LYME DISEASE
ASSOCIATION OF AUSTRALIA

Sarcoidosis Lyme
Australia

ACCESS TO DIAGNOSIS AND TREATMENT FOR PEOPLE IN AUSTRALIA WITH TICK-BORNE DISEASES – SUPPLEMENTARY SUBMISSION - QON

February 2025

TABLE OF CONTENTS

Introduction

This supplementary submission aims to address multiple components of questions posed to witnesses during the public hearing on 29 January 2025 regarding Lyme disease in Australia.

Our intent is to provide clarity and additional context to the complex issues surrounding Lyme disease diagnosis, treatment and patient care. We seek to unravel some of the obfuscating complexity offered by certain witnesses and present a comprehensive picture of the challenges faced by patients and healthcare providers alike from the patient point of view.

This submission includes supplementary information drawn from recent research, patient experiences and international best practices to support our recommendations for improving the recognition and management of Lyme disease and related tick-borne illnesses in Australia.

The Patient Perspective

The medical system's systemic neglect and gaslighting creates a cruel paradox: **patients desperately seeking care are forced to repeatedly advocate** for themselves in an environment that dismisses their suffering. This vicious cycle traps them between worsening health and institutional indifference.

Patients, especially from marginalised groups, face a **labyrinthine nightmare of disbelief and dismissal**. They **return not by choice, but driven by survival instinct**, to a system that invalidates their experiences.

This **uphill battle for acknowledgment is traumatic, eroding trust and hope**. Yet, for these patients, **advocacy is not a luxury but a lifeline**. They persist because surrender means accepting a death sentence. Their resilience is both inspiring and tragic—a damning indictment of a system requiring such Herculean efforts for basic care.

This failure not only **jeopardises lives but undermines medical ethics**. It is a stark reminder that healing begins with listening and believing. The onus must shift from patients fighting to be heard to a system that responds with compassion and competence.

A Paradigm Shift: Redefining Tick-Borne Disease Management in Australia

In response to the Committee's Question on Notice regarding suggestions on how we might approach tick-borne diseases (TBDs) differently, we have carefully considered the challenges and opportunities presented and offer the following:

The Failures of the Current System

1. **Ineffective Multi-Disciplinary Care:** The current referral system is a "handball" experience, lacking coordinated, integrated care plans and leaving patients navigating siloed specialties without a leader or affordable solutions.
2. **Lack of Accountability and Evaluation**: Past and current initiatives lack check sums, validations and accountability, hindering progress and preventing correction. Future endeavours must include rigorous evaluative mechanisms. The 2016 recommendations were too broad, leading to manipulation and disagreement about their fulfillment.
3. **Misdirected Research Funding**: There is a significant disparity in research outcomes. The DSCATT studies received substantial funding but have yielded limited patient-relevant results, particularly compared to the Biotoxin study,[1] which achieved more with fewer resources. A concerning portion of DSCATT funding was allocated to a team specialising in Functional Neurological Disorder, suggesting a pre-conceived bias against organic disease explanations.
4. **Flawed Clinical Pathway**: The DSCATT Clinical Pathway is actively detrimental, restricting diagnosis, treatment and recovery.
5. **Myth of "Evidence-Based Medicine":** There are concerns about the application of "evidence-based medicine" as suggested in many medical representative testimonies, arguing it can create a false sense of scientific rigour and may not adequately address the complexities of tick-borne diseases. The *Deconstructing the "evidence-based" discourse* medical practice paper[2] provides the example of serotonin and depression to highlight instances where "best practice" treatments are not based on conclusive evidence.
6. **Limited Access to Care**: Patients are denied a fair chance of recovery due to limited access to care, often based on evidence that lacks clinical validation, for example, false positive test results.

---

[1] NHMRC. (2025). Biotoxin-related illnesses: Annual progress reports. National Health and Medical Research Council. https://www.nhmrc.gov.au/funding/targeted-calls-research/biotoxin-related-illnesses/annual-progress-reports

[2] Holmes, D., Murray, S. J., Perron, A., & Rail, G. (2006). Deconstructing the evidence-based discourse in health sciences: Truth, power and fascism. International Journal of Evidence-Based Healthcare, 4(3), 180-186. https://doi.org/10.1111/j.1479-6988.2006.00041.x

7. **Restricted Medical Autonomy**: Doctors face potential repercussions for providing Lyme disease treatments not universally accepted, hindering their ability to provide individualised care based upon their clinical judgment of the patient.

We acknowledge the urgent need for change based upon the failures of the current system and propose the following comprehensive strategy to move forward.

The Path Forward: A New Approach

Our recommendations aim to revolutionise the approach to tick-borne diseases in Australia, focusing on patient-centric care, evidence-based practices and collaborative efforts across the healthcare ecosystem. By implementing these proposals, we believe Australia can significantly improve outcomes for those affected by Lyme disease and establish itself as a global leader in this critical area of public health.

1. Establish an Independent Oversight Committee

Create an independent committee to oversee the implementation of recommendations, ensuring transparency and accountability. This committee should:

- Monitor progress on recommendations
- Conduct regular audits
- Provide periodic reports to the public and government
- Investigate potential systemic medical negligence regarding the treatment of Lyme disease patients in Australia
- Include patients with lived experience, and medical practitioners who are treating them

2. Revise Clinical Guidelines and Pathways

- Retract the current DSCATT Clinical Pathway due to its limitations
- Remove all references to DSCATT as a diagnostic category, ensuring it does not serve to dismiss patient symptoms
- Abolish the harmful use of "medically unexplained symptoms" as a justification for withholding diagnostic testing and treatment in patients with persistent symptoms following tick bites
- Endorse the ACIIDS Clinical Pathway as an alternative clinical choice
- Develop separate clinical pathways for acute and chronic presentations of TBDs
- Endorse prophylactic treatment for tick bites to prevent chronic illness and disease progression

3. Enhance Medical Education and Autonomy

- Implement mandatory education for healthcare professionals on TBDs, addressing common biases and misconceptions

- Legislate to protect medical practitioners' autonomy in clinical decision-making related to Lyme disease and tick-borne infections, like the approach outlined in Professor Ahern's testimony - see footnote for legislative instruments in each jurisdiction[3]
- Allow for clinical diagnosis of early Lyme disease without requiring positive test results

4. Improve Research and Funding Allocation

- Allocate research funding to frontline clinicians and researchers actively working with Lyme disease patients
- Ensure that future clinical trials for Lyme-like illness prioritise biomedical approaches rather than defaulting to psychological interventions as the primary mode of care
- Implement a challenge-based funding model for innovative Lyme disease research and project to rapidly advance our knowledge, like the Australian Digital Health Agency's Digital Challenge Program (Australian Digital Health Agency, 2020) used during COVID
- Fund the development of an Australian 'tick surveillance app" to facilitate citizen science and accelerate data collection

5. Enhance Diagnostic and Treatment Options

- Immediately legitimise international testing methods, particularly those approved by reputable international bodies
- Approve and provide local access to progressive medical treatments currently only available overseas
- Implement a "Right to Try" policy for Lyme disease patients, allowing access to experimental treatments

---

[3] **Connecticut** - Connecticut General Assembly. (2009). Public Act No. 09-128: An Act Concerning the Long-Term Use of Antibiotics for The Treatment of Lyme Disease. Retrieved from https://www.cga.ct.gov/2009/ACT/PA/2009PA-00128-R00HB-05793-PA.htm

Rhode Island -Rhode Island General Assembly. (2002). Public Law 159: An Act Relating to Health and Safety - Lyme Disease Diagnosis and Treatment. Retrieved from https://www.lymedisease.org/wp-content/uploads/2014/04/Legislation-PDF-12.5.14-2.pdf

Massachusetts -Massachusetts General Court. (2010). House Bill 4683: An Act Relative to Lyme Disease Treatment Coverage. Retrieved from https://www.lymedisease.org/wp-content/uploads/2014/04/Legislation-PDF-12.5.14-2.pdf

New York - New York State Senate. (2014). Bill S7854: An Act to Amend the Public Health Law in Relation to the Diagnosis and Treatment of Lyme Disease. Retrieved from https://projectlyme.org/reviewing-current-lyme-legislation/

Illinois -Illinois General Assembly. (2019). House Bill 4515: An Act Concerning Regulation of Health Care Providers for the Treatment of Lyme Disease and Other Tick-Borne Diseases. Retrieved from https://projectlyme.org/reviewing-current-lyme-legislation/

6. Improve Patient Support and Recognition

- Enable NDIS access for patients with chronic Lyme disease symptoms
- Recognise Lyme disease as potential underlying causation in multi-system, psychiatric, neurodegenerative, autoimmune and inflammatory illnesses
- Investigate potential systemic medical negligence regarding the treatment of Lyme disease patients in Australia

7. Legislative and Policy Changes

- Introduce legislation to protect doctors from investigation based solely on providing Lyme disease treatments not universally accepted by the medical profession, like the approach described in New York
- Issue a clear health policy statement acknowledging that ticks can cause illness in Australians and endorsing the interim ACIIDS clinical pathway

8. Establish a Comprehensive Evaluation Framework

- Implement a robust monitoring and evaluation system for all tick-borne disease-related initiatives, like the approach used in the Medical Research Future Fund[4]

---

[4] Department of Health and Aged Care. (n.d.). Monitoring, Evaluation and Learning. https://www.health.gov.au/our-work/mrff/about/monitoring-evaluation-learning

Mental Health and Lyme Disease: Impact of Misdiagnosis and Medical Neglect

Discussions surrounding Lyme disease and mental health are often framed through a lens that prioritises psychological explanations over biomedical causes. Many Lyme disease patients report being misdiagnosed with anxiety, depression or other psychiatric conditions **before receiving proper medical investigations**. This misclassification results in prolonged suffering, delayed treatment and worsening health outcomes.

One of the most harmful consequences of this trend is the use of the diagnostic categories such as Debilitating Symptom Complexes Attributed to Ticks (DSCATT) and Medically Unexplained Symptoms (MUS), both of which serve to invalidate the lived experiences of patients and shift the burden away from medical research and treatment.[5]

The Ethical and Medical Conundrum of DSCATT

Professor Richard Kanaan's study investigates a **psychological and behavioural skills-based program** as an **adjunct therapy** for people with DSCATT.[6] However, this presents a significant ethical and medical conundrum: **DSCATT is not a recognised disease or diagnosis**; it is a vague label used to categorise patients with unexplained symptoms following tick bites. This means that patients lack a clear diagnostic pathway, making any proposed "adjunct" treatment fundamentally flawed and begs the question: **adjunct to what?**

Adjunct to a Non-existent Standard of Care

- The study's design assumes that patients already receive adequate **medical treatment**, but the reality is that many **cannot access any meaningful care** [7]
- Because **DSCATT is not a formal diagnosis**, there are **no established treatments** in mainstream Australian medicine. Patients face outright **denial of care**, with doctors refusing to acknowledge their condition as anything beyond psychosomatic distress

---

[5] Feder, H. M., Johnson, B. J., O'Connell, S., Shapiro, E. D., Steere, A. C., & Wormser, G. P. (2007). A critical appraisal of "chronic Lyme disease." *New England Journal of Medicine, 357*(14), 1422–1430

[6] Kanaan, R., et al. (2023). Psychological approaches to tick-borne illness: A review. Australian Journal of General Practice, 52(5), 234–245.

[7] Cameron, D. J., Johnson, L. B., & Maloney, E. L. (2014). Evidence assessments and guideline recommendations in Lyme disease: The clinical management of known tick bites, erythema migrans rashes and persistent disease. Expert Review of Anti-infective Therapy, 12(9), 1103–1135.

- If there is no biomedical treatment protocol to which this therapy can be an adjunct, then **its premise is inherently flawed**.

