Submission to the Medical Board of Australia: Public consultation on clearer regulation of medical practitioners who provide complementary and conventional medicine and emerging treatments

27 JUNE 2019

LYME DISEASE
Association of Australia

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Dear Sir / Madam;

Thank you for the opportunity to provide feedback to the Medical Board of Australia's *Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.*

The Lyme Disease Association of Australia (LDAA) represents members, predominantly Australians suffering with a Lyme-like illness, who support a broad and inclusive discussion of the issues surrounding Lyme disease and its yet to be researched, Australian equivalent. The consultation and its presentation of Lyme disease as a poster illness for 'unconventional medicine' is alarming to the Australian patient community and to the brave, yet diminishing, group of medical practitioners who treat them.

The LDAA questions whether the excessive focus on Lyme disease and Lyme-like illness reflects an unbiased and deep examination of the issues in Australia or whether they merely consolidate a shallow consensus arrived at through the perpetuation of imported dogma.

Ambiguous documents containing clear biases and inferences undermine the confidence that health professionals and consumers need to have in their medical regulator. The cited motivations for the consultation and the assertion that Australia needs strengthened guidance and medical practitioner regulation has not been demonstrated. There is no quantifiable evidence of the size and scope of the issues presented. More specifically, the token evidence provided for the disproportionate focus on Lyme disease is entirely inconsistent with the implied harms.

Moreover, the Medical Board has selectively chosen the evidence upon which it relies and inconceivably ignores the fact that Australians are being bitten by ticks at alarming rates and are progressing into chronic debilitating illness. When patients are treated according to internationally accepted guidelines for Lyme disease, irrespective of the label they are branded with, their symptoms abate.

Instead of supporting the medical practitioners working at the edge of medical knowledge on tick-borne illness in Australia, the medical community seemingly vilifies them for seeking proven treatment alternatives for their patients. Australian authorities have made no attempt to collect, collate or analyse data from Lyme treating medical practitioners on the efficacy and utility of these types of treatments.

The mainstream medical position of 'don't treat' is **not evidence-based** and is merely the default position of medical conservatism. This simplistic position, with no viable alternatives offered, is both negligent and harmful to patients. It subjects them to a future of debilitating illness because of exposure to as-yet-unknown Australian pathogens.

The Medical Board's *Discussion paper* promotes a harmful bias to justify the denial of medical diagnosis and proper medical care when it comes to Lyme disease. The reality is that many Australian medical practitioners will now not even consider a tick-borne diagnosis because of the associated medico-legal issue, hence justifying continued discrimination against patients affected by tick bites. This creates a situation in which 'doing nothing' *does* harm patients.

We call upon the Medical Board to thoroughly examine the issues surrounding Lyme disease, and an Australian-acquired equivalent, and to advocate for an end to the political-scientific quagmire that exists in this country.

With regards,

Sharon Whiteman
CEO

About the Lyme Disease Association of Australia

The Lyme Disease Association of Australia (LDAA) is a registered charity and Australia's peak patient body. It is run by a small number of volunteers who work to change how 'Lyme-like' illness is viewed and how patients are treated.

We represent patients and undertake activities in four key areas: information, support, education and awareness. Our mission is to:

- advocate for individuals and families living with Lyme-like illness;
- educate and seek support from governments, doctors and local communities;
- act as a conduit between international developments, treatments and other Lyme communities; and
- raise money to assist people living with Lyme disease and Lyme-like illness.

We are committed to leading collaboration towards a new model of scientific and medical excellence in Australia to facilitate world class standards in Lyme-like disease prevention, research, diagnostics, patient care and treatment protocols.

We: educate people on awareness, prevention and diagnosis; inform government and medical associations on policy and best practice; and empower patients to recover fully without experiencing bias, denial, bureaucracy, distraction, and most importantly, burden of disease.

Contents

Executive Summary

This submission has been developed by the LDAA in collaboration with the patient community and Lyme disease and associated support groups and their members.

This submission addresses the questions posed in the *Discussion paper.* It also highlights the critical issue of innovation in medicine and its certain collision with the draconian position outlined by the Medical Board through its targeting of practitioners utilising 'new and emerging therapies' for stricter regulation.

The *Discussion paper* is at odds with the thought leadership of the Medical Research Future Fund[1] and Innovation and Science Australia[2] who are actively encouraging the application of innovative and emerging technologies to address serious and chronic disease.

In summary, the LDAA provides the following feedback in response to the questions:

- The Medical Board's focus on Lyme disease is perceived as discriminatory because it supports the prevailing medical prejudice and builds upon the considerable stigma associated with Lyme disease and Lyme-like illness in Australia. The Board has harnessed the existing prejudice and uses the stigma and threat of medico-legal action to create a fear of 'difference' because practitioners deviate from traditionally conservative, and often outdated, medical 'norms'.

- The Medical Board is vague in its discussion of:
  - the position, motivations, authority and potentially vested interests of the 'stakeholders' who have raised concerns about the practices described;
  - evidence to support the assertions it makes, specifically in relation to the disproportionate focus on Lyme disease.
- The Medical Board's use of Lyme disease as an example of 'unconventional' medicine:
  - builds upon the underlying conventional medical bias that holds the position 'there is no Lyme in Australia';
  - demonstrates the lack of contemporary knowledge in Australia about this expanding worldwide epidemic; and,
  - contributes to the real and perceived medico-legal threat for practitioners who dare to use their own clinical judgement in responsively and responsibly treating patients.
- The Medial Board's use of Lyme disease in its discussion of 'unconventional diagnostic techniques and methods':
  - neglects to examine the specific issues encountered in Lyme disease testing;

[1] Medical Research Future Fund https://beta.health.gov.au/initiatives-and-programs/medical-research-future-und/aboutthe-mrff

[2] https://www.industry.gov.au/data-and-publications/australia-2030-prosperity-through-innovation p.90

- uses the argument about accredited laboratories as a decoy to the issue that diagnostic techniques and methods for Lyme disease are inadequate and outdated, irrespective of who performs the test; and perpetuates the implication that non-NATA-accredited laboratories are not trustworthy; and,

- ignores the Guideline established in Australia for the diagnosis of overseas-acquired Lyme disease[3].

- The Medical Board's inclusion of the use of 'long term antibiotics' in Lyme disease:

  - fails to make clear which 'accepted therapies' and 'accepted therapeutic guidelines' it relies upon as part of its proposed guidelines for overseas-acquired Lyme disease; and

  - ignores the issue of Australian-acquired Lyme disease and how it should be treated.

- The Medical Board's inclusion of 'new and emerging treatments' for Lyme disease as part of its strengthened regulatory guideline for practitioners:

  - leaves medical practitioners and patients in a Catch-22, where guidelines for Australian-acquired Lyme disease do not exist, so any treatment is classed as 'new and emerging';

  - diminishes the role of medical practitioners to mere administrators of published guidelines; and,

  - will force more Australian patients with Lyme disease to seek alternative treatment overseas at considerable cost.

- The Medical Board's inclusion of 'off-label prescribing' in relation to Lyme disease:

  - presents an insurmountable challenge, as it precludes all antibiotic treatment in Australia for patients suffering from Lyme disease and Lyme-like illness; and

  - fails to recognise that the internationally recommended antibiotics to treat Lyme disease are not specified on the ARTG.

- The Medical Board fails to provide a definition of 'conventional medicine':

  - as such, it is difficult to comprehend how it might regulate 'unconventional medicine'; and,

  - the absence of a clear and comprehensive definition for 'conventional medicine' inhibits the development of or consensus on any definition of 'unconventional medicine' especially in relation to Lyme disease.

- The Medical Board cannot absolve itself of the threat to patient safety following their punitive actions; they must do more to minimise harm caused as a result of the actions they take against medical practitioners who are treating patients with Lyme disease or a Lyme-like illness.

- The Medical Board must recognise that the harmful consequence in imposing greater restrictions on medical practitioners who treat Lyme disease or Lyme-like illness is that patients will continue to seek 'alternate and unconventional' treatment options but will be deprived of the guidance and oversight of qualified medical practitioners whose training and

[3] Australian Government Department of Health - An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis

experience would ameliorate some of the more serious potential harms of pursuing this direction.

- The Medical Board must appreciate that many Lyme patients, as consumers of health care services, are more educated and well-researched than many of the practitioners they consult and are likely to want to be active participants in their own healthcare decisions and choices.
- The Medical Board is reminded that health care is a 'service' industry. As such, Australian health industry providers, and their regulator, need to learn to be more 'responsive' to consumer needs and preferences. Consumers of health services are the primary stakeholders in the types of service they wish to receive.
- The Medical board should seek to better understand the issues and the reasons practitioners elect to utilise non-NATA- accredited and overseas laboratories and the reasons patients seek alternative treatments.
- The notion of a single definition to encompass a broad range of practices, including those that are unable to be described because they are emerging, is unhelpful in a regulatory environment and goes against the principles of procedural fairness.
- The LDAA advocates for a retention of the status quo as there is no evidence that the guidelines as they currently exist are inadequate particularly in relation to the punitive actions already taken against medical practitioners diagnosing and treating Lyme disease.

Innovation in medicine

Digital technology is expected to add $139 billion to the Australian economy by 2020[4], and is predicted to have a profound effect on all aspects of our daily lives. Healthcare is about to undergo transformational changes that will drive positive impacts for patients, caregivers and healthcare professionals. However, it seems that Australian medical authorities are underprepared for such changes. The Medical Board's *Discussion paper* does little to embrace or encourage medical innovation. Instead, it appears intent on stifling it.

