinity for 'immune privileged sites' such as the central nervous system. Four of the fourteen codes identify complications documented as life threatening: Lyme Neuroborreliosis, Lyme Carditis, Dementia due to Lyme Disease, and Central Nervous System demyelination due to Lyme borreliosis.

Thirteen of the fourteen ICD11 codes can be applied to late stage and persistent forms of the illness. The numerous codes for late stage and persistent forms of the illness indicate the high frequency of delayed diagnosis and unreliability of the recommended serology diagnostics —meaning they do not capture infection. The multiple codes for late stage and systemic complications also demonstrates widespread treatment failure following the standard short-term antibiotics. The need for multiple ICD11 codes for late stage and systemic complications demonstrates the infection is not easy to diagnose, treat or cure.

Contrary to the Pathway's advice, the risk of infections passed on through tick bites occurs much more widely than 'during bushwalking'. Native animals that are carriers of infected ticks are common in suburban Australian backyards and parks - in particular possums (brushtail and ringtail), bandicoots and marsupial mice, as well as introduced deer, rodents and rabbits[18, 19, 20]. These animals are also regularly seen in city areas such as northern Sydney, central Melbourne, Hobart, and Brisbane. Furthermore, tick bites can be infectious even during the early 'nymph[21, 22] stages, in which ticks are virtually undetectable. Emphasis by the Pathway on bushland exposure and detecting tick bites is thus erroneous and ignores the high risk of obtaining tick bites in our own backyards.

2. Testing: It is notable that the authors of the Pathway provided no references for the dangerously misleading advice, "Do NOT test for Lyme Disease if patients have NOT travelled to Lyme disease endemic areas as tests may show false positives." This advice is harmful and restrictive as there is not enough research conducted in Australia to definitively know which and how many pathogens are endemic. Any diagnostic search needs to include patient samples (not just ticks), it needs to be open to novel borrelia species or other pathogens for which there are not yet specific tests, and it needs to state with which antigens the so-called "false-positives" are cross-reacting, in an evidence-based fashion. The subject of ***proving*** false positives is ignored by the Pathway.

In June 2015, the DoH commissioned the National Serology Reference Laboratory Australia (NRL) to undertake a comparison of the ability of *in vitro* diagnostic devices (IVDs) to detect only *Borrelia burgdorferi* (Bb) sensu lato, but specifically "excluded other *Borrelia* species"[23]. The project concluded that the IVDs were not reliable serological tests, even for diagnosis of *Bb* sensu lato. The report by Best[23] recommended the establishment of a national reference laboratory, but the DoH has failed in this, as of July 2021.

An essential aspect of the Pathway is the use of immunoblots during the pathology testing phase. The NRL report to the DoH stated that only two immunoblot kits are available in Australia through distributors, and both were found to be unacceptable[14]. It remains unestablished whether these immunoblots are supported by Medicare/pathology testing rebates. In the absence of a national reference laboratory, no further testing of immunoblot kits has been performed, despite innovative leaps in testing methods in other jurisdictions. Thus, even Australians returning from overseas with *Bb* sensu lato infections cannot confidently be diagnosed here, despite the false claim by the DoH that "diagnosis and treatment for classical Lyme disease is readily available".

In addition, antibodies against tick-borne disease organisms do not reliably appear in the blood until 3-4 weeks after infection[24, 25], by which time there is a high risk that the infective agent will spread beyond the infection site, becoming systemic and difficult to treat with a short course of antibiotics. The advice by the Pathway that physicians **must** rely on serological confirmation is thus placing patients at risk of systemic, refractory disease.

