Submission to the Senate Inquiry
Access to diagnosis and treatment for people in Australia with tick-borne diseases

Addressing Terms of Reference (b)
"the adequacy and effectiveness of the 'debilitating symptom complexes attributed to ticks' clinical pathway to support patients"

This submission discusses the inadequacy of the DSCATT Clinical Pathway to support Australian patients and the contributing Government processes.

Organisation: Lyme Australia Recognition and Awareness
Authors: [redacted] Ms Karen Smith B. Psych (Hons)

Lyme Australia Recognition & Awareness
Awareness : Research : Advocacy : Education

Email: lymeaustralia@live.com.au
Website: http://www.lymeaustralia.com/

Submission Contents

1.0 Introduction

1.1 Background

This submission has been prepared by the patient research, advocacy, education and awareness group, Lyme Australia Recognition and Awareness (LARA). Ms. Karen Smith, founder of LARA, has been researching and advocating for Lyme / Tick Borne Disease awareness since 2010. During this time, she has presented research to both Labor and Liberal Governments, evidencing the risks and harm of tick-borne diseases and the shortcomings in current treatment systems and medical policy. To date, successive administrations have failed to act appropriately.

Brief summary of research presented to Governments/ Inquires:

2012: Met with Qld Chief Health Officer Dr Jeannette Young and provided research.
2014: Submitted a research response to the Clinical Advisory Committee on Lyme Disease (CACLD) Scoping Study
Feb 2016: Met with The Hon. Malcolm Turnbull MP Prime Minister, providing research and discussing the 2016 Senate Inquiry, 'Growing evidence of an emerging tick-borne disease that causes a Lyme like illness for many Australian patients'
Apr 2016: Submitted research and spoke at the Senate Inquiry hearing in Brisbane
2018-2019: Attended Government Forums on Lyme Borreliosis (DSCATT) and Allen & Clark Clinical pathway patient stakeholder consultations.

1.2 Submission Overview

The Debilitating Symptom Complexes Attributed to Ticks (DSCATT) Clinical Pathway was prepared in response to the Senate Committee's final recommendations arising from the 2016 Senate Inquiry "Growing Evidence of an Emerging Tick-Borne Disease that Causes a Lyme-Like Illness for many Australian Patients". Recommendation 12[1] of the final Senate Report detailed the requirements for treatment guidelines to be developed (Excerpt B). The Clinical Pathway was developed by Allen and Clarke Policy and Regulatory Specialists Ltd, under DOH contract (Reference ID Health/18-19/04745). The scope of this contract included community consultation, preparation of a literature review and development of the DSCATT Clinical Pathway. The patient community were key stakeholders to the community consultation.

In January 2020, the DSCATT Clinical Pathway was rejected by the patient community as it represented a continuation/worsening of the Australian patient situation. This is summarised in **Section 2.0** of this submission.

The Department of Health (DOH) specified a clinical pathway, as opposed to a guideline. How the DSCATT Clinical Pathway would fit within the Australian health system was unclear, including the authority of the document and practitioner compliance requirements. Requirements were clarified after publication of the DSCATT Clinical pathway, the process taking a year with both the DOH and the Australian Commission on Safety and Quality in Healthcare (ACSQHC) referring the responsibility to each other. This indicates a failure to abide by common practice government processes and resulted in ambiguous practitioner compliance requirements. These issues are discussed in **Section 3.0 and 4.0** of this submission.

The patient community has relied upon lengthy and ongoing Freedom of Information process, complicated by the DOH refusing access to the Draft DSCATT Literature review to protect the commercial interests of the Contractor. This is discussed in **Section 5.0** of this submission.

[1] https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lymelikeillness45/~/media/Committees/clac_ctte/Lymelikeillness45/b01.pdf

Material obtained through the FOI processes revealed that the DSCATT Clinical Pathway did not consider relevant epidemiological and patient / practitioner data in formulating the Clinical Pathway. This raises serious concerns as to the suitability of the DSCATT Clinical Pathway. **Section 6.0** of this submission examines this.

Questions for the Senate Inquiry are presented in **Section 7.0**.

2.0 Rejection of DSCATT Clinical Pathway

On the 29th of January 2020, the DSCATT Clinical Pathway was rejected by the Patient Collaborative, comprising of 15 patient support groups (Attachment 1). At this time the Lyme Disease Association of Australia also submitted a letter of response rejecting the pathway[2].

The rejection of the clinical pathway was on the basis of the stakeholder exclusion, exclusions in the literature review, non-compliance with NHMRC Guidelines for guidelines and the restrictions to patient access to diagnostic testing and treatment.

Letters from Lyme Australia Recognition and Awareness (LARA) relating to the rejection of the DSCATT Clinical Pathway are listed in Table 1 and contained within Attachment 1.