Implied Medical Negligence and Ethical Concerns

- The absence of a formal **disease classification** means that patients are left in **diagnostic limbo**, labelled as having anxiety, depression or "medically unexplained symptoms", rather than being treated for a potential infectious or immune-related condition [8]
- If the medical system **refuses to provide primary care**, then conducting a trial for a **secondary, adjunctive intervention** not only overlooks the root problem but may **border on malpractice by omission**—withholding or deferring necessary medical investigations and treatments under the guise of a behavioural approach [9]

Reinforcing Systemic Medical Neglect

- The framing of DSCATT as a **symptom complex rather than a disease** allows the system to **sidestep responsibility** for providing genuine medical treatment
- By positioning **a psychological program as an intervention**, the (Kanaan) study risks reinforcing the **false narrative that patients' symptoms are primarily psychosomatic** rather than biomedical. This can, in turn, **justify further medical neglect**, leaving patients **trapped in a cycle of dismissal and inadequate care** [10]
- The growing trend of "**passing the buck**" in healthcare, where patients are shuffled between specialists without anyone taking overall responsibility for their care,[11] exacerbates the neglect

The Harm of the "Medically Unexplained Symptoms" Label

- The classification of patients as having **medically unexplained symptoms (MUS)** is used to justify **non-investigation of serious medical conditions**, leading to delayed or denied treatment[12]

---

[8] Weitzner, E., McCarthy, K., & Morgan, L. (2017). Misdiagnosis of Lyme disease patients as psychiatric patients. *Journal of Psychiatry & Neuroscience, 42*(6), 416–417. https://doi.org/10.1503/jpn.170132

[9] DeLong, A. K., Blossom, B., Maloney, E. L., & Phillips, S. E. (2019). Antibiotic retreatment of Lyme disease in patients with persistent symptoms: A meta-analysis. Pathogens, 8(4), 299.

[10] Horowitz, R. I., Freeman, P. R., & Coggins, B. J. (2017). Lyme disease and chronic illness: Controversies, challenges, and opportunities for research. Future Microbiology, 12(9), 999–1027

[11] Marrs, C. (2025, January 27). A crisis of responsibility in modern medicine. Hormones Matter. https://hormonesmatter.com/a-crisis-of-responsibility-in-modern-medicine/

[12] Kidd, M. R., Boyle, D. I. R., & Hewett, D. G. (2013). Telehealth for general practice: Benefits for patients and the profession. *Australian Family Physician, 42*(6), 401–405.

- This label is disproportionately applied to patients with chronic, complex or poorly understood conditions, including those with Lyme disease symptoms [13]
- By framing symptoms as "unexplained", the burden is shifted to the patient to prove their illness rather than the medical system to **properly diagnose and treat** [14]
- Many patients with **Lyme-like illness are forced into psychiatric care** instead of receiving appropriate infectious disease testing and treatment, further compounding their suffering
- The long-term consequences of this misclassification include **worsening health outcomes, loss of trust in the medical system and increased disability rates** among affected individuals

An Unethical Cycle of Non-Treatment

By failing to recognise tick-borne illness as a disease, the medical establishment **avoids developing a legitimate treatment protocol**. Yet, at the same time, a study is being conducted to test an **adjunct therapy for a non-existent primary treatment**. This creates a **double bind** where patients:

1. **Cannot obtain proper medical care** because their condition is not recognised as a disease.
2. **Are then offered an adjunct therapy** under the assumption that they are receiving care they cannot actually access.
3. **Have their suffering medicalised as a psychological issue** rather than investigated as a biomedical condition.
4. Suffer delayed proper treatment adding to the **patient's psychological burden**, creating a **self-fulfilling prophecy** of mental health issues.

This borders on **malpractice by systemic neglect**, effectively leaving patients without options while maintaining the illusion that research is being conducted to help them. Unless the **root cause—biomedical investigation and treatment—is addressed**, offering psychological interventions in isolation may do more harm than good.

---

[13] Johnson, L., Wilcox, S., Mankoff, J., & Stricker, R. B. (2014). Severity of chronic Lyme disease compared to other chronic conditions: A quality-of-life survey. *PeerJ, 2*, e322. https://doi.org/10.7717/peerj.322 (Johnson, Wilcox, Mankoff, & Stricker, 2014).

[14] Shor, S., Green, C., Szantyr, B., Phillips, S. E., Liegner, K. B., & Burrascano, J. (2019). Chronic Lyme disease: An evidence-based definition by the ILADS Working Group. *BMC Infectious Diseases, 19*(1), 281. https://doi.org/10.1186/s12879-019-3706-x

Integrating Mental Health Support in Lyme Disease Care

Senator Kovacic – "I have a question about the MH impacts of TBD on patients. How should MH services be integrated?"

The integration of mental health services into Lyme disease treatment requires a careful and nuanced approach that prioritises biomedical diagnosis and treatment while acknowledging the psychological impact of chronic illness. Given the history of misdiagnosis, medical neglect and the harmful use of vague labels, like DSCATT and MUS, faced by many Lyme disease patients in Australia, any mental health intervention must be designed to complement rather than replace essential medical care.

Dr. Robert Bransfield, a psychiatrist specialising in Lyme disease and neuropsychiatric disorders, has observed that many patients with mental health symptoms experience significant improvement when treated with antimicrobials. His work suggests that infections, particularly tick-borne diseases, can contribute to various psychiatric conditions, and that appropriate antibiotic treatment can lead to the resolution of these symptoms in many cases.[15] This approach highlights the importance of considering infectious causes in the diagnosis and treatment of mental health disorders.

The following recommendations aim to address the systemic failures in Lyme disease care, ensure proper recognition and treatment of the condition, and provide appropriate mental health support without reinforcing harmful narratives about the psychosomatic nature of symptoms. By implementing these recommendations, we might begin to correct the ethical and medical conundrums surrounding Lyme disease treatment and work towards a more comprehensive, patient-centered approach to care.

1. **Prioritise biomedical diagnosis and treatment**: Mental health services should only be integrated after a thorough medical evaluation and appropriate treatment for Lyme disease have been initiated. This ensures that psychological interventions are truly adjunctive rather than substitutive.

2. **Address trauma from medical neglect**: Many Lyme patients have experienced dismissal, misdiagnosis and inadequate care. Mental health services could help process this trauma and rebuild trust in the healthcare system.

3. **Provide coping strategies**: Chronic illness can be emotionally challenging. Mental health support could offer tools for managing stress, pain and adverse lifestyle changes associated with Lyme disease, as demonstrated in the Lyme Support

---

[15] Bransfield, R. C. (2018). Neuropsychiatric Lyme Borreliosis: An Overview with a Focus on a Specialty Psychiatrist's Clinical Practice. Healthcare, 6(3), 104.

Program offered by the LDAA. Reinstate and expand mental health support programs like those previously offered by the LDAA, focusing on patient advocacy and education.

4. **Avoid psychologising physical symptoms**: Mental health professionals should be trained to recognise that many symptoms in Lyme disease have biological origins and should not be attributed solely to psychological factors.

5. **Support advocacy skills:** Mental health services could help patients develop self-advocacy skills to navigate complex healthcare systems and communicate effectively with medical providers.

6. **Interdisciplinary approach**: Mental health professionals should work closely with Lyme-literate medical doctors to ensure a holistic, integrated approach to care.

7. **Education on mind-body connection**: Provide information on how chronic infections can affect mental health, emphasising that this is a normal physiological response rather than a primary psychological issue.

It is crucial that any integration of mental health services does not reinforce harmful narratives about Lyme disease being a primarily psychological condition. The focus should remain on comprehensive medical care, with mental health support as a complementary component of overall treatment.

Overlooked & Misdirected: The Research Gap is Failing Patients

Senator Reynolds - In context of discussion around the Murdoch study, **QoN Do we have any more analysis about the Murdoch methodology? Please provide it.**

The current state of DSCATT research in Australia is potentially letting patients down due to a significant weakness shared among the three contemporary studies underway. Each study relies on a flawed dataset, specifically Professor Kanaan's original 29-person case study.[16]

The CSIRO's research into microRNA biomarkers for DSCATT aligns its working definition with that used in the Murdoch University's Troublesome Ticks Research Protocol, which includes both acute and chronic onset definitions.[17] Murdoch's research protocol considered Kanaan's case study in developing its own case definition.

Murdoch's study references Kanaan's work in its introduction, citing a cohort of 29 patients experiencing DSCATT with symptoms including fatigue, headache, and arthralgia, sometimes resulting in severe physical impairment and financial stress.

Kanaan described his own study as "weak evidence".[18] Publications to date referring to Kanaan's study do not refer to the weakness of the study's evidence. It begs the question of how rigorously other DSCATT researchers examine published research. Kanaan provided the information that the study created no data. The reliability of a study without data is very questionable. Kanaan also provided the information that his team just used all the published data they could find which was all "weak evidence". So, data-less weak evidence created by weak evidence.

Kanaan's study was based on a retrospective review with significant limitations. There could not have been adequate criteria in place to gather useful information or data would have been created. Kanaan's admissions raise serious concerns about the validity of using the outcomes of the case study as a foundation for further research.

By building upon this flawed dataset, the current funded research projects risk perpetuating inaccuracies and potentially misguiding future DSCATT investigations. This

---

[16] Kanaan, R., Letheby, C., Rotstein, K., Mullen, G., Parratt, K., Beilharz, J., Vindigni, G., & Perillo, S. (2023). Debilitating symptom complexes attributed to ticks: A descriptive study of an Australian cohort. Internal Medicine Journal, 53(1), 62-69. https://doi.org/10.1111/imj.15486

[17] Barbosa, A. D., Long, M., Lee, W., Austen, J. M., Cunneen, M., Ratchford, A., Burns, B., Kumarasinghe, P., Ben-Othman, R., Kollmann, T. R., & et al. (2022). The Troublesome Ticks Research Protocol: Developing a Comprehensive, Multidiscipline Research Plan for Investigating Human Tick-Associated Disease in Australia. Pathogens, 11(11), 1290. https://doi.org/10.3390/pathogens11111290

~~[18] Kanaan in private communications with a patient, March 2024 (copy available if requested)~~

reliance on weak evidence could lead to skewed results, ineffective diagnostic criteria, and ultimately, inadequate treatment strategies for DSCATT patients and thus, further harms.

To truly serve the DSCATT patient community, researchers must acknowledge these limitations and seek to establish more robust, data-driven foundations for their studies. This should involve conducting new, well-designed prospective studies with clearly defined criteria and rigorous data collection methods. Only by addressing these fundamental weaknesses can the research community hope to make meaningful progress in understanding and treating DSCATT.

Assessment of Murdoch University: Troublesome Ticks research

To comprehensively answer the question posed by Senator in the context of discussion around the Murdoch study,[19] we formally reviewed the study and provide an evaluation of the study's structure, methods and results, pointing out areas that need to be improved in future studies for *The Troublesome Ticks Research Protocol: Developing a Comprehensive, Multidiscipline Research Plan for Investigating Human Tick-Associated Disease in Australia*.

The research protocol[20] was assessed for scientific shortcomings, concentrating on the following aspects:

1. **Study Design and Hypotheses**: Evaluating if the design effectively addresses the research questions.
2. **Methodology**: Assessing sample selection, data collection methods and analytical techniques.
3. **Data Interpretation**: Identifying biases, overgeneralisations or unsupported conclusions.
4. **Ethical Considerations**: Ensuring ethical protocols are appropriately addressed.

Study Design Limitations

One of the notable limitations in the study design is the **exclusion criteria bias**. The exclusion of patients with pre-existing conditions such as Myalgic Encephalomyelitis (ME), chronic fatigue syndrome (CFS), fibromyalgia and chronic "Lyme-like" illness may result in an underestimation of potential associations between tick bites and chronic disease manifestations. These conditions often share overlapping symptoms with tick-borne illnesses and excluding such patients could obscure the full spectrum of tick-associated diseases.[21]

---

[19] Senator Linda Reynolds- **QoN Do we have any more analysis about the Murdoch methodology?**

[20] See 15

[21] Lantos, P.M., et al. (2010). Evidence-based guidelines for the management of Lyme disease. Clinical Infectious ~~Diseases. & Feder, H.M., et al. (2007). A critical appraisal of "chronic Lyme disease". New England Journal of Medicine.~~

Furthermore, the study faces **control group matching challenges**. Although control groups (Gp2 - situational controls and Gp3 - healthy blood donors) are matched based on geographic location, sex and age, they may still differ in unmeasured confounders such as environmental exposures, lifestyle factors or subclinical infections. This mismatch could lead to residual confounding, making it difficult to attribute observed differences solely to tick exposure. [22]

Methodological Weaknesses

The study exhibits a **limited temporal scope for pathogen detection**. By relying on skin biopsies and blood samples collected within 72 hours of tick removal, it risks missing pathogens that have delayed dissemination or transient bacteraemia occurring beyond this window. This limitation could result in **false negatives**, thereby underestimating pathogen prevalence and diversity. [23]

Additionally, there is an **overreliance on 16S rRNA and 18S rRNA sequencing**. While these sequencing methods are valuable for identifying a broad range of microorganisms, they may lack the sensitivity to detect **low-abundance pathogens** and cannot distinguish between viable and non-viable organisms. This limitation could lead to the overinterpretation of clinically irrelevant microbial DNA, or the omission of pathogens present at low copy numbers.[24]

Data Interpretation Concerns

There is a **risk of overinterpretation in psychometric profiling**. The study investigates psychological factors influencing symptom development, but without careful framing, this could **inadvertently pathologise or dismiss legitimate physical symptoms** as psychogenic. Such an approach may stigmatise patients and undermine efforts to investigate the biological basis of tick-associated diseases.[25]

The study also presents **ambiguity in defining causality**. It suggests that pathogens found in both ticks and patients, but not in controls, are likely causal. This assumption overlooks the potential for incidental colonisation, background microbial noise or reverse causality, such as opportunistic infections in immunocompromised hosts. Consequently, spurious associations may be misclassified as causal relationships. [26]

---

[22] Rothman, K.J., et al. (2008). Modern Epidemiology. *Lippincott Williams & Wilkins*

[23] Steere, A.C., et al. (2004). Lyme borreliosis. *Nature Reviews Disease Primers*.

