Stakeholder Engagement Strategy

Supporting consultation on developing a clinical pathway and multidisciplinary care model for Australian patients suffering from debilitating symptom complexes attributed to ticks (DSCATT)

26 March 2019

ALLEN+CLARKE

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1. INTRODUCTION

1.1. Purpose

This Stakeholder Engagement Strategy (the Strategy) will support and facilitate engagement and consultation with stakeholders to inform the development of an evidence-based clinical pathway and multidisciplinary care model (the Clinical Pathway) for patients experiencing debilitating symptom complexes attributed to ticks (DSCATT). The Department of Health (the Department) has engaged *Allen + Clarke*) to develop the Clinical Pathway in consultation with relevant stakeholders, including medical professionals, government health authorities and patient groups.

The purpose of stakeholder consultation is to ensure the Clinical Pathway is fit for purpose and acceptable to the majority of stakeholders and can be endorsed by the Australian Health Ministers' Advisory Council (AHMAC) and its subcommittees, the Australian Health Protection Principal Committee (AHPPC) and Clinical Principal Committee (CPC). Consultation will ensure the Clinical Pathway can be flexibly applied in both the private and public healthcare settings.

This Strategy outlines the reasons for engagement, identifies relevant stakeholders (Key Stakeholders), describes the processes for engagement, and articulates timeframes and methods of engagement.

1.2. Context

There is a group of Australian patients suffering from the symptoms of a chronic debilitating illness, which many associate with a tick bite. The Australian Government has chosen to describe this patient group as having Debilitating Symptom Complexes Attributed to Ticks (DSCATT). This term was carefully considered to appropriately acknowledge this patient group and the multifaceted illness they are experiencing, whilst moving away from the stigma and controversy associated with the use of "Lyme Disease", "Lyme disease-like Illness" and "Chronic Lyme Disease" that has previously been used to describe this patient group.

Many patients experiencing debilitating symptom complexes are living in turmoil as their illness is poorly understood, making accurate diagnosis and treatment difficult. It is imperative for government health authorities, clinicians and patients to be open minded as to the causes of these symptoms and work together to achieve a patient-centred multidisciplinary approach to care.

In addition, overseas travellers to Lyme-endemic areas may return to Australia before becoming symptomatic and/or being diagnosed. In Australia, Lyme disease should be considered in patients presenting with a travel history to Lyme-endemic areas along with supporting symptoms and/or a known tick bite. However, due to the controversy and stigma attached to Lyme disease in Australia some patients have also not received an appropriate assessment of their symptoms.

The Clinical Pathway will contribute to fulfilling the Australian Government's response to Recommendation 5 of the Senate Community Affairs References Committee Final Report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients,* where the Australian Government agreed to consult with key stakeholder groups to develop a cooperative multidisciplinary framework which can accommodate patient and medical needs. The development of the Clinical Pathway will build on the consultation about the concept of multidisciplinary care undertaken through consultation forums with medical professionals, state and territory health authorities and patient groups in April and July 2018.

2. IDENTIFICATION OF STAKEHOLDERS

2.1. Key Stakeholders

Table 1 shows an indicative list of Key Stakeholders, capturing attendees at both 2018 DSCATT Forums and other stakeholders identified by the Department as important to the development of the Clinical Pathway. This is a 'living' list, acknowledging that the consultation process will be inclusive, with individuals and their carers, or other groups not identified in Table 1, able to participate.

Table 1: Indicative list of 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* Public Health Laboratory Network	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 Physiotherapy Association Australian Psychological Society Australian Primary Health Care Nurses Association (APNA) Australasian Society for Infectious Diseases (ASID) 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)	Lyme Australia and Friends Group (Facebook Group)* **ACT** Canberra Area Lyme disease support group* Consumers Health Forum of Australia (CHF) **NSW** Australian Chronic Infectious & Inflammatory Disease Society (ACIIDS)* Hunter Region MDIDS* Karl McManus Foundation (KMF)* Lyme Disease Association Australia (LDAA)* NSW Far South Coast Lyme group* NSW Riverina Lyme support group* Sarcoidosis Lyme Australia* **QLD** Global Lyme and Invisible Illness Organisation (GLiIO)* Gold Coast Lyme group* Lyme Australia: Recognition and Awareness (LARA)* **VIC** Emerge Australia Tickborne Illness Community Network Australia (TICNA)* Vic Lyme Support *

Government	Medical Professionals	Patient Groups
	Dr Richard Schloeffel, LLMD, Pymble Grove Medical Centre; Member of the Scientific Advisory Committee of the LDAA* Professor M. Lindsay Grayson, Austin Health* Dr Armin Schwarzbach, CEO of Armin Labs; Member of the German Borreliosis Society **Relevant Private Health Sector stakeholders:** Private Healthcare Australia (PHA)	**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* Southwest Coastal MSIDS Support Group (WA)* **Other** Relevant ME/CFS, emerging biotoxins, or other similar disease patient groups.

*Attended 2018 April or July Forums

2.2. Other interested stakeholders

There may be other individuals and groups interested in the development of the Clinical Pathway. Our default approach is to be inclusive of those who wish to participate in meetings and contribute ideas, noting that we are operating within resource and time constraints.

3. ENGAGEMENT APPROACH

This section outlines and describes the points at which *Allen + Clarke* will engage with Key Stakeholders during the development of the Clinical Pathway, how this engagement will occur and the principles that will underpin engagement.

Allen + Clarke will consult with Key Stakeholders in two phases of the project:

1. Via a Think Tank in May 2019 to discuss similarities and future support pathways and to inform the development of the Clinical Pathway. We will then consult with Key Stakeholders who participated in the Think Tank on the Draft Think Tank Report, prior to submitting the Think Tank Report to the Department on 24 May 2019.
2. Via face-to-face and virtual interviews during July and August 2019 to further develop the Draft Clinical Pathway and ensure it is fit for purpose and acceptable to the majority of Key Stakeholders, including AHMAC, AHPPC and CPC (i.e. acceptable to, at a minimum, all State and Territory Health Authorities).

3.1. Principles of engagement

For all individuals and groups of Key Stakeholders, engagement will be undertaken according to the following principles. Participation in the consultation process will be voluntary.

- *Inclusiveness*: Everyone (within reason) who would like to contribute should be able to do so.
- *Receptiveness*: Being open to the contributions made by participants and giving them due consideration in the outcome of the process.
- *Reciprocity*: Being clear about what Key Stakeholders are being offered, including the benefit to them of engagement.
- *Respect*: All participants and their contributions are treated with sensitivity and respect throughout the engagement process.
- *Timeliness*: Key Stakeholders should be given sufficient time to provide considered responses, recognising that time for consultation has to be balanced with timeframes for *Allen + Clarke* to draft, finalise and submit required reports to the Department.
- *Transparency*: The objectives, process and outcomes of the engagement should be clearly explained to participants.

3.2. Stakeholder engagement via the Think Tank

3.2.1. An accessible, central venue

The Think Tank will be held at the Rydges Hotel, Sydney International Airport on 8 May 2019. The Think Tank will be a face-to-face meeting with remote access options for patient stakeholder groups and other invitees who cannot attend in person. The venue will enable breakout sessions. The venue will have full disability access and facilities and will cater for participants with specific dietary requirements.

Prior to the Think Tank *Allen + Clarke* will, in addition to the approved Think Tank materials, circulate to invitees and confirmed participants any specific additional reasonable requests from participants that can increase their level of comfort and ability to participate, such as other participants not wearing perfumes /aftershaves.

3.2.2. Advance notification of the Think Tank

To maximise attendance and participation at the Think Tank, *Allen + Clarke* will approach identified Key Stakeholders by email in the week beginning 25 March 2019 to ensure stakeholders are aware of the Think Tank as early as possible and to provide as much time as possible for stakeholders to arrange attendance at the Think Tank. In this email, we will:

- provide information about the purpose, background, consultation phases and the intended dates, the anticipated time commitment and intended output of the consultation;
- invite Key Stakeholders to the Think Tank, and the subsequent consultation during the development of the Clinical Pathway; and
- advise that as all relevant and interested government, medical professional and patient stakeholder groups will be invited to the Think Tank, we respectfully request that to keep numbers manageable, only one representative attends the face-to-face meeting in Sydney from each stakeholder group (whereas there will be no limit on stakeholders teleconferencing in to the Think Tank).

The emails will be customised to each organisation. For Key Stakeholders in organisations listed in Table 1 that did not attend the 2018 Forums, email contacts will be sourced from the relevant organisation's website. The emails will be approved by the Department along with all other materials sent to Key Stakeholders.

We will send a thank you email to all Key Stakeholders who respond. We will follow up by email with any Key Stakeholder who has not responded within seven days.

3.2.3. Plenary and interactive sessions

The Think Tank will be primarily facilitated by the Project Sponsor with the Project Lead, Lead Analyst, Project Manager, Expert Medical Technical Advisor and the Expert Guidelines Technical Advisor leading specific sessions. To maximise opportunities for engagement, we will use a mix of techniques including small group discussions, plenary sessions and activities such as brainstorming and prioritisation exercises. The discussions will be facilitated to ensure space for less forthright members to voice their opinions.

3.2.4. Think Tank follow up

At the conclusion of the Think Tank we will thank attendees and acknowledge their valuable input into the discussions. We will advise attendees of the process for Key Stakeholder feedback into the Draft Think Tank Report. Specifically, any stakeholder whose input is attributed to them will have the opportunity to check the wording to ensure that they are comfortable with how their views are presented. We will email those specific stakeholders with the information to be attributed to them on 15 May 2019 with the request that stakeholder feedback be sent via email by 20 May 2019 for finalisation of the Think Tank Report by 24 May 2019. We will acknowledge the short time for Key Stakeholder feedback on this report.

We will also update attendees on the next steps in the consultation process during development of the Clinical Pathway. This will include dates for face-to-face meetings in Sydney, Melbourne, Canberra, Perth and Brisbane, and the process we will use to arrange virtual interviews and focus groups with all other Key Stakeholders who wish to participate.

3.3. Stakeholder consultation during Clinical Pathway development

After the Department has approved the Draft Clinical Pathway for consultation, *Allen + Clarke* will re-engage with Key Stakeholders. We will use a variety of methods to enable Key Stakeholders to participate in the consultation on the Draft Clinical Pathway in ways that are accessible and convenient for them.

This will involve face-to-face meetings with Key Stakeholders in four cities where several Key Stakeholder organisations or groups are physically located (Melbourne, Sydney, Canberra, Perth and Brisbane), as well as written and telephone/virtual-based engagement methods with stakeholders outside these centres including government, professional and consumer representatives.

3.3.1. Advance notification of consultation on the Draft Clinical Pathway

We intend to consult with Key Stakeholders throughout July and August 2019, with the Project Lead, Lead Analyst, Expert Medical Technical Advisor and the Expert Guidelines Technical Advisor participating in face-to-face and virtual consultations.

In early June 2019 we will contact via email all of the Key Stakeholders in Table 1 (whether or not they attended the Think Tank) and any other Key Stakeholders who have been added to the initial list, to invite them to participate in the consultation process on the development of the Clinical Pathway. The email, including information on the dates, time commitment and process, and any accompanying material, will be approved by the Department. An example email is in Appendix 1.

We will send via email at least one week in advance of any meetings the Draft Clinical Pathway and any accompanying material including a list of discussion items, to enable Key Stakeholders to prepare for the meeting. All material will be agreed with the Department prior to circulation.

3.3.2. Face-to-face consultation meetings: Melbourne, Sydney, Canberra, Perth and Brisbane

A number of Key Stakeholders are located in Melbourne, Sydney, Canberra, Perth and Brisbane (see Table 2).

We will notify Key Stakeholders located in these cities at the earliest possible time (estimated early June) via email of the confirmed dates that the *Allen + Clarke* project team (Project Lead, Lead Analyst, Expert Medical Technical Advisor, Expert Guidelines Technical Advisor) will be in these cities. Key Stakeholders who agree to participate will be followed up with a confirmation email to thank them for their intended participation and to arrange a mutually agreeable time to undertake the consultation interview.

Rather than asking Key Stakeholders to travel to a venue of our choosing and have the additional time commitment and cost of travel, we will offer to travel to the Key Stakeholder's work premises and ask to hold the interview at their work premises, or at a location of their choosing.

Table 2: Key Stakeholders located in jurisdictions of face-to-face consultation meetings

Key Stakeholders in Melbourne	Key Stakeholders in Sydney	Key Stakeholders in Canberra	Key Stakeholders in Perth	Key Stakeholders in Brisbane
Victoria Health Royal Australian and New Zealand College of Psychiatrists (RANZCP) Australasian College for Emergency Medicine (ACEM) Therapeutic Guidelines Limited Australian Primary Health Care Nurses Association	NSW Health Royal Australasian College of Physicians (RACP) Royal College of Pathologists of Australasia (RCPA) Royal Australian College of General Practitioners (RACGP) Karl McManus Foundation (KMF) Australian Chronic Infectious & Inflammatory	Representatives from the Commonwealth, State and Territory Government Health Departments, through the: • Australian Health Ministers' Advisory Council (AHMAC) • Australian Health Protection Principal Committee (AHPPC)	WA Health Chrysalis Lyme Disease Support Group Perth ME/CFS and Lyme Association of WA, Inc. Kojonup Lyme Supporters Association Inc Multiple Systemic Infectious Disease Syndrome (MSIDS) Network	Queensland Health LDAA [+others to be agreed with the Department]

Key Stakeholders in Melbourne	Key Stakeholders in Sydney	Key Stakeholders in Canberra	Key Stakeholders in Perth	Key Stakeholders in Brisbane
Professor M. Lindsay Grayson, Austin Health Tickborne Illness Community Network Australia (TICNA) Emerge Australia Australian Physiotherapy Association Australian Psychological Society	Disease Society (ACIIDS) Lyme Disease Association Australia (LDAA) Sarcoidosis Lyme Australia	• Clinical Principal Committee (CPC) National Health and Medical Research Council (NHMRC) Public Health Laboratory Network Therapeutic Goods Administration (TGA) ACT Health Australian Medical Association (AMA) Australian College of Nursing Consumers Health Forum of Australia (CHF) Relevant Private Health sector stakeholders: • Private Healthcare Australia (PHA)		

We envisage each consultation interview or focus group will last 60 – 90 minutes. We anticipate undertaking at least six face-to-face interviews over a three-day period in each of the five cities.

Key Stakeholders in these cities who wish to participate in the consultation process but are unable to meet during the dates the *Allen + Clarke* project team are visiting the relevant city, will be given the option of a virtual consultation interview at a mutually agreeable time in July/August 2019, or they will be able to submit their comments via email if they wish by 30 August 2019.

We acknowledge that some of the larger patient Key Stakeholder Groups who have attended the 2018 Forums and do not have physical headquarters (e.g. Australian Chronic Infectious & Inflammatory Disease Society, Lyme Disease Association of Australia) may wish to meet face-to-face for a consultation interview in one of the five cities. We will work with these Key Stakeholders, via email, to organise either a face-to-face meeting in one of the five cities or a virtual consultation meeting, similar to those we will organise for the State and Territory Health

Authority officials, as described below. After the face-to face interview or feedback via email, *Allen + Clarke* will send an email to the organisation's representative(s) who took part in the consultation thanking them for their participation and input.

3.3.3. Virtual consultation with NT Health, SA Health and Tasmania Health

To ensure a consistent approach to consultation with the State and Territory Health Authorities the *Allen + Clarke* project team will not be travelling to, we will invite officials from NT Health, SA Health and Tasmania Health to either travel to meet us for face-to-face interviews in Brisbane, Melbourne or Sydney (at their cost) or to participate in virtual interviews with the *Allen + Clarke* project team (Project Lead, Lead Analyst, Expert Medical Technical Advisor, Expert Guidelines Technical Advisor).