The Pathway insists that diagnostic testing be performed by NATA / RCPA registered laboratories. This is normal practice for common tests, but most of the relevant tests **DO NOT EXIST** in Australian pathology labs, are difficult to standardise, or are tests chosen to meet Medicare budget rather than chosen as the best available diagnostic measure. Rapid diagnosis of *Ehrlichia* infection is available for dogs but not humans. Humans can contract ehrlichiosis from infected dog bites, but transmission through native Australian fauna has not been studied – a typical oversight by the DoH. The *Australian Rickettsial Reference Laboratory* (ARRL) in Geelong includes Lyme among the tests for which it advertises expertise but fails to apply international standards to its diagnostic result. As a result, patients have no option but to send pathology samples abroad, at considerable cost, primarily to registered laboratories in the USA or Germany, for reliable diagnosis of borreliosis and co-infections. This unsatisfactory situation has arisen because the DoH has not encouraged research into relevant testing in Australia. As mentioned above, it expended a large amount of funding and time on the irrelevant testing of Bb kits. Propagating a "Don't Look, Don't See" strategy, the DoH provides a dangerous Pathway for physicians, failing to provide advice on how to correctly diagnose and treat Lyme/DSCATT and co-infections, or alert medical and surveillance authorities to new and emerging tick-associated illnesses, for example, alpha-gal allergy[32].

It is notable that many Australian patients, some with international positive *Borrelia* results, have pushed their GPs for testing of co-infections at ARRL, usually after long periods of illness and no treatment. Many of these patients have returned results positive to current or past infections of one or more pathogen(s). Every test showing past infection in an unwell, untreated patient is evidence of a physician missing a diagnosis and evidence of a history of tick (or other vector) bite. The DoH website states, incorrectly, "the concept of chronic Lyme disease is disputed and not accepted by most conventional medical practitioners, not only in Australia but around the world" (see below). The only other option is for ARRL to decide that all positive results for past infections are false-positive, which would imply its entire suite of tests is unreliable.

3. Borrelia species: The Pathway fails to advise doctors that Lyme-like disease or 'relapsing fever' is associated with at least 3 other *Borrelia* species in the UK (*B. turicatae, parkeri* & *miyamotoi*)[27], 8 other species in Scandinavia[28], and 3 other species in Central Europe (*B. afzelii, garinii* & *valaisiana*)[29]. Research into Australian variants of *Borrelia* have been starved of funding by the DoH, despite a study discovering unique regional *Borrelia* spp in Australia. Testing for these (novel and emerging) species is not routinely available in Australia. In stark contrast, the Pathway falsely asserts that Lyme disease testing is reliable and available here (while in the same document admitting testing may result in false positives).

4. Co-infections: These are common in tick bites, and the Pathway has been forced to acknowledge this by formulating its acronym 'DSCATT' to cover the diversity of co-infections. Rickettsial infections are caused by bacteria of the Rickettsiales order (*Rickettsia, Anaplasma, Ehrlichia, Neorickettsia, Neoehrlichia, Orientia*). There is now a serious national spread of ehrlichiosis, which can infect humans. Spotted fever typhus, including Queensland tick typhus, is common, for example, in the hinterland of the Gold Coast, QLD, a fact that is not widely publicised nor realised by tourists. Scrub typhus, spread by mites, is a risk in northern Australia. Presentation of these diseases, often characterised by non-seasonal flu-like symptoms, can be difficult to distinguish from borreliosis, and can be misdiagnosed as a virus, according to *Health.gov.nsw.au*.

Babesia is a common tick-borne co-infection in the experience of American and some Australian physicians; the first severe cases were outlined in 2012[30, 31]. However, the Pathway fails to mention this serious disease, usually experienced early post-infection as severe breathlessness or 'air hunger' and night sweats. *Babesia* infects the red blood cells like malaria (*Plasmodium* spp) and can be equally difficult to treat as it is not responsive to

antibiotics; evidence from some physicians indicates that it responds to the artemisia compounds being increasingly adopted for malaria. The Pathway is also blind to *Bartonella* and *Coxiella*, other serious tick-borne co-infections, as well as tick-induced allergies[32, 33, 34].

Unsurprisingly, this suite of co-infections and symptoms is known by patients and clinicians around the world as 'Lyme' (not the absurdly obscure DSCATT, with its overtone of MUS). Some of these are mentioned in passing by the Pathway, but their diagnosis remains difficult due to lack of human infectious disease expertise in Australia. Yet it is of critical importance to regularly update clinicians' knowledge about infectious diseases, provide improved clinical support and expertise. A reference laboratory should be equipped to test/diagnose all infectious diseases, international and domestic, to assess puzzling presentations, conduct innovative research, and use high-throughput screening and state-of-the-art diagnostics.