[24] Janda, J.M., & Abbott, S.L. (2007). 16S rRNA gene sequencing for bacterial identification. *Journal of Clinical Microbiology*.

[25] Bransfield, R.C. (2017). Neuropsychiatric Lyme borreliosis. *Psychiatric Clinics of North America*.

[26] Hill, A.B. (1965). The environment and disease: association or causation? *Proceedings of the Royal Society of Medicine*.

Ethical and Practical Considerations

The study raises ethical concerns in sample collection, particularly regarding invasive skin biopsies. There is no clear justification of the risk-benefit ratio, especially when non-invasive alternatives like blood-based pathogen detection exist. This issue is further compounded if participants are not fully informed about alternative diagnostic methods, raising ethical concerns about informed consent.[27]

Moreover, there is **limited Indigenous and regional representation**. Although the study aims for national representation, it does not sufficiently emphasise the inclusion of Indigenous populations or individuals from remote communities, who may have distinct tick exposure patterns and health outcomes. This limitation affects the generalisability of the findings across Australia's diverse populations. [28]

Statistical and Analytical Pitfalls

The study faces challenges related to **inadequate power for rare outcomes**. A sample size of approximately 300 patients per year may lack the statistical power needed to detect associations with rare tick-borne pathogens, increasing the risk of type II errors (false negatives). [29]

Additionally, there is a **potential for multiple testing errors**. The use of multi-omics technologies and broad pathogen screening increases the likelihood of false positives due to multiple comparisons. Without stringent statistical corrections, such as Bonferroni or False Discovery Rate (FDR) adjustments, spurious associations could be reported as significant. [30]

To address if this paper fulfilled the NHMRC aims, the following analysis was performed. Specifically, the evaluation focused on whether the study effectively addresses the following objectives:

1. Understanding the Nature, Prevalence and Causes of DSCATT
2. Assessing the Impact on Physical, Social and Psychological Health
3. Providing Evidence for Diagnosis, Treatment and Symptom Management

1. Understanding the Nature, Prevalence and Causes of DSCATT

Strengths: The study employs comprehensive pathogen screening through metagenomics, multi-omics and molecular diagnostics to investigate both known and novel tick-borne pathogens. Its longitudinal design, following tick-bitten patients over

---

[27] Beauchamp, T. L., & Childress, J. F. (2001). Principles of Biomedical Ethics (5th ed.). Oxford University Press

[28] Anderson, I., et al. (2016). Indigenous health in Australia. *The Lancet*.

[29] Button, K.S., et al. (2013). Power failure: why small sample size undermines the reliability of neuroscience. *Nature Reviews Neuroscience*.

[30] Benjamini, Y., & Hochberg, Y. (1995). Controlling the false discovery rate. *Journal of the Royal Statistical Society*.

12 months, captures both acute and chronic symptom development. The inclusion of both internal and external control groups enhances its ability to identify associations between tick exposure and symptomatology.

Limitations: However, the study lacks a systematic approach to prevalence estimation due to recruitment biases toward healthcare-presenting individuals. Additionally, the focus is heavily pathogen-centric, with limited exploration of non-infectious causes like immune dysregulation or toxic exposures. The absence of a clear, validated case definition for DSCATT further hampers the generalisability of its findings.

2. Assessing the Impact on Physical, Social and Psychological Health

Strengths: The study incorporates psychometric profiling to assess mental health influences and broad symptom surveillance to capture physical health impacts.

Limitations: It offers a superficial assessment of social impacts, lacking robust tools to measure quality of life, work disability or economic burden. The inclusion of psychometric profiling without validating biological mechanisms risks stigmatising patients. Moreover, the study does not adequately address the diversity of participant demographics, neglecting vulnerable populations such as Indigenous Australians and rural communities.

3. Providing Evidence for Diagnosis, Treatment and Symptom Management

Strengths: The study shows potential for diagnostic innovation through the development of new molecular and serological tests tailored to Australian conditions. The integration of immunological and transcriptomic data could help identify biomarkers for diagnosis and disease monitoring.

Limitations: The absence of interventional components limits its ability to inform treatment or symptom management strategies. While new diagnostic tools are proposed, there is no clear pathway for clinical validation or integration into healthcare systems. Additionally, the lack of efforts to develop management guidelines fails to address a key NHMRC objective of improving patient outcomes.

Table 1: ***Analysis of the TCR Aims in Respect to Study Outcomes***

TCR Aim	**Fulfillment by the Study**	**Assessment**
Understanding the nature, prevalence and causes of DSCATT	Strong on exploring causes (pathogen-focused), but weak on prevalence estimation and comprehensive case definitions.	Partially Fulfilled
Assessing physical, social and psychological health impacts	Adequate focus on physical and psychological impacts, but minimal attention to social determinants and quality of life.	Partially Fulfilled
Providing evidence for diagnosis, treatment and management	Potential for diagnostic insights, but no direct contributions to treatment or symptom management strategies.	Partially Fulfilled

Recommendations for Improvement

To address the limitations, several recommendations are proposed. First, **broadening the inclusion criteria** to encompass patients with chronic conditions would help capture the full spectrum of tick-associated illnesses. This approach ensures that overlapping conditions are adequately represented, reducing bias in disease associations. Second, **enhancing control selection** by using controls with similar environmental exposures can minimise confounding variables, leading to more accurate comparisons. Third, **diversifying sampling strategies** to include longitudinal follow-ups beyond the acute phase is essential for detecting delayed infections and understanding chronic disease progression. Fourth, a focus on **ethical oversight** is critical, involving the reassessment of the necessity for invasive procedures and the strengthening of informed consent processes to ensure participants are fully aware of potential risks and alternatives. Finally, ensuring **statistical rigour** through robust corrections for multiple testing and performing adequate power calculations for rare outcomes will improve the reliability and validity of study findings.

Murdoch University's Patient Pilot Research

The Vector and Waterborne Pathogens Research Group (CrypTick Lab) at Murdoch University, led by Professors Peter Irwin and Una Ryan, conducted a pilot study into chronic tick-borne illness in Australia. This study, announced on 15 March 2017, was supported by contributions from the Country Women's Association of NSW, the LDAA and public donations through the Murdoch University Veterinary Trust, totalling $38,710.[31]

The study recruited 107 patients, predominantly adults, from various Australian states, with the majority from Western Australia and New South Wales. Dr Jill Austen, a part-time post-doctoral researcher, was responsible for patient communication, sample collection and laboratory analyses, including microscopy and DNA extraction for various assays.

Key findings from the study included:

1. No evidence of piroplasm infections (e.g., Babesia) was found in the blood samples tested
2. Next Generation Sequencing (NGS) of bacterial communities in blood samples revealed no sequences assigned to known tick-borne bacterial genera such as Borrelia, Anaplasma, Bartonella, Ehrlichia, Francisella or Neoehrlichia
3. Some bacterial genera were identified, including Acinetobacter, Legionella, Pseudomonas, unknown Rickettsia, Rickettsiella, Coxiella, Spirochaeta and Treponema. However, the researchers noted that further investigation was needed to determine their significance and whether they were from skin surface contamination or circulating blood.

The researchers concluded that while they applied highly sensitive molecular techniques, they found no molecular evidence of persistent blood infections, even in patients who had previously tested seropositive. They suggested that this could mean the source of infection was no longer circulating in the blood, possibly hidden in other parts of the body or removed by antimicrobial therapy, or that the antibody results were cross-reactions with other bacteria.

The study team emphasised that their analysis was ongoing and that they would continue to search and analyse all received samples, promising further updates as the research progressed.

However, several critical issues have been raised by the LDAA regarding the scientific rigour and methodology of the research. One of the primary concerns is the lack of detailed scientific information provided about the testing methods and primers used in the study. This omission makes it difficult for other researchers to evaluate or replicate the findings, which is a crucial aspect of scientific research.

The study's design also raises questions about the appropriateness of comparing a positive control cohort in the acute stage of disease with a chronic cohort. This type of comparison is problematic, as many illnesses exhibit markedly different characteristics

---

[31] A copy of the Final Study report can be provided upon request.

in their acute and chronic stages. Examples include rheumatic heart disease following strep infection, and the relationship between chicken pox and shingles.

Another issue highlighted is the use of northern hemisphere antigens in the testing process. Given the potential differences in tick-borne pathogens between hemispheres, this choice of antigens may not accurately represent the Australian context, potentially leading to skewed results.

The overall lack of scientific rigour in the study report is a significant concern. While it is possible that such rigour exists in the actual research process, its absence in the report makes it challenging for the scientific community to evaluate the validity of the findings.

The quality of this research, as presented, would not meet the standards for publication in a peer-reviewed journal and therefore has never been published. Furthermore, the LDAA was alerted to a formal ethics complaint about a study participant’s samples, which was not reported to the LDAA as a funding body for the research.

Given these concerns, the LDAA faced a challenging position in how to respond to and discuss this research. It is recommended that any public statements about this study should be carefully considered, as the research raises more questions than it answers and may not provide a solid foundation for drawing conclusions about tick-borne illnesses in Australia.

Psychotherapy for DSCATT: A Contested Clinical Trial

Professor Kanaan's study on psychotherapy for patients with symptoms attributed to tick bites raises several concerns and contradictions that contribute to the conundrum of offering "adjunct therapy" when there is no established primary treatment. We have covered this extensively in the section on *Adjunct to a Non-existent Standard of Care*.

To further the Committee's knowledge, we provide a review and evaluation of the Clinical trial titled *Pilot Testing a psychology-based treatment Intervention for Debilitating Symptom Complexes Attributed to Ticks (DSCATT)* by Professor Kanaan.[32] The Clinical Trial is currently being conducted and was assessed for scientific shortcomings, using the same assessment criteria applied in the review of the Murdoch Troublesome Tick study.

Assessment of the Clinical Trial Protocol for ACT Intervention in DSCATT

The clinical trial protocol for the Acceptance and Commitment Therapy (ACT) intervention targeting DSCATT aims to explore whether psychological therapy can help individuals manage their symptoms. While the intentions behind this study are commendable—seeking to provide relief for patients suffering from a poorly understood condition—the scientific design of the trial has several critical shortcomings. These flaws affect the research's reliability and have profound implications for patient care, public health policy and the responsible allocation of healthcare resources.

Study Design and Hypotheses

At the core of any clinical trial is its design, which should clearly show whether a treatment works. Unfortunately, this study **lacks a control group**—meaning there is no comparison to patients who did not receive the treatment. Without such a comparison, it is impossible to know whether patient health improvements are due to the therapy or just natural recovery over time, placebo effects or other unrelated factors. This is a fundamental flaw because it prevents us from drawing meaningful conclusions about the therapy's effectiveness.

Moreover, the **study is not randomised**. In robust scientific studies, participants are randomly assigned to different treatment groups to ensure fairness and eliminate bias. Without randomisation, there is a risk that the results could be skewed by factors such as patients chosen to participate or severity of illness upon treatment commencement. In addition, the study planned to include 12 participants but only enrolled 8—a sample

---

[32] Pilot Testing a psychology-based treatment Intervention for Debilitating Symptom Complexes Attributed to Ticks (DSCATT) Registration number ACTRN12621001032842 https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=382136&isReview=true

size far too small to provide reliable results. Such a limited number increases the likelihood of inaccurate conclusions, whether overestimating the benefits or missing potential harms.

Impact on Patients

Without a strong study design, there is a real danger that unproven treatments could be recommended to patients based on unreliable evidence. This could lead to ineffective care, delays in receiving appropriate treatments and unnecessary emotional and financial strain on patients and their families.