Significant aspects of health care require urgent updates. For example, the mainstreaming of previously inaccessible medical technology into everyday devices means that many patients now play an active role in understanding their own health situations and are better equipped to manage their treatment. Advancements in digital therapeutics like the delivery of Insulin using flash glucometers already challenges the medical engagement system. Advancements in medical analytics and real-time data capture means that patients will hold and control their own comprehensive medical data. For patients with Lyme disease the value of consolidated patient data is already demonstrated through programs like My Lyme Data and Patients Like Me[5].

A recent report by McKinsey[6] highlighted a vision for innovation in medical affairs and recommended: innovation in evidence generation; accelerating access to treatment; transformation and personalisation in medical engagement (patient and physician); and better medical leadership.

The Medical Research Future Fund[7] validates the need for precision and personalised medicine and revolutionary ways to treat serious and chronic illness. Personalised medicine models involving genomics, biobanking and integrated platforms that allow for early diagnosis and personalised treatment are urgently needed to address a better quality of life for people with Lyme-like illness.

To that end, a consortium of researchers from Macquarie University, University of Sydney and St Vincent's Centre for Applied Medical Research have proposed a unique platform to collect, test and store an integrated and comprehensive biobank of samples from patients with Lyme-like illness This is a critical resource missing for all researchers working in this area.

Using longitudinal samples, the team proposes to identify new biomarkers for diagnostic and prognostic purposes as well as measure a patient's response to treatment. A registry and database will house all clinical and biological information collected from patients. The integrated platform will provide a faster and more accurate diagnostic tool and will ultimately allow personalised treatment for patients with Lyme-like illness.

It is essential the Medical Board support an innovative approach to this complex and poorly understood disease, as directed by the objectives of the national registration and accreditation

[4] Deliotte Access Economics, 2015: The Connected Continent II

[5] My Lyme Data is a patient powered Lyme disease research platform; Patients Like Me provide consolidated data on Lyme disease

[6] McKinsey, June 2019 - A vision for Medical affairs in 2025

[7] Medical Research Future Fund https://beta.health.gov.au/initiatives-and-programs/medical-research-future-und/aboutthe-mrff

scheme. The Schedule Health Practitioner Regulation National Law section 3 (2) f. states the requirement to **enable innovation** in the education of, and service delivery by, health practitioners.

The Medical Board is in a leadership position, yet it is hard to reconcile the proposal for strengthened sanctions on medical practitioners employing 'new or emerging therapies' with the opportunities available through medical innovation in the coming decade. The *Discussion paper* presents us with a prohibitive, anachronistic, desk-based, academic view of medicine, not a real-world approach responsive to a rapidly changing medical landscape.

It is difficult to understand how any medical practitioner in Australia should treat an emerging illness they have never seen before without falling foul of the disciplinary consequences inherent in the Medical Board's proposed restrictive guidelines.

Medical practitioners should be supported in the management of uncertainty in an emerging epidemic. It should be the medical practitioners' role, in company with their patient, to negotiate the appropriate degree of precaution, risk and benefit a treatment might have. The process cannot be reduced to quantitative, one-size-fits-all formulas. It involves personal and clinical judgement in consideration of individual patient symptom presentation and overall physical constitution to evaluate the likely efficacy and utility of any emerging treatment protocol. The Board's proposed changes to regulatory guidelines would add to this process an unnecessary burden of practitioners also being required to evaluate whether the treatment meets its ambiguous criteria for 'conventional' or 'unconventional'.

In a future-focused medical model, horizon scanning would show there is an emerging issue surrounding tick-borne illness in Australia and evidence would be systematically collected to better understand the problem. Instead, we have ignorance squared[8] in Australia, where no such understanding is even aspired to. Those who have sought to understand have been publicly decried charlatans and accused of practicing quackery[9].

These much-maligned medical practitioners are working at the edge of medical and scientific knowledge because the Australian medical research community has been preoccupied with perpetuating the Lyme disease associated dogma and have not researched Australian-acquired Lyme-like illness. There can be no 'certainty' because there has been no patient focused research to enable it.

[8] Ravetz, J. R. (1993). The Sin of Science: Ignorance of Ignorance. *Knowledge*, *15*(2), 157–165

[9] ABC Background Briefing: Lyme a four letter word, 12 May 2013

Comments on the Background to the Consultation

The Medical Board asserts that "***concerns have been raised by stakeholders about this area of practice suggesting that additional guidance for medical practitioners is needed*** …" yet fails to provide any detail on the position, motivation, or authority of the 'stakeholders' who've raised these concerns. This deliberate vagueness about stakeholders raises sensible questions about exactly who is influencing the Medical Board and whether there are conflicts or potential vested interests being protected.

There is no quantitative data reported within the consultation material on the individual practices under scrutiny to enable any judgment about the appropriateness of the mitigations proposed in relation to the size and scale of the issues. The Medical Board uses '***Complaints as a source of information'*** to provide insights into patient issues but provides no quantification or information on the severity of those complaints, or who raised them.

The use of Lyme disease to illustrate 'unconventional medicine' throughout the *Discussion paper* is entirely disproportionate to the size of the problem. Professor Stephen Bradshaw, then Acting Chair of the Medical Board, provided testimony to the Senate Committee for Community Affairs in their investigation of Lyme-like illness in 2016 and reported that, "*the number of practitioners that have regulatory action taken against them on this topic is extremely small. There are huge other areas of practice that have a lot more practitioners before us than practitioners looking after patients with Lyme disease.*"[10]

In further testimony in November, Associate Professor Bradshaw quantified the issue and testified that, "*as a figure, we have over 2,000 notifications a year to AHPRA, not including New South Wales. In all those cases, there are now only three doctors, over a total of 100,000 registered medical practitioners, who have conditions on their practice relating to Lyme or Lyme-like disease".*[11]

As such, the LDAA questions why Lyme disease has become the poster illness of 'unconventional medicine'? There is a perception among medical practitioners and the patient community that the Medical Board and the Australian Health Practitioner Regulation Agency (AHPRA) are targeting Lyme disease and all practitioners who dare to diagnose and treat it. This perception is now widespread throughout the Australian medical community. The LDAA has received many reports from medical practitioners who have been summoned by their superiors in clinics and regional hospitals and warned that they risk their medical registration if they treat patients for tick-borne illness.

During the Senate Inquiry into Lyme-like illness, the senators sought to address the concerns raised by numerous medical practitioners who made submissions and requested their name be withheld due to fear of disciplinary action by the Medical Board. As such, the Committee decided to redact the names of all doctors named in submissions, including Lyme-literate practitioners.[12]

[10] Hansard, Community Affairs References Committee, Emerging tick-borne disease, Hearing 15 April 2016, p.66.
[11] Hansard, Community Affairs References Committee, Emerging tick-borne disease, Hearing 2 November 2016. P.61
[12] Senate Committee Inquiry, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients,* Interim Report, May 2016

Comments in reference to the Senate Inquiry

The *Discussion paper* refers to the Senate Inquiry on the *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients* conducted in 2016.

Despite thousands of pages of evidentiary data illustrating the epidemiology of Australian Lyme disease and thousands more pages of testimony submitted by patients about their appallingly discriminatory experiences at the hands of some Australian medical practitioners, the Medical Board focuses on **'treatment protocols'** and the **'use of prolonged antibiotic therapy'** as the only issues.

The Medical Board is complicit in this systemic discrimination through its wilful ignorance of the quantifiable issues. Multiple submissions to the Senate Inquiry provided rich descriptions of the appalling experiences patients encountered with medical practitioners who refused to treat them, misdiagnosed them or failed to properly assess and manage their medical conditions. Yet there has been no action that might address the substantial number of medical practitioners who have failed in their multiple obligations to patients.

Comments in reference to the development of 'supporting documents'

Within the *Discussion paper,* the Medical Board highlights its intent to develop "supporting document" that will provide information on the scope of the guidelines and include examples to further explain the definitions of 'complementary and unconventional medicine' and 'emerging treatments'. The Board justifies the requirement for this additional information to be provided "separately from approved guidelines" to "enable the Board to update it as needed as the scope of this area of practice can be subject to rapid change".[13]

While the Board might rationalise its need for agility, it cannot evade its obligation to conduct transparent, broad and open consultation, especially when dealing with ambiguous and contentious definitional issues.

To comply with the consultation requirements of the Health Practitioner Regulation National Law, "the Board must ensure there is wide-ranging consultation about its content". Consulting on one aspect of a guideline, while relegating definitional explanations to 'supporting documents' or 'additional information' intended for periodic, but potentially covert updates, is a huge concern. Any future amendments to definitional explanations should be subject to the same rigorous criteria for public consultation as the initial guideline process.

The tone of submissions already made to the Medical Board in this consultation highlights the intense opposition the proposed definitions have already attracted.

Furthermore, it is not clear whether the Medical Board has developed a Regulation Impact Statement for the regulatory guideline it proposes.

[13] Medical Board *Discussion paper,* page 3 'Issues for Consultation'

Addressing the Questions for consideration

Question 1

Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'?

No.

Each of these terms are individual, with three different concepts, intent and outcomes and should be separately defined to omit ambiguity.

Conflating these terms to a single highly ambiguous statement that will be further determined by the Medical Board's 'subjective' opinion proposed in the 'working definition' "considered to be part of ..." is unhelpful and obfuscates the issue.

The Medical Board, and indeed any regulatory body, has an obligation to clearly define the terms by which they intend to govern registrants, and which may form the basis for punitive action or expulsion.