Table 1 - Letters from/to Lyme Australia Recognition and Awareness (LARA)

Date	To	From	Description
25/11/2019	Allen and Clarke Project Leader DSCATT Clinical Pathway Robyn Haisman-Welsh	LARA	Letter advising DSCATT stakeholder consultation processes are inadequate. Rejects the final draft clinical pathway citing non-compliance with NHMRC requirements for guidelines, scientific inadequacy, impacts on patient access to diagnostic testing and treatment of nearly any modality.
26/11/2019	Federal Health Minister, Greg Hunt and Senator Jacquie Lambie	LARA	Letter providing correspondence dated 25/11/2019 to Allen and Clarke and a copy of the Draft DSCATT Clinical Pathway and timetable.
14/01/2020	Allen and Clarke Project Leader DSCATT Clinical Pathway Robyn Haisman-Welsh	LARA	Discussed inadequacy of stakeholder consultation process for DSCATT.
24/01/2020	Allen and Clarke Project Leader DSCATT Clinical Pathway Robyn Haisman-Welsh	LARA	Letter outlined concerns the clinical pathway was a continuation of the 'no lyme' dogma in Australia. Reiterated that relying on pathology was flawed and the pathway was rejected. Provided references to previous technical research circ. 2012 onwards.
29/01/2020	Federal Health Minister, Greg Hunt	Patient Collaborative (15 patient groups)	Letter rejected DSCATT Clinical pathway and was signed by 15 patient groups. This letter also endorsed a letter sent by a further three patient groups rejecting the pathway. Requested moratorium on DSCATT Clinical pathway until all stakeholders were consulted and a risk assessment was undertaken. Provides list of queries regarding pathway fit within the healthcare system and practitioner compliance requirements.
23/04/2020	LARA Distributed to Patient collaborative (15 patient groups)	DOH Health Protection Policy Branch Assistant Secretary	Responded to letter dated 29/01/2020, refused moratorium / extensions. Directs questions regarding pathway fit within the healthcare system and practitioner compliance requirements to the Australian Commission on Safety and Quality in Health Care.

[2] https://lymedisease.org.au/lyme-in-australia/ldaa-response-to-the-dscatt-clinical-pathway/

3.0 DSCATT Clinical Pathway - Practitioner Compliance

The DSCATT Clinical Pathway was published in October 2020, however the practitioner compliance requirements for this document and it's fit within the Australian healthcare system were unclear / unknown. From Nov 2019 to Jan 2021 questions regarding the above (Excerpt A) were repeatedly directed to the Department of Health and the Australian Commission on Safety and Quality in Healthcare (ACSQHC), each responding the other party was responsible for advice.

Excerpt A - Questions directed to the DOH and ACSQHC

1. *What are the key points of difference between a clinical pathway document and a clinical care standard. Can a clinical pathway document be used to inform other document such as clinical care standards?*
2. *What are the compliance requirements for a clinical pathway document with respect to existing clinical care standards?*
3. *Who is ultimately responsible to ensure clinical pathway documents are vetted appropriately and are fit for purpose?*
4. *What are the requirements for consultation with community and other government stakeholders in the development of a clinical pathway document?*
5. *Can a clinical pathway document be published if several key stakeholders reject the document - which department would adjudicate this process?*
6. *Does the Australian Commission on Quality and Safety in Healthcare review clinical pathway documents and if so, what is assessed in the review and at what stage of the document development does the review take place?*
7. *Likely outcomes for health care practitioners with respect to non-compliance with a clinical pathway.*

The questions were then directed to the Federal Health Minister, by the Tick-Borne Disease Patient Representative Collaborative, comprising of 15 patient advocate groups **(Attachment 1)** and also via Federal MP Darren Chester (Attachment 2). The DOH responded with advice from Rebecca Newton, (Health Protection Policy Branch DOH) who advised that the ACSQHC was the appropriate body to respond. This correspondence demonstrates confused jurisdiction of authority and is partially provided in Attachment 2.

In January 2021 the Department of Health provided clarification on the practitioner compliance requirements in relation to the DSCATT Clinical Pathway by email (Excerpt B). This clarification would be of interest to many practitioners.

Excerpt B - From Email (12th January 2021):

In relation to your second query, there is no obligation or requirement for medical practitioners to use the DSCATT clinical pathway. The pathway is intended to be a flexible resource for medical practitioners to use to ensure that their patients' complex clinical presentations are appropriately diagnosed and managed. The specific treatment identified for each patient remains at the discretion of the treating practitioner in line with their clinical assessment of their patient and their patient's individual health care needs. With the recent finalisation of the Literature Review and its publication on the Department's website, we are now actively advising medical professional stakeholder groups and colleges of the clinical pathway and encouraging them to bring these resources to the attention of their members.

I trust this information is of assistance.

Kind regards

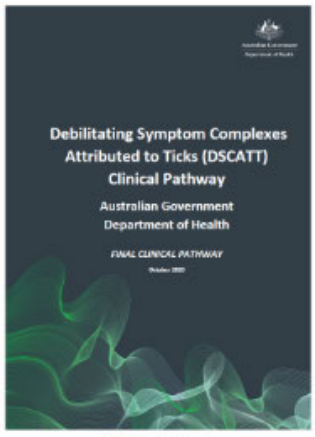
First Assistant Secretary
Office of Health Protection and Response
Australian Government Department of Health

This advice contained in Excerpt B is not on the DHAC webpage nor is it contained within the DSCATT Clinical Pathway[3]. The clinical pathway states on page v *"The DSCATT Clinical Pathway is not instructive; rather a tool/pathway to help structure assessments and management of patients with a wide variety of symptoms and severity of disability."*, this statement is open to interpretation.