Methodology

The way the trial collects and analyses data also raise serious concerns. The study relies heavily on self-reported questionnaires in which participants rate their symptoms, mood and quality of life. While patient feedback is essential, personal expectations can influence these measures, especially when patients know they are receiving treatment.

This is particularly problematic because the **study is not blinded**—the patients and the therapists know what treatment is being given, increasing the risk of biased reporting.

Another issue is the **lack of objective, measurable health data**. There are no clinical tests, biological markers or independent assessments to confirm whether the therapy has had a tangible impact on the participants' health. Furthermore, the treatment is highly individualised, meaning each person may receive a slightly different version.

While this flexibility can be helpful in clinical practice, it makes it difficult to standardise the therapy for broader use or compare results across participants.

The data analysis plan is overly simplistic. The researchers plan to rely mainly on basic statistics and subjective feedback, without using more advanced methods that could uncover deeper insights or control for other factors that might influence the results. This limits the study's ability to draw firm, evidence-based conclusions.

Impact on Patients

Weak data collection and analysis methods mean that the results may not accurately reflect the actual effects of the therapy. If decisions about healthcare policy or treatment recommendations are based on flawed data, patients may receive ineffective or inappropriate care for their condition.

Data Interpretation

Even if the study collects data successfully, interpreting that data correctly is crucial—and this is another area where the protocol falls short. Because there is no control group, it will be challenging to determine whether any reported improvements are due to the therapy or just the result of other factors, such as the natural course of the illness, changes in lifestyle or psychological factors like hope and expectation.

There is also a **risk that the researchers could overgeneralise** their findings. With only eight participants, any conclusions drawn will be based on the experiences of a very small, specific group of people. These results might not apply to the broader population of individuals with DSCATT, especially those with different backgrounds, severity of symptoms or co-existing health conditions.

Another concern is the failure to control for confounding variables—other factors could influence the outcomes, such as participants' use of different treatments, varying levels of illness severity or personal support systems. Without accounting for these variables, it is impossible to confidently say that any changes are due to the therapy alone.

Impact on Patients

If the data is misinterpreted, the therapy could be presented as more effective than it is. This could lead to false hope for patients and their families and wasted time and resources on treatments that do not deliver tangible benefits. Problematically, it might divert attention from therapies that could be genuinely helpful.

Ethical Considerations

On the positive side, the study has received approval from an ethics committee, and procedures are in place to ensure that participants give informed consent. This means that participants are made aware of the study's purpose, procedures and potential risks before agreeing to participate.

However, ethical concerns arise from the study's design flaws. Participants may believe the therapy is more effective than it is, especially given the lack of a control group and objective measures. This "**therapeutic misconception**" can create false hope, which may lead to emotional distress if the expected improvements do not occur.

Another ethical issue is the potential risk of exposing participants—and, by extension, future patients—to treatments that have not been adequately validated. This is particularly concerning for individuals with chronic, debilitating conditions like DSCATT, who may be especially vulnerable and desperate for relief.

Impact on Patients

Ethical shortcomings can erode trust in medical research and healthcare recommendations. If patients feel misled or harmed by participation in poorly designed studies, they may become reluctant to engage in future research, even when it involves promising new treatments. This affects individual patients and undermines public confidence in the healthcare system generally.

Conclusion

Several key changes could be made to improve the significant pitfalls identified in this clinical trial protocol to strengthen its scientific rigour and ensure reliable outcomes for patients. First, **introducing a control group**, such as a waitlist or standard care group, would allow researchers to compare results and determine whether the therapy is truly effective. **Randomising participants** into different groups would help eliminate bias, ensuring that outcome differences are due to the treatment, not other factors.

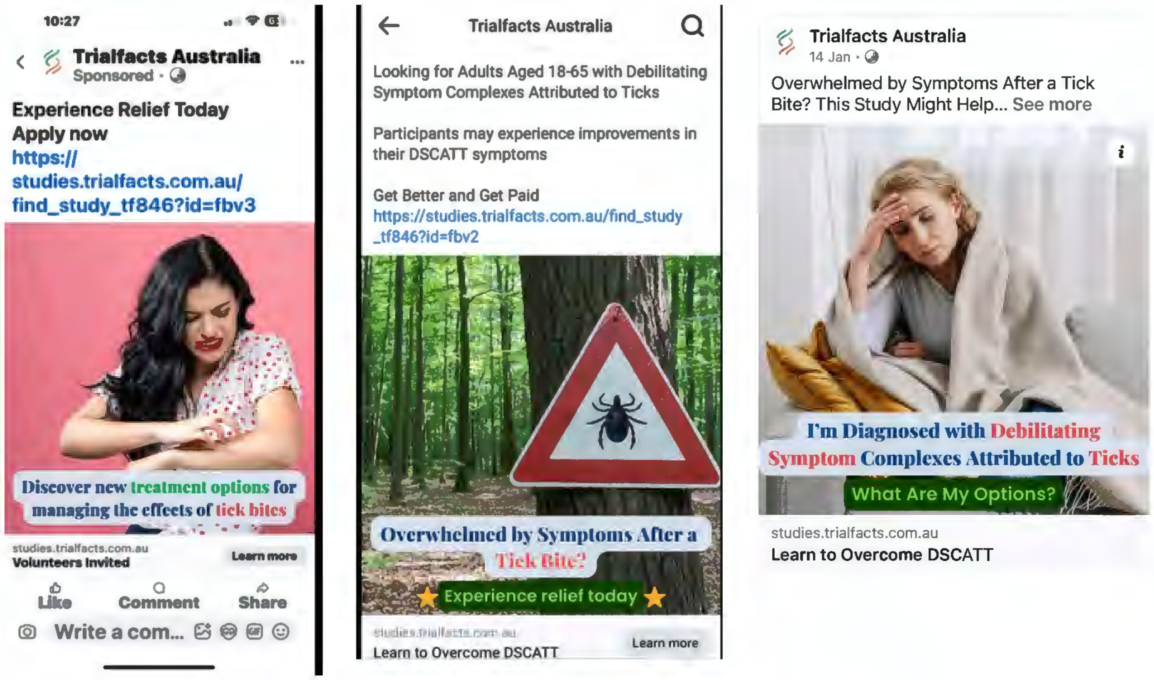
Increasing the sample size would provide more robust data, making it easier to identify actual trends and apply the findings to a broader population. To reduce bias, the study should **include objective measures**—like clinician assessments or biological health markers—**alongside self-reported questionnaires**, offering a more accurate picture of patient outcomes.

Additionally, **implementing blinding**, where possible, would prevent participants and clinicians from being influenced by expectations about the therapy. Finally, **more detailed data analysis plans** that account for variables such as other ongoing treatments or differing levels of illness severity would ensure the results are meaningful and trustworthy. These improvements would make the study more scientifically sound and ensure that patients receive treatments backed by solid evidence, ultimately leading to better health outcomes.

While the goal of finding effective treatments for DSCATT is both essential and urgent, this clinical trial protocol falls short in several key areas. The lack of a control group, small sample size, reliance on subjective data and weak analytical methods all undermines the reliability of the study's findings.

These scientific flaws have real-world consequences: patients may be directed toward therapies that do not work, delaying access to more effective treatments and potentially causing harm. For research to truly benefit patients, it must be rigorous, transparent and based on sound scientific principles. Policymakers, healthcare providers and the public deserve evidence that can be trusted and leads to safe and effective treatments. Future studies addressing conditions like DSCATT must be designed with greater scientific rigour to ensure that patients receive the best possible care, based on solid evidence.

The recruitment strategy for the study is also concerning. The ongoing advertisements promising to "Experience relief today" could be considered misleading, as it suggests immediate benefits from a therapy that is still under investigation. This approach may create unrealistic expectations among potential participants and could be interpreted as false advertising.



10:27

Trialfacts Australia
Sponsored

Experience Relief Today
Apply now
https://studies.trialfacts.com.au/find_study_tf846?id=fbv3

studies.trialfacts.com.au
Volunteers Invited

Trialfacts Australia

Looking for Adults Aged 18-65 with Debilitating Symptom Complexes Attributed to Ticks

Participants may experience improvements in their DSCATT symptoms

Get Better and Get Paid
https://studies.trialfacts.com.au/find_study_tf846?id=fbv2

studies.trialfacts.com.au
Learn to Overcome DSCATT

Trialfacts Australia
14 Jan

Overwhelmed by Symptoms After a Tick Bite? This Study Might Help... See more

studies.trialfacts.com.au
Learn to Overcome DSCATT

Figure 1: TrialFacts Australia - Social Media Posts recruiting trial participants

Furthermore, the study's focus on psychotherapy for what many patients consider a physical disease is contentious. The research team's examination of "what might seem to be a physical disease" through a psychological lens may be misaligned with patients' experiences and beliefs about their condition. This disconnect could explain the difficulty in achieving desired participant numbers and the reported suspicion from the patient population about a psychotherapy-based option.

The self-reported positive feedback from participants introduces a potential bias. As Professor Kanaan noted, patients who participated were likely more open to psychotherapy than the average patient, predisposing them to a positive outcome. This self-selection bias could skew the results and limit their generalisability to the broader patient population.

The study's approach of combining psychological therapy with current care as an "adjunct therapy" is problematic when there is no established primary treatment for the condition, as covered earlier.[33] This situation creates a paradox where patients are offered strategies to manage symptoms of a disease that is not yet fully understood or effectively treated.

---

[33] Holmes, D., Murray, S. J., Perron, A., & Rail, G. (2006). Deconstructing the evidence-based discourse in health sciences: truth, power and fascism. International Journal of Evidence-Based Healthcare, 4(3), 180–186. https://pubmed.ncbi.nlm.nih.gov/20367689/

Lastly, the focus on acceptance and commitment therapy, which aims to help people live with their symptoms, may be perceived as psychologically cruel by patients who are seeking physiological treatments for what is a physical illness. This approach is dismissive of patients' experiences and could discourage them from seeking further medical investigation or treatment.

While this clinical trial aims to provide support for patients, its methodology, recruitment strategy and underlying assumptions raise significant concerns. These issues highlight the complex challenges in researching and treating conditions that sit at the intersection of physical and psychological health, particularly when the primary condition itself is not well-defined or understood.

The Challenges of Lyme Disease Diagnosis in Australia

Coexistent to the significant discussion that surrounds the issue of diagnostic tests using appropriate biomarkers (better covered by those more qualified), one of the key challenges in diagnosing Lyme-like illness in Australia is the **uncertainty surrounding disease prevalence**. Without clear and reliable data on how common Lyme disease or Lyme-like illnesses are in Australia, interpreting test results becomes difficult, and the medical system faces the dilemma of **false positives** versus **true negatives**.

Understanding False Positives in the Context of Lyme Disease Testing

Since there are many actors who seek to obfuscate the issues that surround medical testing and constantly refer to test reliability, we take the opportunity to explain it. A **false positive** result occurs when a test incorrectly indicates that a person has a disease when they do not. This is particularly problematic when the disease in question is **rare**. This is the position occupied by the medical fraternity in Australia – it is rare. Without definitive prevalence data, it is difficult to know whether a positive result means the patient truly has Lyme disease or whether the test result is an error.

A test with **high specificity**—such as those used for Lyme disease (e.g., ELISA and Western Blot)—is great at correctly identifying healthy individuals who do not have the disease, if they are used correctly and use the right biomarkers. However, in **low-prevalence populations,** the **risk of false positives increases**. This means that if Lyme disease is rare in Australia, because we will not survey for it, a positive test could simply be the result of the **test reacting to something else**, not a Lyme bacterium.
For example, if 5% of a population has Lyme-like illness, and a test has a **5% false positive rate**, it means that **1 out of 20 healthy people** will incorrectly test positive. If Lyme-like illness were more common, the **false positive rate would be less of an issue**, but in the current uncertainty, these false positives lead to patients being misdiagnosed and potentially mis/over-treated.

High Risk of False Positives or Missing True Cases?

Without known **prevalence figures**, the question becomes: is Lyme disease, or a related bacterium, **common enough** in Australia that false positives are the real problem, or is it **so rare** that the test fails to identify the true cases (false negatives)?

Both outcomes can have significant consequences for patients. This conundrum makes it incredibly difficult to trust test results in Australia. The **lack of reliable prevalence data** leads to uncertainty, and doctors are caught in a difficult position, unsure whether to trust positive or negative test results.

What Needs to Change?