The use of Lyme disease within the definition of 'unconventional medicine'

The *Discussion paper* uses examples of Lyme disease to illustrate its 'definition' of unconventional medicine. The many references to Lyme disease build upon the underlying conventional medical bias that holds the position 'there is no Lyme in Australia'.

The statement "***diagnosis of conditions which are not generally accepted, for example: Lyme disease (in patients who have not been outside Australia***" does not accord with contemporary thinking and ignores the thousands of patients who have provided substantial evidence to the contrary. The Medical Board omits to recognise the compelling evidence presented by patients and observed in clinical practice, which resulted in the allocation of funds through the National Health and Medical Research Council's Targeted Call[14] to research the phenomena.

Statements that imply or perpetuate the notion that Lyme disease, or an Australian-acquired equivalent illness, is not in Australia should not be made by public authorities until adequate research has been conducted in this area.

Lyme disease and 'unconventional diagnostic techniques and methods'

The *Discussion paper* focuses on the use of *"**unconventional diagnostic techniques and methods, for example pathology testing in non-accredited laboratories**"* but neglects to examine or even mention the specific issues encountered in Lyme disease.

There are two separate issues within this statement that require discussion. First is the notion of 'unconventional diagnostic techniques and methods' and second is the notion of 'non-accredited'

[14] National Health and Medical Research Council's 2018 Targeted Call for Research on DSCATT

versus accredited laboratories. Noting that the latter discussion is continually used as a distraction to the fundamental issue that the existing diagnostic techniques and methods for Lyme disease are inadequate and outdated[15].

Furthermore, diagnostic methods to determine the specific pathogens for people acquiring a Lyme-like illness in Australia do not exist. Until appropriate tests that identify the specific indigenous pathogens causing such an illness exist, a clinical diagnosis is the only method for diagnosing Australian Lyme disease.

Emerging diagnostic techniques, using high-throughput sequencing (HTS), or next generation sequencing (NGS) are providing breakthroughs in medical diagnostics in other fields and could be evaluated for utility as a direct detection method.

Notwithstanding the points above, even this revolutionary approach to direct detection of organisms using metagenomics might fall within the Medical Board's definition of 'new and emerging therapies' as it is definitely progressive practice and provides the platform for precision medicine where therapies are matched with the unique health needs of the patient.

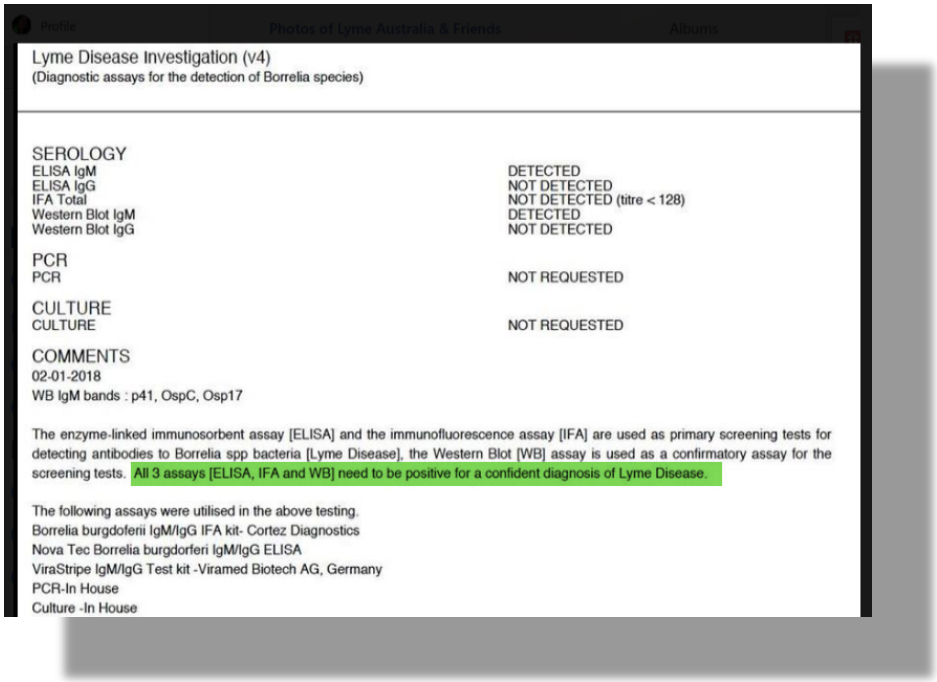
The Medical Board's obfuscation regarding accepted versus unaccepted diagnostics is unhelpful to practitioners and the position needs to be made clear. The *'Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis'*[3] (*the Guideline*) currently requires definitive laboratory evidence for the diagnosis of Lyme in Australia, yet a 'confirmed' diagnosis relies upon inadequate and outdated processes. As such, practitioners face a conundrum while their patients become progressively ill; it benefits no one.

LYME DISEASE AND 'PATHOLOGY TESTING IN NON-ACCREDITED LABORATORIES'

It is disappointing to see the Medical Board, as a regulatory body, perpetuating the implication that non-accredited laboratories are not trustworthy, and that only Australian 'accredited' laboratories are. It highlights that the Board does not understand the issue and has not properly examined the regulatory environment surrounding laboratory accreditation either in Australia or internationally.

The standard of accreditation for laboratories testing for Lyme disease is clearly established in *the Guideline*[9]. The *Guideline* relies upon positive results in a two-tier testing protocol. However, the interpretive criteria used to determine a positive test result under the two-tier regime is not defined within *the Guideline*. As such, some Australian 'accredited' laboratories produce discordant test results.[16] Some devise their own diagnostic criteria (see **Error! Reference source not found.**), and have applied a three-tier diagnostic regime effectively operating outside *the Guideline* without accountability or consequence.

[15] IDSA -Direct Diagnostic Tests for Lyme Disease Clin Infect Dis. 2019 Mar 5;68(6):1052-1057. doi: 10.1093/cid/ciy614.
[16] Baggoley, C (former Chief Medical Officer) 2016, Health Media Statement, Media Release, Woden, Canberra, February 2016.



Lyme Disease Investigation (v4)
(Diagnostic assays for the detection of Borrelia species)

SEROLOGY

ELISA IgM	DETECTED
ELISA IgG	NOT DETECTED
IFA Total	NOT DETECTED (titre < 128)
Western Blot IgM	DETECTED
Western Blot IgG	NOT DETECTED

PCR

PCR	NOT REQUESTED

CULTURE

CULTURE	NOT REQUESTED

COMMENTS
02-01-2018
WB IgM bands : p41, OspC, Osp17

The enzyme-linked immunosorbent assay [ELISA] and the immunofluorescence assay [IFA] are used as primary screening tests for detecting antibodies to Borrelia spp bacteria [Lyme Disease], the Western Blot [WB] assay is used as a confirmatory assay for the screening tests. All 3 assays [ELISA, IFA and WB] need to be positive for a confident diagnosis of Lyme Disease.

The following assays were utilised in the above testing.
Borrelia burgdoferii IgM/IgG IFA kit- Cortez Diagnostics
Nova Tec Borrelia burgdorferi IgM/IgG ELISA
ViraStripe IgM/IgG Test kit -Viramed Biotech AG, Germany
PCR-In House
Culture -In House

Figure 1: Australian Laboratory Testing result for Borrelia

The results from an Australian 'accredited' laboratory outlined in Figure 1 were assessed as negative using a three-tier diagnostic regime. However, using the interpretive criteria contained within the test kit manufacturer's instructions for use (IFU) "bands of the following antigens are considered as highly specific for Borrelia species: p41 (limited specificity), p39, OspC, Osp17 and VlsE"[17].

The presence of these specific bands indicates a Borrelia infection, concurs with the clinical observations of the medical practitioner who requested the test and should have initiated a Lyme disease treatment protocol. Yet, under the Medical Board's proposal, if this medical practitioner had treated their patient for Lyme disease they would be in breach of the proposed *Guidelines for registered medical practitioners – Complementary and unconventional medicine and emerging treatments* and be subject to punitive action.

Instead, the medical practitioner who relied upon this test result from an Australian 'accredited' laboratory informed the patient they were negative for Lyme disease and neither the practitioner nor the laboratory, acting in opposition to *the Guideline*, are held accountable. Recommendations from the IFU to repeat the test at a later stage and to conduct additional testing to rule out cross-reactivity were also not advised by the laboratory to the patient's practitioner. Meanwhile the patient developed a chronic illness that might have been managed more efficiently while the infection was in the acute stage.

It is not clear if the *Code of conduct for doctors in Australia* applies to practitioners in pathology practice. In regard to pathology testing for Lyme disease, there is a clear case for better public safety and associated safeguards should be applied equally to practitioners signing off on

[17] ViraMed Borrelia ViraStripe IgM Test Kit, Instructions for Use

pathology tests. Standardised practices should apply to all pathology laboratories, all testing kits, and all medical practitioners working within those laboratories.

The criteria for determining and interpreting laboratory results should be made clear in the Australian *Guideline.* Laboratories should also be compelled to report which test kit was used and the limitations of the kit. Laboratories should be compelled to report the FULL set of results and, where it includes a Western Blot, a full set of bands should be reported. Where a negative test result is provided, pathologists should be compelled to advise the practitioner about the limitations of a negative test result.