The DHAC Webpage classifies the DSCATT Clinical Pathway "Publication Type" as a "Guideline". The DSCATT Clinical Pathway was not located on the National Health and Medical Research's (NHMRC) database of approved guidelines. It is uncertain what the publication type "Guideline" relates to, however guidelines generally confer practitioner compliance requirements and the classification of the publication type as a guideline may be inappropriate.

The practitioner compliance requirements/expectations are not clearly defined in the online material. Ambiguous requirements for compliance with the DSCATT Clinical Pathway contribute to practitioner reluctance to order pathology or treat infections that may be associated with ticks. It is unknown what advice the Department of Health directly issued to medical professionals, professional groups, colleges, public health laboratories, and hospitals regarding practitioner compliance.

Screenshot of the DHAC Webpage 25/01/2025:



Downloads

Debilitating symptom complexes attributed to ticks (DSCATT) clinical pathway

Download PDF - 2.02 MB - 65 pages
Download Word - 2.75 MB - 65 pages

We aim to provide documents in an accessible format. If you're having problems using a document with your accessibility tools, please contact us for help.

Publication date:
October 2020

Date last updated:
15 October 2020

Publication type:
Guideline

Audience:
Health sector

Language:
English

Description:
This clinical pathway is based on evidence presented in the Literature review to support the debilitating symptom complexes attributed to ticks clinical pathway.

[3] https://www.health.gov.au/sites/default/files/documents/2021/07/debilitating-symptom-complexes-attributed-to-ticks-dscatt-clinical-pathway.pdf

4.0 Clinical Pathway vs Guideline

The DSCATT Clinical Pathway was prepared in response to the Senate Committee's final recommendations arising from the 2016 Senate Inquiry "Growing Evidence of an Emerging Tick-Borne Disease that Causes a Lyme-Like Illness for many Australian Patients". Recommendation 12[4] of the final senate report discusses the requirements for treatment guidelines to be developed (Excerpt C).

Excerpt C – Recommendation 12 of the 2016 Senate Inquiry "Growing Evidence of an Emerging Tick-Borne Disease that Causes a Lyme-Like Illness for many Australian Patients".

> *"Recommendation 12 The committee recommends that treatment guidelines developed by Australian medical authorities emphasise the importance of a multidisciplinary, case conference approach to patient care, involving consultation between general practitioners and specialists with expertise in neurology, psychiatry, rheumatology, immunology, infectious diseases and microbiology."*

As discussed in Section 2.0, the use of a clinical pathway as opposed to a guideline, resulted in ambiguity as to practitioner compliance and enforceability. Guidelines differ from clinical pathways in that:

- Guidelines - The National Health and Medical Research Council (NHMRC) specifies standards for guidelines as per the *2016 NHMRC Standards for Guidelines*. These standards ensure the Guideline is relevant and useful for decision making, transparent, overseen by a guideline development group, identify and manage conflicts of interest, focused on health and related outcomes, evidence informed, make actionable recommendations, be up to date and accessible.[5] These Standards specify that the guideline *"Will clearly state the purpose of the guideline and the context in which it will be applied"* .
- Clinical pathways vary in purpose and mandatory adoption requirements and while they are not a 'clinical care standard' or a 'policy' they may inform these, depending on the State or Territory Government Health Department's approach[6].

The requirement for a Clinical Pathway was stipulated in the Approach to Market prepared by the DOH (Reference ID: Health/18-19/04745) and thereafter in the Contract between the DOH and Allen and Clarke Policy and Regulatory Specialists Ltd (Reference ID Health/18-19/04745) for the development of the DSCATT clinical pathway (Excerpt D). The Contract for the DSCATT Clinical Pathway is provided in Attachment 3. As of the 19/01/2024 it is not published on the DOHAC Disclosure Log and forms an important part of this Senate Inquiry Submission.

The reasons a clinical pathway was specified instead of the 2016 senate committee's recommended guideline is unknown, particularly given the NHMRC was a key government stakeholder to the DSCATT Clinical Pathway (Excerpt E).

[4] https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lymelikeillness45/~/media/Committees/clac_ctte/Lymelikeillness45/b01.pdf

[5] https://www.nhmrc.gov.au/guidelinesforguidelines/standards

[6] Advice from Clinical Care Standards Secretariat, Australian Commission on Safety and Quality in Healthcare. Email 18/12/2019.

Excerpt D - Page 3 of Federal Government Contract (Health/18-19/04745), released under FOI 1421

SERVICES

The Supplier is required to develop an evidence-based clinical pathway and multidisciplinary care model (the Clinical Pathway) for patients suffering from debilitating symptom complexes attributed to ticks (DSCATT) that can be flexibly applied in both private and public healthcare settings. The Clinical Pathway must be informed by the relevant literature and key documents, and must be developed in consultation with Key Stakeholders (Table 1), including medical professionals, government health authorities and patient groups to ensure that the Clinical Pathway is fit for purpose and acceptable to the majority of stakeholders, including Australian Health Ministers' Advisory Council (AHMAC) endorsement. The Department also requires the Supplier to assist with the preparation of agenda papers, briefing notes and presentations for AHMAC subcommittees, the Australian Health Protection Principal Committee (AHPPC) and Clinical Principal Committee (CPC) meetings.