We will work with the State and Territory Health Authority officials via email from early June 2019 to organise a mutually agreeable time for the consultation interview, in July/August 2019. As with the face-to-face interviews, we anticipate the consultation interviews with State and Territory Health Authority officials will take 60 – 90 minutes. We will use Zoom or another similar technology to undertake the virtual consultation interviews. Once the consultation interview time has been agreed, *Allen + Clarke* will send a formal invite, via email, to the virtual interview along with any pre-approved accompanying material.

If State and Territory Health Authority officials are unable to or not comfortable to participate in the virtual consultation interview, they will be able to submit their comments via email if they wish by 30 August 2019.

After the interview or feedback via email, *Allen + Clarke* will send an email to the State and Territory Health Authority officials who took part in the consultation thanking them for their participation and input.

3.3.4. Virtual consultation with patient groups

We will contact the patient stakeholder groups via email in June 2019 (date to be agreed with the Department following our meeting on 4 June 2019) to invite them to participate in virtual consultation focus groups in July/August 2019. To maximise this group of Key Stakeholders to participate in the consultation on the development of the Clinical Pathway we will offer six dates and times in July/August 2019. We will ask Key Stakeholders to rank the dates in order of preference using the meeting schedule tool Doodle Poll. The four sessions most commonly sought will be conducted as group consultations, with *Allen + Clarke* allocating participants across the four sessions according to the preferred timing indicated by each participant.

We anticipate the group consultation interviews with patient Key Stakeholder groups will take 60 – 90 minutes. We will use Zoom or another similar technology to undertake the virtual consultation group interviews. Once the consultation group interview dates and times have been decided, *Allen + Clarke* will send a formal invite, via email, to the virtual group interview participants along with any pre-approved accompanying material.

Participants will be informed that they can withdraw while the discussion is taking place at any time. The discussion will be facilitated to ensure space for less forthright members to voice their opinions. Due to the potential for some focus group members to become distressed during or after the focus group discussion, a list of potential sources of support (to be approved by the Department) will be provided to patient Key Stakeholder group participants, should they wish to seek support following the group discussion.

If patient Key Stakeholder groups and their representatives are unable to or not comfortable to participate in the virtual group consultation interviews, they will be able to submit their comments via email if they wish by 30 August 2019.

After the patient Key Stakeholder group consultation interviews or feedback via email, *Allen + Clarke* will send an email to the Key Stakeholders who took part in the consultation thanking them for their participation and input.

3.4. Out of scope communication

We assume the Department will be responsible for notifying all stakeholders of the publication of the Think Tank Report, Stakeholder Consultation Report and the Final Clinical Pathway.

We assume all website posts updating stakeholders on progress will be managed by the Department.

We will refer to the Department any ad hoc requests from stakeholders for updates or further information relating to DSCATT or the Clinical Pathway development that is beyond the operational organisation of stakeholder engagement for the Think Tank and the development of the Clinical Pathway.

We will agree a nominated Department contact for escalating queries.

4. RISKS

There are a number of risks to consider and manage throughout consultation on the Clinical Pathway.

Table 3: DSCATT Clinical Pathway risk identification and mitigation strategies

Risk	Probability	Impact	How this risk will be mitigated
Phase 2: Think Tank			
Key Stakeholders do not hear about the Think Tank until it is too late for them to participate.	Low	High	• The Department approves the Stakeholder Engagement Strategy to ensure clarity around the timing of messages. • Invitations to Key Stakeholders are sent out in the week beginning 25 March 2019, giving stakeholders six weeks' notice of the Think Tank.
Difficulty engaging with or contacting stakeholders to ensure quality consultation. For example, availability, relative priority for stakeholders.	Medium	High	• The Department approves the Stakeholder Engagement Strategy to ensure clarity around the and content of messages. • Stakeholders will be provided with a clear explanation of the project and how their contribution may affect the outcome. To maximise participation, any invited Key Stakeholders who have not replied to the invitation email after seven days will be followed up by email. • Ensure the invitations include the opportunity for the named individual or another representative from the organisation to attend the Think Tank. • Advise Key Stakeholders there will video-conferencing available for invites who cannot attend in person.
Some Key Stakeholders are not able to participate in the Think Tank and miss the opportunity to provide their input. This reduces the robustness of the information provided to the Department, and there is the risk it will undermine the process more generally if Key Stakeholders do not have confidence in the process.	Medium	Low	• Ensure the invitations include the opportunity for the named individual or another representative from the organisation to attend the Think Tank. • Advise Key Stakeholders there will be video-conferencing available for invitees who cannot attend in person. • Advise Key Stakeholders a report from the Think Tank will be published by the Department soon after the Think Tank to ensure transparency in the process. • Advise Key Stakeholders there will be opportunities for further stakeholder consultation with all Key Stakeholders during the development of the Clinical Pathway.

Key Stakeholders do not feel they have been engaged/consultation at the Think Tank is viewed as 'perfunctory', and they do not have trust in the process.	Medium	Medium	• A mix of techniques including small group discussions, plenary sessions and activities such as brainstorming and prioritisation exercises will be used to maximise stakeholder engagement for Key Stakeholders participating in person or via video-conferencing. • The project team are skilled at hosting consultations/events where participants' opinions are diverse. • All Key Stakeholders participating in the Think Tank will receive a thank you email, and information about next steps including the consultation on the development of the Clinical Pathway.
Patient Key Stakeholders become distressed discussing the impact of living with DSCATT on their lives and wellbeing.	Medium	High	• Our core project team for the Think Tank are experienced in sensitive subjects and will develop and undertake the consultation in a manner that will reduce the possibility of distress for participants. • Additionally, we will agree with the Department on how participants can be best supported and the services they should be referred to should participants require them.
There is pressure to extend the consultation feedback period on the Think Tank Report, placing pressure on all other timelines of the project.	High	High – the stakeholder feedback period is very short (six days) for the expected Key Stakeholder interest	• The process for preparing and finalising the Think Tank report, including the short timeline for Key Stakeholder feedback on the draft Think Tank Report will be clearly outlined to Key Stakeholders in the invitation letter and again at the Think Tank. • Key stakeholders will also be advised of the intended style (similar to the April and July 2019 Department-hosted Forum reports) and level of detail (high-level recommendations only) of the Think Tank Report to cover off stakeholder expectations regarding depth of content to review.
Difficulty of Think Tank discussions balancing personal health experiences and more technical aspects required for the development of a Clinical Pathway.	Low/ Moderate	Low	• The Think Tank discussions will include specific allowance for scientific and technical experts to provide their views on the requirements for the Clinical Pathway, alongside views and advice from consumer groups.

Large volume of Key Stakeholder feedback on the draft Think Tank Report puts pressure on timelines for finalising the Think Tank Report.	High	High	• Additional resources will be made available to ensure that Key Stakeholder feedback is incorporated into the Think Tank within required timeframes. • *Allen + Clarke* will use Survey Monkey and NVivo to manage the Key Stakeholder feedback.
Phase 3: Clinical Pathway Development			
Difficulty engaging with or contacting stakeholders to ensure quality consultation. For example, availability, relative priority for stakeholders.	Low	High	• The Department approves the Stakeholder Engagement Strategy to ensure clarity around the timing and content of messages. Stakeholders will be provided with a clear explanation of the project and how their contribution may affect the outcomes of the project and future decision-making. • Key Stakeholders will be advised in the invitation email to the Think Tank that further stakeholder consultation on the development of the Clinical Pathway will be held during July/August. Key Stakeholders will be advised of likely/confirmed dates for the consultation (face-to-face and virtual consultation) at the Think Tank. • To continue to encourage ongoing participation, Key Stakeholders invited to the Think Tank but who are unable to attend (and do not provide a substitute to represent their organisation) will be emailed to advise them of the opportunity to be involved in consultation on the development of the Clinical Pathway. • Any Key Stakeholders who are not available on the scheduled dates for face-to-face meetings in Melbourne, Sydney, Canberra, Perth and Brisbane will be followed up by email to organise virtual consultations to ensure Key Stakeholders are given every opportunity to participate in the consultation.
Many Key Stakeholders situated in Canberra, Melbourne, Sydney and Perth are not available to meet at the scheduled dates and more virtual consultations have to be arranged impacting on the completion of consultation and delivery of the Draft Clinical Pathway.	Medium	High	• Key Stakeholders will be given advance notice about the proposed face-to-face consultation dates in Melbourne, Sydney, Canberra, Perth and Brisbane being planned for July/August 2019 in the invitation to the Think Tank and at the Think Tank. • All efforts will be made to agree a suitable time for face-to-face consultation. For those stakeholders who are unavailable during the scheduled consultation visits, we will offer up to two alternative virtual consultation appointments. If these times are unacceptable, Key Stakeholders will be able to provide feedback directly to the project team via email.

Participants representing Patient groups become distressed discussing the impact of living with DSCATT, their experiences accessing care previously and their expectations of the Clinical Pathway.	Medium	High	• Our core project team for the consultation during the development of the Clinical Pathway are experienced in sensitive subjects and will develop undertake the focus groups and interviews in a manner that will reduce the possibility of distress for participants • Additionally, we will agree with the Department how participants can be best supported and the services they should be referred to should participants require them.
There is pressure to extend the consultation period, placing pressure on all other timelines of the project.	Medium	High	• Key Stakeholders will be given information about the timeframes for the development of the Clinical Pathway and consultation period early in the project, including advanced notice about the proposed face-to-face consultation dates in Melbourne, Sydney, Canberra, Perth and Brisbane being planned for July/August 2019 in the invitation to the Think Tank and at the Think Tank.
Key Stakeholders located in States and Territories where face-to-face consultation meetings are not being held feel undervalued.	Medium	Medium	• Key Stakeholders will be advised that all Key Stakeholder feedback will be collected face-to-face, whether in the meetings in Melbourne, Sydney, Canberra, Perth or Brisbane, or in the virtual interviews and focus group sessions. • In the Department-hosted Forums on DSCATT in April and July 2018, many Key Stakeholders located in areas outside Sydney or Melbourne participated by video conferencing.

APPENDIX 1: DRAFT EMAIL TO KEY STAKEHOLDERS

From: Robyn Haisman-Welsh

Subject: Invitation to participate in Key Stakeholder consultations to develop a Clinical Pathway for patients suffering from debilitating symptom complexes attributed to ticks (DSCATT)

Dear s47F ,

The Australian Department of Health has commissioned Allen + Clarke, Policy and Regulatory Specialists Limited *(Allen + Clarke)* 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) which can be flexibly applied in both private and public health care settings. I am the Project Lead for the development of the Clinical Pathway.

Allen + Clarke would like to invite you (and/or a representative from the Royal Australian College of General Practitioners, RACGP) to participate in two consultation processes to inform and develop the Clinical Pathway.

The Clinical Pathway will be informed by the relevant literature and key documents and will be developed in consultation with Key Stakeholders, including medical professionals, government health authorities and patient groups. This consultation will ensure the Clinical Pathway is fit for purpose and acceptable to the majority of stakeholders, including endorsement by the Australian Health Ministers' Advisory Council (AHMAC).

The Clinical Pathway will contribute to fulfilling the Australian Government's response to Recommendation 5 of the Senate Community Affairs References Committee Final Report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients,* where the Australian Government agreed to consult with key stakeholder groups to develop a cooperative multidisciplinary framework which can accommodate patient and medical needs. The development of the Clinical Pathway will build on the consultation about the concept of multidisciplinary care previously undertaken through consultation forums with medical professionals, state and territory health authorities and patient groups in April and July 2018.

Consultation via a Think Tank on 8 May 2019 in Sydney

The first consultation with Key Stakeholders will be via a Think Tank at the Rydges Hotel, Sydney International Airport on 8 May 2019. The Think Tank will be a full-day face-to-face meeting with remote access options for patient stakeholder groups and other invitees who cannot attend in person. The purpose of the Think Tank is to discuss similarities and future support pathways to inform the development of the Clinical Pathway.

Consultation during July/August 2019 to further develop the Clinical Pathway

The second consultation with Key Stakeholders will take place in July and August to further develop a Draft Clinical Pathway to ensure it is fit for purpose and acceptable to the majority of Key Stakeholders, including AHMAC. These consultations will be via face-to-face interviews with Key Stakeholders in Sydney, Melbourne, Canberra and Perth, or via virtual interviews with

Key Stakeholders not located in these four cities using videoconferencing/telephone or feedback via email.

We, and the Department, would greatly value you, or a representative of RACGP participating in the upcoming consultations to develop the Clinical Pathway. We acknowledge your and RACGP participation and input at the April forum and would be delighted to have your participation again in these consultations.

To inform our planning, I would be most grateful if you could please let me know if you, or a RACGP representative are able to attend the Think Tank on 8 May, either in person, or remotely, as soon as you are able to.

Thank you, in advance.

Kind regards,

Robyn

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New Zealand

From: s22
To: "Paul Houliston"
Cc: s22
Subject: DSCATT Clinical Pathway [SEC=UNCLASSIFIED]
Date: Friday, 22 February 2019 5:13:33 PM
Attachments: #41 AHPPC - Agenda Paper Template.DOCX
image001.jpg

Hi Paul

Thank you again for meeting with us today.

To follow up from our conversation today:

(a) AHPPC is meeting is on 5 April at Melbourne Airport.

- Agenda Item description: Debilitating Symptom Complexes Attributed to Ticks (DSCATT) – consultation on the project plan for a clinical pathway for this patient group (15 mins). Sharon Appleyard will lead the session but we anticipate A+C to attend in support.
- Agenda Paper template attached.
- The latest date for an agenda paper to be submitted to the AHPPC Secretariat is 21 March and the latest date for the project plan is 29 March 2019. Therefore, the department would need to have a copy 5 working days before these deadlines.

(b) The Think Tank day has tentatively been booked for 8 May 2019 in the CMO, FAS and AS calendars.

(c) The initial project planning meeting is tentatively scheduled for 2.00-4.00pm on 19 March 2019 and is in the CMO, FAS and AS calendars.

(d) Other material as discussed:

- Chronic fatigue syndrome Clinical practice guidelines — 2002 https://www.mja.com.au/system/files/issues/cfs2_2.pdf
- 1995 Lyme Paper by Michelle Wills: https://ogma.newcastle.edu.au/vital/access/manager/Repository/uon:30560
- Minister Hunt's media release for the DSCATT NHMRC TCR: https://nhmrc.gov.au/about-us/news-centre/3-million-tick-bite-medical-research

Also, I had meant to mention today that the UK NICE guidelines are also a good model and appear to be generally acceptable to the patient groups.

We are looking forward to hearing further from you by next Wednesday.

Cheers

s22

s22
Director | Global Health Protection & Environmental Health Coordination
Health Protection Policy Branch | Office of Health Protection
Department of Health | 02 6289 s22 | s22
s22 @health.gov.au

41st Australian Health Protection Principal Committee Meeting

Meeting Date: 5 April 2019

Item Number: Allocated by Secretariat
Sponsor: Start typing here
Speaker: Start typing here

Start typing here – Title of paper

Recommendations

That AHPPC Members:

1. **Start typing here** – Clearly indicate what actions/decisions the author of the paper wish members to take. Recommendations should start with actions such as 'Note', 'Agree' or 'Endorse'. Actions should not be written in all capitals. No more than one action per recommendation.