The reporting of Lyme disease testing is such a critical issue that several States in the USA, where the incidence of Lyme disease is considerable, have enacted legislation to address it. The State of Maine enacted *An Act To Inform Persons of the Options for the Treatment of Lyme Disease, 2013,* requiring that the Maine Centre for Disease Control and Prevention update their website to include the following statement: "a *negative result for a Lyme disease test does not necessarily mean that Lyme disease is not present*".[18]

Similarly, the Virginia government introduced the *Lyme Disease Testing Information Disclosure Act*. It requires patients to be provided with written notification advising that "*If you are tested for Lyme disease, and the results are negative, this does not necessarily mean you do not have Lyme disease".*[19]

In these areas, a clinical diagnosis by a medical practitioner experienced with recognising Lyme disease is accepted.

Sadly, many Australian patients are living with debilitating illness due to the inexplicable dismissal of their testing result, even if the result detects antigenic bands that are highly specific to Borrelia infections.

As a result of this situation, medical practitioners order pathology tests from specialist laboratories overseas to clarify their diagnosis, usually at significant expense and inconvenience to patients.

The international laboratories commonly used by Lyme-literate medical practitioners meet the international standards (ISO 15189) as required in *the Guideline* and are, under Australia's international agreements, eligible for reciprocal recognition through the National Association of Testing Authorities (NATA). *The Guideline* provides clear information on this requirement:

> *"Testing should be performed in a laboratory which has Lyme disease testing in its scope of accreditation, and which is compliant with "AS ISO 15189 Medical laboratories — Particular requirements for quality and competence" or in nationally accredited laboratories where the patient was infected. Commercial serological assays used in Australian laboratories with AS ISO 15189 Medical Testing accreditation are suitable for testing for Lyme disease acquired overseas in endemic regions."*

[18] http://www.mainelegislature.org/legis/bills/bills_126th/chapters/PUBLIC340.asp

[19] https://lis.virginia.gov/cgi-bin/legp604.exe?131+sum+HB1933

However, the results provided by these international accredited laboratories are routinely dismissed along with the implication that the medical practitioners who use them are defrauding Australian patients.[20] Given this untenable situation, and the Medical Board's lack of examination of the issue, it is difficult to comprehend how any Medical Board might adjudicate such 'clinical practice'. This is not a trivial problem.

To provide some quantification of the size of the issue, a single private laboratory reported that medical practitioners – with clinical evidence their patients were suffering from a Lyme-like illness - collectively requested 5628 pathology tests.[21] Over a period of 23 months (from September 2014 – July 2016) a significant number of medical practitioners used at least one Australian 'accredited' laboratory group to make diagnostic decisions about a Lyme-like illness on behalf of their patients.

There is no data that might provide national insight across all laboratories, however the data provided by a single laboratory should trigger a deeper review into the conundrum of negative diagnostic tests and the conflicting clinical situation medical practitioners face.

While the tests being performed in Australian laboratories have not been designed to detect a yet unknown Australian pathogen, there are interesting and unique antigenic patterns for Borrelia emerging, which should be fully investigated. A consolidation of laboratory diagnostic information, including test type and the mandatory reporting of all bands could provide immediate insights that might inform the Australian diagnostic position.

There is a distinction to be made between diagnosis versus diagnostics; diagnosis encompasses an explanation of a patient's clinical symptoms whereas diagnostics relate to the laboratory and other tests used to aid medical practitioners in making a diagnosis. In many other countries Lyme disease is considered a clinical diagnosis based upon a full and complete evaluation of the patient and their clinical presentation. This may or may not be supported by appropriate laboratory tests to confirm a clinical diagnosis. There is no recognition of this issue in the Medical Board's discussion paper or its proposed guidelines.

The Medical Board advocates patient safety as its motivation for strengthening its guidelines, especially in the area of Lyme disease, yet it fails to examine the systemic issues associated with laboratory testing for Lyme disease in Australia or evaluate the risks to patient safety resulting from under-diagnosis of tick-borne infections based on inadequate diagnostic testing

LYME DISEASE AND 'LONG-TERM ANTIBIOTICS IN THE ABSENCE OF IDENTIFIED INFECTION'

These are two separate issues:

1. the use of **long-term antibiotics for Lyme disease** and Lyme disease-like syndromes; and
2. the definition of **'identified infection'**.

In reference to the long-term use of antibiotics in Lyme disease, it is unclear which ***'accepted therapeutic guidelines or protocols'*** the Medical Board relies upon for Lyme disease.

[20] RCPA Position Statement on Diagnostic testing for Borreliosis-Lyme

[21] Does Lyme disease exist in Australia? Peter J Collignon, Gary D Lum and Jennifer MB Robson Med J Aust 2016; 205 (9): 413-417. Published online: 7 November 2016

In the absence of clarification, the *Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis'* recommends the Infectious Diseases Society of America's (IDSA) *Lyme disease Treatment protocol (2008)*. This Treatment protocol did not recommend the use of antibiotics beyond an initial 10 to 14-day period. While considered 'conventional', this protocol has attracted serious criticism from expert medical practitioners.

The IDSA *Lyme disease Treatment protocol* has since been removed from the National Guideline Clearinghouse (NGC) due to its failure to conform to the rigorous evidentiary review standards adopted by the Institute of Medicine in 2011 for creating trustworthy standards[22]. Despite this, the *Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis* recommending the use of the IDSA *Lyme disease Treatment protocol* remains unamended.

The IDSA protocol has consistently failed patients and its recommendations have contributed to bacterial persistence. A suite of contemporary research[23] shows that 'persister' cells resist antibiotic therapy through the formation of biofilms. As such, the short monotherapies recommended in the IDSA *Lyme disease Treatment protocols* (tetracycline, fluoroquinolone etc) have proven inadequate. These treatment protocols fail to eliminate spirochetes in *in vitro* culture, leaving behind viable and effective persisters that contribute to chronic forms of disease.

Alternatively, the International Lyme and Associated Disease Society (ILADS) Treatment protocol is listed by the NGC and complies with the strict guidelines for evidence-based medicine. The ILADS Treatment protocol recommends that:

> *"patients with persistent (chronic) signs and symptoms of Lyme disease receive individualized care that tailors antibiotic treatment to their specific situation. The duration of treatment and the choice of antibiotic or antibiotic combinations are clinical decisions to be made with several factors in mind."*[24]

Furthermore, the efficacy of long-term antibiotics and the implied threats of antibiotic resistance hold little weight in relation to several serious diseases. When it comes to Lyme disease, the long-lasting effects of a disease left untreated or inadequately treated may be more detrimental to patients and the wider community. The ILADS 2008 treatment guidelines warn of this issue:

> *"Over two decades of experience in treating thousands of patients with Lyme has proven that therapy… although intense, is generally well tolerated…Remember, years of experience with chronic antibiotic therapy in other conditions, including rheumatic fever, acne, gingivitis, recurrent otitis, recurrent cystitis, COPD, bronchiectasis, and others have not revealed any consistent dire consequences as a result of such medication use. Indeed, the very real consequences of untreated, chronic persistent infection by B. burgdorferi can be far worse than the potential consequences of this treatment."*[25]

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[22] 2016, Lyme Disease Association, Official Word on IDSA Guidelines' Removal from NGC

[23] *Metamorphoses of Lyme disease spirochetes: phenomenon of* Borrelia *persisters, Parasites & Vectors, 2019, Volume 12, Number 1*

[24] Controversies and Challenges, ILADS Treatment Guidelines

[25] Burrascano, *Advanced Topics in Lyme disease – diagnostic hints and treatment guidelines for Lyme and other tick-borne illnesses*, 2008, p22, http://www.ilads.org/lyme/B guidelines 12 17 08.pdf

In the United States this issue has attracted the attention of legislative law makers, where seven state governments were so concerned by the perception that long term antibiotic treatment was inappropriate that they introduced 'doctor protection' legislation. These laws acknowledge the existence of chronic Lyme disease (CLD) and the right of doctors to treat it with long term antibiotics.[26]

The Medical Board should make it clear which '***accepted therapies***' and ***'accepted therapeutic guidelines***' it relies upon as part of its proposed guidelines for overseas acquired Lyme disease.

Furthermore, the Medical Board's proposed guidance must also consider an Australian-acquired Lyme disease, described by the Australian Government Department of Health as 'Debilitating Symptoms Complexes Attributed To Ticks' (DSCATT) and should recognise the work underway to develop a case definition and clinical pathway for the diagnosing, treating and managing the illness.

In the immediate absence of a case definition for Australian Lyme disease and adequate laboratory tests for identifying potential infectious causative agents, the Medical Board cannot justifiably define the term '***identified infection'***.

In relation to the previous discussion on laboratory testing and the conundrum faced by medical practitioners and patients, the Medical Board must make clear which standards, and which interpretive criteria are to be relied upon for evidence of '***identified infection'***.

The description is inadequate considering the complexity of a patient's immune response, the performance limitations in, and lack of accuracy and reproducibility of, laboratory tests.

We urge the Medical Board to seek a resolution to this issue for medical practitioners.

'NEW AND EMERGING THERAPIES'

The entire concept that new and emerging therapies, in the context of Lyme disease and associated tick and vector borne illness, could become part of the proposed guidelines is alarming. Medical treatment is at its best when the medical practitioner tests the patient's response to treatment.

When an emerging disease is poorly understood, experimental practice is the best way to ensure each individual patient is prescribed effective treatment. The direct evidence the medical practitioner observes, and can often objectively measure, in the patient's response when trialling a treatment protocol underpins the development of evidence-based medicine. Evidence-based medicine (based on published, peer-reviewed guidelines) might increase the predictability of efficacy, but success depends on what works on a case by case basis.