This project will be conducted in three phases (Figure 1):

- Phase 1: Project initiation and review of literature.
- Phase 2: Stakeholder engagement via Consultation Forum (Think Tank) and preparation of the Consultation Forum report (Think Tank Report).
- Phase 3: Develop the Clinical Pathway and Multidisciplinary Care Model (the Clinical Pathway).

Excerpt E - Page 4 of Federal Government Contract (Health/18-19/04745) , released under FOI 1421

Commonwealth Contract – Services

Table 1: Key Stakeholders

Government	Medical Professionals	Patient Groups
Representatives from the Commonwealth, State and Territory Government Health Departments, through the: • Australian Health Ministers' Advisory Council (AHMAC). • Australian Health Protection Principal Committee (AHPPC). • Clinical Principal Committee (CPC). National Health and Medical Research Council (NHMRC) Therapeutic Goods Administration (TGA) ACT Health NSW Health NT Health Queensland Health SA Health Tasmania Health Victoria Health WA Health	Australasian College for Emergency Medicine (ACEM) Australian College of Nursing (ACN) Australian College of Rural and Remote Medicine (ACRRM) Australian Indigenous Doctors Association (AIDA) Australian Medical Association (AMA) Australian Primary Health Care Nurses Association (APNA) Royal Australasian College of Physicians (RACP) Royal College of Pathologists of Australasia (RCPA) Royal Australian College of General Practitioners (RACGP) Royal Australian and New Zealand College of Psychiatrists (RANZCP) Therapeutic Guidelines Limited Dr Richard Horowitz, Patron at the Lyme Disease Association of Australia (LDAA) Dr Richard Schloeffel, LLMD, Pymble Grove Medical Centre; Member of the Scientific Advisory Committee of the LDAA Dr Armin Schwarzbach, CEO of Armin Labs and member of the German Borreliosis Society Relevant Private Health Sector stakeholders.	Lyme Australia and Friends Group (Facebook Group) **ACT** Consumers Health Forum of Australia (CHF) **NSW** Australian Chronic Infectious & Inflammatory Disease Society (ACIIDS) Karl McManus Foundation (KMF) Lyme Disease Association Australia (LDAA) Sarcoidosis Lyme Australia **QLD** Global Lyme and Invisible Illness Organisation (GLIIO) Lyme Australia: Recognition and Awareness (LARA) **VIC** Emerge Australia Tickborne Illness Community Network Australia (TICNA) **WA** Chrysalis Lyme Disease Support Group Perth Kojonup Lyme Supporters Association ME/CFS and Lyme Association of WA, Inc. Multiple Systemic Infectious Disease Syndrome (MSIDS) Network **Other** Relevant ME/CFS, emerging biotoxins, or other similar disease patient groups.

5.0 Freedom Of Information (FOI) requests

The DOH processes and documents pertaining to the development of the DSCATT clinical pathway have been queried through FOI processes by various organisations and individuals.

FOI requests (summarised in Table 1) are brought to the attention of the Senate Committee as information that has been released to date raises significant questions concerning the DSCATT Clinical Pathway processes which will be discussed in this report as follows:

- DSCATT Clinical Pathway did not consider relevant epidemiological and patient / practitioner data.
- Financial interests of the Contractor impeding stakeholder access to the draft literature review.
- Acceptance of the DSCATT Clinical Pathway by the Majority of Stakeholders and Australian Health Minister's Advisory Council Endorsement.

All FOI requests were subject to initial refusal under the FOI Act and thereafter lengthy delays associated with the Office of the Australian Information Commissioner (OAIC) review process which continue to impede transparency and proper review of the DSCATT Clinical Pathway Processes.

Two of the FOI process, FOI 1421 and FOI 3510 are ongoing, exceeding 5 years and 3 years in duration respectively. Table 1 provides a summary of these FOI Requests.

The applicants for FOI 1421 and FOI 1677 would be pleased to provide all correspondence to the Senate Committee upon request.