   Sentence case – Calibri font – Size 14pt, bold – Spacing: Before 0pt, After 6pt

Purpose of Paper

Start typing here – Brief summary of the purpose of the item – one or two sentences.

Sentence case – Calibri font – Size 12pt – Spacing: Before 0pt, After 6pt

Summary of issues for discussion

Start typing here – Provide a brief summary of the key and significant issues.

Sentence case – Calibri font – Size 12pt – Spacing: Before 0pt, After 6pt

Background

Start typing here – Include a brief history of the item and the current status, including any previous considerations by AHPPC. Where applicable, note if the item relates to a priority under the AHPPC Strategic Plan.

Sentence case – Calibri font – Size 12pt – Spacing: Before 0pt, After 6pt

Aboriginal and Torres Strait Islander health impact statement

Start typing here – To help determine the Aboriginal and Torres Strait Islander health impact the following questions should be considered. If relevant, any impact on Aboriginal and Torres Strait Islander health should be discussed throughout the paper, and not confined to this section.

1. Does the project align with any other specific Aboriginal and Torres Strait Islander initiatives?
2. Will the project have an impact on Aboriginal and Torres Strait Islander people?
3. Have Aboriginal and Torres Strait Islander people been engaged and will they continue to be?

Sentence case – Calibri font – Size 12pt – Spacing: Before 0pt, After 6pt

Attachments

Attachment 1: Start typing here – Attachments should be numbered in the order they appear in the paper. If there are no attachments state 'Nil'. Please supply attachments in a separate document to this paper. Attachments should be labelled as *#41 Item X – Attachment A*.

Attachment 2: Start typing here – Attachments should be numbered in the order they appear in the paper

NOTE: Agenda papers should not exceed two pages. Please use attachments if necessary.

Contact information

Branch/Jurisdiction/Standing Committee:	Start typing here
Contact person:	Start typing here – AS, Chair, Secretariat or AHPCC member (please indicate titles)
Phone:	Start typing here
Email:	Start typing here
Cleared by:	Start typing here – Areas should seek AS clearance before providing the paper to the AHPPC Secretariat. Standing Committee papers should be cleared by the Chair of the Standing Committee. Jurisdictional papers should be cleared by the jurisdictional member
Date:	Start typing here – Please insert the date you received AS / Standing Committee Chair/ AHPPC member clearance

Stakeholder Engagement Strategy

Supporting consultation on developing a clinical pathway and multidisciplinary care model for Australian patients suffering from debilitating symptom complexes attributed to ticks (DSCATT)

15 March 2019 [Draft]

ALLEN+CLARKE

NOTES

This strategy is a draft for comment. We appreciate your feedback on the proposed approach.

Document status:	Draft for comment
Version and date:	V0.6
Author(s):	Dr Robyn Haisman-Welsh
Filing Location:	DSCATT Clinical Pathway/Deliverables/Stakeholder Engagement Strategy
Peer / technical review:	s47F
Verification that QA changes made:	Dr Robyn Haisman-Welsh
Proof read:	s47F
Formatting:	s47F
Final QA check and approved for release:	Paul Houliston, Project Sponsor

Allen + Clarke has been independently certified as compliant with ISO9001:2015 Quality Management Systems

Telarc. Registered TM
Quality ISO 9001

CONTENTS

1. INTRODUCTION

1.1. Purpose

This Stakeholder Engagement Strategy (the Strategy) will support and facilitate engagement and consultation with stakeholders to inform the development of an evidence-based clinical pathway and multidisciplinary care model (the Clinical Pathway) for patients experiencing debilitating symptom complexes attributed to ticks (DSCATT). The Department of Health (the Department) has engaged *Allen + Clarke* to develop the Clinical Pathway in consultation with relevant stakeholders, including medical professionals, government health authorities and patient groups.

The purpose of stakeholder consultation is to ensure the Clinical Pathway is fit for purpose and acceptable to the majority of stakeholders and can be endorsed by the Australian Health Ministers' Advisory Council (AHMAC) and its subcommittees, the Australian Health Protection Principal Committee (AHPPC) and Clinical Principal Committee (CPC). Consultation will ensure the Clinical Pathway can be flexibly applied in both the private and public healthcare settings.

This Strategy outlines the reasons for engagement, identifies relevant stakeholders (Key Stakeholders), describes the processes for engagement, and articulates timeframes and methods of engagement.

1.2. Context

There is a group of Australian patients suffering from the symptoms of a chronic debilitating illness, which many associate with a tick bite. The Australian Government has chosen to describe this patient group as having Debilitating Symptom Complexes Attributed to Ticks (DSCATT). This term was carefully considered to appropriately acknowledge this patient group and the multifaceted illness they are experiencing, whilst moving away from the stigma and controversy associated with the use of "Lyme Disease", "Lyme disease-like Illness" and "Chronic Lyme Disease" that has previously been used to describe this patient group.

Many patients experiencing debilitating symptom complexes are living in turmoil as their illness is poorly understood, making accurate diagnosis and treatment difficult. It is imperative for government health authorities, clinicians and patients to be open minded as to the causes of these symptoms and work together to achieve a patient-centred multidisciplinary approach to care.

In addition, overseas travellers to Lyme-endemic areas may return to Australia before becoming symptomatic and/or being diagnosed. In Australia, Lyme disease should be considered in patients presenting with a travel history to Lyme-endemic areas along with supporting symptoms and/or a known tick bite. However, due to the controversy and stigma attached to Lyme disease in Australia some patients have also not received an appropriate assessment of their symptoms.

The Clinical Pathway will contribute to fulfilling the Australian Government's response to Recommendation 5 of the Senate Community Affairs References Committee Final Report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients,* where the Australian Government agreed to consult with key stakeholder groups to develop a cooperative multidisciplinary framework which can accommodate patient and medical needs. The development of the Clinical Pathway will build on the consultation about the concept of multidisciplinary care undertaken through consultation forums with medical professionals, state and territory health authorities and patient groups in April and July 2018.

2. IDENTIFICATION OF STAKEHOLDERS

2.1. Key Stakeholders

Table 1 shows an indicative list of Key Stakeholders, capturing both attendees at the 2018 Patient Forums, other stakeholders identified by the Department as important to the development of the Clinical Pathway, and additional stakeholders for consideration by the Department. This is a 'living' list, acknowledging that the consultation process will be inclusive, with individuals and their carers, or other groups not identified in Table 1, able to participate.

Table 1: Indicative list of 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* *NPS MedicineWise*	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 Physiotherapy Association* *Australian Psychological Society* Australian Primary Health Care Nurses Association (APNA) *National Rural Health Alliance* *Congress of Aboriginal and Torres Strait Islander Nurses and Midwives* 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	Lyme Australia and Friends Group (Facebook Group)* **ACT** *Canberra Area Lyme disease support group** Consumers Health Forum of Australia (CHF) **NSW** Australian Chronic Infectious & Inflammatory Disease Society (ACIIDS)* *Hunter Region MDIDS** Karl McManus Foundation (KMF)* Lyme Disease Association Australia (LDAA)* *NSW Far South Coast Lyme group** *NSW Riverina Lyme support group** Sarcoidosis Lyme Australia* **QLD** Global Lyme and Invisible Illness Organisation (GLiIO)* *Gold Coast Lyme group** Lyme Australia: Recognition and Awareness (LARA)* **VIC** Emerge Australia Tickborne Illness Community Network Australia (TICNA)* *Vic Lyme Support **

Government	Medical Professionals	Patient Groups
	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 M. Lindsay Grayson, Austin Health* Dr Armin Schwarzbach, CEO of Armin Labs; Member of the German Borreliosis Society Relevant Private Health Sector stakeholders: *Ramsay Health Care* *BUPA* *SilverChain* *Medibank Insurance*	**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* *Southwest Coastal MSIDS Support Group (WA)** **Other** Relevant ME/CFS, emerging biotoxins, or other similar disease patient groups.

*Attended 2018 April or July Forums
Suggested additional stakeholders

2.2. Other interested stakeholders

There may be other individuals and groups interested in the development of the Clinical Pathway. Our default approach is to be inclusive of those who wish to participate in meetings and contribute ideas, noting that we are operating within resource and time constraints.

3. ENGAGEMENT APPROACH

This section outlines and describes the points at which *Allen + Clarke* will engage with Key Stakeholders during the development the Clinical Pathway, how this engagement will occur and the principles that will underpin engagement.

Allen + Clarke will consult with Key Stakeholders in two phases of the project:

1. Via a Think Tank in May 2019 to discuss similarities and future support pathways and to inform the development of the Clinical Pathway. We will then consult with Key Stakeholders who participated in the Think Tank on the Draft Think Tank Report, prior to submitting the Think Tank Report to the Department on 24 May 2019.
2. Via face-to-face and virtual interviews during July and August 2019 to further develop the Draft Clinical Pathway and ensure it is fit for purpose and acceptable to the majority

of Key Stakeholders, including AHMAC, AHPPC and CPC (i.e. [seek agreed definition of 'acceptable' with Department]).

3.1. Principles of engagement

For all individuals and groups of Key Stakeholders, engagement will be undertaken according to the following principles. Participation in the consultation process will be voluntary.

- *Inclusiveness*: Everyone (within reason) who would like to contribute should be able to do so.
- *Receptiveness*: Being open to the contributions made by participants and giving them due consideration in the outcome of the process.
- *Reciprocity*: Being clear about what Key Stakeholders are being offered, including the benefit to them of engagement.
- *Respect*: All participants and their contributions are treated with sensitivity and respect throughout the engagement process.
- *Timeliness*: Key Stakeholders should be given sufficient time to provide considered responses, recognising that time for consultation has to be balanced with timeframes for *Allen + Clarke* to draft, finalise and submit required reports to the Department.
- *Transparency*: The objectives, process and outcomes of the engagement should be clearly explained to participants.

3.2. Stakeholder engagement via the Think Tank

3.2.1. An accessible, central venue

The Think Tank will be held in a venue in Sydney on 8 May 2019. The Think Tank will be a face-to-face meeting with remote access options for patient stakeholder groups and other invitees who cannot attend in person. The venue will have multiple areas enabling breakout sessions and smaller group discussions. The venue will have full disability access and facilities and will cater for participants with specific dietary requirements.

Prior to the Think Tank *Allen + Clarke* will in addition to the approved Think Tank materials circulate to invitees and confirmed participants any specific additional reasonable requests from participants that can increase their level of comfort and ability to participate, such as other participants not wearing perfumes /aftershaves.

3.2.2. Advance notification of the Think Tank

To maximise attendance and participation at the Think Tank, *Allen + Clarke* will approach identified Key Stakeholders by email in the week beginning 25 March 2019 to ensure stakeholders are aware of the Think Tank as early as possible and to provide as much time as possible for stakeholders to arrange attendance at the Think Tank. In this email, we will:

- provide information about the purpose, background, consultation phases and the intended dates, the anticipated time commitment and intended output of the consultation; and

- invite Key Stakeholders to the Think Tank, and the subsequent consultation during the development of the Clinical Pathway.

The emails will be customised to each organisation. For Key Stakeholders in organisations listed in Table 1 that did not attend the 2018 Forums, email contacts will be sourced from the relevant organisation's website. The emails will be approved by the Department along with all other materials sent to Key Stakeholders. An example email is in Appendix 1.

We will send a thank you email to all Key Stakeholders who respond. We will follow up by email with any Key Stakeholder who has not responded within seven days.

3.2.3. Plenary and interactive sessions

The Think Tank will be primarily facilitated by the Project Lead and Lead Analyst with the Expert Medical Technical Advisor and the Expert Guidelines Technical Advisor leading specific sessions based on their areas of expertise. To maximise opportunities for engagement, we will use a mix of techniques including small group discussions, plenary sessions and activities such as brainstorming and prioritisation exercises. The discussions will be facilitated to ensure space for less forthright members to voice their opinions.

3.2.4. Think Tank follow up

At the conclusion of the Think Tank we will thank attendees and acknowledge their valuable input into the discussions. In addition to the information about the Think Tank and the process and timeframe for feedback on the draft Think Tank report Key Stakeholders would have received in the email inviting them to the Think Tank, we will again advise attendees of the process for Key Stakeholder feedback into the draft report on key discussion points and outcomes of the Think Tank. Specifically, that the draft Think Tank Report will be circulated for stakeholder comment on 15 May 2019, and that stakeholder feedback via email will required by 20 May 2019 for finalisation of the Think Tank Report by 24 May 2019. We will acknowledge the short time for Key Stakeholder feedback on this report [timeframe to be discussed with DoH at inception meeting].

We will also update attendees on the next steps in the consultation process during development of the Clinical Pathway. This will include dates for face-to-face meetings in Sydney, Melbourne, Canberra and Perth, and the process we will use to arrange virtual interviews and focus groups with all other Key Stakeholders who wish to participate.

3.3. Stakeholder consultation during Clinical Pathway development

After the Department has approved the Draft Clinical Pathway for consultation, *Allen + Clarke* will re-engage with Key Stakeholders. We will use a variety of methods to enable Key Stakeholders to participate in the consultation on the Draft Clinical Pathway in ways that are accessible and convenient for them.

This will involve face-to-face meetings with Key Stakeholders in four cities where several Key Stakeholder organisations or groups are physically located (Sydney, Melbourne, Canberra and Perth), and written and telephone/virtual-based engagement methods with stakeholders outside these centres including government, professional and consumer representatives.

3.3.1. Advance notification of consultation on the draft Clinical Pathway

We intend to consult with Key Stakeholders throughout July and August 2019. The Project Lead, Lead Analyst, Expert Medical Technical Advisor and the Expert Guidelines Technical Advisor will participate in face-to-face and virtual consultations.

In early June 2019 we will contact via email all of the Key Stakeholders in Table 1 (whether or not they attended the Think Tank) and any other Key Stakeholders who have been added to the initial list, to invite them to participate in the consultation process on the development of the Clinical Pathway. The email, including information on the dates, time commitment and process, and any accompanying material, will be approved by the Department.

We will send via email at least one week in advance of any meetings the Draft Clinical Pathway and any accompanying material including a list of discussion items, to enable Key Stakeholders to prepare for the meeting. All material will be agreed with the Department prior to circulation.

3.3.2. Face-to-face consultation meetings: Sydney, Melbourne, Canberra and Perth

A number of Key Stakeholders are located in Sydney, Melbourne, Canberra and Perth (see Table 2).

We will notify Key Stakeholders located in these cities at the earliest possible time (estimated early June) via email of the confirmed dates the *Allen + Clarke* project team (Project Lead, Lead Analyst, Expert Medical Technical Advisor, Expert Guidelines Technical Advisor) will be in these cities. Key Stakeholders who agree to participate will be followed up with a confirmation email to thank them for their intended participation and to arrange a mutually agreeable time to undertake the consultation interview.

Rather than asking Key Stakeholders to travel to a venue of our choosing and have the additional time commitment and cost of travel, we will offer to travel to the Key Stakeholder's work premises and ask to hold the interview at their work premises, or at a location of their choosing.