To solve this problem, Australia needs to **gather more reliable data on Lyme disease prevalence**. With better understanding of how common the disease really is, we could better interpret test results and adjust diagnostic approaches accordingly. Without this data, healthcare providers are left in a state of confusion, and patients continue to suffer as a result.

We need a **comprehensive national study** on the prevalence of Lyme disease and Lyme-like illnesses, including tick borne diseases, particularly in areas where tick exposure is high. This data would allow for **more accurate interpretation of test results** and ultimately improve patient outcomes.

Until such data is available, Australia must adopt a more **flexible diagnostic approach**, one that prioritises clinical symptoms, exposure history and associated empirical test results, rather than relying solely on the imperfect results of a single diagnostic test. In doing so, we can ensure that **patients receive the most appropriate care**, whether they have Lyme disease, Lyme-like illness or another condition altogether.

The following are direct suggestions on improving testing algorithms in Australia, as there are robust accredited diagnostic tests already existing in other countries that can be personalised for the use in Australia or to stand alone.

Modernising Serological Tests

One way forward is to update our **serological tests**, which check for antibodies produced by the body to fight infection. Right now, many kits rely on proteins (antigens) from American or European bacteria. These may not perfectly match the Australian species, leading to potential false negatives or missed diagnoses. Also, most existing kits test for only one pathogen and a single type of antibody at a time. Utilising a **multiplex test kit** that detects several infections (and their antibodies) simultaneously would speed up diagnosis and treatment. By validating “locally relevant antigens” and incorporating them into tests such as ELISA, IFA, and Western Blot, Australian labs can better identify tick-borne diseases in our own communities. Widespread use of these improved tests by reference labs and diagnostic centers will produce more reliable and consistent results.

Molecular Tests for Faster, More Accurate Results

Another valuable approach involves **molecular tests** like PCR (Polymerase Chain Reaction) and qPCR (quantitative PCR). These tests look for the genetic material (DNA) of the disease-causing organisms. Through **multiplex PCR panels**, a single sample can be screened for multiple infections—such as *Rickettsia*, *Babesia*, and *Bartonella*—all at once. Detecting *Borrelia* (the bacterium linked to Lyme-like illness) can be challenging because it often appears in very small quantities, so using Australian strains to fine-tune these tests is crucial for reliable results.

Acceptance of Foreign Laboratory Tests in Tick-Borne Disease Diagnostics

It is important for the Committee to understand the critical importance of accepting foreign laboratory tests for tick-borne diseases, particularly Lyme disease, based on internationally recognised standards—ISO 13485:2016 and ISO 15189. These standards ensure the quality, reliability and regulatory compliance of diagnostic devices and laboratory operations globally. In the context of Australia, where tick-borne diseases present unique public health challenges, and there are unresolved issues with the existing diagnostics, embracing these standards can significantly enhance diagnostic capabilities and improve patient outcomes.

Key International Standards

1. ISO 13485:2016[34]

Purpose: Specifies requirements for a Quality Management System (QMS) for medical devices, ensuring safety, efficacy and compliance with global regulations (International Organisation for Standardisation, 2016).

Impact: Ensures that In Vitro Diagnostic (IVD) devices undergo rigorous analytical and clinical validation, verifying their accuracy, reliability and clinical relevance. This includes sensitivity, specificity and reproducibility, which are critical in diagnosing complex diseases like Lyme disease (U.S. Food and Drug Administration, 2021).[35]

Global Acceptance: Recognised by regulatory bodies worldwide, including the FDA (USA), EMA (EU), TGA (Australia) and others through Mutual Recognition Agreements (MRAs), facilitating smoother regulatory processes and broader acceptance of diagnostic devices.[36]

2. ISO 15189

Purpose: Establishes criteria for competence and quality in medical laboratories, covering all aspects of laboratory operations from management to technical procedures (International Laboratory Accreditation Cooperation, 2024).

Impact: Laboratories accredited under ISO 15189 are required to independently validate diagnostic tests, ensuring analytical and clinical performance, regardless of the

---

[34] International Organization for Standardization. (2016). *ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes.* ISO.

[35] U.S. Food and Drug Administration. (2021). *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*. FDA.

[36] International Laboratory Accreditation Cooperation (ILAC). (2024). *ILAC Mutual Recognition Arrangement (MRA) and Signatories.* Retrieved fromhttps://ilac.org/ilac-mra-and-signatories/.

manufacturer's validation. This independent validation enhances diagnostic accuracy, reducing the risk of false positives or negatives (Santini et al., 2021).[37]

Global Recognition: Accreditation bodies like the College of American Pathologists (CAP), UK Accreditation Service (UKAS) and Australia's National Association of Testing Authorities (NATA) ensure compliance with these standards, providing international assurance of diagnostic quality.[38]

---

[37] Santini, G., et al. (2021). *Validation of diagnostic tests: Analytical and clinical performance considerations.* Journal of Medical Diagnostics.

[38] ILAC. (2024). *Global accreditation standards and mutual recognition agreements.* ILAC Publications.

Why Accept Foreign Laboratory Tests?

International Trust and Recognition: Tests validated under ISO 13485:2016 and conducted in ISO 15189-accredited laboratories are globally recognised for their reliability. The ILAC Mutual Recognition Arrangement (ILAC MRA) supports this by ensuring accredited laboratories meet consistent international standards (ILAC, 2024).

Consistency in Diagnostic Quality: The ILAC MRA facilitates global equivalence of accredited laboratories, ensuring diagnostic results are consistent across borders, thus reducing the need for redundant testing when patients seek care across different healthcare systems.

Improved Patient Outcomes: Timely and accurate diagnoses enabled by recognised foreign tests can lead to better patient care and disease management, particularly critical in tick-borne diseases where early intervention is key. For Australian patients, this means quicker diagnoses, reduced suffering and more effective treatment plans.

Regulatory Efficiency: Acceptance of internationally validated tests reduces redundancy, minimises delays in diagnosis and aligns with global best practices, ultimately streamlining healthcare delivery in Australia.

Impact on Australian Patients and Healthcare System

Accepting foreign laboratory tests will have profound benefits for Australian patients. It ensures that individuals suffering from tick-borne diseases receive timely, accurate diagnoses, which are crucial for initiating appropriate treatment and improving health outcomes. The burden of delayed diagnoses often leads to chronic illness, increased healthcare costs and diminished quality of life. By recognising tests from ISO-accredited laboratories, Australia can mitigate these risks, ensuring equitable access to high-quality diagnostics.

Furthermore, this acceptance strengthens Australia's healthcare system by reducing diagnostic gaps, promoting international collaboration and fostering innovation in diagnostic technologies. It also alleviates the strain on domestic laboratories, allowing resources to be allocated more efficiently.

Human Rights Implications

Denying recognition of validated foreign tests can lead to delayed diagnoses and treatment, potentially infringing on the right to health. Recognising these tests ensures equitable access to high-quality diagnostics, regardless of geographical origin, aligning with Australia's commitment to upholding human rights and health equity.

No laboratory or clinician should question the validity of Lyme disease diagnostics if the laboratory adheres to ISO 15189 and the IVD is manufactured under ISO 13485:2016 standards.

Recommendations: Bold Action for Real Change

While efforts to resolve the myriad issues that surround diagnostic testing are in progress, Australia can redefine its approach to Lyme disease and Lyme-like illnesses. By embracing new ideas and adopting more patient-centered policies, we could create a system that better serves those affected by these complex and often misunderstood conditions. The following recommendations provide a pathway forward:

1. **Immediately recognise foreign laboratory tests that meet ISO:** Australian regulatory bodies and healthcare providers should recognise foreign laboratory tests that comply with ISO 13485:2016 and ISO 15189 standards. This approach fosters global collaboration, enhances diagnostic accuracy and ultimately supports better health outcomes for Australians affected by tick-borne diseases. The adoption of these standards is not merely a technical issue but a critical public health strategy that upholds the rights and well-being of Australian citizens.
2. **Fund a National Tick Genome Project:** To solve the puzzle of Lyme-like illness in Australia, we need to better understand the pathogens carried by Australian ticks. A National Tick Genome Project would sequence the microbes in local ticks, helping to identify new strains or co-infections that are not currently detected by existing tests. This research would ensure that future diagnostic tests are accurate and specific to Australian strains, increasing the likelihood of correct diagnoses.
3. **Implement a Lyme Disease Risk Scoring System:** Rather than relying solely on diagnostic tests, Australia should adopt a multi-factor risk scoring system[39] that combines clinical symptoms, exposure history and immunological markers. This system would better capture the complex nature of Lyme-like illness and inform and provide a more comprehensive approach to diagnosis.
4. **Introduce Real-Time Monitoring for Tick Exposure:** To address Lyme-like illness early on, we propose introducing a system to track tick exposure and serve as tick surveillance. This could involve wearable health devices that monitor changes in a patient's immune response, such as inflammation or immune markers, following tick bites. Patients who have been exposed to ticks could be part of a real-time monitoring program to catch potential infections before they become chronic.
5. **Empower Patient-Led Research Through Crowdsourcing:** The patients themselves are often the best source of data when it comes to rare and emerging diseases. We propose creating a citizen science platform where Lyme disease patients can contribute their symptoms, treatment outcomes and diagnostic data. By harnessing big data and AI, this platform would allow for the identification of patterns and trends that could lead to improved tests and treatment strategies. An

---

[39] Horowitz, R. I., & Freeman, P. R. (2018). Precision medicine: The role of the MSIDS model in defining, diagnosing, and treating chronic Lyme disease/Post Treatment Lyme Disease Syndrome and other chronic illness: Part 2. *Healthcare*, 6(4), 129. https://doi.org/10.3390/healthcare6040129

international example is MyLymeData Project. We are already working on Project TIDE to achieve this aim.

By implementing these bold and necessary changes, we can leapfrog traditional reliance on diagnostic testing systems that do not adequately serve patients and, instead, create a system that not only better addresses Lyme disease but also provides a model for tackling other **emerging infectious diseases** in Australia. If we embrace these ideas, we could improve the lives of thousands of patients.

When the Fox Guards the Henhouse: Australian CDC's Independence

The establishment of the Australian Centre for Disease Control (CDC) raises significant concerns, particularly among patient advocacy groups representing individuals affected by Lyme disease. While the CDC's independence is presented to ensure a more effective public health response, we are worried that the medical mindset of dismissing Lyme disease in Australia—one that has long hindered proper diagnosis and treatment—may simply be transplanted into this new institution. This could prevent much-needed progress for those suffering from Lyme disease. We highlight some issues that we urge the Committee to explore:

1. **Continuation of Historical Neglect:** The historical medical stance of "no Lyme here" has led to systemic delays in diagnosis, misdiagnosis and lack of treatment options for patients. We fear that as key medical personnel from existing government health agencies transition to the CDC, they will bring with them the same reluctance to embrace Lyme disease as a legitimate concern. The DHAC's submission to this inquiry, and the testimony provided by its Principal Medical Advisor Professor Lum, is a strong indicator that this is already occurring. If these mindsets are carried over into the CDC's operations, there is a real risk that the status quo of neglect will persist, continuing to marginalise those who need recognition and proper care.

2. **Risk of Institutional Inertia:** The personnel involved in the CDC's formation have strong ties to existing medical systems, which have historically downplayed Lyme disease. This raises concerns that, despite the CDC's independent structure, it may still be influenced by the outdated medical perspectives that have hindered progress in Lyme disease recognition and care. This inertia could manifest in a reluctance to establish new diagnostic criteria or research avenues that could benefit Lyme disease patients, as demonstrated in the DHAC's 'cut and paste' Submission. As such, rather than being a fresh start for Lyme disease management in Australia, the CDC could inadvertently reinforce the biases and barriers that patients have long faced.

3. **Potential for a "Business as Usual" Approach:** Rather than embracing an opportunity to bring about the necessary reforms to address Lyme disease effectively, there is a fear that the Australian CDC will mirror the failings of the systems that have historically underplayed the disease's significance. This "business as usual" approach could limit meaningful change by reinforcing the

same diagnostic and treatment protocols that have failed to provide answers or relief to those suffering from Lyme-like illnesses.

6. **Need for Reform and True Patient-Centered Care:** For Lyme disease patients, the real challenge is ensuring that the CDC operates in a way that prioritises their needs. This means not only recognising the disease's existence in Australia but also implementing transparent, evidence-based guidelines for diagnosis and treatment. A failure to reform the current system could leave patients stranded in a medical landscape that continues to ignore their struggles, with the CDC unintentionally perpetuating this neglect by failing to advocate for comprehensive care.