Table 1 FOI - DSCATT Clinical Pathway

FOI & OAIC Ref. No.	Status	FOI Request Description	Document Links
FOI 1421 MR20/00289 **03/11/2019**	**Ongoing** 03/11/2019 to present. OAIC decision issued 28/11/2024, DOH to provide all information by 27/01/2025 **Duration >5 yr 2m**	FOI 1421 contained 11 requests[7], summarised as follows: 1) DSCATT Clinical Pathway Final Draft Document 2) Information that Allen & Clarke were directed to comply with/consider in preparing the DSCATT Clinical Pathway 3) DoH requirements for risk / impact assessment 4) DoH contract termination conditions 5) DoH scientific review requirements 6) DoH conditions for including/excluding stakeholder feedback 7) DoH requirements for Contractor personnel qualification/experience 8) Tender assessment weighting criteria 9) DoH & Allen & Clarke conflict of interest declarations 10) List of stakeholders 11) Copy of the scientific assessment done by Allen & Clarke as used to produce the final draft of the Clinical Pathway document	28/11/2024 OAIC Decision Notice: *"'AQR' and Department of Health and Aged Care (Freedom of information) [2024] AICmr 255 (28 November 2024)"* https://www8.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/AICmr/2024/255.html Released Documents: i) 9/02/2020 Tender Evaluation Criteria & DSCATT Think Tank Report https://www.health.gov.au/resources/foi-disclosure-log/foi-request-1421-clinical-pathway-for-debilitating-symptom-complexes-attributed-to-ticks?language=und ii) 23/07/2024 DSCATT Clinical Pathway Draft for consultation https://www.health.gov.au/resources/foi-disclosure-log/foi-1421-information-commissioner-review-dscatt-clinical-pathway-draft-for-consultation iii) 11/09/2024 Stakeholder List DSCATT Clinical Pathway Not currently published on the DOH Disclosure Log (16/01/2025) Provided in Attachment 4 iv) 24/12/2024 Contract between Allen and Clarke and the Department of Health. Reference ID: Heath/18-19/04745 (Contract for the DSCATT Clinical Pathway Literature Review, Stakeholder Engagement and DSCATT Clinical Pathway) Not currently published on the DOH Disclosure Log (16/01/2025) Provided in Attachment 3
		Note that Submission 34[8] to the Senate Standing Committee on Legal and Constitutional Affairs (05/06/2023) regarding the operation of the Commonwealth freedom of information laws detailed the nature of the delays FOI 1421 (MR20/00289) was experiencing, which was at that time before the OAIC as MR20/00289 for 3 years and 2.5 months (ongoing).	
FOI 1677 MR20/00554	**Completed** Information released by DOH prior to any OAIC decision. **Duration 3yr 11m** (28/04/2020 to 06/06/2024)	Literature Review for the DSCATT Clinical Pathway (at that time in Draft format).	06/06/2024 DSCATT Literature Review https://www.health.gov.au/resources/foi-disclosure-log/foi-1677-dscatt-literature-review
FOI 3510 MR22/01331	**Ongoing** 23/12/2021 to present Partial information released, awaiting OAIC decision[9]. **Duration >3yr 1m**	Scope unknown Correspondence, reports and communications and documents (refer to disclosure log).	15/06/2022 Partially redacted correspondence, reports and communications. https://www.health.gov.au/sites/default/files/documents/2022/07/foi-3510-release-documents-documents-relating-to-dscatt.pdf

[7] exact wording of the requests are provided in Annexure A of the OAIC Decision "*'AQR' and Department of Health and Aged Care (Freedom of information) [2024] AICmr 255 (28 November 2024)"* https://www8.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/AICmr/2024/255.html

[8] https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/CommonwealthFOI2023/Submissions

[9] Source: The Black Dot Project

5.1 DSCATT Clinical Pathway – Omission of Epidemiological and Patient Data

The Final Report of the 2016 Senate Inquiry "Growing Evidence of an Emerging Tick-Borne Disease that Causes a Lyme-Like Illness for many Australian Patients", contained Recommendations 7 & 8 (Excerpt F). These recommendations were for scientific investigations presenting epidemiological assessment of tick-borne infections in Australia and studies establishing the prevalence and geographic distribution of overseas acquired Lyme Disease in Australia. If completed, this work would have informed the development of valid and appropriate patient clinical management in the Australian context. This work was not undertaken and therefore could not inform the scientific assessment underpinning the DSCATT Clinical Pathway.

Excerpt F – Recommendation 7 & 8, 2016 Senate Inquiry "Growing Evidence of an Emerging Tick-Borne Disease that Causes a Lyme-Like Illness for many Australian Patients".

Recommendation 7

3.58 The committee recommends that the Australian Government Department of Health urgently undertake an epidemiological assessment of the prevalence of suspected tick-borne illness in Australia, the process and findings of which are to be made publicly available.

Recommendation 8

3.59 The committee recommends that the Australian Government Department of Health establish the prevalence and geographical distribution of overseas-acquired Lyme disease in Australia.

The scientific evidence required by Senate Recommendations 7 & 8 may have been obtained through:

a) Examining the tick-borne disease patient pathology data held by the Australian Government's Public Health Laboratory Network (PHLN).
b) A peer reviewed compilation and analysis of the data presented by the 698 public (viewable) submissions from patients submitting to the 2016 Senate Inquiry[10].

In absence of the above, the scientific basis underpinning the DSCATT Clinical Pathway was limited to a literature review (peer reviewed work). Attachment 5 presents an Allen and Clarke document titled "Literature Review to Inform an Evidence-Based Clinical Pathway for DSCATT In Australia". An Excerpt from this document (Excerpt G) discusses epidemiological information.