Table 2: Key Stakeholders located in jurisdictions of face-to-face consultation meetings

Key Stakeholders in Melbourne	Key Stakeholders in Sydney	Key Stakeholders in Canberra	Key Stakeholders in Perth
Victoria Health Royal Australian and New Zealand College of Psychiatrists (RANZCP) Australasian College for Emergency Medicine (ACEM) Therapeutic Guidelines Limited Australian Primary Health Care Nurses Association	NSW Health Royal Australasian College of Physicians (RACP) Royal College of Pathologists of Australasia (RCPA) Royal Australian College of General Practitioners (RACGP) Karl McManus Foundation (KMF)	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).	WA Health Chrysalis Lyme Disease Support Group Perth ME/CFS and Lyme Association of WA, Inc. Kojonup Lyme Supporters Association Inc Multiple Systemic Infectious Disease Syndrome (MSIDS) Network

Key Stakeholders in Melbourne	Key Stakeholders in Sydney	Key Stakeholders in Canberra	Key Stakeholders in Perth
Tickborne Illness Community Network Australia (TICNA) Emerge Australia *Australian Physiotherapy Association* *Australian Psychological Society* *Psychotherapy and Counselling Federation of Australia* Relevant Private Health sector stakeholders	Australian Chronic Infectious & Inflammatory Disease Society (ACIIDS) Lyme Disease Association Australia (LDAA) Sarcoidosis Lyme Australia Relevant Private Health sector stakeholders: • *Ramsay Health Care*	National Health and Medical Research Council (NHMRC) Therapeutic Goods Administration (TGA) ACT Health Australian Medical Association (AMA) Australian College of Nursing Consumers Health Forum of Australia (CHF) Relevant Private Health sector stakeholders	Relevant Private Health sector stakeholders • *SilverChain*

We envisage each consultation interview or focus group will last 60 – 90 minutes. We anticipate undertaking at least six face-to-face interviews over a three-day period in each of the four cities.

Key Stakeholders in these cities who wish to participate in the consultation process but are unable to meet during the dates the *Allen + Clarke* project team are visiting the relevant city, will be given the option of a virtual consultation interview at a mutually agreeable time in July/August, or they will be able to submit their comments via email if they wish by 30 August 2019.

We acknowledge that some of the larger patient Key Stakeholder Groups who have attended the 2018 Forums and do not have physical headquarters (e.g., Australian Chronic Infectious & Inflammatory Disease Society, Lyme Disease Association of Australia) may wish to meet face-to-face for a consultation interview in one of the four cities. We will work with these Key Stakeholders, via email, to organise either a face-to-face meeting in one of the four cities or a virtual consultation meeting, similar to those we will organise for the State and Territory Health Authority officials, as described below. After the face-to face interview or feedback via email, *Allen + Clarke* will send an email to the organisation's representative(s) who took part in the consultation thanking them for their participation and input.

3.3.3. Virtual consultation with NT Health, QLD Health, SA Health and Tasmania Health

To ensure a consistent approach to consultation with the State and Territory Health Authorities the *Allen + Clarke* project team will not be travelling to, we will invite officials from NT Health, Queensland Health, SA Health and Tasmania Health to participate in virtual interviews with the *Allen + Clarke* project team (Project Lead, Lead Analyst, Expert Medical Technical Advisor, Expert Guidelines Technical Advisor).

We will work with the State and Territory Health Authority officials via email from early June 2019 to organise a mutually agreeable time for the consultation interview, in July/August. As with the face-to-face interviews, we anticipate the consultation interviews with State and Territory

Health Authority officials will take 60 – 90 minutes. We will use Zoom or another similar technology to undertake the virtual consultation interviews. Once the consultation interview time has been agreed, *Allen + Clarke* will send a formal invite, via email, to the virtual interview along with any pre-approved accompanying material.

If State and Territory Health Authority officials are unable to or not comfortable to participate in the virtual consultation interview, they will be able to submit their comments via email if they wish by 30 August 2019.

After the interview or feedback via email, *Allen + Clarke* will send an email to the State and Territory Health Authority officials who took part in the consultation thanking them for their participation and input.

3.3.4. Virtual consultation with patient groups

We will contact the patient stakeholder groups via email in June 2019 [agree date with Department] to invite them to participate in virtual consultation focus groups in July/August. To maximise this group of Key Stakeholders to participate in the consultation on the development of the Clinical Pathway we will offer six dates and times in July/August. We will ask Key Stakeholders to rank the dates in order of preference using the meeting schedule tool Doodle Poll. The four sessions most commonly sought will be conducted as group consultations, with *Allen + Clarke* allocating participants across the four sessions according to the preferred timing indicated by each participant.

We anticipate the group consultation interviews with patient Key Stakeholder groups will take 60 – 90 minutes. We will use Zoom or another similar technology to undertake the virtual consultation group interviews. Once the consultation group interview dates and times have been decided, *Allen + Clarke* will send a formal invite, via email, to the virtual group interview participants along with any pre-approved accompanying material.

Participants will be informed that they can withdraw while the discussion is taking place at any time. The discussion will be facilitated to ensure space for less forthright members to voice their opinions. Due to the potential for some focus group members to become distressed during or after the focus group discussion, a list of potential sources of support (to be approved by the Department) will be provided to patient Key Stakeholder group participants, should they wish to seek support following the group discussion.

If patient Key Stakeholder groups and their representatives are unable to or not comfortable to participate in the virtual group consultation interviews, they will be able to submit their comments via email if they wish by 30 August 2019.

After the patient Key Stakeholder group consultation interviews or feedback via email, *Allen + Clarke* will send an email to the Key Stakeholders who took part in the consultation thanking them for their participation and input.

3.4. Out of scope communication

We assume the Department will be responsible for notifying all stakeholders of the publication of the Think Tank Report, Stakeholder Consultation Report and the Final Clinical Pathway.

We assume all website posts updating stakeholders on progress will be managed by the Department.

We will refer to the Department any ad hoc requests from stakeholders for updates or further information relating to DSCATT or the Clinical Pathway development that is beyond the operational organisation of stakeholder engagement for the Think Tank and the development of the Clinical Pathway.

We will agree a nominated Department contact for escalating queries.

4. RISKS

There are a number of risks to consider and manage throughout consultation on the Clinical Pathway.

Table 3: DSCATT Clinical Pathway risk identification and mitigation strategies

Risk	Probability	Impact	How this risk will be mitigated
Phase 2: Think Tank			
Key Stakeholders do not hear about the Think Tank until it is too late for them to participate.	Low	High	• The Department approves the Stakeholder Engagement Strategy to ensure clarity around the timing of messages. • Invitations to Key Stakeholders are sent out in the week beginning 25 March, giving stakeholders six weeks' notice of the Think Tank.
Difficulty engaging with or contacting stakeholders to ensure quality consultation. For example, availability, relative priority for stakeholders.	Medium	High	• The Department approves the Stakeholder Engagement Strategy to ensure clarity around the and content of messages. • Stakeholders will be provided with a clear explanation of the project and how their contribution may affect the outcome. To maximise participation, any invited Key Stakeholders who have not replied to the invitation email after seven days will be followed up by email. • Ensure the invitations include the opportunity for the named individual or another representative from the organisation to attend the Think Tank. • Advise Key Stakeholders there will video-conferencing available for invites who cannot attend in person.
Some Key Stakeholders are not able to participate in the Think Tank and miss the opportunity to provide their input. This reduces the robustness of the information provided to the Department, and there is the risk it will undermine the process more generally if Key Stakeholders do not have confidence in the process.	Medium	Low	• Ensure the invitations include the opportunity for the named individual or another representative from the organisation to attend the Think Tank. • Advise Key Stakeholders there will video-conferencing available for invitees who cannot attend in person. • Advise Key Stakeholders a report from the Think Tank will be published by the Department soon after the Think Tank to ensure transparency in the process. • Advise Key Stakeholders there will be opportunities for further stakeholder consultation with all Key Stakeholders during the development of the Clinical Pathway.

Risk	Probability	Impact	How this risk will be mitigated
Key Stakeholders do not feel they have been engaged / consultation at the Think Tank is viewed as 'perfunctory', and they do not have trust in the process.	Medium	Medium	• A mix of techniques including small group discussions, plenary sessions and activities such as brain storming and prioritisation exercises will be used to maximise stakeholder engagement for Key Stakeholders participating in person or via video-conferencing. • The project team are skilled at hosting consultations/events where participant's opinions are diverse. • All Key Stakeholders participating in the Think Tank will receive a t hank you email, and information about next steps including the consultation on the development of the Clinical Pathway.
Patient Key Stakeholders become distressed discussing the impact of living with DSCATT on their lives and wellbeing.	Medium	High	• Our core project team for the Think Tank are experienced in sensitive subjects and will develop undertake the consultation in a manner that will reduce the possibility of distress for participants. • Additionally, we will agree with the Department how participants can be best supported and the services they should be referred to should participants require them.
There is pressure to extend the consultation feedback period on the Think Tank Report period, placing pressure on all other timelines of the project.	High	High – the stakeholder feedback period is very short (six days) for the expected Key Stakeholder interest	• The process for preparing and finalising the Think Tank report, including the short timeline for Key Stakeholder feedback on the draft Think Tank Report will be clearly outlined to Key Stakeholders in the invitation letter and again at the Think Tank. • Key stakeholders will also be advised of the intended style (similar to the April and July DoH hosted Forum reports) and level of detail (high-level recommendations only) of the Think Tank Report to cover off stakeholder expectations. Regarding depth of content to review.
Difficulty of Think Tank discussions balancing personal health experiences and more technical aspects required for the development of a Clinical Pathway.	Low/ Moderate	Low	• The Think Tank discussions will include specific allowance for scientific and technical experts to provide their views on the requirements for the Clinical Pathway, alongside views and advice from consumer groups.

Risk	Probability	Impact	How this risk will be mitigated
Large volume of Key Stakeholder feedback on the draft Think Tank Report puts pressure on timelines for finalising the Think Tank Report.	High	High	• Additional resources will be made available to ensure that Key Stakeholder feedback is incorporated into the Think Tank within required timeframes. • Allen + Clarke will use Survey Monkey and NVivo to manage the Key Stakeholder feedback.
Phase 3: Clinical Pathway Development			
Difficulty engaging with or contacting stakeholders to ensure quality consultation. For example, availability, relative priority for stakeholders.	Low	High	• The Department approves the Stakeholder Engagement Strategy to ensure clarity around the timing and content of messages. Stakeholders will be provided with a clear explanation of the project and how their contribution may affect the outcomes of the project and future decision-making. • Key Stakeholders will be advised in the invitation email to the Think Tank that further stakeholder consultation on the development of the Clinical Pathway will be held during July/August. Key Stakeholders will be advised of likely/confirmed dates for the consultation (face-to-face and virtual consultation) at the Think Tank. • To continue to encourage ongoing participation, Key Stakeholders invited to the Think Tank but who are unable to attend (and do not provide a substitute to represent their organisation) will be emailed to advise them of the opportunity to be involved in consultation on the development of the Clinical Pathway. • Any Key Stakeholders who are not available on the scheduled dates for face-to-face meetings in Sydney, Melbourne, Canberra and Perth will be followed up by email to organise virtual consultations to ensure Key Stakeholders are given every opportunity to participate in the consultation.
Many Key Stakeholders situated in Canberra, Melbourne, Sydney and Perth are not available to meet at the scheduled dates and more virtual consultations have to be arranged impacting on the completion of consultation and delivery of the Draft Clinical Pathway.	Medium	High	• Key Stakeholders will be given advanced notice about the proposed face-to-face consultation dates in Melbourne, Canberra, Sydney and Perth being planned for July/August in the invitation to the Think Tank and at the Think Tank. • All efforts will be made to agree a suitable time for face-to-face consultation. For those stakeholders who are unavailable during the scheduled consultation visits, we will offer up to two alternative virtual consultation appointments. If these times are unacceptable, Key Stakeholders will be able to provide feedback directly to the project team via email.

Risk	Probability	Impact	How this risk will be mitigated
Participants representing Patient groups become distressed discussing the impact of living with DSCATT, their experiences accessing care previously and their expectations of the Clinical Pathway.	Medium	High	• Our core project team for the consultation during the development of the Clinical Pathway are experienced in sensitive subjects and will develop undertake the focus groups and interviews in a manner that will reduce the possibility of distress for participants • Additionally, we will agree with the Department how participants can be best supported and the services they should be referred to should participants require them.
There is pressure to extend consultation period, placing pressure on all other timelines of the project.	Medium	High	• Key Stakeholders will be given information about the timeframes for the development of the Clinical Pathway and consultation period early in the project, including advanced notice about the proposed face-to-face consultation dates in Melbourne, Canberra, Sydney and Perth being planned for July/August in the invitation to the Think Tank and at the Think Tank.
Key Stakeholders located in States and Territories where face-to-face consultation meetings are not being held feel undervalued.	Medium	Medium	• Key Stakeholders will be advised that all Key Stakeholder feedback will be collected face-to-face, whether in the meetings in Melbourne, Sydney, Canberra or Perth or in the virtual interviews and focus group sessions. • In the Department hosted Forums on DSCATT in April and July, many Key Stakeholders located in areas outside Sydney or Melbourne participated by video conferencing.

APPENDIX 1: DRAFT EMAIL TO KEY STAKEHOLDERS

From: Robyn Haisman-Welsh

Subject: Invitation to participate in Key Stakeholder consultations to develop a Clinical Pathway for patients suffering from debilitating symptom complexes attributed to ticks (DSCATT)

Dear s47F ,

The Australian Department of Health has commissioned Allen + Clarke, Policy and Regulatory Specialists Limited *(Allen + Clarke)* 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) which can be flexibly applied in both private and public health care settings. I am the Project Lead for the development of the Clinical Pathway.

Allen + Clarke would like to invite you (and/or a representative from the Royal Australian College of General Practitioners, RACGP) to participate in two consultation processes to inform and develop the Clinical Pathway.

The Clinical Pathway will be informed by the relevant literature and key documents and will be developed in consultation with Key Stakeholders, including medical professionals, government health authorities and patient groups. This consultation will ensure the Clinical Pathway is fit for purpose and acceptable to the majority of stakeholders, including endorsement by the Australian Health Ministers' Advisory Council (AHMAC).

The Clinical Pathway will contribute to fulfilling the Australian Government's response to Recommendation 5 of the Senate Community Affairs References Committee Final Report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients,* where the Australian Government agreed to consult with key stakeholder groups to develop a cooperative multidisciplinary framework which can accommodate patient and medical needs. The development of the Clinical Pathway will build on the consultation about the concept of multidisciplinary care previously undertaken through consultation forums with medical professionals, state and territory health authorities and patient groups in April and July 2018.

Consultation via a Think Tank on 8 May 2019 in Sydney

The first consultation with Key Stakeholders will be via a Think Tank in Sydney at the X on 8 May 2019. The Think Tank will be a full-day face-to-face meeting with remote access options for patient stakeholder groups and other invitees who cannot attend in person. The purpose of the Think Tank is to discuss similarities and future support pathways to inform the development of the Clinical Pathway.

Consultation during July /August 2019 to further develop the Clinical Pathway

The second consultation with Key Stakeholders will take place in July and August to further develop a Draft clinical Pathway to ensure it is fit for purpose and acceptable to the majority of Key Stakeholders, including AHMAC. These consultations will be via face-to-face interviews with Key Stakeholders in Sydney, Melbourne, Canberra and Perth, or via virtual interviews with

Key Stakeholders not located in these four cities using videoconferencing/telephone or feedback via email.

We, and the Department, would greatly value you, or a representative of RACGP participating in the upcoming consultations to develop the Clinical Pathway. We acknowledge your and RACGP participation and input at the April forum and would be delighted to have your participation again in these consultations.

To inform our planning, I would be most grateful if you could please let me know if you, or a RACGP representative are able to attend the Think Tank on 8 May, either in person, or remotely, as soon as you are able to.

Thank you, in advance.