5. Diagnosis: The Pathway **dictates** that general practitioners (GPs) consult with an "appropriate expert in tick-borne diseases including specialist microbiologists." GPs can diagnose, treat and/or manage mosquito-borne Murray Valley encephalitis virus, Ross River virus, Barmah Forest virus, and Dengue virus without the guidance of a restrictive Clinical Pathway. A GP's diagnoses of infection with these vector-borne pathogens does not require confirmation by a specialist. This situation exists despite the fact that Dengue fever, for example, is not widespread in Australia, while conversely tick-borne diseases are found throughout Australia[35-38]. The Pathway dictates that tick-bite patients must satisfy onerous requirements to gain diagnosis and treatment for these kinds of vector-borne illnesses compared with other vector-borne infections, demonstrating unequal and discriminatory access to diagnosis and treatment for borreliosis patients/tick-borne disease patients. Given that the majority of cases will occur in regional areas, in the Pathway's estimation, the opportunity for a country physician to find such experts, **IF THEY EXIST,** would be low. Thus, this irrational demand will further endanger the patient by delaying or preventing treatment, whether the patient is regional or metropolitan. The necessity for this diagnostic requirement is belied by the testimony of patients and their treating doctors (largely GPs) obtained via the 2016 Senate inquiry, including that of the Australian Chronic Infectious and Inflammatory Diseases Society, which reports recovery in approx 70% of the 4000 patients they have treated using peer-reviewed protocols[39, 40].

The Pathway's specification for the presence of erythema migrans (EM) prior to antibiotic treatment is also dangerously misguided: even in high infection regions of the USA, EM occurs in only 70% of LD cases[26]. It is almost impossible for those 30% of patients presenting without a well-defined EM, and in the absence of positive *accurate* serological laboratory test results, to ever receive treatment. The Pathway thus puts these patients at risk of long-term complications, or death. Australian patients who DO present with EM rashes are routinely dismissed by doctors[14] without serological or other investigations to confirm the cause of the rash, because the DoH website insists "likelihood that Australia has an indigenous form of classical Lyme disease is questionable."

The Pathway inexplicably uses the unverifiable psychosomatic illness theory of Medically Unexplained Symptoms (MUS). The concept of MUS was thoroughly repudiated by the American Psychiatric Association and was deleted from the 2013 Diagnostic and Statistical Manual of Mental Disorders, 5th Edition[15]. The application of this obsolete theory of psychosomatic illness creates a harmful bias against recognition of infection and wrongly promotes palliative care. In this case, the resurrection of MUS misdirects to wrongful care practices by negating clinical diagnosis of infection and the need to treat subclinical, persistent and/or recurring infection.

6. Treatment Recommendations: The LDAA agrees with prior medical exclusion (by standard blood testing) of other causes of fatigue-like symptoms, such as diabetes, hypothyroidism, hypokalaemia *et al*, as well as subsequent exclusion of tumours, MS and MND. The LDAA then recommends that every patient presenting with symptoms typical of Lyme/DSCATT, e.g. non-seasonal flu-like symptoms especially following a bite or rash, be prescribed prophylactic doxycycline therapy (e.g. as provided to soldiers in the Australian Army). Doxycycline Rx should be maintained for at least 4 weeks, not the "2 courses" wrongly recommended by the Pathway that have been demonstrated by physicians in the USA and UK to be wholly inadequate to remove infection. Note that so-called "antibiotic resistance" has not been documented as originating in Australia but is commonly found to originate in Africa, Asia, and South America, and particularly in relation to agriculture and animal husbandry, including by plasmid transfer from commensal to pathogenic bacteria with quorum sensing[41]. In the clinic, it can arise from under-treatment, not over-treatment, with antibiotics. By advising a dangerously inadequate course of treatment, the Pathway risks development of resistant 'DSCATT' species in Australia.