Excerpt G, Allen and Clark document titled "Literature Review to Inform an Evidence-Based Clinical Pathway for DSCATT In Australia". Full document contained in Attachment 5

Research questions
1. What is the clinical epidemiology of DSCATT in Australia?
Supplementary Questions
What information is available on the prevalence, demographics and geographic distribution of patients experiencing DSCATT in Australia?
What information is available on the symptoms and clinical signs that have been associated with DSCATT as reported by Australian patients and treating physicians?

[10] Note that 1289 Submissions were received, some of which were private from patients and others which were from treating medical practitioners.

It was not within the scope of the DSCATT Clinical Pathway Contract to scientifically validate the 698[11] public patient submissions to the 2016 Senate Inquiry. Refer to Excerpt H containing Page 2 of Document 27 released under FOI 3510[12] These submissions did contain valuable scientific evidence including pathology, but were not integrated into DSCATT Clinical Pathway. This document shows that the scientific review processes to inform the DSCATT Clinical Pathway classified the 2016 Senate Inquiry practitioner data as 'anecdotal' and patient data as 'self-reported'. Patient pathology results, like all pathology results, are open to interpretation but are scientifically valid.

Excerpt H – Page 2 of Document 27 released under FOI 3510 (DOH comments in the last column)

More rigour about the hierarchy of evidence would be valuable – for example, statements and self-reported information from the senate enquiry must still meet the same criteria for inclusion as all other evidence.	We have done the quality review of papers but this hasn't been articulated in the working draft of literature review yet. The Senate Inquiry reports were provided as key documents which were to be used to inform the development of the Clinical Pathway (irrespective of their quality). As grey literature the reports will be assessed using AACODS. However, within those reports all of the evidence presented to the Inquiry about symptoms and co-morbidities was by patients and was self-reported or was anecdotal evidence from Lyme literate doctors.	We will assess the Senate Inquiry reports using AACODS as stated in the ToR, however, within those reports as much of the evidence presented to the Inquiry was by patients and was self-reported. It would be really helpful to discuss the inclusion/exclusion of information from the Senate Inquiry/DSCATT Forum reports given that these documents are key documents. Also how we respectfully acknowledge the self-reported and anecdotal evidence provided by patients and patient advocacy groups to the Senate Inquiry (where it is the only information available, while also acknowledging the level of evidence	Senate Inquiry documents should be used to *inform* the work (as stated in the ToR). The methodology of the review needs to clearly articulate a hierarchy of sources, for example the WHO>> Australian Government guidelines>> published peer-reviewed reports in reputable journals. Any grey literature should be explored for reference to black literature (e.g. published peer-reviewed references) and only the black literature cited.

The public health laboratory network (PHLN) was not listed as a stakeholder to the DSCATT Clinical Pathway in the Contract documents, however, was listed as a stakeholder in an information release under FOI 1421 by the Department of Health 11/09/2024 (Attachment 3). The extent of involvement of the PHLN in the DSCATT process is unknown. It was not within the scope of the DSCATT Clinical Pathway contract to examine the PHLN data.

The PHLN data and the 2016 patient data represent the only sources of patient data that could have been obtained to satisfy Recommendations 7 & 8 of the 2016 Senate Inquiry. Is exclusion of this information a reasonable or fair way to inform the treatment of Australians? In absence of the PHLN and 2016 patient data, does the DSCATT Clinical Pathway meet the Contract specified requirement for an "evidence based clinical pathway" (Excerpt D). If the PHLN and the 2016 data had been examined, would the evidence base have been robust as to satisfy the NHMRC standards for a clinical guideline?

Many patients and medical professionals invested significant resources to contribute to patient forums and submitted scientific evidence of infection to the senate evidence to inform future treatment processes. Patient evidence is highly significant as Australian medical Authorities deny the existence of locally acquired Lyme Borreliosis. Patients have, out of necessity, researched, obtained proof of infection and have undertaken many modalities of treatments. There are highly credentialled patients in Australia. By virtue of lived experience, patients form the top tier of expertise, and the consultation should have reflected this.

[11] Brown, J. D. A description of 'Australian Lyme disease' epidemiology and impact: an analysis of submissions to an Australian senate inquiry. *Intern Med J* **2018**, *48* (4), 422-426. DOI: 10.1111/imj.13746 https://onlinelibrary.wiley.com/doi/10.1111/imj.13746

[12] https://www.health.gov.au/sites/default/files/documents/2022/07/foi-3510-release-documents-documents-relating-to-dscatt.pdf

The scientific evidence underpinning the DSCATT Clinical pathway is limited to a literature review, this represents a continuation of the previous evidence base which was unable to assist patients and could not adequately inform patient care decisions. The absence of epidemiological studies may constitute a scientific procedural injustice by the government.

5.2 Financial Interests of the Contractor Impeding Document Access

The DSCATT Clinical Pathway Literature Review was not shared with patient stakeholders before finalisation. It is unclear if other stakeholders were given an opportunity to comment. In email dated 16/05/2019, Allen and Clark Project Lead for the DSCATT Clinical Pathway promised that stakeholders would be released the Terms of Reference for the Literature Review, and the Literature Review (refer Excerpt I). These documents were not provided.