The establishment of the Australian CDC has the potential to improve national public health responses, but its success hinges on whether it can genuinely address complex issues like Lyme disease. If the CDC adopts the same medical perspectives that have failed Lyme disease patients for decades, it will continue the cycle of neglect. To make a real difference, the CDC must engage meaningfully with patient groups, adopt up-to-date research, and ensure that the medical community's reluctance to recognise Lyme disease does not become entrenched in this new agency.

The Human Rights Crisis Facing Lyme Disease Patients

In 2016, Jenna Luché-Thayer, a human rights expert with extensive experience working with the U.S. government and United Nations, led a multinational collaborative effort establishing The Ad Hoc Committee for Health Equity in ICD11 Borreliosis Codes. The group presented evidence of human rights violations related to Lyme disease to the UN Special Rapporteur on the right to health. This presentation included documentation of 252 cases of human rights abuses against Lyme disease patients and their advocates.

The UN Special Rapporteur, Dr Dainius Pūras, officially received this testimony in June 2017.[40] The evidence highlighted how medical practitioners, scientists, laboratory owners and parents of children with Lyme disease faced aggressive opposition and attacks from state actors and affiliated interests.[41] These violations were reported to span across 11 human rights treatises, including the right to freedom from torture, cruel and degrading treatment, and the right to the highest attainable standard of health.[42]

Human rights abuses outlined as part of the Ad Hoc Committees representation included the following points - known to occur frequently in Australia and imperative to address:

- The prevention of proper diagnosis [**due to ineffective and inappropriate guidelines**] compounded by the obstruction of access to treatment options that meet internationally accepted standards
- discrimination based on illness manifestations [**and nomenclature**]
- misapplication of somatic diagnosis to deny medical care [**and medically unexplained symptoms as a way of dismissal of patient illness**]
- obstruction of treatments based on illness manifestations [**provision of treatments for misdiagnosed illness – i.e. MS**]
- discrimination based on financial status [**many unable to obtain treatment through expensive and inaccessible Lyme literate medical practitioners**]
- attacks on human rights defenders —including medical practitioners, scientists and researchers who act on behalf of this vulnerable patient group [**targeted vilification by medico's reporting Lyme doctors to AHPRA for action,**

---

[40] Luché-Thayer, J. (2017, December 12). Testimony to the Tick-Borne Disease Working Group. U.S. Department of Health and Human Services. https://www.hhs.gov/sites/default/files/TBDWG-Transcripts-Day_2-Part_2_508.pdf

[41] Human rights violations of relapsing fever and Lyme disease patients under international investigation. (2020, July 27). CanLyme.

[42] Luché-Thayer, J. (2017, June). Human rights violations of relapsing fever and Lyme disease patients under international investigation. CanLyme.

discrimination by AHPRA due to disease status, use of MBA consultation to incite fear]

- restricting information regarding treatment options that meet internationally accepted standards (**compounded by ineffective guidelines that rely upon IDSA position and DSCATT**)
- routine exclusion of key stakeholders —such as medical practitioners, researchers, patients and caretakers who are concerned with persistent and complicated cases of Lyme disease —from decision-making venues, making these stakeholders invisible to policy makers, economists and other practitioners and researchers [**lack of proper and detailed consultation, ignorance and dismissiveness of 1200 items of evidence, contrary and contradictory representation of Health Dept positions, lack of action to escalate issues to APHHC and COAG**]
- sick children under treatments that meet internationally accepted standards are forcibly removed from their parents —and there are many cases where such parents are falsely accused of poisoning their children or 'Munchausen by Proxy' syndrome [**Australian cases known**]
- alarming cases where euthanasia is encouraged over treatments that meet internationally accepted standards [**some evidence in Australia,**[43] **considerable evidence of tendency for suicide where patients find themselves in systemically neglectful situations**]

Since the initial UN hearing, the issue of human rights violations in relation to Lyme disease has continued to be a concern. Recent developments include:

1. **Medical Gaslighting:** A 2024 study published in an international peer-reviewed medical journal highlighted the persistent problem of medical gaslighting experienced by Lyme disease patients across 28 countries.[44]
2. **Regulatory Concerns**: The LDAA has raised concerns about the potential targeting of medical practitioners who diagnose and treat Lyme disease, citing fears of disciplinary action by medical boards.[45]

---

[43] Refer Anonymous patient submission contained with the LDAA's Submission to this Inquiry

[44] Fagen, J. L. (2024, March 1). Study on medical gaslighting and Lyme disease captures global attention. Lamar University News and Events.

[45] Lyme Disease Association of Australia. (2021, April 30). Submission to the Senate Community Affairs References Committee inquiry into the administration of registration and notifications by the Australian Health Practitioner Regulation Agency (AHPRA) and related entities under the Health Practitioner Regulation National Law. Parliament of Australia. https://www.aph.gov.au/DocumentStore.ashx?id=28060dcd-dde7-4a84-b6be-f7e59dfc440b&subId=708258[2]

The Medical gaslighting Study (Fagen) revealed significant disparities between Australia and other countries regarding Lyme disease diagnosis and treatment, which warrant the committee's attention:

1. **Test Request Granting**: Australian doctors were significantly less likely to grant requests for Lyme disease tests (19%) compared to the average across other countries (38%)
2. **Belief in Positive Test Results**: Only 6% of Australian doctors believed a positive Lyme disease test result, compared to the 17% average across other countries. This is notably lower than the US (22%) and Ireland (23%)
3. **Dismissal of Bullseye Rash**: Australian doctors (M = 6.21, SD = 11.04) were more likely to tell patients they did not have Lyme disease despite the presence of a bullseye rash, a characteristic sign of the disease. This contrasts sharply with US doctors, who were statistically less likely to dismiss the rash (M = 3.24, SD = 8.37)

These findings highlight for the world, the concerning trend in Australia, where patients face greater challenges in obtaining Lyme disease tests, diagnoses, and recognition of symptoms compared to other countries in the study. The stark differences confirm a systemic issue in Australia regarding Lyme disease recognition and patient care, which requires immediate attention from the Committee to address these disparities and improve patient outcomes.

Addressing Human Rights Violations in Lyme Disease: A Call for Reform in Australia

The human rights issues surrounding Lyme disease remain complex and contentious. While the initial UN hearing brought attention to the problem, concrete global action to address these violations appears limited and is much worse in Australia. To address these challenges, the Committee should seek action on:

1. Establishing official recognition of Lyme disease and Lyme-like illnesses, developing comprehensive, evidence-based guidelines for diagnosis and treatment.
2. Launching an independent inquiry into the handling of Lyme disease cases by medical boards and regulatory bodies, ensuring transparency and accountability.

If these issues are not addressed, patients will initiate class action lawsuits against medical boards, health departments and insurance companies for denial of care and human rights violations. The United Nations Human Rights Council, already alerted to human rights violations related to Lyme disease, may intervene, potentially damaging Australia's international reputation.

Additional information

The Crushing Cost of Lyme: Recommending a Patient-First Approach in Australia

The out-of-pocket medical costs for Lyme disease patients in Australia are significantly higher than the national average, creating a substantial financial burden for those affected. While the average Australian spends around $1,195 per year on health-related expenses,[46] Lyme disease patients face costs that are 3570% higher, averaging $42,561 per person, according to patient surveys conducted as part of the 2016 Senate Inquiry into Lyme-like illness.[47]

Patient Impacts of Cost with Lyme Disease

Lyme disease patients in Australia face exorbitant medical expenses, often leading to severe financial hardship:

- Average out-of-pocket health costs of $42,561 per patient.
- Total estimated health-related costs for the Lyme disease community in Australia: $964 million.
- Some patients report spending between $200,000 to $300,000 on treatment.
- 65% of patients spend their entire savings on health care.
- 11% of patients report selling their family home to cover medical expenses.

The high costs associated with Lyme disease treatment create significant barriers to care:

- Many patients travel overseas for treatment due to limited options in Australia.
- Those who cannot afford overseas treatment may need to travel over 500km to find experienced practitioners.
- Non-PBS listed medications result in hundreds of dollars in out-of-pocket expenses.
- Loss of income compounds the financial burden, with an average reported loss of $43,122 per patient.

The financial strain of Lyme disease treatment has far-reaching consequences:

---

[46] Australian Institute of Health and Welfare (AIHW). *Patients' out-of-pocket spending on Medicare services, 2016–17*

[47] ~~Senate Inquiry into Lyme-like Illness. (2016). *Public Patient Submissions*. Analysis of 349 patient submissions~~

- 64% of patients report leaving their jobs, school or exiting their studies.
- 25% of patients cannot drive or leave their home unaided.
- Some patients become totally isolated, unable to leave their homes at all.
- Multiple family members may be affected, further compounding the financial and emotional burden.

Bold Recommendations to Put Patients First

1. **Establish a Lyme Disease Treatment Fund:** Create a dedicated government fund to cover the out-of-pocket expenses for diagnosed Lyme disease patients, ensuring they can access necessary treatments without financial ruin.
2. **Expand PBS Coverage**: Include all medications commonly used for Lyme disease treatment in the Pharmaceutical Benefits Scheme, reducing the financial burden on patients.
3. **Implement a Lyme Disease Medicare Item Number**: Create a specific Medicare item number for Lyme disease, allowing for higher rebates and specialised care.
4. **Develop Lyme Disease Centres of Excellence**: Establish specialised treatment centres across Australia to reduce travel costs and improve access to expert care.
5. P**rovide Financial Support for Caregivers**: Expand the national caregiver allowance for family members supporting Lyme disease patients, recognising the impact on their ability to work.
6. **Fast-Track Disability Support**: Streamline the process for Lyme disease patients to access disability support payments and access the NDIA, acknowledging the debilitating nature of the condition.

These recommendations aim to alleviate the disproportionate financial burden on Lyme disease patients and ensure they receive the support and care they desperately need. By implementing these measures, Australia can take significant steps towards putting patients first and addressing the hidden epidemic of Lyme disease.

Children and Lyme Disease: A Critical Priority

The impact of Lyme disease on children is a pressing concern that demands immediate attention and action. Dr Debby Hamilton, a paediatrician with extensive experience in integrative medicine and research, has highlighted several critical points regarding Lyme disease in children: [48]

Prevalence and Underdiagnosis

1. In the United States, approximately 75,000 paediatric cases of Lyme disease occur annually, representing 25% of all reported cases
2. Extrapolating to Australia, an estimated 5,640 children may contract a Lyme-like illness each year
3. The lack of diagnostic knowledge in Australia often leads to delayed diagnosis and chronic infections in children

Diagnostic Challenges

Dr Hamilton emphasises the importance of recognising non-acute signs of Lyme disease in children, particularly in cases of long-term illness. Key observations include:

1. Children with 18-month to 2-year histories of symptoms like dizziness, headaches and extreme fatigue
2. Cases of postural orthostatic tachycardia syndrome (POTS) and sensorineural hearing loss associated with Lyme disease
3. The presence of multiple infections (e.g., EBV, HHV6, Mycoplasma) in chronic Lyme cases due to depleted immune systems

Comorbidities and Associations

Research indicates strong associations between Lyme disease and other conditions in children:

1. Higher rates of PANDAS, ADHD, ASD, hearing loss and POTS in children with Lyme disease
2. Approximately 25% of children with autism spectrum disorder in the US test positive for tick-borne diseases[49]

---

[48] https://drdebbyhamilton.com/about-dr-debby-hamilton/

[49] Sanctuary Functional Medicine. (n.d.). Let's Talk Mold: Debby Hamilton - The Environmental Impact of Toxins and Infections on Children. Retrieved February 7, 2025, from https://sanctuaryfunctionalmedicine.com/topics/functional-medicine/lets-talk-mold-debby-hamilton-the-environmental-impact-of-toxins-and-infections-on-children/

Congenital Lyme Disease

The transmission of Lyme disease from mother to foetus is a significant concern:

1. Gestational manifestations of Lyme disease can have severe impacts on the foetus[50]
2. There is a critical need for longitudinal studies on children born with congenital Lyme disease to understand long-term prognosis and effects[51]

Protecting Our Children: Urgent Actions for Addressing Paediatric Lyme Disease

Recommendations for the Committee to consider in prioritising efforts for children:

1. Immediately establish and endorse a child directed 'tick bite' prevention program and disseminate it nationally.
2. Prioritise research funding for paediatric Lyme disease, including long-term studies on congenital cases.
3. Enhance education and training for healthcare providers on recognising and diagnosing Lyme disease in children.
4. Develop specialised treatment protocols for paediatric Lyme cases, considering the unique needs of developing bodies.
5. Establish a national registry for paediatric Lyme disease cases to better track and understand the disease's impact on children.
6. Implement comprehensive screening programs for at-risk children, including those with unexplained chronic symptoms or developmental disorders.
7. Create support systems for families dealing with paediatric Lyme disease, including access to specialised care and educational resources.