Kind regards

Robyn

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Senior Consultant

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New Zealand

Terms of Reference for Literature Search

Supporting an evidence-based approach to developing a clinical pathway and multidisciplinary care model for Australian patients suffering from debilitating symptom complexes attributed to ticks (DSCATT)

15 March 2019 [Draft]

ALLEN+CLARKE

NOTES

This approach is a draft for comment. We appreciate your feedback on the proposed research questions and any areas of literature that we may have missed. If you consider particular documents to be indispensable to the literature review or Australian or international authority organisations or websites, please alert us to them.

Document status:	Draft for comment
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Authors:	Dr Robyn Haisman-Welsh
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Formatting:	s47F
Final QA check and approved for release:	Paul Houliston, Project Sponsor

Allen + Clarke has been independently certified as compliant with ISO9001:2015 Quality Management Systems

Telarc. Registered
Quality ISO 9001

CONTENTS

1. INTRODUCTION

1.1. Purpose of this document

The Australian Department of Health (the Department) has commissioned Allen + Clarke Policy and Regulatory Specialists Limited (*Allen + Clarke*) 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 health settings.

The Department requires the Clinical Pathway to be informed by relevant literature and key documents. The Department has provided a set of key documents to be included in the literature review. *Allen + Clarke* will also undertake a supplementary online search to identify additional Australian and international evidence-based research and best practice/guideline documents relevant to DSCATT and to developing the Clinical Pathway.

This document sets out the terms of reference for a search strategy to identify and appraise published literature and describe the process and methodology for a robust integrative review.

Allen + Clarke will use this as the basis for conducting the search of published literature and websites. Annexe A contains the critical appraisal tools designed for particular literature types that will be systematically applied in order to rate the level of evidence for identified outcomes presented across the included research.

1.2. Why is this literature review important?

The Australian Government acknowledges that there is a group of Australian patients suffering from the symptoms of a chronic debilitating illness, which many associate with a tick bite. The Australian Government has chosen to describe this patient group as having Debilitating Symptom Complexes Attributed to Ticks (DSCATT). This term was carefully considered to appropriately acknowledge this patient group and the multifaceted illness they are experiencing, whilst moving away from the stigma and controversy associated with the use of "Lyme Disease", "Lyme disease-like illness" and "chronic Lyme disease" that have previously been used to describe this patient group.

Many of these patients experiencing debilitating symptom complexes are living in turmoil as their illness is poorly understood, making accurate diagnosis and treatment difficult. It is imperative for government health authorities, clinicians and patients alike to remain open minded as to the causes of these symptoms and work together to achieve a patient-centred multidisciplinary approach to their care.

In addition, overseas travellers to Lyme-endemic areas may return to Australia before becoming symptomatic and/or being diagnosed. In Australia, Lyme disease should be considered in patients presenting with a travel history to Lyme-endemic areas along with supporting symptoms and/or a known tick bite. However, due to the controversy and stigma attached to Lyme disease in Australia some of these patients have also not received an appropriate assessment of their symptoms.

The literature review, which will be published, will inform the development of an evidence-based approach to developing a draft clinical pathway. The draft Clinical Pathway will then be further

developed in consultation with key stakeholders to ensure it is fit for purpose, and acceptable to the majority of stakeholders, including the Australian Health Ministers' Advisory Council (AHMAC) and its subcommittees, the Australian Health Protection Principal Committee (AHPPC) and Clinical Principal Committee (CPC).

The Clinical Pathway will contribute to fulfilling the Australian Government's response to Recommendation 5 of the Senate Community Affairs References Committee Final Report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients,* where the Australian Government agreed to consult with key stakeholder groups to develop a cooperative multidisciplinary framework which can accommodate patient and medical needs. The development of the Clinical Pathway will build on the consultation about the concept of multidisciplinary care previously undertaken through consultation forums with medical professionals, state and territory health authorities and patient groups in April and July 2018.

2. SCOPE AND TOPICS

The literature review will focus only on debilitating symptom complexes attributed to ticks (DSCATT).

As discussed above, the Australian Government has chosen to describe this patient group as having Debilitating Symptom Complexes Attributed to Ticks (DSCATT) with this term being only very recently adopted in Australia. A preliminary PubMed search revealed there is no published academic literature using this term.

For this literature review, therefore, we will need to revert to the terminology most commonly used to describe this set of symptoms in Australia and internationally, including Lyme-like disease, Lyme-like illness, chronic Lyme disease and Australian Lyme disease. Additionally, other terms are also used to describe the condition suffered by these patients, including chronic arthropod-borne neuropathy (in the UK) and multiple systemic infectious diseases syndrome.

While extensive literature and literature reviews exist for classical Lyme disease (particularly from Europe and North America), DSCATT and "Lyme-like" disease in the Australian literature is more limited and less restricted to the peer-reviewed medical and scientific literature.

Specifically, we propose to identify and review Australian (as a priority) and international evidence-based research and best practice/guideline documents and literature (including primary studies, secondary research and grey literature) to support the development of the Clinical Pathway.

We propose a robust integrative review methodology that will include clearly defined Australia-specific research questions, a thoroughly documented search strategy (including key Australian material from multiple official sources and the "grey" literature) and the use of suitable frameworks to guide synthesis of evidence. We will find and summarise available systematic reviews and meta-analyses for Lyme disease, particularly where these have been used in the development of clinical guidelines internationally. A systematic and transparent peer review process will assess the quality of evidence, give confidence in the validity of the analysis, and enable the evidence to be presented in summary of evidence tables, supplemented with detailed commentary.

The literature review will not cover other ethical, legal or social issues associated with Lyme disease advocacy groups' activities.

3. DRAFT RESEARCH QUESTIONS

Table 1: Research questions

Research questions
Research Question 1 What is the epidemiology of DSCATT in Australia? *Supplementary Questions* • What is the prevalence, incidence and geographic distribution of DSCATT in Australia? • What are the symptoms of DSCATT and prevalence of these symptoms among Australian patients?
Research Question 2 What are the currently diagnosable diseases and conditions with which DSCATT has been linked?
Research Question 3 What is the current evidence on the potential causes or causative agents of DSCATT among Australian patients?
Research Question 4 What are the issues associated with diagnostic testing for Lyme disease and DSCATT in Australia? *Supplementary Questions* • What is the current seroprevalence of potential DSCATT-specific antibodies (and other tick-borne infections) in people in Australia who have been given a diagnosis of Lyme disease or Lyme-like illness? • What is the most clinically and cost-effective serological antibody-based test, biomarker or other test for diagnosing DSCATT at all stages?
Research Question 5 What are effective treatment modalities that have been provided to patients (including subgroups of patients) with DSCATT in Australia and what is the evidence base to support these treatment modalities? *Supplementary Questions* • What is the evidence-base on long-term therapy for patients with chronic Lyme disease?
Research Question 6 What are the views and expressed needs of patients with DSCATT regarding their access to medical care, their medical care needs and wider system support?
Research Question 7 What other Lyme-like illnesses have been identified internationally?
Research Question 8 What approaches to diagnosis, treatment and ongoing syndromic management of tick-borne Lyme and Lyme-like diseases of relevance to DSCATT have been found effective internationally?

4. TERMS OF REFERENCE FOR THE LITERATURE SEARCH

4.1. Breadth of search (Databases)

- Discover (CINAHL Complete, Medline and PsycINFO)
- Cochrane Library database
- National Institute for Health and Clinical Excellence
- PubMed
- ProQuest (including Sociological Abstracts), and
- Guidelines International Network (www.g-i-n.net) guideline library.

4.2. Inclusions

From the results of the search, literature will be prioritised according to the following criteria:

- Published, peer-reviewed literature
- Official reports and government inquiries
- Guidelines (International and Australian) produced by clinical and professional bodies
- Currency (published between 1 January 2008 and current)
- Relevance to primary research questions, and
- Full article available in English language.

4.3. Exclusions

The literature review will exclude any material that does not relate to the research questions, non-English language sources, and material published before 31 December 2007. Misidentified, irrelevant papers and duplicates will be removed.

4.4. Search terms

Subject to the flexibility of individual database search functions, examples of the keywords and search strings included in the search strategy are outlined below. Exact terms and strings will be informed by findings as the work progresses.

4.5. Sources

4.5.1. Academic / medical literature

Example of a search string: each initially AND Australia *(ti.ab = words in title and abstract)*

1. exp Borrelia infection/
2. exp Lyme disease/
3. 2 and guidelines; not Australia
4. Lyme*.ti.ab. (this should also pick up Lyme like and chronic Lyme and 3rd stage Lyme)
5. (borreliosis or borrelia* or neuroborreliosis or ixodidae or ixodes or ixodid or b burgdorferi or b afzelii or b garinii or b bissettii or b valaisiana or b microti):ti,ab
6. Erythemia Chronium Migrans/
7. (erythema adj3 migrans).ti.ab.
8. (tick* adj2 (bite* or bitten or biting or borne)).ti.ab.

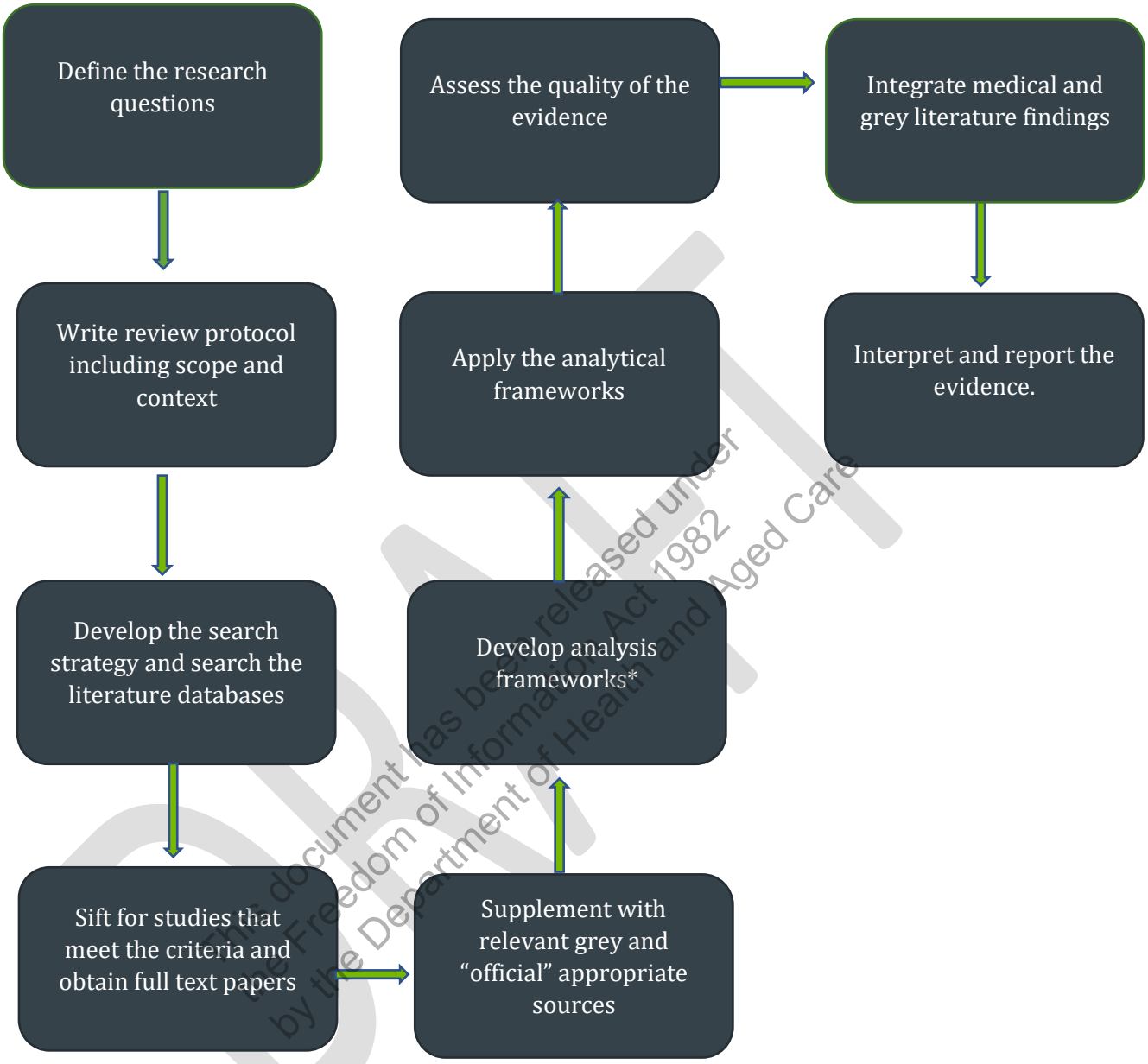
4.5.2. Grey / official literature

Other search criteria each initially AND Australia *(pt. = publication type)*

9. Letter.pt. or letter/
10. Note.pt.
11. Editorial.pt.
12. Report.pt.

Cross-checking for completeness (following up authors and references listed in suitable reviews to check they appear in our capture strategy for example) will add rigour. A senior team approach will be taken to the review process to ensure consistency. The integrative review methodology is shown in Figure 1.

Figure1: Step by step review process



4.6. Documentation

Searches will be tabulated by source, search string, any inclusions and exclusions, and results will be illustrated using a standard review results flow chart (in annexes).

4.7. Provision of materials

Allen + Clarke will perform the searches, and source the documents for which we require full-text. Citations will be managed with Zotero.

5. ANALYTICAL FRAMEWORKS

The analytical framework will be a multi-stage, systematic approach:

- Systematic reviews and Randomised Controlled Trials will be described using a PICOT framework (Population, Intervention, Comparison, Outcome and Timeframe). Exact PICOT criterion will be informed by initial literature scans. An example is given below in Annexe 2.
- Reviews of diagnostic test accuracy will be analysed using a PTRT framework of population, index tests, reference standard and target condition.
- Qualitative reviews and reports will be analysed using a framework of population, setting and context.

This use of these frameworks will guide the literature searching process, critical appraisal and synthesis of evidence, and facilitate the development of recommendations by the pathway committee.

ANNEXE 1: CRITICAL APPRAISAL (QUALITY TESTS)

Quantitative research:

AMSTAR Systematic Review Checklist –

https://amstar.ca/Amstar_Checklist.php

CASP Randomised Controlled Trials checklist –

https://casp-uk.net/wp-content/uploads/2018/01/CASP-Randomised-Controlled-Trial-Checklist-2018.pdf

CASP Case Control Study Checklist –

https://casp-uk.net/wp-content/uploads/2018/01/CASP-Case-Control-Study-Checklist-2018.pdf

CASP Diagnostic Checklist –

https://casp-uk.net/wp-content/uploads/2018/01/CASP-Diagnostic-Checklist-2018.pdf

Qualitative research

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist –

http://cdn.elsevier.com/promis_misc/ISSM_COREQ_Checklist.pdf

ANNEXE 2: SAMPLE PICO

For question: What is the evidence-base on long-term antibiotic therapy for patients with chronic Lyme disease?