[26] Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients Submission 528 - Supplementary Submission 2

The Medical Board's proposed approach appears to diminish the function of highly trained medical practitioners into becoming mere administrators of published guidelines.

New approaches to treatment are required and must be urgently applied because the 'conventional' approach has consistently failed to deliver favourable outcomes to a growing percentage of patients who 'fail' the standard treatment protocols recommended by the IDSA. These treatment protocols have even less relevance when applied to a unique Australian situation in which most patients have not received treatment in the 'acute' stage and are, therefore, more likely to present with symptoms indicating disseminated and debilitating infection.

Yet the Medical Board proposes that the application of new and emerging treatments for Lyme disease would be constrained by strengthened and ambiguous guidelines. This leaves both patients and medical practitioners in a Catch-22.

Multiple domains of ignorance prevail in the discussion of Lyme disease in Australia. Of concern is the perpetual ignorance that encompasses a case definition, diagnosis and treatment, particularly when we can't even agree upon a name for the condition.

Australian patients presenting with an illness following a tick bite do not fit into well-researched and defined categories that are supported by case definitions, where treatment guidelines exist and are clinically proven through trials. Instead, they present with complicated and perplexing conditions that confound the medical practitioners they consult.

Patients typically present with tomes of medical records and reveal lists of highly complex signs and symptoms, which generally require hours to review and understand. The Australian model of medicine is not well-suited for patients with chronic conditions, let alone a chronic form of Lyme-like illness, irrespective of where it might have been acquired.

As such, many of the Australian medical practitioners treating Lyme-like illness are integrative practitioners who are prepared to devote the time necessary to investigate the whole patient and the multi-systemic effects of illness. Many have become extensively educated about tick-borne illness, have attended professional education on the topic and have studied under, and seek counsel from, some of the world's leading Lyme disease experts, who possess considerably more clinical experience. They participate in international discussion groups, share research and expertise and are continually updating their knowledge about the efficacy of treatment modalities through this information-sharing network. Their additional training and development has earned them the label, 'Lyme-literate medical practitioner', yet this very label is used by the Medical Board to illustrate a 'concerning practice'.

It is incomprehensible to the patient community that the medical practitioners who have devoted extensive time to expanding a knowledgebase that informs the development of responsive personalised treatment protocols have now become the subjects of the Medical Board's discriminatory targeting of practitioners requiring further restrictive guidelines. Surely these highly trained medical practitioners can be trusted to make clinical decisions with their patients about the utility of new and emerging treatments that might match patients' clinical presentations?

In the absence of an Australian Lyme disease case definition, or any epidemiological information and translational research, medical practitioners are compelled to study the body of research and literature on new and emerging treatments, which by their very 'newness' may be considered 'unconventional' by the Medical Board.

Australia is seriously lagging in its knowledge of, and research in, vector-borne diseases. Our medical knowledge is already decades behind the scientific discovery of organisms in ticks and expediting our clinical knowledge of emerging pathogens is consistently stalled by the Australian medical authorities' combined failure to invest in medical research.

The data collected by the LDAA on the Australian patient situation indicates that increasing numbers of Australians are travelling overseas for treatment. Some patients are so chronically debilitated by the effects of Lyme disease they have little choice but to travel overseas to access new and emerging treatments that are restricted or unavailable in Australia. They are forced to pay for private treatment, seek overseas tests and use alternate treatment and complementary methods because 'conventional' medicine does not provide for their needs as health care consumers.

The patients who are too sick to travel or unable to afford the costs of overseas treatments are left to navigate the medical system in Australia. Many find themselves in an uncertain medical situation, complicated by an unexpected lack of accurate diagnostics. They are routinely denied treatment or medical support when they report a tick bite, which often sets them on a path to a debilitating and chronic illness and places unnecessary economic burden upon them and their families.

The Medical Board's proposed strengthening of their guideline, especially in relation to the issues highlighted for Lyme disease, are likely to force more patients down the path of treatments that are not supported by the Medical Board, and with unscrupulous or unregistered alternate practitioners. They are likely to find themselves with no choice but to adopt more do-it-yourself and alternative type treatments, including unsupervised administration of IV antibiotics. This situation is extremely concerning for already seriously ill patients.

Off-label prescribing and Lyme disease

'Off-label prescribing' presents the Medical Board with a challenging situation as it would preclude ***all*** antibiotic treatment in Australia for patients suffering from Lyme disease.

As the Medical Board is aware, some practitioners in Australia have had specific conditions placed upon their registration for prescribing antibiotics to treat patients with Lyme-like illness. In one punitive action taken by the Medical Board reported in the *Discussion paper,* the conditions imposed included that the medical practitioner was "to only prescribe medication in accordance with the Australian Therapeutic Guidelines". There appears to be no understanding by the Medical Board of the ramifications of that condition and what it means in practice.

According to the Australian Therapeutic Guidelines (ATG), no medical practitioner is safe in prescribing the internationally recommended antibiotics for Lyme disease which are covered under the Pharmaceutical Benefits Scheme **AND** operate within the ATG's. For example, the

recommendations on the type of antimicrobial treatment from the removed IDSA *Lyme disease Treatment guideline* that our government recommends is shown in ***Error! Reference source not found.***.[27]

The most common antibiotic used in first-line defence for Lyme disease for adults is Doxycycline; for children it is Amoxicillin. Depending on the severity of symptoms, other antibiotics like Cefuroxime and Ceftriaxone are sometimes used and often IV administration is recommended.

Table 1: IDSA recommended treatment

Recommended antimicrobial regimens for treatment of patients with Lyme disease.

Drug	Dosage for adults	Dosage for children
Preferred oral regimens		
Amoxicillin	500 mg 3 times per day[a]	50 mg/kg per day in 3 divided doses (maximum, 500 mg per dose)[a]
Doxycycline	100 mg twice per day[b]	Not recommended for children aged <8 years For children aged ⩾8 years, 4 mg/kg per day in 2 divided doses (maximum, 100 mg per dose)
Cefuroxime axetil	500 mg twice per day	30 mg/kg per day in 2 divided doses (maximum, 500 mg per dose)
Alternative oral regimens		
Selected macrolides[c]	For recommended dosing regimens, see footnote *d* in table 3	For recommended dosing regimens, see footnote in table 3
Preferred parenteral regimen		
Ceftriaxone	2 g intravenously once per day	50–75 mg/kg intravenously per day in a single dose (maximum, 2 g)
Alternative parenteral regimens		
Cefotaxime	2 g intravenously every 8 h[d]	150–200 mg/kg per day intravenously in 3–4 divided doses (maximum, 6 g per day)[d]
Penicillin G	18–24 million U per day intravenously, divided every 4 h[d]	200,000–400,000 U/kg per day divided every 4 h[d] (not to exceed 18–24 million U per day)

[a] Although a higher dosage given twice per day might be equally as effective, in view of the absence of data on efficacy, twice-daily administration is not recommended.
[b] Tetracyclines are relatively contraindicated in pregnant or lactating women and in children <8 years of age.
[c] Because of their lower efficacy, macrolides are reserved for patients who are unable to take or who are intolerant of tetracyclines, penicillins, and cephalosporins.
[d] Dosage should be reduced for patients with impaired renal function.

Gary P. Wormser et al. Clin Infect Dis. 2006;43:1089-1134

Clinical Infectious Diseases

The Australian Therapeutic Guidelines (eTG Complete for Practitioners) shows that these antimicrobials are not approved for use in Australia for Lyme disease (Borrelia), despite their recommended use internationally. The Australian Therapeutic Register of Therapeutic Goods (ARTG) sets out the specific indications for which drugs may be prescribed. For Doxycycline, the online public ARTG summary includes Borrelia (relapsing fever) and *Bartonella bacilliformis* (Bartonellosis) as shown in the following extract:

[27] IDSA Treatment Guideline accessed: 19 December 2015: http://www.ilads.org/lyme/ILADS_Guidelines.pdf

Specific Indications

Infections caused by the following organisms; Mycoplasma pneumoniae (primary atypical pneumonia); Rickettsiae (Queensland tick typhus, epidemic typhus fever, Q fever, murine endemic typhus fever, Australo-Pacific endemic scrub typhus); Chlamydia psittaci (psittacosis); Chlamydia trachomatis (lymphogranuloma venereum, trachoma, inclusion conjunctivitis). (Doxycycline is indicated in the treatment of trachoma, although the infectious agent is not always eliminated, as judged by immunofluorescence. Inclusion conjunctivitis may be treated with oral doxycycline alone, or in combination with topical agents.) Borreliae (relapsing fever), Calymmatobacterium (Donovania) granulomatis (granuloma inguinale). Infection caused by the following Gram-negative microorganisms: Vibrio species (chlorea), Brucella sp. (Brucellosis; in conjunction with streptomycin), Haemophilus ducreyi (chancroid), Yersinia pestis (plague), Francisella turarenis (tularaemia), Bartonella bacilliformis (Bartonellosis), Bacteroides sp. When penicillin is contraindicated, Doxy-100 is an alternative drug in the treatment of infections due to : Treponema pallidum (syphilis); Treponema pertenue (yaws); Neisseria gonorrhoea (see Dosage and Administration). Doxy-100 is not the drug of choice in the treatment of any type of staphylococcal infection or infections due to Streptococcus pneumoniae, Haemophilus influenzae, Streptococcus pyogenes, Streptococcus faecalis or any type of enteric bacteria because many strains of these organisms have been shown to be resistant to doxycycline. Doxy-100 should not be used in these infections unless the organism has been shown to be sensitive. For upper respiratory infections due to group A beta-haemolytic streptococci (including prophylaxis of rheumatic fever), penicillin is the usual drug of choice. In acute intestinal amoebiasis, doxycycline may be a useful adjunct to amoebicides. In severe acne, doxycycline may be useful adjunctive therapy. Doxycycline is indicated, in adults and children older than 10 years, as chemoprophylaxis for malaria caused by Plasmodium falciparum and, in combination with other antimalarial agents, against malaria caused by Plasmodium vivax. Doxycycline is only able to suppress malaria caused by P. vivax. As there are relatively few locations where P. vivax does not co-exist to some extent with P. falciparum, it is recommended that doxycycline should be used routinely with other agents, for example, chloroquine.