7. Investigation: The LDAA proposes that "Final Clinical Pathway", dated October 2020, is based on false and incomplete information, and lacks important and recent clinical references.

The LDAA draws attention to the Pathway's denial of the possibility of so-called "Chronic Lyme". The serological requirements for diagnosis required by the Pathway are the same as and reference the current serological parameters promoted by the Infectious Diseases Society of America (IDSA). As of April 2021, these parameters were demonstrated to the US District Court to have been developed by the Lyme Disease 'specialist panel' of the IDSA (the defendant) and…

> "treated as mandatory requirements by the IDSA…by: (1) denying the existence of chronic Lyme disease, (2) condemning the use of long-term antibiotics, (3) allowing doctors who treat chronic Lyme patients to be sanctioned by medical boards, and (4) using the guidelines as a basis to deny insurance coverage of chronic Lyme treatments. The power of the IDSA…restrains trade, therefore, the IDSA guidelines have significantly reduced the Lyme treatment market…".[42]

Significantly, all eight insurance companies were charged with conspiring with the IDSA panellists to influence the guidelines in contravention of anti-trust laws. The insurance companies elected to settle out of court, leaving the IDSA to defend the 'guidelines', which the Pathway is also defending.

Given the immediate dangers to health and life created by the Pathway for patients who contract Lyme/DSCATT, the LDAA and global expert doctors listed below request, with both the broad public interest and public safety in mind, that AHPRA and AMA, or a competent, qualified independently-appointed body be instructed to investigate the conduct, in context, of physician members of the Department of Health committee[s] or sub-committee[s] responsible for publishing the alleged false Pathway, ultimately to consider prosecution and/or de-licensing.

Conclusion

Thousands of patients are becoming increasingly debilitated as our medical and scientific community ruminate on a causative agent[s], appropriate diagnostic tools, case definitions, and treatment guidelines. Legacy thinking and cognitive dissonance underpin widespread ambivalence in the medical community and reinforce the apathy of policy makers who fail to properly investigate the issue, increasing the risks for Australians.

A progressive and contemporary approach to this problem is urgently overdue. Recent developments in molecular technologies and next generation sequencing provide new frontiers in discovery. Fully informed and

proactive medical professionals, medical colleges, state, territory and Commonwealth health organisations can stem the flow of Australians declining into sickness, disability and death.

Aside from the matters of Lyme, co-infections, and tick-borne diseases in general, the Pathway assumes that physicians can competently test, diagnose and treat most chronic diseases. Patient experience is that this assumption is erroneous and harmful when applied to chronic, complex diseases. Rigid case definitions, a lack of personalised medicine, enforced physician adherence to inadequate guidelines and avoidance of audits, are translating into withheld diagnostics and treatment, guaranteeing that 'MUS' remains an overused alternative to a rigorous diagnosis. The right test from a knowledgeable physician can turn a symptom into a sign and provide cause/reason for the symptom. Nothing has changed about the patient's condition; the change was solely the physician's knowledge and action. Again, we highlight the difference between medically unexplained and medically unexplored.

On behalf of all medically abandoned patients with Lyme and associated diseases (i.e. 'DSCATT'), we implore you to take a leadership position on this issue and take urgent action which will immediately benefit patients. By working together, nationally and internationally, we can acknowledge the warning signs, then leap-frog old thinking, apply innovative medical technology, and design solutions for what is being described as "the first epidemic of climate change"[43].

Summary

We have shown definitive evidence that the Pathway is dangerous to patients and unacceptable in its inadequacy. We urge the Federal Minister of Health, AHPRA and AMA, as a first and professionally responsible step, to recommend it be removed from the Australian Government's Department of Health website. Physicians following the regulatory Pathway potentially risk causing harm to patients and may themselves become liable through formal patient complaint(s). The physician members of the Department of Health committee[s] or sub-committee[s] responsible for publishing the alleged false Pathway must be publicly accountable for their actions, and for the consequences of possible adverse effects on patients (harm or death), and thereby, consequentially adverse effects on the careers of physicians exposed to complaint to AHPRA and reporting to health commissioners.

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External Endorsement: Listed from page 11 onwards

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