Criterion	Description
Population	• Adults over the age of 18 with documented symptoms defined in the literature as being associated with Lyme, Lyme-like or Chronic Lyme disease • Presenting symptoms • Australian, with or without history of travel to Lyme endemic areas • With or without known history of tick bite • With or without documented serology
Intervention	• Long-term treatment (with antibiotics)
Comparator	• No treatment (with antibiotics)
Outcomes	• Symptom amelioration • Additional diagnostic tests undertaken and outcomes • Anxiety and depression • Additional costs incurred by patient
Timeframes	• Initial • Chronic
Study types	• Systematic reviews, RCTs

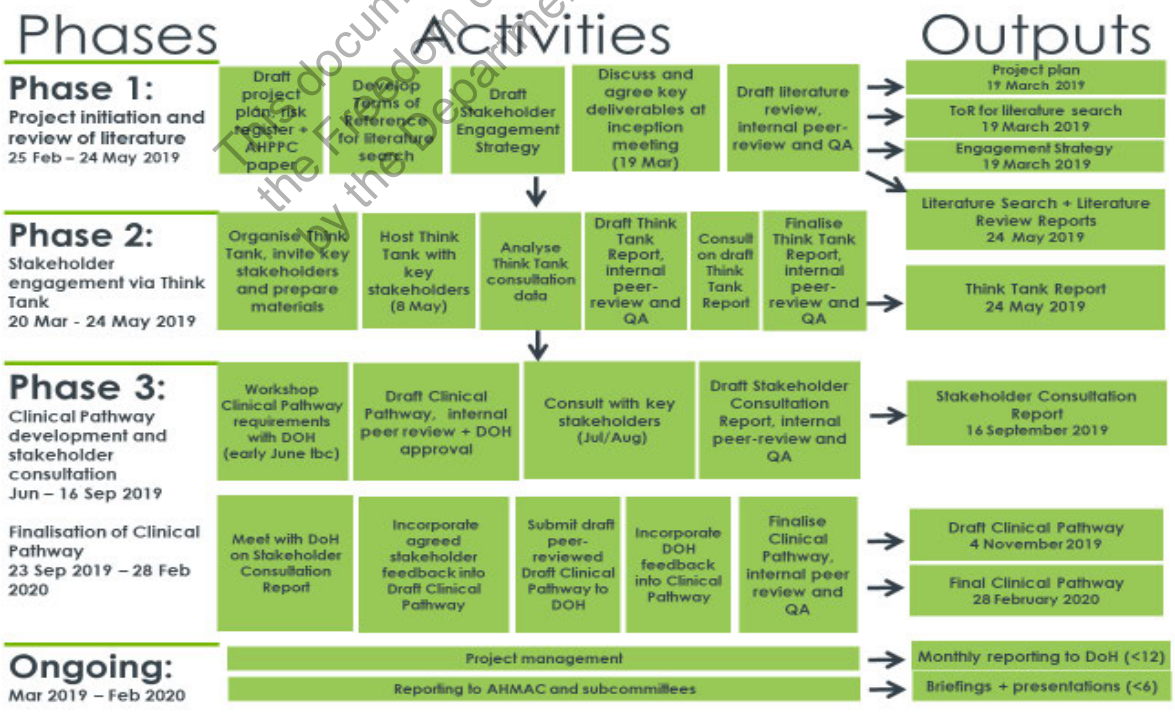
DEVELOPMENT OF A CLINICAL PATHWAY FOR PATIENTS SUFFERING FROM DEBILITATING SYMPTOM COMPLEXES ATTRIBUTED TO TICKS (DSCATT) PROJECT PLAN SUMMARY

The Australian Department of Health has engaged Allen and Clarke, Policy and Regulatory Specialists (*Allen + Clarke)* 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) which can be flexibly applied in both private and public healthcare settings. The development of the Clinical Pathway will contribute to fulfilling the Australian Government's response to Recommendation 5 of the Senate Community Affairs References Committee Final Report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients,* and will build on the consultation about the concept of multidisciplinary care previously undertaken through consultation forums with medical professionals, state and territory health authorities and patient groups in April and July 2018.

The Clinical Pathway will be informed by the relevant literature and key documents, and will be developed in consultation with key stakeholders, including medical professionals, government health authorities and patient groups. This will ensure the clinical pathway and model is fit for purpose and acceptable to the majority of stakeholders, including the Australian Health Ministers' Advisory Council (AHMAC) and its subcommittees, the Australian Health Protection Principal Committee (AHPPC) and Clinical Principal Committee (CPC).

Project Approach

The Clinical Pathway will be developed over three phases and completed in February 2020. A summary of the phases, high-level timing, key activities and outputs is set out in the overview below.



DEVELOPMENT OF A CLINICAL PATHWAY FOR PATIENTS SUFFERING FROM DEBILITATING SYMPTOM COMPLEXES ATTRIBUTED TO TICKS (DSCATT) STAKEHOLDER ENGAGEMENT STRATEGY SUMMARY

Purpose of the Stakeholder Engagement Strategy

This Stakeholder Engagement Strategy (the Strategy) will support and facilitate engagement and consultation with stakeholders to inform the development of an evidence-based clinical pathway and multidisciplinary care model (the Clinical Pathway) for patients experiencing debilitating symptom complexes attributed to ticks (DSCATT). The Australian Department of Health has engaged Allen and Clarke, Policy and Regulatory Specialists *(Allen + Clarke)* to develop the Clinical Pathway in consultation with relevant stakeholders, including medical professionals, government health authorities and patient groups.

The purpose of stakeholder consultation is to ensure the Clinical Pathway is fit for purpose and acceptable to the majority of stakeholders and can be endorsed by the Australian Health Ministers' Advisory Council (AHMAC) and its subcommittees, the Australian Health Protection Principal Committee (AHPPC) and Clinical Principal Committee (CPC). Consultation will ensure the Clinical Pathway can be flexibly applied in both the private and public healthcare settings.

Key Stakeholders

The development of the Clinical Pathway will build on the consultation about the concept of multidisciplinary care previously undertaken through consultation forums with medical professionals, state and territory health authorities and patient groups in April and July 2018. All stakeholders who attended these forums will be invited to participate in the consultation processes to develop the Clinical Pathway, along with additional stakeholders identified as relevant and having an interest in developing the Clinical Pathway. The list of Key Stakeholders to be consulted will be a 'living list' acknowledging the consultation process will be inclusive, with individuals and their carers or other groups not already identified being able to participate.

Principles of engagement

Allen + Clarke will undertake all engagement with stakeholders with inclusiveness, receptiveness, reciprocity, respect, timeliness and transparency. Participation by stakeholders in the consultation process will be voluntary.

Engagement approach

Allen + Clarke will consult with Key Stakeholders in two phases of the project:

1. Via a Think Tank in Sydney in May 2019 to discuss similarities and future support pathways and to inform the development of the Clinical Pathway.
2. Via face-to-face and written and telephone/virtual-based engagement methods in July and August of 2019 to further develop a draft Clinical Pathway which will have been developed by *Allen + Clarke* following the Think Tank consultation. This consultation phase is to ensure the Clinical Pathway is fit for purpose and acceptable to the majority of Key Stakeholders, including AHMAC, AHPPC and CPC.

Terms of Reference for Literature Search

Supporting an evidence-based approach to developing a clinical pathway and multidisciplinary care model for Australian patients suffering from debilitating symptom complexes attributed to ticks (DSCATT)

26 March 2019

ALLEN+CLARKE

Document status:	Final
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Authors:	Dr Robyn Haisman-Welsh, s47F
Filing Location:	DSCATT Clinical Pathway\04a Deliverables Phase 1\Literature Review\ToRs
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Verification that QA changes made:	s47F
Proof read:	s47F
Formatting:	s47F
Final QA check and approved for release:	Paul Houliston, Project Sponsor

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The Department requires the Clinical Pathway to be informed by relevant literature and key documents. The Department has provided a set of key documents to be included in the literature review. *Allen + Clarke* will also undertake a supplementary online search to identify additional Australian and international evidence-based research and best practice/guideline documents relevant to DSCATT and to developing the Clinical Pathway.

This document sets out the terms of reference for a search strategy to identify and appraise published literature and describe the process and methodology for a robust integrative review.

Allen + Clarke will use this as the basis for conducting the search of published literature and websites. *Allen + Clarke* will use a range of critical appraisal tools (see Annexe 1) to assess the quality of publications, as appropriate for the methodologies employed.

Annexe 1 contains the critical appraisal tools designed for particular literature types that will be systematically applied in order to rate the level of evidence for identified outcomes presented across the included research.

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The Australian Government acknowledges that there is a group of Australian patients suffering from the symptoms of a chronic debilitating illness, which many associate with a tick bite. The Australian Government has chosen to describe this patient group as having Debilitating Symptom Complexes Attributed to Ticks (DSCATT). This term was carefully considered to appropriately acknowledge this patient group and the multifaceted illness they are experiencing, whilst moving away from the stigma and controversy associated with the use of "Lyme disease", "Lyme disease-like illness" and "chronic Lyme disease" that have previously been used to describe this patient group.

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The literature review, which will be published, will inform the development of an evidence-based approach to developing a draft Clinical Pathway. The draft Clinical Pathway will then be further developed in consultation with key stakeholders to ensure it is fit for purpose and acceptable to the majority of stakeholders, including the Australian Health Ministers' Advisory Council (AHMAC) and its subcommittees, the Australian Health Protection Principal Committee (AHPPC) and Clinical Principal Committee (CPC).

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While extensive literature and literature reviews exist for classical Lyme disease (particularly from Europe and North America), DSCATT and "Lyme-like" disease in the Australian literature is more limited and less restricted to peer-reviewed medical and scientific literature.

Specifically, we propose to identify and review Australian (as a priority) and international peer reviewed research and evidence-based practice/guideline documents and literature (including primary studies and secondary research) to support the development of the Clinical Pathway.

We propose a robust integrative review methodology that will include clearly defined Australia-specific research questions, a thoroughly documented search strategy (including key Australian material from multiple official sources, summaries from forums and material included in the Senate Inquiry reports) and the use of suitable frameworks to guide synthesis of evidence. We will find and summarise available systematic reviews and meta-analyses for Lyme disease, particularly where these have been used in the development of clinical guidelines internationally. A systematic and transparent peer review process will assess the quality of evidence, give confidence in the validity of the analysis, and enable the evidence to be presented in summary of evidence tables, supplemented with detailed commentary.

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Table 1: Research questions

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Research Question 3 What is the current evidence on the potential causes or causative agents of DSCATT among Australian patients?
Research Question 4 What are the issues associated with diagnostic testing for Lyme disease and DSCATT both in Australia and by overseas laboratories?
Research Question 5 What are effective treatment modalities that have been provided to patients (including subgroups of patients) with DSCATT in Australia and what is the evidence base to support these treatment modalities?
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4.1. Breadth of search (Databases)

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- National Institute for Health and Clinical Excellence

- PubMed
- ProQuest (including Sociological Abstracts), and
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From the results of the search, literature will be prioritised according to the following criteria:

- Published, peer-reviewed literature
- Official Australian reports and government inquiries including submissions within relevant Senate Inquiry reports
- (Inter)national authority and intergovernmental reports and guidelines
- Guidelines (International and Australian) produced by clinical and professional bodies
- Currency (published between 1 January 2008 and current)
- Relevance to primary research questions, and
- Full article available in English language.

4.3. Exclusions

The literature review will exclude non-peer reviewed material (other than that associated with the Senate Inquiry and 2018 DSCATT forum reports), any material that does not relate to the research questions, non-English language sources, and material published before 31 December 2007. Misidentified, irrelevant papers and duplicates will be removed.

4.4. Search terms

Subject to the flexibility of individual database search functions, examples of the keywords and search strings included in the search strategy are outlined below. Exact terms and strings will be informed by findings as the work progresses.

4.5. Sources

4.5.1. Academic / medical literature

Example of a search string: each initially AND Australia *(ti.ab = words in title and abstract)*

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2. Lyme*.ti.ab. (this should also pick up Lyme like and chronic Lyme and 3rd stage Lyme)
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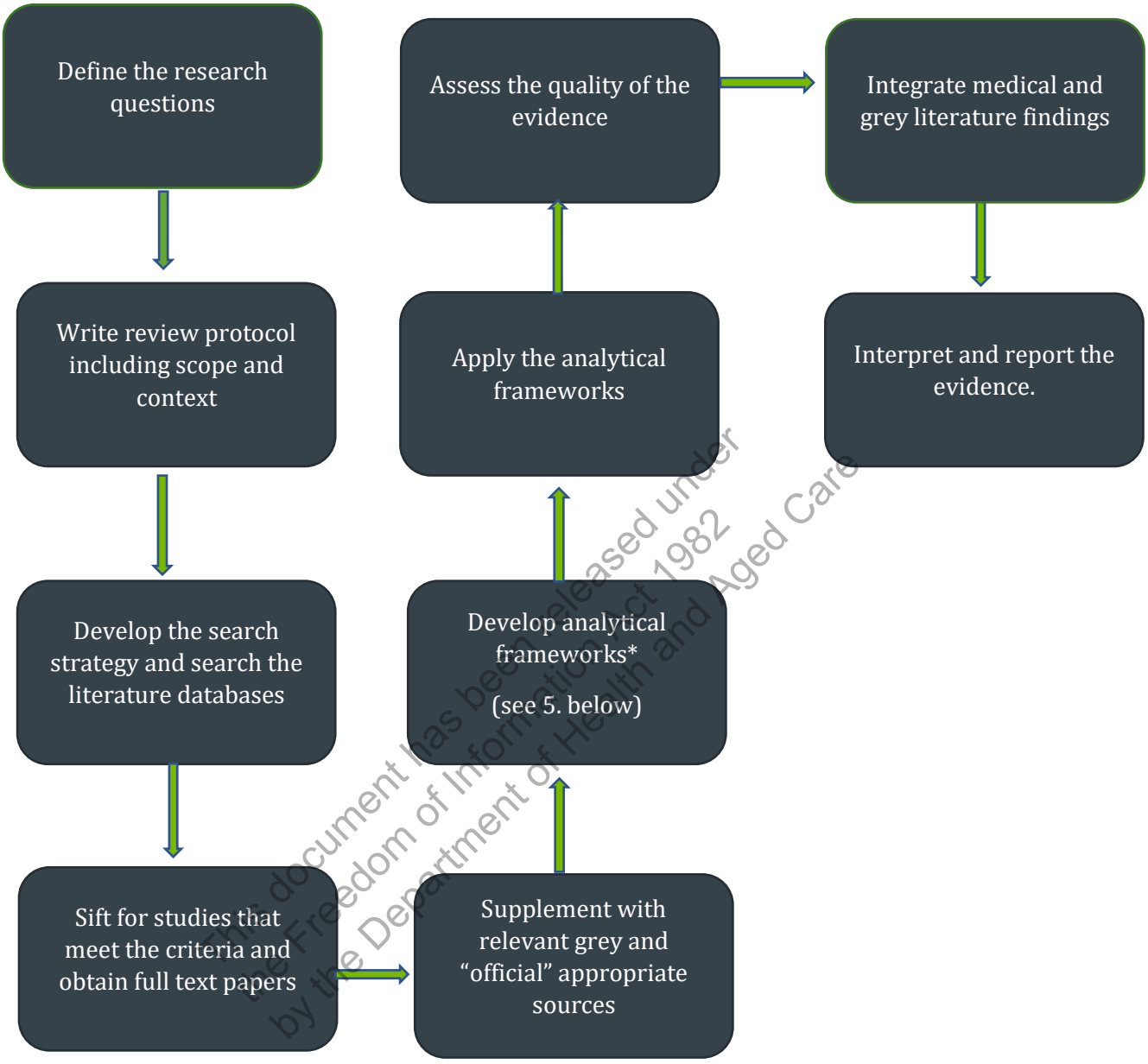
5. Erythema Chronicum Migrans/
6. (tick* adj2 (bite* or bitten or biting or borne)).ti.ab.

4.5.2. Official literature

Official literature will be sourced using full text Google Scholar.

Cross-checking for completeness (for example, following up authors and references listed in suitable reviews to check they appear in our capture strategy) will add rigour. A senior team approach will be taken to the review process to ensure consistency. The integrative review methodology is shown in Figure 1.

Figure1: Step by step review process



4.6. Documentation

Searches will be tabulated by source, search string, any inclusions and exclusions, and results will be illustrated using a standard review results flow chart (in Annexes).