According to our combined health departments we do not have 'Relapsing Fever' in Australia, despite the novel Borrelia species discovered at Murdoch University in 2015 identified as part of the Relapsing Fever family.

The second common antibiotic used for the treatment of Lyme disease, as recommended by the Centres for Disease Control (CDC), the IDSA and ILADS is Cefuroxime, known as Zinnat commercially. Yet the ARTG makes no reference to its utility in vector borne diseases.

Specific Indications

Cefuroxime is indicated for the treatment of the following mild to moderately severe infections in adults caused by sensitive bacteria. . Acute upper respiratory infections: otitis media, sinusitis, tonsillitis and pharyngitis. . Acute exacerbations of chronic bronchitis, or acute bronchitis. . Skin and skin structure infections, for example, furunculosis, pyoderma and impetigo. . Acute uncomplicated gonococcal urethritis, and cervicitis due to non-penicillinase producing gonococci.

The third common recommended antibiotic used in the treatment of more severe and chronic cases of Lyme disease, and generally administered as IV, is Ceftriaxone. The ARTG recommendation for this antibiotic also makes no reference to vector-borne diseases:

Specific Indications

Treatment of the following infections when caused by susceptible aerobic organisms. LOWER RESPIRATORY TRACT INFECTIONS caused by Strep. pneumoniae, Streptococcus sp. (excluding Enterococci), methicillin sensitive Staph. aureus, H. influenzae, H. Parainfluenzae, Klebsiella sp. (including K. pneumoniae), E. coli, E. aerogenes, P. mirabilis and Serratia marcescens. SKIN AND SKIN STRUCTURE INFECTIONS caused by methicillin sensitive Staph. aureus, methicillin sensitive Staph. epidermidis, Streptococcus group B, Streptococcus group G, Strep. pyogenes, Strep. viridans, Streptococcus sp. (excluding Enterococci), Peptostreptococcus sp., E. coli, E. cloacae, Klebsiella sp . (including K. pneumoniae and K. oxytoca), P. mirabilis, M morganii and S. marcescens. URINARY TRACT INFECTIONS (complicated and uncomplicated) caused by E. coli, P. mirabilis, P. vulgaris, M morganii and Klebsiella sp. (including K. pneumoniae). UNCOMPLICATED GONORRHOEA (cervical/ urethral and rectal) caused by N. gonorrhoeae, including both pencillinase and nonpenicillinase producing strains. BACTERIAL SEPTICAEMIA caused by Strep. pneumoniae, E. coli and H. influenzae. BONE INFECTIONS caused by methicillin sensitive Staph. aureus, methicillin sensitive Staph. epidermidis, Streptococcus group B, Strep. pneumoniae, Streptococcus sp. (excluding Enterococci), E. coli, Enterobacter sp., P. mirabilis and K. pneumoniae. JOINT INFECTIONS caused by methicillin sensitive Staph. aureus, Strep. pneumoniae, Streptococcus sp. (excluding Enterococci), E. coli, P. mirabilis, K. pneumoniae and Enterobacter sp. MENINGITIS- The initial treatment, as a single agent, of meningitis in children and immunocompetent adults when presumed or proven to be caused by H. influenzae type b, N. meningitidis, Strep. pneumoniae or Enterobacteriaceae pending culture and sensitivity results. SURGICAL PROPHYLAXIS- The preoperative administration of a single 1 g dose of ceftriaxone may reduce the incidence of postoperative infections in patients undergoing vaginal or abdominal hysterectomy or cholecystectomy in high risk patients, surgical procedures which are classified as contaminated or potentially contaminated, and patients undergoing coronary artery bypass surgery. Although ceftriaxone has been shown to have been as effective as cefazolin in the prevention of infection following coronary artery bypass surgery, no placebo controlled trials have been conducted. Susceptibility testing: Before instituting treatment with ceftriaxone, appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug. Therapy may be instituted prior to obtaining results of susceptibility testing.

According to the Medical Boards punitive actions taken against Lyme treating medical practitioners, the current situation is that any patient presenting with a tick bite and with associated symptoms is meant to be referred to an infectious disease specialist. It is rare that an infectious disease specialist will order a test for Lyme disease from a NATA accredited laboratory, however if they do, the result will generally be returned as a negative or 'false positive' result, allowing the specialist to discount a Lyme disease diagnosis; this is the typical patient experience.

Should a patient receive a positive test result their medical practitioner is unable to prescribe ANY of the recommended antibiotics and remain compliant with the ARTG. Practitioners are forced to prescribe with a private script, or 'off label' placing the doctor at-risk of disciplinary action from AHPRA and imposing significant financial burdens on patients.

For less than thirty dollars, a 30-day course of Doxycycline can significantly alter the course of future debilitating disease if provided early – at acute stage. While the diagnosis of endemic 'classical Lyme disease' remains controversial in Australia, it should be noted that Doxycycline is the first-line treatment recommended for other undisputed endemic infections commonly encountered as co-infections in the 'Lyme' patient cohort; for example, Bartonella, Rickettsia, and Q-Fever[28].

It should also be noted that this is the same drug prescribed long term to teenagers with acne and is commonly prescribed as a prophylactic medication for people travelling to areas with Malaria. However, under the Medical Board's proposal, practitioners who prescribe Doxycycline for suspected Lyme disease are likely to be operating in contravention of the ATG's and may attract punitive action.

Given the Medical Board's current consultation and the implied inclusion of 'off-label prescribing' within the proposed definition for 'unconventional medicine' it is difficult to see how a front-line medical practitioner might help a patient with tick bite at all.

The inclusion of 'off-label prescribing' within this consultation is curious. If therapeutic allopathic products are available that are unsafe, the Therapeutic Goods Association should address the issue and ensure their advice remains appropriate and contemporary.

Question 2

Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice, medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.'

No.

Defining 'conventional medicine'

The Medical Board has defined what it is targeting or trying to regulate but does not define what 'conventional medicine' is. All medical practitioners and patients could benefit from a clear and unambiguous definition of conventional medicine.

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28 Tick-borne infectious diseases in Australia, Stephen R Graves and John Stenos Med J Aust 2017; 206 (7): Published online: 17 April 2017

Is it only medical practices supported by peer-reviewed research? Is it only treatments or practices described within existing Australian guidelines? This is a core component missing from this entire consultation. It is difficult to understand how the Medical Board, as administrative decision makers, could demonstrate they have accorded with the rules of procedural fairness, especially those concerning the rule against bias, when progressing punitive actions against practitioners using such poorly defined terms.

If the Medical Board cannot define or describe 'conventional' medicine, how can it regulate 'unconventional' medicine? It defies belief that a regulatory body could fail to define exactly what they regulate.

Furthermore, it is unclear why particular sectors of medical practice are being singled out for additional regulation outside those that already apply to all practitioners. There appears to be a discriminatory aspect to the consultation, which is underpinned by selective bias that should be challenged.

All medical practitioners should be subject to the same regulations and guidelines. Singling out certain groups based on unquantified representation in disciplinary proceedings and using those groups as examples throughout the *Discussion paper*, makes it very clear which sectors will be targeted.

Practitioners diagnosing and treating Lyme disease and Lyme-like illness in Australia appear to have been disproportionately affected by the Medical Boards ambiguity for some time. The focus on Lyme disease is not immediately perceived as being discriminatory because it supports the prevailing medical prejudice and builds upon the considerable stigma that has been comprehensively described in the 2016 Senate Inquiry. [29]. However, to the vast majority of Australians who sit outside the prevailing medical culture in which the discrimination has been 'normalised', it is obvious and unacceptable.

The *Discussion paper* presumes we should agree to these 'special' regulations and ambiguous definitions, especially in the area of Lyme disease, because the Medical Board has harnessed existing prejudice and uses the threat of medico-legal action to create a fear of 'difference' and restrict the practice of responsive and innovative medicine.

The reality is that this *Discussion paper* promotes a harmful bias to justify the denial of medical diagnosis and proper medical care. It is likely that many Australian medical practitioners will be afraid to consider a tick-borne diagnosis because of the associated medico-legal threat, hence justifying their continued discrimination against patients affected with Lyme-like illness; this is harmful for patients.

Indeed, since such negative focus has been directed at Lyme disease there is increasing evidence that the medical practitioners are neglecting to test for known[26], prevalent and treatable tick-borne infections including Rickettsia species.

[29] https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lyme-like_Illness/Interim_Report pp.32-36

It is disgraceful that Australian patients with locally acquired tick-borne illness are kept outside official diagnostic and treatment guidelines while they, and the medical practitioners who help them, are seemingly vilified for seeking viable treatment alternatives. It is impossible for 'proven therapies' to exist for diseases that are not researched or recognised.

This approach falls short of the guiding principle described in the Health Practitioner Regulation National Law Part 1, point 3 (2) f, to enable the continuous development of a flexible, responsive and sustainable Australian health workforce and to enable innovation in the education of, and service delivery by, health practitioners.