Excerpt I - Email 16/05/2019 to patient stakeholders from the Allen and Clark Project Lead for the DSCATT Clinical Pathway:

The Powerpoint presentation from last Wednesday, and a list of the attendees, is attached. The Literature Review document inclusion/exclusion list is still being finalised as part of ongoing work on the literature review. We will share this and the Terms of Reference for the Literature Review with you in future.

The Draft Literature Review was requested in FOI 1677 and refused by the DOH in its Decision Notice. The DOH cited Section 47G for the Freedom of Information Act (1982) - disclosure of information could unreasonably and adversely affect the business affairs of third parties. (Excerpt J). The third party being affected was Allen and Clarke, the Government Contractor responsible for preparing the Draft Literature Review for the DSCATT Clinical Pathway. All correspondence relating to FOI 1677 can be provided to the Senate committee upon request.

The DSCATT Literature review Working Draft 31st May 2019 formed the basis of the scientific review underpinning a treatment pathway for Australians. It should not be open to financial interests, accordingly the financial motive behind the DOH refusal to provide this document and its reasonableness warrant investigation.

Excerpt J - Decision Notice FOI 1677 (12/05/2020)

Section 47G - Business affairs

Section 47G(l)(a) of the FOI Act permits conditional exemption of documents containing information concerning the business, commercial or financial affairs of an organisation if disclosure would or could reasonably be expected to unreasonably affect that organisation in respect of its lawful business, commercial or financial affairs.

I have decided the documents indicated in the Schedule at Attachment A consists of a draft literature review produced in conjunction with a third party. The documents therefore contain information in relation to the business affairs of third parties. The literature review draft, contains information of a commercial value that, if released prior to formal publication could reasonably be expected to be diminished.

Providing you with access to the identified documents would involve the disclosure of information which could unreasonably and adversely affect the business affairs of third parties. Disclosure would reveal specific commercial information about Allen & Clarke. It would also disclose significant intellectual property of the third parties and most likely lead to significant commercial disadvantage and heavy financial loss to a third party. Disclosure would also likely lead to seriously damaging the relationship between the third party and the department. Furthermore, I am satisfied the information in the identified documents is not publicly available.

Accordingly, I am satisfied that document 1 is conditionally exempt in full, under section 47G(l)(a) of the FOI Act.

5.3 DSCATT Clinical Pathway Acceptance by the Majority of Stakeholders

The DSCATT Clinical Pathway was required to be accepted by the majority of key stakeholders and endorsed by the AHMAC (Excerpt K). Key Stakeholders are listed in Excerpt D, Section 3 .0 of this Submission.

Excerpt K - Page 7 of Federal Government Contract (Health/18-19/04745), released under FOI 1421

Phase 3: Develop Clinical Pathway and Multidisciplinary Care Model (the Clinical Pathway) (June 2019 – February 2020)

Informed by the outcomes of Phases 1 and 2, the supplier will develop a Clinical Pathway and continue to consult with the Customer and Key Stakeholders through its drafting process to develop a Clinical Pathway that is fit for purpose and acceptable to the majority of Key Stakeholders for endorsement by AHMAC.

No documentation showing proof of majority key stakeholder approval has been made public to date. The list of stakeholders involved in the Clinical Pathway process (Attachment 4) was not made available until (11/09/2024), under (FOI 1421/MR20/00289). This list is not wholly consistent with the key stakeholders listed in the Contract (Attachment 3) which was disclosed under MR20/00289 on December 24 2024.

6.0 Actionable Items for the Senate Committee

General

1) Lyme Australia Recognition and Awareness requests the Senate initiate a Royal Commission to address the continuing failure of the Australian Healthcare system with respect to treatment of patients with tick borne infection.

Pertaining to Section 3.0 DSCATT Clinical Pathway – Practitioner Compliance

2) Investigate why the fit of the clinical pathway into the health care system, including the enforceability requirements and compliance requirements of the pathway were not clarified by the DOH prior to the DSCATT Clinical pathway development or publication and make this information publicly available.
3) Establish the reasons why the DSCATT Clinical Pathway practitioner compliance requirements have not been clearly communicated in the DSCATT Clinical pathway and on the DOHAC Webpage and make this information publicly available.
4) Ensure that DSCATT Clinical Pathway practitioner compliance requirements are placed on the DOHAC Webpage and in the Clinical Pathway.
5) Obtain copies of documents issued by the Department of Health to medical professionals, professional groups, colleges, public health laboratories, and hospitals regarding the DSCATT Clinical Pathway (including practitioner compliance) and make this information publicly available.

Pertaining to Section 4.0 Clinical Pathway vs Guideline

6) Obtain explanation as to the why a Clinical Pathway was specified by the DOH Approach to Market and Contract, in preference to a Clinical Guideline and make this information publicly available.
7) Obtain the advice provided by the National Health and Medical Research Council's in relation to the use of a Clinical Pathway and make this information publicly available.
8) Define the nature of involvement of the NHMRC in the DSCATT Clinical Pathway Project and make this information publicly available.