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Allen + Clarke will perform the searches, and source the documents for which we require full-text. Citations will be managed with Zotero.

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The analytical framework * will be a multi-stage, systematic approach:

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ANNEXE 1: CRITICAL APPRAISAL (QUALITY TESTS)

Quantitative research

GRADE Systematic Review Checklist –

http://libguides.utoledo.edu/litreview/GRADE

CASP Randomised Controlled Trials checklist –

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CASP Case Control Study Checklist –

https://casp-uk.net/wp-content/uploads/2018/01/CASP-Case-Control-Study-Checklist-2018.pdf

CASP Diagnostic Checklist –

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Qualitative research

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist –

http://cdn.elsevier.com/promis_misc/ISSM_COREQ_Checklist.pdf

ANNEXE 2: SAMPLE PICOT

For question: What is the evidence-base for particular therapies for patients with chronic Lyme disease?

Criterion	Description
Population	• Adults over the age of 18 with documented symptoms defined in the literature as being associated with Lyme, Lyme-like or Chronic Lyme disease • Presenting symptoms • Australian, with or without history of travel to Lyme endemic areas • With or without known history of tick bite • With or without documented serology
Intervention	• Treatment
Comparator	• No treatment
Outcomes	• Symptom amelioration • Additional diagnostic tests undertaken and outcomes • Anxiety and depression • Additional costs incurred by patient
Timeframes	• Initial • Chronic
Study types	• Systematic reviews, RCTs

Literature Search Report

To support development of a DSCATT Clinical Pathway

DRAFT FOR DISCUSSION

24 May 2019

ALLEN+CLARKE

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EXECUTIVE SUMMARY

A robust assessment of the evidence base for a DSCATT Clinical Pathway

The Australian Department of Health (the Department) has commissioned the development of an evidence-based clinical pathway and multidisciplinary care model (the Clinical Pathway) for patients suffering from debilitating symptom complexes attributed to ticks (DSCATT), which can be flexibly applied in both private and public healthcare settings. The Clinical Pathway will support decision making on differential diagnosis and referral pathways for patients presenting with systemic symptoms with or without a history of tick bite and that cannot be attributed to diagnosable overseas-acquired Lyme disease or vector-borne illnesses in Australia.

The Clinical Pathway must be informed by relevant literature and key documents. A Terms of Reference was agreed to guide the literature review and the search strategy. This Literature Search Report reports on the robust process underpinning the literature review, and documents the search strategy, including the sourcing, selection and review process, and search outcomes. The Literature Review Summary Report is provided as a separate, companion report, articulating the substantive findings of the literature review.

A comprehensive approach…

The search strategy, and subsequent agreed material followed a pragmatic, rigorous process appropriate for the production of a very wide-ranging integrated review. It encompasses peer reviewed academic literature, documents provided by the Department, material referred to in the Senate Inquiry provided by patient advocacy groups, and literature sourced online.

An initial priority was to locate all appropriate Australian literature, and to source the highest quality systematic reviews. A large number of high quality, recent, and mostly Australia-specific journal articles were found. Given the extremely broad subject areas covered, priority was given to Australia material and to review articles. All official material, and all relevant (recent, geographically appropriate, high quality) clinical guidelines were included in the review.

While treatment guidelines for well-defined diseases are based on rigorous meta-analysis of Randomised Controlled Trials, this is less appropriate for even classical Lyme disease, where different case definitions and few large-scale trials of very different regimes have been reported. For DSCATT, this is not applicable, as no case definition or agreed treatment approach currently exists. Where material subsequently was reported in the high-quality reviews, especially on the treatment side, by the very recently produced (2018) and comprehensive NICE guidelines, NICE was used as the citation. Where NICE rejected papers as being of poor-quality evidence, those papers were also removed from our search.

… with notable challenges…

DSCATT is complex and a number of factors and limitations had to be considered regarding the scope and topics for this literature search. These included being able to distinguish between the illnesses classical Lyme disease, a defined infectious disease, and DSCATT, and there being no published academic literature using the very recently adopted term DSCATT. This meant we needed to revert to the terminology most commonly used to describe this set of symptoms in the literature both in Australia and internationally, including Lyme-like disease, Lyme-like illness, chronic Lyme disease and Australian Lyme disease. Similarly, the scope of the search was

necessarily wide to be able to address DSCATT rather than just classical Lyme disease, and to cover microbiology, genetics, Australian animal ticks, and the diagnosis and treatment of other disorders and syndromes with similar symptoms or complexes of symptoms to DSCATT.

While we acknowledge the Australian Government's position that debilitating symptom complexes described as DSCATT is not overseas-acquired (classical) Lyme disease, we found and summarised appropriate systematic reviews and meta-analyses for Lyme disease, particularly where these were used in the development of clinical guidelines internationally and are relevant to the development of a clinical pathway for Australian patients experiencing debilitating symptom complexes that are, for example, similar to non-specific symptoms associated with Lyme disease.

… appropriately iterative

Over and above the robust literature search process detailed in this document, additional literature was included in the literature review. Beyond the initial set of documents, the Department subsequently provided an additional list of Australian guidelines and materials that could help inform the development of the Clinical Pathway. These were considered and some of them included. More recently we were able to obtain access to Therapeutics Guidelines Limited guidelines, some of which were relevant to DSCATT and were included in the literature review.

1. INTRODUCTION

1.1. Purpose

The Australian Department of Health (the Department) has commissioned Allen + Clarke Policy and Regulatory Specialists Limited (*Allen + Clarke*) 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), which can be flexibly applied in both private and public health settings. The Clinical Pathway will support decision making on differential diagnosis and referral pathways for patients presenting with systemic symptoms with or without a history of tick bite and that cannot be attributed to diagnosable overseas-acquired Lyme disease or vector-borne illnesses in Australia.

The Clinical Pathway must be informed by relevant literature and key documents. A Terms of Reference was agreed to guide the literature review and the search strategy. This Literature Search Report reports on the robust process underpinning the literature review, and documents the search strategy, including the sourcing, selection and review process, and search outcomes. The Literature Review Summary Report is provided as a separate, companion report, articulating the substantive findings of the literature review.

1.2. Structure of this report

Section 2 of this literature search report describes our search methodology, including the Terms of Reference and search questions, our search approach, and our quality assurance method.

Section 3 provides the outcome of the search in the form of a tabulated search history (date, database, search terms, results and decision flow), and sets out the documents that were selected for inclusion in the review, and those that were excluded, with supporting rationale. This section also includes a PRISMA flow chart (with further detail on inclusion/exclusion numbers), and tables of all studies that were included, excluded and appraised.

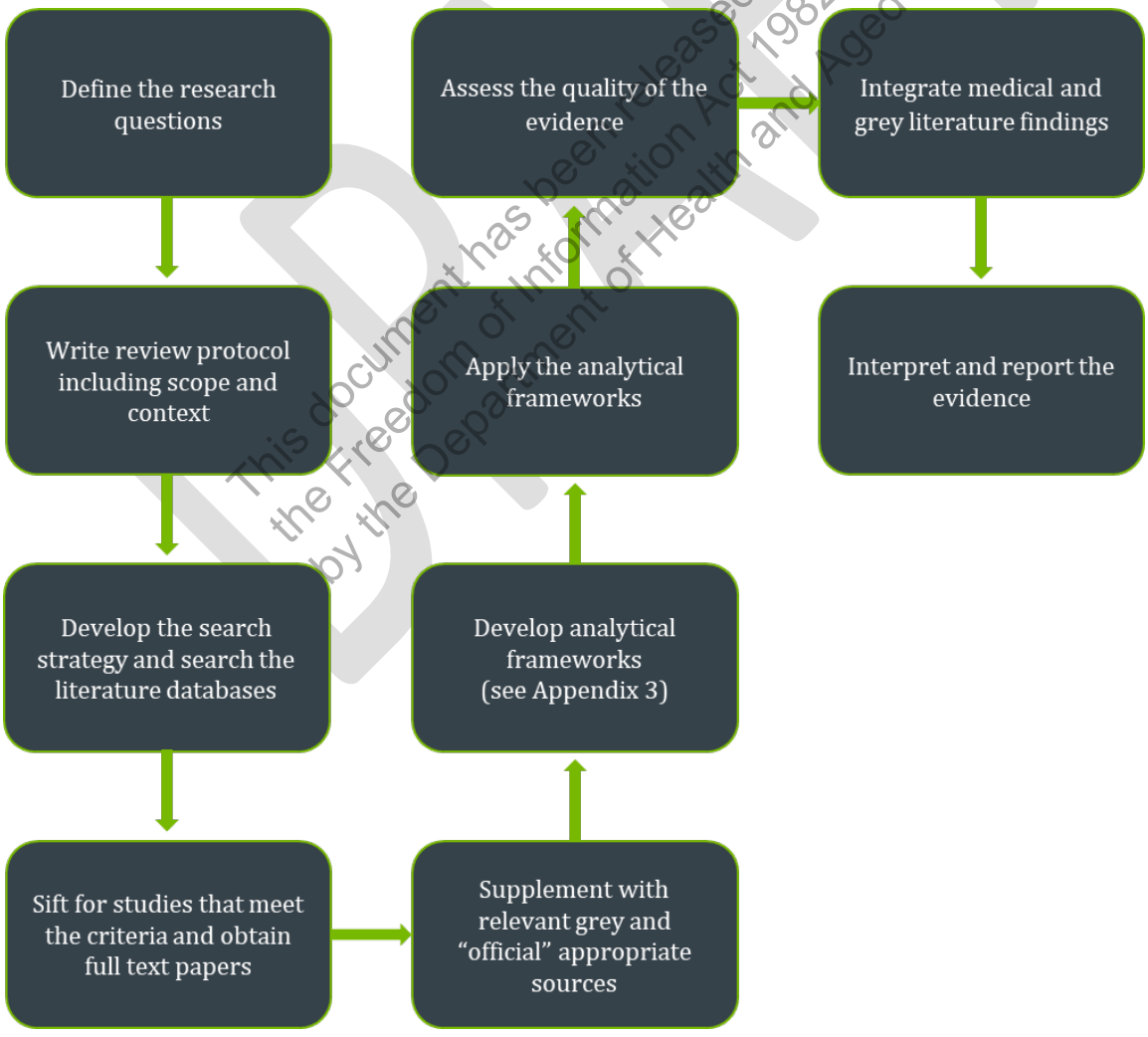
2. SEARCH METHODOLOGY

2.1. Overview

A robust integrative review methodology was used to source material to answer clearly defined, Australia-specific research questions. We implemented and documented the search strategy (including key Australian material from multiple official sources, summaries from forums and material included in the Senate Inquiry reports) to produce a final list of relevant, recent and high-quality material of the scale required by the Department (set initially at 75-100 documents). Suitable frameworks were then used to guide synthesis of evidence.

A systematic and transparent peer review process assessed the quality of evidence, giving confidence in the validity of the analysis, and enabling the evidence to be presented in summary of evidence tables, supplemented with detailed commentary. The review team met regularly in order to agree selection of search terms, initially screen the outputs to ensure that relevant material was being captured by the search strategy and make decisions as to inclusions and exclusions. The overall integrative review methodology for the literature review is shown at Figure 1. The full Terms of Reference for the Literature Search are available separately.

Figure 1: Step by step review process



2.2. Terms of reference for the search

2.2.1. Research questions

We set out to answer the five research questions shown in Table x. In the following research questions, the term 'DSCATT' is intended to cover the range of terms formerly used to describe this set of symptoms including 'Lyme-like disease', 'Lyme-like illness', 'chronic Lyme disease', 'Australian Lyme disease' and 'Lyme'.

Table x: Research questions

Research questions
Research Question 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?
Research Question 2 What information is available on diseases or disorders Australian patients experiencing DSCATT symptoms have been diagnosed with and what are the most likely differential diagnoses?
Research Question 3 What are the issues associated with diagnostic testing for Lyme disease both in Australia and by overseas laboratories?
Research Question 4 What are the treatment modalities that have been provided to patients (including subgroups of patients) with DSCATT in Australia and what is the evidence base to support these treatment modalities?
Research Question 5 What current guidelines and approaches to investigation and ongoing syndromic management of symptoms associated with DSCATT have been found effective internationally?

2.2.2. Sources and search parameters

The Department provided an initial set of key documents for inclusion in the literature review. *Allen + Clarke* undertook a supplementary online search to identify additional Australian and international evidence-based research and best practice/guideline documents relevant to DSCATT and to developing the Clinical Pathway. We set out to:

- search both academic and medical literature, and official Australian and international literature, reports, policies and guidelines
- search a range of databases: Discover (CINAHL Complete, Medline and PsycINFO); Cochrane Library database; National Institute for Health and Clinical Excellence;

PubMed; ProQuest (including Sociological Abstracts), and Guidelines International Network (www.g-i-n.net) guideline library

- search particular terms and strings by database (see Table 1)
- search terms in Google Scholar including Lyme, Lyme disease, Lyme-like, Lyme-like illness, Tick-borne, Ticks, guidelines, treatment (AND Australia) or (AND United States) or (AND UK) or (AND Canada) or (AND International).

2.2.3. Selection criteria for document inclusion in the review

Literature shown through the search were to be prioritised according to whether the particular document was:

- published, peer-reviewed literature;
- official Australian reports and government inquiries including submissions within relevant Senate Inquiry reports;
- (inter)national authority and intergovernmental reports and guidelines; and
- guidelines (International and Australian) produced by clinical and professional bodies.

In addition, in order to be considered, material had to have the following characteristics:

- currency (published between 1 January 2008 and current);
- relevance to primary research questions; and
- full article available in English language.

The literature review therefore excluded non-peer reviewed material (other than that associated with the Senate Inquiry and 2018 DSCATT forum reports), any material that does not relate to the research questions, non-English language sources, and material published before 31 December 2007, unless it was of particular relevance to the research questions. Misidentified, irrelevant papers and duplicates were removed.