A systematic method to collect data to develop evidence of emerging diseases is urgently required. If such a method exists there has been a systemic failure to apply it to Australian Lyme disease. A framework is needed to address situations where patients who are suffering from an unconventional condition can access medical care in the interim of any guideline development.

Furthermore, if the current regulatory framework for medical practitioners is not working, then fix the framework and apply it to ***all*** practitioners equally, rather than creating a subset of rules that apply to one sector based on its 'difference' or because it is emerging and not fully or widely understood.

If not, how should it be defined?

As previously discussed, the absence of a clear and comprehensive definition for 'conventional medicine' inhibits the development or consensus of any definition of 'unconventional medicine', especially when applied to the diagnosis and treatment of Lyme disease.

Question 3

Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'?

No.

The Medical Board provides no evidence to support the 'extent' of the problems they assert occur in Lyme disease. The Board's own testimony to the Senate Committee investigating Lyme disease stated '*the number of practitioners that have regulatory action taken against them on this topic is extremely small*'[30].

The Medical Board fails to articulate that there is a clear distinction between the two terms **'Lyme-like illness and Lyme disease'**

[30] See section Comments on the Background to the Consultation

The term **'Lyme-like illness'** is used to describe Australian patients who have an illness, complete with signs, symptoms and often laboratory results, that resemble the well-categorised and described Lyme disease in other parts of the world. However, the Australian medical communities' 'no Lyme here' position leaves patients and practitioners unable to describe the illness in any other way. As such, the Australian Government Department of Health (DoH) elusively labels the illness 'Debilitating Symptom Complexes Attributed to Ticks (DSCATT)', while the LDAA uses the term 'Australian Lyme disease, which it defines as illness(es) and disease(s) caused by both known and yet to be identified pathogens in ticks that result in Lyme disease like symptoms in Australian patients.

The DoH has acknowledged that many people become sick after a local tick bite and should be treated. Even so, risk averse and untrained medical authorities refuse to support practitioners who are providing treatment, due to a lack of research evidence, rather than a lack of clinical evidence. Medical practitioners who treat Australian Lyme disease patients are already liable for punitive action due to the lack of guidelines and TGA approved treatments, regardless of the Medical Boards additional proposal to strengthen the guidelines.

Conversely, **'Lyme disease'**, caused by a Borrelia infection, is well described throughout the world and it has a commonly accepted case definition. It is the largest and fastest growing tick-borne disease in the world.

Given the prevalence of Lyme disease throughout the world and the number of Australians who travel, a large percentage of Australian patients have Lyme disease (*Borrelia burdorferi sensu lato),* that was acquired in endemic areas to which they have travelled. Irrespective of the origin of the illness, patients continue to have difficulty accessing medical practitioners for treatment because of the medico-legal stigma associated with the general term 'Lyme disease' and adherence to the IDSA's guidance that chronic manifestations of the disease are to be ignored/not treated.

The *Discussion paper* fails to acknowledge that a lack of contemporary Australian research compounds these issues.

Question 4

Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners that the Board has not identified?

Yes, the issue of adverse impacts that burden the community as a result of the Medical Board's punitive actions.

The Medical Board fails to acknowledge the consequences of its actions when punitive measures are taken against a medical practitioner, in which there is also a significant number of patients harmed by the loss of their treating practitioner. While the Board has testified that its actions have not helped patients, it must do more to facilitate a solution for those affected.

When raised as part of the Senates Inquiry into Lyme disease Mr Fletcher, CEO of AHPRA, in response to these issues stated:

> *"Mr Fletcher: I have personally received a great deal of feedback from patients. Indeed, I have responded to over 55 letters from people who have written to me concerned about their access to health services. As Dr Bradshaw said, as regulators we do not provide health services, so we are not in a position to directly assist. We certainly have, and I have personally have, raised the concerns that have been expressed to me with representatives from the Commonwealth and our state Department of Health, particular here in Victoria, where a number of these patients are based, to try to make sure there is visibility about the concerns that are being raised and, if there is anything that either of those entities are able to do, in terms of facilitating access to services and referral options for these people so those options are fully explored".*

The material effects of those interventions are illustrated in the example where one punitive action saw more than 300 patients suffering with a Lyme like illness referred to an Infectious Disease clinic in a metropolitan hospital. Representatives of that hospital have reported in testimony to the Senate Inquiry and in other fora about the 'inconvenience' these chronically ill patients placed upon their 'system'.

Some early, but minimal data has been reported[31] by the organisation on their assessment of the referred patients, all 50 (16 percent of the referred cohort). However, no follow up of those patients has occurred and no longitudinal data that supports the diagnostic and treatment conclusions has been made available. Despite this, the organisation has used their early diagnostic data to support a successful application to the NHMRC. While some in the medical community will applaud this outcome, the situation is the opposite for patients. There are nearly 250 patients affected by the Board's punitive action who have been left without medical care or lost to follow-up care, some of whom have died while awaiting their Infectious Disease clinic appointment.

Information provided as part of the DoH's *Patient Forum to address people suffering with debilitating symptom complexes attributed to ticks (DSCATT),* in 2018 illustrates the appalling effect of this situation on one man who cares for his wife: -

> *"Upon arrival,[to our Lye-literature GP appointment] we were told that our doctor could no longer treat my wife and we must report immediately to the Austin Health Clinic. We were too shocked by this news after a fruitless 200km drive, so we returned home and made an appointment to attend this clinic a couple of weeks later.*
>
> *By this stage, my wife had begun experiencing a rapid deterioration in health following cessation of treatments prescribed by the Melbourne GP. After a two hour-drive, with my wife's pain levels at 10/10, we had to take a number and endure another two-hour wait in the 'cattle-run'. In our 10-15-minute appointment with the Austin Health Infectious Disease Specialist, we were told "Lyme disease doesn't exist in Australia"; the test results, earlier GP's diagnosis and clinical evidence of radical improvement in symptoms were dismissed. He*

[31] DSCATT Ministerial Forum Report: 18 April 2018

said she should go back to her Neurologist and we were summarily dismissed – no tests; no investigations for other vector-borne infections; nada!

The appointment with the Neurologist a few weeks later was a traumatic experience, with him angrily slamming his fist on the desk as he insisted, there is no Lyme disease in Australia!!"

As soon as we returned to our country town, we began the experience of being 'red-flagged' in the Australian medical system. Our overseas-trained GP apologised that he would be unable to continue my wife's treatment because he'd been warned that, in doing so, he'd risk both his medical license and his Citizenship application. The community health service manager summoned me and said we had put their jobs in danger by asking them to manage the administration of IV and intramuscular antibiotic treatment. She'd been instructed to remove my wife's PICC line immediately and, if we resisted, she would have me arrested and my wife removed so they could forcibly extract the device. When my wife's condition continued to decline due to cessation of antibiotics and over-prescription of opiates via the pain clinic, we were sent home twice from the local hospital ED and only admitted on the third occasion when the ambulance officer took the staff to task.

After weeks of watching my wife's life slipping away, with the help of a whip-around, I managed to scrounge the petrol money and drove 1600kms to Sydney with my wife slipping in and out of consciousness in the back of the car. She collapsed as she walked into the Sydney GP's surgery, had to be resuscitated and was immediately transferred to a Sydney hospital where she spent two weeks in ICU and another four weeks in undergoing intensive investigations.

The Medical Board cannot absolve itself of the threat to patient safety following their punitive actions. The Senate Inquiry heard testimony and received submissions from several patients about the detrimental effect of the Medical Board's punitive actions on their treatment.

In the case of one patient, where the metropolitan location for treatment was inaccessible to them, the stigma surrounding Lyme disease meant no locally accessible medical practitioner would help them. As a result, the patient was inappropriately left to deal with a portacath and learnt to manage it by watching YouTube videos.[32]

The LDAA would caution that there is a future suite of complaints that will be directed at medical practitioners who, despite clinical and laboratory evidence, fail to include Lyme disease or an Australian Lyme disease equivalent, as a differential diagnosis for their complex and chronic illness. All patients were once normal people with once normal lives who, through their adversity, have learnt to advocate for their own health. They are well-researched and well-informed about their conditions and are unlikely to tolerate further discrimination.

An example of the type of email regularly received by patient support groups provides an illustration of the diabolical situation that exists within the medical community when faced with a

[32] Senate Inquiry – Interim Report, footnotes - *Submission 23*, p. [1]. See also: *Submission 109*

patient who has become chronically ill following tick bite. The account has been redacted for both patient and practitioner privacy:

> *"Thanks for the very informative reply to my first contact … I've suffered discrimination regarding this. Well, the discrimination and cruelty shown have been as difficult as the symptoms themselves. Certainly not conducive to any healing environment. I have been bumped from GP to GP, all of them sounding too paranoid about Lyme, e.g. telling me they'll get deregistered etc if they help me. The original GP I showed the EM rash to didn't tell me what it was, told me I had rosacea and put me on a month's antibiotics. The condition has become chronically debilitating to the point that I haven't been able to work in ages, I pay my rent from a bank loan. XX Hospital's treatment of me has been unforgivable, minimising my debilitating symptoms, fudging my records claiming I didn't turn up to an appointment, my paralysis not mentioned in many of their records. Absolute torture from Professor XX there, promptly asked to leave by the immunologist when I mentioned tick bites. So many unnecessary (expensive) tests, procedures and misdirection away from the vector bites I keep mentioning. The opinion I've formed from all of this is that there is certainly an attempt to cover up just how many of us are suffering in this way."*

In this instance, there are multiple breaches of the existing guidelines for medical practitioners and serious allegations of discrimination based on an illness label. This situation is not unique; it is, sadly very common.