By prioritising early diagnosis, treatment and care for children with Lyme disease, we can significantly reduce the long-term health impacts and improve outcomes for affected families. This proactive approach is essential for addressing the growing concern of Lyme disease in Australia's paediatric population.

---

[50] Lambert JS. An Overview of Tickborne Infections in Pregnancy and Outcomes in the Newborn: The Need for Prospective Studies. Front Med (Lausanne). 2020 Mar 6;7:72. doi: 10.3389/fmed.2020.00072. PMID: 32211414; PMCID: PMC7069275. and. Waddell LA, Greig J, Lindsay LR, Hinckley AF, Ogden NH. A systematic review on the impact of gestational Lyme disease in humans on the fetus and newborn. PLoS One. 2018 Nov 12;13(11):e0207067. doi: 10.1371/journal

[51] McLennan G, Dale SE, Gillim L, Weinblatt V, Wallerstein R, Naides SJ. Developing a Prospective Gestational Lyme Disease Study. Methods Mol Biol. 2024;2742:259-278. doi: 10.1007/978-1-0716-3561-2_18. PMID: 38165628.

Project TiDE: Global Tick-Borne Disease Engagement: A Citizen Science and Big Data Initiative

Tick-borne illnesses are a pressing and escalating public health issue worldwide, impacting millions annually. Many persons with chronic or severe tick-borne symptoms feel disregarded, encounter difficulties in obtaining proper diagnoses and endure without definitive treatment options. *The Global Tick-Borne Disease Engagement: A Citizen Science and Big Data Initiative*, guided by our colleagues and LDAA, seeks to tackle these challenges by establishing an international citizen science big-data initiative that enables patients, researchers and clinicians to collaboratively collect, analyse and derive insights from real-world data on tick-borne diseases.

Participants worldwide can submit information regarding tick bites, symptoms, health histories and laboratory results via an intuitive digital portal. By consolidating and standardising these unique experiences, we generate a robust dataset that, when examined using sophisticated big data and machine learning techniques, will assist in identifying trends, determining risk factors and revealing potential biomarkers. This empirical technique guarantees that ideas derived are grounded in substantial, evidence-based data rather than singular anecdotes.

This initiative's primary strength is its inclusion. Patients and community members serve as co-producers of knowledge, providing essential, real-time insights into tick-borne diseases' varied manifestations and experiences. Researchers from other disciplines—epidemiology, immunology, bioinformatics, among others—will collaborate to analyse the data, fostering cross-disciplinary discoveries. These initiatives are expected to produce novel insights into chronic illnesses, enhanced diagnostic standards, and the possibility of innovative, more efficacious therapies.

In addition to its direct medical and scientific implications, this research offers considerable societal advantages. A substantial body of evidence regarding chronic tick-borne diseases can educate public health policies, direct resource allocation and stimulate additional study funding. Healthcare professionals will provide more educated care, legislators will possess the means to develop more adaptive healthcare systems, and individuals who have historically been ignored or misinterpreted will finally receive acknowledgment and validation for their experiences.

This citizen research and significant data endeavor could revolutionise our global comprehension of tick-borne diseases and validate the existence of chronic tick-borne diseases. By illuminating underexamined symptoms, enhancing diagnostic and therapeutic methodologies, and linking individuals globally, we aspire to cultivate a more collaborative and significant medical research paradigm that genuinely prioritises patients in the discovery process.

LDAA & GLOBAL EXPERTS RESPOND TO THE DSCATT CLINICAL PATHWAY

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

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

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

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

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

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

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

2nd August 2021

To Whom It May Concern:

Key points that justify urgent remedial action:

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

Critical Synopsis

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Babesia is a common tick-borne co-infection in the experience of American and some Australian physicians; the first severe cases were outlined in 2012[30, 31]. However, the Pathway fails to mention this serious disease, usually experienced early post-infection as severe breathlessness or 'air hunger' and night sweats. *Babesia* infects the red blood cells like malaria (*Plasmodium* spp) and can be equally difficult to treat as it is not responsive to antibiotics; evidence from some physicians indicates that it responds to the artemisia compounds being increasingly adopted for malaria. The Pathway is also blind to *Bartonella* and *Coxiella*, other serious tick-borne co-infections, as well as tick-induced allergies[32, 33, 34].

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

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

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

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

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

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

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

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

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

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

Conclusion

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

A progressive and contemporary approach to this problem is urgently overdue. Recent developments in molecular technologies and next generation sequencing provide new frontiers in discovery. Fully informed and proactive medical professionals, medical colleges, state, territory and Commonwealth health organisations can stem the flow of Australians declining into sickness, disability and death.

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

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

Summary

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

Authored: LDAA Scientific Advisory Committee

Chair: Adjunct Professor Leona Gilbert PhD |**FN**
Professor Christian Perronne MD, PhD | **FR**
Dr Lance Sanders PhD | **AUS**
Professor Vett Lloyd PhD | **CAN**

Patron: Dr Richard Horowitz MD | **US**
Associate Professor Monica Embers PhD | **US**
Dr John Duley PhD | **AUS**

External Endorsement: Listed from page 11 onwards

References

1. Chalada MJ, Stenos J, Bradbury RS. Is there a Lyme-like disease in Australia? Summary of the findings to date. One Health, 2016; 2:42-54
2. Schiffman EK, McLaughlin C, Ray JAE, Kemperman MM, Hinckley AF, Friedlander HG, Neitzel DF. Underreporting of Lyme and Other Tick-Borne Diseases in Residents of a High-Incidence County, Minnesota, 2009. Zoonoses Public Health. 2018 (Mar); 65(2):230-237.
3. Kugeler KJ, Schwartz AM, Delorey MJ, Mead PS, Hinckley AF. Estimating the Frequency of Lyme Disease Diagnoses, United States, 2010–2018. Emerg Infect Dis. 2021; v27(2):616-619.
4. Lloyd VK, Hawkins RG. Under-Detection of Lyme Disease in Canada. Healthcare (Basel). 2018 (Oct); 15:6(4):125.
5. Vector control - World Health Organization 1995. Public health importance CHAPTER 4 • BEDBUGS, FLEAS, www.who.int/water_sanitation_health/resources/vector262to287.pdf
6. McMichael AJ, Campbell-Lendrum DH, et al, Eds, LICE, TICKS AND MITES p268 - Tick-borne relapsing fever, p269 - Lyme disease http://www.who.int/globalchange/publications/climchange.pdf
7. Patz JA, Githeko AK, McCarty JP, Climate change and human health RISKS AND RESPONSES - WHO 2003 (IPCC contribution) CHAPTER 6 - Climate change and infectious diseases.
8. Hussein U, Confalonieri N, de Wet Ecological influences and Lyme disease p125 - BOX 6.2 www.euro.who.int/data/assets/pdf_file/0008/98765/e82481.pdf
9. THE VECTOR-BORNE HUMAN INFECTIONS OF EUROPE - THEIR DISTRIBUTION AND BURDEN ON PUBLIC HEALTH https://www.euro.who.int/en/publications/abstracts/lyme-borreliosis-in-europe.-influences-of-climate-and-climate-change,-epidemiology,-ecology-and-adaptation-measures
10. Lindgren E, Jaenson TG, Lyme borreliosis in Europe: influences of climate and climate change, epidemiology, ecology and adaptation measures by © World Health Organization 2004
11. Sponsored by the Vector Biology and Control unit in WHO/EMRO Eastern Mediterranean Health Journal, Vol. 15, No. 3, 2009 761 Case report Congenital tick- borne relapsing fever: report of a case with transplacental transmission in the Islamic Republic of Iran, M. Mahram and M.B. Ghavami. © World Health Organization 2006 www.who.int/iris/handle/10665/117697
12. Report of the Regional Director, The Work of WHO in the Western Pacific Region 1 July 2011–30 June 2012 http://www.who.int/tdr/stewardship/global_report/en/ Global report for Research Infectious http://iris.wpro.who.int/handle/10665.1/7999
13. WHO publication A global brief on vector-borne diseases © World Health Organization 2014, Diseases of Poverty 2012 Chapter 1 - Why research infectious diseases of poverty? http://apps.who.int/iris/bitstream/10665/111008/1/WHO_DCO_WHD_2014.1_ eng.pdf
14. Lyme Disease Association of Australia. A patient perspective: Submission to the Senate Inquiry on the Growing Evidence of an Emerging tick-borne disease that causes a Lyme-like illness for many Australian patients. 2016; Submission 528.
15. Diagnostic and Statistical Manual of Mental Disorders Fifth Edition DSM-5TM https://cdn.website-editor.net/30f11123991548a0af708722d458e476/files/uploaded/DSM%2520V.pdf
16. ICD Codes 2018 version, https://medicalcodingnews.org/icd-10-code-for-lyme-disease/
17. ICD11 https://icd.who.int/browse11/l-m/en - enter Lyme in search bar
18. Beard D, Stannard HJ, Old JM. Morphological identification of ticks and molecular detection of tick-borne pathogens from bare-nosed wombats (Vombatus ursinus). Parasite Vectors. 2021 (Jan); 14(1):60
19. Tadepalli M, Vincent G, Hii SF, Watharow S, Graves S, Stenos J. Molecular Evidence of Novel Spotted Fever Group Rickettsia Species in Amblyomma albolimbatum Ticks from the Shingleback Skink (Tiliqua rugosa) in Southern Western Australia. Pathogens. 2021 (Jan); 10(1):35.
20. Taylor CL, Lydecker HW, Lo N, Hochuli DF, Banks PB. Invasive rabbits host immature Ixodes ticks at the urban-forest interface. Ticks Tick Borne Dis. 2020 (Jul); 11(4):101439.

21. Baxter C, Vogelnest Lj, Doggett S. Dermatoses caused by infestations of immature Ixodes spp. on dogs and cats in Sydney, Australia. Aust Vet J. 2009 (May); 87(5):182-7.
22. Marendy D, Baker K, Emery D, Rolls P, Stutchbury R. Haemaphysalis longicornis: the life-cycle on dogs and cattle, with confirmation of its vector status for Theileria orientalis in Australia. Vet Parasitol X. 2019 (Dec); 3:100022.
23. Best, S. Investigation of the Performance of Assays for Lyme Disease in Australia. 2017, NRL, Fitzroy, VIC, p3.
24. Aguero-Rosenfeld ME, Wang G, Schwartz I, Wormser GP. 2005. Diagnosis of Lyme borreliosis. Clin Microbiol Rev 2005; 18:484–509.
25. Theel ES. The past, present, and (possible) future of serologic testing for Lyme disease. J Clin Microbiol 2016; 54:1191-6
26. Steere AC, Sikand VK. The presenting manifestations of Lyme disease and the outcomes of treatment. N Engl J Med. 2003 (Jun) 12; 348(24):2472-4.
27. Livesley AM, Thompson IP, Rainey PB, Nuttall PA. Comparison of Borrelia isolated from UK foci of Lyme disease. FEMS Microbiology Letters 1995; 130:151-7.
28. Wilhelmsson P, Lindblom P, Fryland L et al. Ixodes ricinus ticks removed from humans in Northern Europe: seasonal pattern of infestation, attachment sites and duration of feeding. Parasites Vectors, 2013; 6:362.
29. Rauter C and Hartung T. Prevalence of Borrelia burgdorferi sensu lato genospecies in Ixodes ricinus ticks in Europe: a metaanalysis. Applied and environmental microbiology, 2005; 71:7203-16.
30. Senanayake SN, Paparini A, Latimer M, Andriolo K, Dasilva AJ, Wilson H, Xayavong MV, Collignon PJ, Jeans P, Irwin PJ. First report of human babesiosis in Australia. Med J Aust. 2012 (Mar); 196(5):350-2.
31. Fuller A, Manitta J, Marks R, Tencic S, Gordon CL. First reported case of imported human Babesia microti infection in Australia. Pathology. 2012 (Oct); 44(6):580-2
32. van Nunen S. Tick-induced allergies: mammalian meat allergy, tick anaphylaxis and their significance. Asia Pac Allergy 2015; 5:3-16
33. van Nunen S. Galactose-alpha-1,3-galactose, mammalian meat and anaphylaxis: a world-wide phenomenon? Curr Treat Options Allergy 2014; 1:262-77.
34. Rappo TB, Cottee AM, Ratchford AM, Burns BJ. Tick bite anaphylaxis: incidence and management in an Australian emergency department. Emerg Med Australas 2013; 25: 297-301
35. https://www.health.nsw.gov.au/environment/pests/parasites/Pages/ticks.aspx
36. https://www.healthdirect.gov.au/dengue-fever
37. https://www.racgp.org.au/afp/2009/november/dengue/
38. https://www.racgp.org.au/download/Documents/AFP/2009/November/200911esler.pdf
39. Australian Chronic Infectious and Inflammatory Disease Society. Growing Evidence of an Emerging Tick-borne Disease that causes a Lyme-like illness for many Australian Patients, Senate submission 370, p2. https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lyme-like_Illness/Submissions
40. Schloeffel R. Growing Evidence of an Emerging Tick-borne Disease that causes Lyme-like Illness. Committee Hansard, Brisbane, 2 Nov 2016; p56, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lymelikeillness45/Public_Hearings
41. Nji, E et al. High prevalence of antibiotic resistance in commensal Escherichia coli from healthy human sources in community settings. Nature Scientific Reports 2021; 11:3372.
42. Torrey L et al, Plaintiffs, v Infectious Diseases Society of America et al, Defendants; THE US DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS TEXARKANA DIVISION: CIVIL ACTION NO. 5:17-CV-00190-RWS, 2020.
43. Pfeiffer MB. Lyme: The First Epidemic of Climate Change. Washington: Island Press, 2018.