Pertaining to Section 5.0 Freedom of Information Requests

9) Investigate the delays associated with FOI 3510 MR22/01331(>3yrs) and FOI1421 MR20/00289 (>5 yrs) and if possible, expedite these matters.
Note that the Decision notice for MR20/00289[13] (FOI 1421), Clause 18 (below) reveals the Communicable Disease Policy Branch is the area within the DOHAC that is responsible for making decisions regarding FOI 1421. The Communicable Diseases Policy Branch is not a listed Stakeholder to the DSCATT Pathway processes. This is unusual as the DOHAC position is that Lyme borreliosis is not endemic in Australia.

> 18. The searches evidence comprises a confidential annexure containing detailed information in relation to the searches undertaken and a File Note signed by the Director of Communicable Disease and Stakeholder Engagement Services, dated 11 December 2019. This evidence reveals that the Communicable Diseases Policy Branch was the area of the Department which conducted searches to inform its original decision.

Pertaining to Section 5.1 DSCATT Clinical Pathway – Omission of Epidemiological and Patient Data

10) Investigate why Recommendations 7 & 8, of the 2016 Senate Inquiry Report were not undertaken and make this information publicly available.
11) Investigate why the Public Health Laboratory Network data pertaining to tick borne infections has not been utilised in to inform the DSCATT Clinical Pathway and make this information publicly available.
12) Obtain the Public Health Laboratory Network data pertaining to tick borne infections and make this data publicly accessible.
13) Investigate why the publicly available 2016 Senate Inquiry Patient submissions were not utilised to inform the DSCATT Clinical Pathway. Identify how this may occur.

Pertaining to Section 5.2 Financial Interests of the Contractor Impeding Document Access

14) Investigate the nature of the financial interest that impeded the release of the Draft Literature Review (FOI 1677) and its reasonableness.
15) Determine how this situation can be avoided in future contracts.

Pertaining to Section 5.3 DSCATT Clinical Pathway Acceptance by the Majority of Stakeholders

16) Obtain documentation verifying the DSCATT Clinical Pathway was accepted by the majority of key stakeholders and received Australian Health Minister's Advisory Council endorsement. Make this evidence publicly available.

[13] https://www8.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/AICmr/2024/255.html

7.0 List of Attachments

Attachment 1

- Letters to/from LARA expressing rejection of the DSCATT Clinical Pathway

Date	To	From	Description
25/11/2019	Allen and Clarke Project Leader DSCATT Clinical Pathway Robyn Haisman-Welsh	LARA	Letter advising DSCATT stakeholder consultation processes are inadequate. Rejects the final draft clinical pathway citing non-compliance with NHMRC requirements for guidelines, scientific inadequacy, impacts on patient access to diagnostic testing and treatment of nearly any modality.
26/11/2019	Federal Health Minister, Greg Hunt and Senator Jacquie Lambie	LARA	Letter providing correspondence dated 25/11/2019 to Allen and Clarke and a copy of the Draft DSCATT Clinical Pathway and timetable.
14/01/2020	Allen and Clarke Project Leader DSCATT Clinical Pathway Robyn Haisman-Welsh	LARA	Discussed inadequacy of stakeholder consultation process for DSCATT.
24/01/2020	Allen and Clarke Project Leader DSCATT Clinical Pathway Robyn Haisman-Welsh	LARA	Letter outlined concerns the clinical pathway was a continuation of the 'no lyme' dogma in Australia. Reiterated that relying on pathology was flawed and the pathway was rejected. Provided references to previous technical research circ. 2012 onwards.
29/01/2020	Federal Health Minister, Greg Hunt	Patient Collaborative (15 patient groups)	Letter rejected DSCATT Clinical pathway and was signed by 15 patient groups. This letter also endorsed a letter sent by a further three patient groups rejecting the pathway. Requested moratorium on DSCATT Clinical pathway until all stakeholders were consulted and a risk assessment was undertaken. Provides list of queries regarding pathway fit within the healthcare system and practitioner compliance requirements.
23/04/2020	LARA Distributed to Patient collaborative (15 patient groups)	DOH Health Protection Policy Branch Assistant Secretary	Responded to letter dated 29/01/2020, refused moratorium / extensions. Directs questions regarding pathway fit within the healthcare system and practitioner compliance requirements to the Australian Commission on Safety and Quality in Health Care.

Attachment 2

- Letters to/from Greg Hunt, Federal Health Minister from MP Darren Chester regarding DSCATT Clinical Pathway compliance requirements.

Date	To	From	Description
25/11/2019	Darren Chester Federal MP for Gippsland	(name redacted)	Letter seeking DSCATT Clinical Pathway clarification
21/05/2020	(name redacted)	Darren Chester Federal MP for Gippsland	Response from Federal Health Minister Greg Hunt and , Assistant Secretary, Health Protection Policy Brance

Attachment 3

- Contract between the DOH and Allen and Clarke Policy and Regulatory Specialists Ltd (Reference ID Health/18-19/04745) for the development of the DSCATT clinical pathway (refer to Excerpt C).

Attachment 4

- DSCATT Clinical Pathway Consultation Stakeholder List as provided through FOI 1421 on the 16/01/2025.

Attachment 5

- Document titled "Literature review to inform an evidence-based clinical pathway for DSCATT in Australia"