AHPRA encourages patients who experience these scenarios to lodge complaints. According to Professor Bradshaw; "*It is the overall management of cases. If doctors are not following good medical practice, not taking a proper history, not examining them, not investigating and not treating or disregarding something the patient is saying, we would take that as of concern*." **And "***the bottom line is that if a patient is concerned—we get notifications and complaints like this not infrequently, though not necessarily on this topic—and feels that their doctor has not listened to them, has not taken an adequate history and has been dismissive of them—not necessarily with this disease, but with lots of diseases—then they are right to make a notification.*"[33]

Professor Bradshaw's description is typical of the complaints we repeatedly read from patients who have consulted infectious disease and other specialists. Patients are, understandably, resentful about paying expensive specialist fees only to have their medical records disregarded, their debilitating symptoms dismissed and finding themselves berated for even raising the topic of Lyme disease. Very few patients have been provided with viable alternate diagnoses or treatments that have resulted in long-term improvement or remission of their symptoms as a result of these appointments.

[33] Senate Inquiry Public Hearing Brisbane, 15 April 2016 https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id:%22committees/commsen/e4474719-32d3-4e6d-9cb5-b7895ca17465/0000%22 p. 66

Question 5

Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'?

Yes.

Safeguards are required in any medical situation; however, safeguards based on medical conservatism, in the absence of a thorough and current understanding of the illness, rarely benefit patients suffering with chronic debilitating symptoms of Lyme and Australian Lyme disease.

The LDAA asserts that the safeguards already in place for ***all*** medical practitioners are adequate. Any further safeguards under consideration should not limit a patient's right to choose treatments or practices that benefit their health. Safeguards should also apply to all parts of the clinical pathway, including diagnostic processes (See earlier section in relation to Laboratory testing).

Question 6

Is there other evidence and data available that could help inform the Board's proposals?

Yes.

There is a huge body of evidence surrounding Lyme disease internationally and a significant level of high-quality research that supports the treatments and use of multi-modal therapies, including herbs, complementary medicines, and alternative treatments for patients with Lyme disease. The mainstream medical community ignores this evidence but fails to provide mainstream treatment guidelines that are effective in curing or reducing symptoms.

Question 7

Is the current regulation (i.e. the Board's *Good medical practice*) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?

Yes.

In the case of Lyme disease, the Medical Board has already demonstrated it has the power, authority and determination to remove medical licenses, suspend medical practitioners, or impose probationary and cautionary conditions on practitioners for **diagnosing** and **treating** Lyme disease. The three examples quoted within the *Discussion paper* provide ample evidence of the scope and power of the current system.

The Medical Board produces no evidence to support the assertion that the current *Code of Conduct* is inadequate or that the proposed guidelines would improve patient safety, especially in relation to Lyme disease and an Australian Lyme-like illness.

Question 8

Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?

No.

Question 9

The Board seeks feedback on the draft guidelines (option two) – are there elements of the draft guidelines that should be amended? Is there additional guidance that should be included?

The draft guidelines should be abandoned.

Question 10

Are there other options for addressing the concerns that the Board has not identified?

The Medical Board should investigate why Australian Lyme patients choose to pursue 'alternative or complementary treatments' both within Australia and overseas. The presumption that these patients are somehow naïve, gullible or are being exploited is offensive considering most patients who can afford these 'alternative treatments' can chart the recovery of their health empirically.

The group of international medical experts and clinics who are treating increasing numbers of Australians could help to quantify the situation, provide insight into the confounding clinical condition that Australian patients arrive with and can report on the treatments undertaken and the resulting outcomes for patients. No effort has been expended by the Medical Board or the Australian Government Department of Health to seek this data or consolidate the insights to better understand the reason that Australians increasingly choose 'alternative treatment'.

According to Nicola Ducharme, ND, US based but Australian born naturopath: -

> *"The lack of recognition and acknowledgement of tick-borne illness in Australia has led to much suffering in children and adults alike. In my opinion it is imperative that priority be given to this ever-growing issue. Accurate testing must be developed within Australia that incorporates both Western blot and PCR methodologies and recognize that the ELISA is inadequate.*

The persistent denial of need for medical treatment must be lifted, and physicians not scrutinized and punished for treating tick-borne illness. In the long-term, the financial strain on the medical system will be worse trying to treat chronically ill patients who have no official diagnosis and therefore are needing ongoing supportive care; rather than being able to identify, and address, the problem in a timely fashion.

I have consulted with many patients from Australia over the past 10 years from my office in the United States. These are people with tick-borne illness with symptoms pictures that match those of Lyme disease patients in other parts of the world; and who have frequently tested positive through testing from reputable labs, some of whom have never left Australia and thus must have contracted the illness within Australia. The research, funding and education relating to tick-borne illness must be a priority, along with a resolution in the political environment that has been denying the existence of this massive problem.

Following testimony at the Senate Inquiry hearing on Lyme disease, Dr Richard Horowitz, leading world expert on Lyme disease, reported on his experience. It is reproduced here:

"The Australian Senate recently held a hearing on tick-borne diseases in Sydney, and I provided testimony by teleconference with an associated scientific submission. Australia is mired in a political-scientific quagmire regarding Lyme, where some doctors "down under" are denying the existence of chronic tick-borne diseases.

This has resulted in patients coming to me from Australia in wheelchairs, unable to get help in their own country. In fact, at the recent ILADS conference in Philadelphia, a man flew from Australia just to meet me in the lobby and discuss his wife's case because no one could help relieve her suffering!

The dire situation that some Australian citizens face is partly a result of the lack of adequate blood testing to diagnose the multiple strains of emerging tick-borne illnesses, and partly due to longstanding dysfunctional politics surrounding Lyme and associated diseases.

New PCR technologies which are being developed will hopefully end the decades long scientific debate, however ***if we continue to ignore the science which shows the inadequacy of standard two-tiered testing, as well as the science proving the persistence of*** **Borrelia** ***and other tick-borne diseases, we will be leaving a health care legacy of suffering and disability for decades to come."***

Dr Horowitz treats hundreds of Australian patients, the specialised Lyme medical clinics in Europe have treated more than 1000 Australian patients, and clinics in Europe the USA and Mexico are supporting even more.

Two international laboratories have provided pathology testing services for thousands of Australians; the LDAA has dispatched over 4,000 test kits for a single laboratory in the past six years. The LDAA reports[34] on the analysis of Australian test results from these laboratories where they consistently find Borrelia and Relapsing Fever in Australian patients' blood.

Instead of perpetuating the myth that these laboratories are unreliable and their tests invalid, the Medical Board should examine the widespread use of them in the context of Lyme disease and advocate for a consolidated examination of their testing results. The results would provide a substantial evidence base that demonstrates, beyond any reasonable doubt, the prevalence of Lyme disease and associated tick-borne pathogens in Australian patients. This data would challenge the eminence-based arguments[35] continually perpetuated by the Royal College of Pathologists Australasia.

More importantly, the Medical Board should advocate for actions that could be taken within the Australian jurisdiction to clarify our understanding and would at least be more relevant to the general Australian patient population. The Board should recommend that health authorities collect, consolidate and analyse the significant data that already resides within Australia. For example data from NATA and non-NATA accredited laboratories that have performed testing for tick-bite associated illnesses within the last decade could provide statistically relevant data. Even, where the results were interpreted 'not detected' or 'negative', a consolidation of data about the test kits used, the interpretive applied and bands detected could provide evaluable data on what is showing up in Australian patients and would inform a local position.

Employing practice surveillance systems like the Australian Sentinel Practices Research Network (ASPREN)[36] to include surveillance on the frequency of reported tick-bite related illnesses would provide further, as yet, uncollected clinical data. Medical practitioners who have already treated patients for illness following a tick-bite also hold valuable clinical information that should highlight common disease patterns. The statistically evaluable data provided as part of the Senate inquiry provides another rich source of epidemiological information.

Furthermore, a case definition for Australian Lyme disease would be welcomed by medical practitioners and patients alike. While we recognise it is not the role of the Medical Board to develop case definitions or treatment guidelines, it would minimise regulatory ambiguity if the Medical Board advocated for the expediting of a case definition and treatment guidelines.

Question 11

Which option do you think best addresses the issues identified in relation to medical practitioners who provide complementary and unconventional medicine and emerging treatments?

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[34] LDAA: Lyme disease and relapsing fever found in Australian patients

[35] Royal College of Pathologists Australasia, 2019. Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand Approval Date: February 2014, March 2016 Review Date: February 2019 Microbiology AC Number: 1/2014

[36] Australian Sentinel Practices Research Network - ASPREN

As previously discussed, the notion of a single definition to encompass a broad range of practices, including those that are unable to be described because they are emerging, is extremely unhelpful in a regulatory environment and goes against the principles of procedural fairness.

The Medical Board should focus on removing the ambiguity of its definitions and confounding descriptions in the existing general guidance. Making clear the type of medical practice that is accepted as 'conventional', without a biased and prejudicial skew towards a specific disease would be a good start.

Other please specify

There is no Option 3 proposing that the current guidelines affecting ***all*** practitioners should be reviewed to incorporate practices proposed for the sub-groups targeted in the *Discussion paper*. For example, a requirement that ALL doctors (equally) should be required to disclose risk factors of any given treatment protocol and matters around 'informed' patient consent.