External Endorsement

<table>
<tr><td>Dr Armin Schwarzbach | MD, PhD | **GERMANY**
CEO, ArminLabs</td><td>Prof Alan B MacDonald | MD | **USA**
Pathologist - Retired</td></tr>
<tr><td>Assoc. Dean Sonja Harris-Haywood | MD |**USA**
NE Ohio Medical Univ; Assoc. Prof, Family Commun Med, College of Medicine</td><td>Professor Sam Lingnam | MD FRCPCH FRCP | **UK**
Consultant Paediatrician</td></tr>
<tr><td>Dr Natalie Rudenko | PhD | **CZECH REPUBLIC**
Institute of Parasitology</td><td>Dr Kenneth Sandstrom | MD | **SWEDEN**
Clinician</td></tr>
<tr><td>Kunal Garg | MSc | **FINLAND**
CTO Tez?ted</td><td>Dr John E Lambert | MD, PhD | **IRELAND**
Consultant in Infectious Diseases</td></tr>
<tr><td>Dr Dinos Xydas | MD | **CYPRUS**
Medical Director, Swiss Biological Medicine Centre</td><td>Dr Lada Svabova | MVDr | **CZECH REPUBLIC**
Veterinary Clinician</td></tr>
<tr><td>Dr Astrid Stückelberger | PhD | **SWITZERLAND**
Privat-Docent Med</td><td>Dr Steven Harris | MD | **USA**
Specialist Lyme Clinician</td></tr>
<tr><td>Dr Nicola Ducharme | ND | **USA**
Medical Director Restore Medicine</td><td>Dr Isaac Meza | MD | **MEXICO**
Medical Director Sanoviv Medical Centre</td></tr>
<tr><td>Dr Fausto Villavicencio | PhD | **MEXICO**
Research Sanoviv Medical Centre</td><td>Dr Mireya Valdéz, CLS | PhD | **MEXICO**
Pharmacy & Laboratory Chief
Sanoviv Medical Centre</td></tr>
<tr><td>Tobi Malcolm | RN | **CANADA**
Stakeholder</td><td>Dr. Sam Rahbar | MD FACP | **USA**
Integrative Gastroenterology & Nutrition</td></tr>
<tr><td>Jenna Luche-Thayer | Director | **USA**
Global Network on Institutional Discrimination™</td><td>Mary-Beth Pfeiffer |Author | **USA**
Investigative Journalist</td></tr>
<tr><td>Elaine Kelly | Secretary | **AUSTRALIA**
Sarcoidosis Lyme Australia</td><td>Jim Wilson | President | **CANADA**
Canadian Lyme Disease Foundation</td></tr>
<tr><td>Vicen | President | **SPAIN**
ALCE Asociación Lyme Crónico España</td><td>Emmanuelle Martin | President | **FRANCE**
Enfance Lyme and Co</td></tr>
<tr><td>Jennifer Barrett | Committee | **USA**
Lyme Global Coalition</td><td>Dominic Smith | Ambassador | **NETHERLANDS**
Dutch TBD Foundation</td></tr>
</table>

NorVect | Charity | **NORWAY**	Dr Linda Williams | MD | **USA** Neuropsychiatrist
Dr Joe Ekgren | MD | **NORWAY** Clinician	Dr Pol De Saedeleer | PhD BVPA | **BELGIUM** Pharmacist
Marjatta Valonen | Chairman | **FINLAND** Finnish Lyme Disease Association	Terja Kuuri-Riutta | Advocate | **FINLAND** Finnish Lyme Disease Association
Milla Pitkänen | Advocate | **FINLAND** Finnish Lyme Disease Association	Timo Tuomala | Advocate | **FINLAND** Finnish Lyme Disease Association
Martti O. Kantola | Advocate | **FINLAND** Finnish Lyme Disease Association	Auli Laakso | Advocate | **FINLAND** Finnish Lyme Disease Association
Dr Ginger Savely | DNP | **USA** TBD Medical Associates	Joonas Berghäll | Director | **FINLAND** Oktober Production
Dr Diana Uitdenbogerd-Drenth | PhD | **NETHERLANDS** Dutch Tick Borne Diseases Foundation	Dr Dan Cameron | MD | **USA** Internationally recognised Lyme Specialist, lead author of two ILADS Lyme Treatment Guidelines
Markus Berger | Manager | **GERMANY** ArminLabs	Associate Professor Maria Shklina | MD, PhD | **UKRAINE** I.Ya. Horbachevsky Ternopil State Medical University
Dr Ursula Talib-Bene | MD | **SWITZERLAND** Specialist in psychiatry and psychotherapy	Associate Professor Kristine Gedroic | MD | **USA** Founder, The Gedroic Medical Institute Rutgers NJMS Clinical Associate Professor, Department of Medicine
Dana Paris | Writer | **USA** SonyATV Songwriter/ Biotech Startup Co-Founder/ Health Reporter/ Author	Dr Steven Phillips| MD, PC | **USA** Clinician, Writer
Neomed | Clinic | **CYPRUS** Specialist Treatment Centre	George Xydas | CEO | **CYPRUS** Swiss Biological Medical Center
Ailo Ovokki Koski | Advocate | **FINLAND** Finnish Lyme Disease Association	Outi Caven | Advocate | **FINLAND** Finnish Lyme Disease Association
Pekka Pihlajakangas | Advocate | **FINLAND** Finnish Lyme Disease Association	Markku Aaltonen | Advocate | **FINLAND** Finnish Lyme Disease Association

Anne Hokkanen | Advocate | **FINLAND**
Finnish Lyme Disease Association

Inkeri Öhberg | Advocate | **Finland**
Finnish Lyme Disease Association

Dr Eboni Cornish | MD | **USA**
Amen Clinics

Dr Ronald Wilson | MD FACOG | **USA**
Clinician

Connie Swan | **USA**
Stakeholder

Anu Ahonen | Advocate | **FINLAND**
Finnish Lyme Disease Association

AONM Academy of Nutritional Medicine | **UK**

Kai Pitkänen | Advocate | **FINLAND**
Finnish Lyme Disease Association

Aile Tar | Advocate | **FINLAND**
Finnish Lyme Disease Association

Toini Lappalainen | Advocate | **FINLAND**
Finnish Lyme Disease Association

Kristen klos-Maki | DC | **USA**
Stakeholder

Jocelyn Strand | ND | **USA**
Stakeholder

Michelle Ross | MS, MA, CNS, LDN | **USA**
Biocidin

The Hon Greg Hunt MP
Minister for Health and Aged Care

Ref No: MC21-025263

Ms Sharon Whiteman
President
Lyme Disease Association Australia

26 AUG 2021

Dear Ms ~~Whiteman~~ Sharon

Thank you for your correspondence of 2 August 2021 concerning the Debilitating Symptom Complexes Attributed to Ticks (DSCATT) clinical pathway.

As you are aware, my Department commissioned Allen and Clarke Policy and Regulatory Specialists Limited (Allen and Clarke) to develop an evidence-based clinical pathway and multidisciplinary care model for patients suffering from DSCATT. The clinical pathway is designed to support clinicians' decision making on differential diagnosis and referral pathways for patients presenting with DSCATT. Rather than instructive, it is a tool and pathway to help structure assessments and management of patients with a wide variety of symptoms and severity of disability.

Recognising that the needs of individual patients varies, the pathway accommodates a significant degree of clinical discretion to address differing patient circumstances and evolving symptoms. Further, the clinical pathway encourages patients with persistent symptoms and who remain undiagnosed or with medically unexplainable symptoms, to be managed through a multidisciplinary approach, incorporating the teamwork of all medical specialties relevant to the individual patient's care. This approach also allows the pathway to interact with current medical and treatment frameworks and align with the Australian health care system, all of which benefit and improve the potential outcomes for patients.

I acknowledge there are elements of Lyme disease and tick-borne illnesses which are contested. The wide range of views, coupled with the gaps in our current knowledge around tick-borne illnesses make it unlikely a consensus on the best way forward is able to be reached. Taking this into consideration, the projects developed by my Department in response to the Senate Community Affairs References Committee Final Report, are based on scientific evidence and take into consideration input from a wide range of stakeholders. The Australian Government remains committed to progressing these important projects and initiatives to support the best possible outcomes for patients presenting with DSCATT, and to better understand the aetiology of tick-borne diseases.

Taking into account, the points above and the positive acceptance of the clinical pathway by the majority of stakeholders involved in its development, I am, at this point in time, satisfied the clinical pathway, and the educational materials currently being developed to support it, do not constitute a risk to patient health or safety.

I appreciate the feedback your organisation provided throughout the development of the DSCATT clinical pathway.

Thank you for writing on this matter.

Yours sincerely

Greg Hunt

The Hon Greg Hunt MP
Minister for Health and Aged Care

Ref No: MC21-025263

Ms Sharon Whiteman
President
Lyme Disease Association Australia
sharon.whiteman@lymedisease.org.au

26 AUG 2021

Dear Ms ~~Whiteman~~ Sharon

Thank you for your correspondence of 2 August 2021 concerning the Debilitating Symptom Complexes Attributed to Ticks (DSCATT) clinical pathway.

As you are aware, my Department commissioned Allen and Clarke Policy and Regulatory Specialists Limited (Allen and Clarke) to develop an evidence-based clinical pathway and multidisciplinary care model for patients suffering from DSCATT. The clinical pathway is designed to support clinicians' decision making on differential diagnosis and referral pathways for patients presenting with DSCATT. Rather than instructive, it is a tool and pathway to help structure assessments and management of patients with a wide variety of symptoms and severity of disability.

Recognising that the needs of individual patients varies, the pathway accommodates a significant degree of clinical discretion to address differing patient circumstances and evolving symptoms. Further, the clinical pathway encourages patients with persistent symptoms and who remain undiagnosed or with medically unexplainable symptoms, to be managed through a multidisciplinary approach, incorporating the teamwork of all medical specialties relevant to the individual patient's care. This approach also allows the pathway to interact with current medical and treatment frameworks and align with the Australian health care system, all of which benefit and improve the potential outcomes for patients.

I acknowledge there are elements of Lyme disease and tick-borne illnesses which are contested. The wide range of views, coupled with the gaps in our current knowledge around tick-borne illnesses make it unlikely a consensus on the best way forward is able to be reached. Taking this into consideration, the projects developed by my Department in response to the Senate Community Affairs References Committee Final Report, are based on scientific evidence and take into consideration input from a wide range of stakeholders. The Australian Government remains committed to progressing these important projects and initiatives to support the best possible outcomes for patients presenting with DSCATT, and to better understand the aetiology of tick-borne diseases.

Taking into account, the points above and the positive acceptance of the clinical pathway by the majority of stakeholders involved in its development, I am, at this point in time, satisfied the clinical pathway, and the educational materials currently being developed to support it, do not constitute a risk to patient health or safety.

I appreciate the feedback your organisation provided throughout the development of the DSCATT clinical pathway.

Thank you for writing on this matter.

Yours sincerely

Greg Hunt