2.2.4. Critical analysis and appraisal

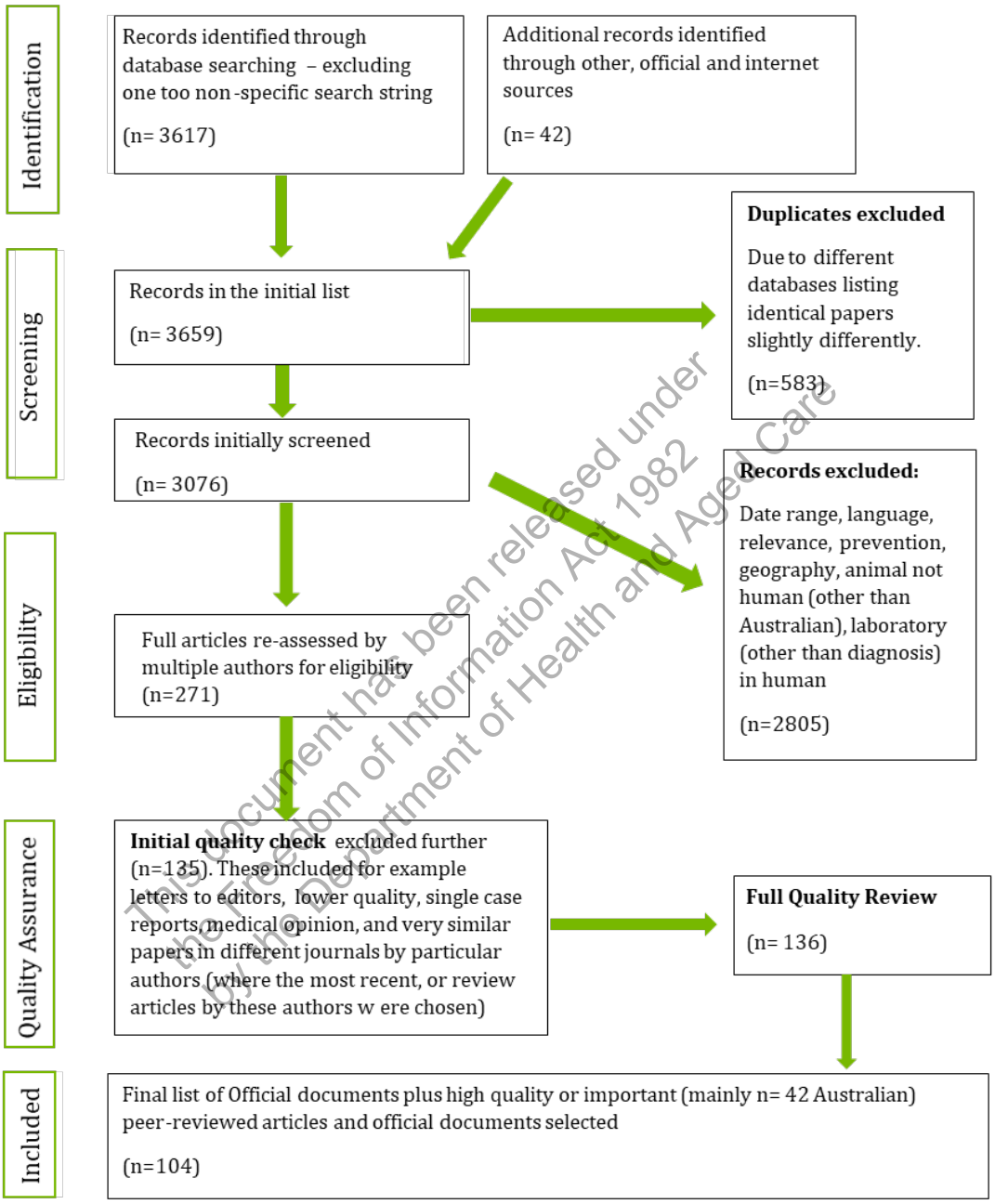
Analytical frameworks were to be used to guide the literature searching process, critical appraisal and synthesis of evidence. Various quality tests were to be applied to assess the quality of the literature sourced through the search.

- For quantitative research, we used the GRADE Systematic Review Checklist; the CASP Randomised Controlled Trials checklist; the CASP Case Control Study Checklist and the CASP Diagnostic Checklist.
- For qualitative research, we used the COREQ (COnsolidated criteria for REporting Qualitative research) Checklist.
- For grey literature, we used the AACODS Checklist.
- For clinical guidelines, we used the AGREE Checklist.

3. SEARCH PROCESS AND OUTCOMES

The overall search and selection pathway is shown in Figure 2 in the form of a PRISMA flow diagram (numbers to be confirmed next draft).

Figure 2: PRISMA flow diagram



3.1. Undertaking the search

Initial review involved a scan and decision on whether to continue. For example, where an author named "Lyme" (or Lyme in part of name) was picked up in the search, (and irrelevant to Lyme disease), it would have immediately been rejected. Most "hits" were found multiple times in the initial few searches of different databases and overlapping search terms and duplicates discarded. Others were excluded due to being out of scope. Some missed the date range despite this being specified in the search where database allowed. Some were discarded as they referred solely to prevention or vaccination or were too specifically related to epidemiology in countries other than Australia.

Official literature was sourced using full text Google Scholar using search terms: Lyme, Lyme disease, Lyme-like, Lyme-like illness, Tick-Borne, Ticks, guidelines, treatment, (AND Australia) or (AND United States) or (UK) or (Canada) or (International).

The full search history is shown in Table 1.

Table 1: Search history

Search date	Database	Search term string	Hits	Notes
11.03.19	Discover	(tick* adj2 (bite* or bitten or biting or borne)).ti.ab. AND Australia	25476	Too generic to be useful - discarded
11.03.19	Discover	Lyme* AND Australia	492	Many irrelevant papers eg author name Lyme* or out of date range or non-English language (despite these being specified) Saved 167 for initial review + 42 "official"
13.03.19	Discover	exp Borrelia AND Australia	206	16 duplicates from the search above
18.03.19	Pub Med	Lyme* AND Australia	111	62 duplicates many not specific enough, or of no or glancing reference to Australia. 6 new.
18.03.19	Pub Med	tick borne disease AND Australia	437	102 duplicates. Kept 12 new review articles and human diseases
18.03.19	Discover	tick borne disease AND Australia	167	135 duplicates, 26 veterinary, 2 prevention papers. Additional 4 identified
19.03.19	Scopus	Lyme* AND Australia	322	259 duplicates. No new Aus specific
19.03.19	Pub Med	TBD and Aus and epidemiology or incidence or prevalence	41	Other than one rickettsial review, no new hits saved
19.03.19	Pub Med	Lyme* AND Australia and epidemiology	178	No new Aus specific. No new hits saved
19.03.19	Scopus	borreliosis or borrelia* or ixodidae or ixodes or ixodid	812	Most duplicates or specific to N America, Canada, or European

Search date	Database	Search term string	Hits	Notes
		or b burgdorferi or b afzelii or b garinii or b bissettii or b valaisiana or b microti		countries. 4 new Australia specific, including patient advocacy
19.03.19	PubMed	Tick* Bite* and Australia	738	Duplicates or lay press articles about individual patients and their fight, or reports about the Senate inquiry. No new hits saved
21.03.19	Cochrane	Lyme* / Tick borne diseases	1	Antibiotic treatment of neuro complications of Lyme. Only other hits were of Nile fever, Q fever, not saved.
21.03.19	www.g-i-n.net	Lyme*	9	Guidelines filed. Reviewed by technical guideline expert
26.03.19	Discover	Erythema Chronicum Migrans AND Australia	6	1 new hit saved
26.03.19	EBSCO A/NZ Ref Centre	Lyme* AND Australia	16	Source of press cuttings etc, and the senate inquiry report. None new.
26.03.19	CINAHL Complete	Lyme* AND diagnosis AND Australia	51	1 new review of molecular diagnosis of ectoparasites saved for review
26.03.19	NICE Guidelines	Lyme disease	3	Recent, essential
26.03.19	Web of Science	Lyme* AND Australia	69	No new hits except opinion pieces- not saved.

We then further reviewed the abstract (where available) for relevance to research questions. If thought potentially useful, full text articles were sourced, downloaded into Zotero group folders for ease of retrieval and for initial expert review by the two primary authors and a technical expert.

In selecting the initial list for further detailed review, the inclusion and exclusion criteria were checked. Two hundred and seventy-one papers were then subjected to expert review for relevance by three of the senior team, before the final list of 136 were subjected to formal quality review using the appropriate critical appraisal tool for the type of paper.

3.2. Quality assessment

Many of the articles were narrative review articles. These were initially assessed using the AMSTAR checklist for the highest quality of study: meta-analysis of systematic reviews. Systematic reviews (including meta-analyses), in contrast to narrative reviews – or overviews – generally follow a specific set of evidence-based criteria. Most of the identified reviews were narrative reviews.

Narrative reviews are "evidence-round ups" on specific health care topics – but do not necessarily follow systematic evidence-based criteria. It should be noted that narrative reviews often do not meet important criteria to help mitigat7e bias. They frequently lack description of explicit criteria for article selection or there is no documented evaluation of selected articles for validity. Authors inevitably have expert opinions (and biases) and may thus (consciously or unconsciously) find studies to support their positions (selection bias). Such review articles are very useful for summarizing the literature and providing guidance provided they are of high methodological quality. Narrative reviews were accepted only if:

- they were published in high quality, peer-reviewed journals;
- their authors were established experts in their field, working in reputable institutions;
- they had clearly defined research question;
- there was transparent analysis of findings;
- they were consistently well referenced; and
- they were Australia-specific (due to additional relevance and relative scarcity).

Additionally, where doubt existed as to inclusion or exclusion, documents were searched for in the 2018 NICE review sets of background papers. Those that were listed as excluded in the NICE guidelines as being of low quality or inadequate or inaccurate interpretation were similarly excluded for this review's purpose.

Clinical guidelines were reviewed for quality using the AGREE checklist by a clinical guideline specialist.

Other papers were assessed using the appropriate critical appraisal tools for type as described above, and inclusion or rejection decisions per Terms of Reference criteria.

This large and complex process was managed across the team using group Zotero libraries, and spreadsheets held on shared drives.

3.3. Literature selected to support the review

The final list of materials accepted for the review is set out in Table 2. A list of materials excluded for the review is set out in Table 3.

Table 2: Final list of documents accepted for inclusion in the review

Year	Author	Title	Publication Title	Quality Review
2006	Wormser et al IDSA	The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America		Out of date superseded NICE but influential

Year	Author	Title	Publication Title	Quality Review
2007	Wilske, B Fingerle, V; Schulte-Spechtel, U.	Microbiological and serological diagnosis of Lyme borreliosis	FEMS Immunology & Medical Microbiology	High quality narrative review
2009	Saisongkorh, W. et al	Emerging Bartonella in Humans and Animals in Asia and Australia	Journal of the Medical Association of Thailand	High quality Australian narrative review
2009	Vilcins, I E.; Old, J M.; Deane, E.	Molecular detection of Rickettsia, Coxiella and Rickettsiella DNA in three native Australian tick species	Experimental and Applied Acarology	High quality CASP diagnostic checklist used
2010	EFNS	EFNS guidelines on the diagnosis and management of European Lyme neuroborreliosis	Guidelines	
2010	Deutsche Borreliose-Gesellschaft	Diagnosis and Treatment of Lyme borreliosis		Superseded by NICE
2010	Lantos, PM et al	Final Report of the Lyme Disease Review Panel of the Infectious Diseases Society of America	Clinical Infectious Diseases	Superseded NICE
2010	Mygland, Å. Et al	EFNS guidelines on the diagnosis and management of European Lyme neuroborreliosis: Guidelines on neuroborreliosis	European Journal of Neurology	Superseded by NICE
2011	Harris, MF et al.	Multidisciplinary Team Care Arrangements in the management of patients with chronic disease in Australian general practice	Medical Journal of Australia	High quality Australian narrative review
2011	Lowbridge, Chris P.; Doggett, S L.; Graves, Stephen	Bug Breakfast in the Bulletin: Tickborne diseases	New South Wales Public Health Bulletin	High quality Australian narrative review
2011	Mayne PJ	Emerging incidence of Lyme borreliosis, babesiosis, bartonellosis, and granulocytic ehrlichiosis in Australia	International Journal of General Medicine,	High quality CASP Case Control checklist used
2012	Banks, P B.; Hughes, N K.	A review of the evidence for potential impacts of black rats (Rattus rattus) on wildlife and humans in Australia	Wildlife Research	High quality Australia animal

Year	Author	Title	Publication Title	Quality Review
2012	Mayne PJ	Investigation of Borrelia burgdorferi genotypes in Australia obtained from erythema migrans tissue	Clinical, Cosmetic and Investigational Dermatology	High quality CASP diagnostic checklist used
2012	Senanayake, SN et al	First report of human babesiosis in Australia	The Medical Journal of Australia	High quality CASP Case Control checklist used
2013	Australian Government CMO	Advice to clinicians - Establishment of the Clinical Advisory Committee on Lyme Disease	Official	
2013	CALD	Discussion Paper on Lyme	Official	
2013	Dawood, KE et al	Observation of a novel Babesia spp. in Eastern Grey Kangaroos (Macropus giganteus) in Australia	International Journal for Parasitology: Parasites and Wildlife	High quality Australian animal
2014	Borgermans, L; Goderis, G; Vandevoorde, J; Devroey, D	Relevance of Chronic Lyme Disease to Family Medicine as a Complex Multidimensional Chronic Disease Construct: A Systematic Review	International Journal of Family Medicine	High quality review
2014	Cameron, D J; Johnson, LB; Maloney, E L	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	Very high-quality review (AMSTAR)
2014	Diuk-Wasser, MA et al	Monitoring Human Babesiosis Emergence through Vector Surveillance New England, USA	Emerging Infectious Diseases	High quality Used CASP Case control checklist
2014	Janakiraman, R; Wan, A	Evaluating the need for a specialist service on Lyme disease in Australia	Australasian Psychiatry	Opinion only but Australian
2014	Lantos, P. M.; Auwaerter, P. G.; Wormser, G. P.	A Systematic Review of Borrelia burgdorferi Morphologic Variants Does Not Support a Role in Chronic Lyme Disease	Clinical Infectious Diseases	Excluded by NICE - "incorrect analysis"?
2014	Lantos, PM.; Wormser, GP.	Chronic Coinfections in Patients Diagnosed with Chronic Lyme Disease: A Systematic Review	The American Journal of Medicine	Medium quality Narrative review, but well described search strategy.

Year	Author	Title	Publication Title	Quality Review
				Fails many elements of AMSTAR
2014	Marques, A; et al.	Xenodiagnosis to detect Borrelia burgdorferi infection: a first-in-human study	Clinical infectious diseases	High quality Cochrane
2014	Mayne, P. et al	Evidence for Ixodes holocyclus (Acarina: Ixodidae) as a Vector for Human Lyme Borreliosis Infection in Australia	Journal of Insect Science	High quality Australian but superseded by Chalada
2014	Mayne, P.J.	Clinical determinants of Lyme borreliosis, babesiosis, bartonellosis, anaplasmosis, and ehrlichiosis in an Australian cohort	International Journal of General Medicine	Australian but superseded by Chalada
2015	Aguero-Rosenfeld, ME; Wormser, G P	Lyme disease: diagnostic issues and controversies	Expert Review of Molecular Diagnostics	High quality review
2015	Borchers, AT et al	Lyme disease: A rigorous review of diagnostic criteria and treatment	Journal of Autoimmunity	Narrative review
2015	Cieszka, J; Dabek, J; Cielik, P	Post-Lyme disease syndrome	Reumatologia	High quality Cochrane but superseded by NICE
2015	Davy, C. et al	Effectiveness of chronic care models: opportunities for improving healthcare practice and health outcomes: a systematic review	BMC Health Services Research	High quality by AMSTAR
2015	Dersch, R. et al	Methodological quality of guidelines for management of Lyme neuroborreliosis	BMC Neurology	High quality
2015	DOH CMO	Progress Report on Lyme disease in Australia	Official	
2015	Dryden, M. S.; Saeed, K.; Ogborn, S.; Swales, P.	Lyme borreliosis in southern United Kingdom and a case for a new syndrome, chronic arthropod-borne neuropathy	Epidemiology and Infection	High quality Case control CASP review
2015	Gofton, AW et al	Bacterial Profiling Reveals Novel "Ca. Neoehrlichia", Ehrlichia, and Anaplasma Species in Australian Human-Biting Ticks	PLOS ONE	Australian

Year	Author	Title	Publication Title	Quality Review
2015	Gofton, A et al	Inhibition of the endosymbiont "Candidatus Midichloria mitochondrii" during 16S rRNA gene profiling reveals potential pathogens in Ixodes ticks from Australia	Parasites & Vectors	Australian but not possible to assess against the CASP diagnostic checklist
2015	Halperin, J	Chronic Lyme disease: misconceptions and challenges for patient management	Infection and Drug Resistance	High quality Narrative review
2015	Lum, G D; Hood, J R; Wright, P	An Australian guideline on the diagnosis of overseas-acquired Lyme disease/borreliosis		Guidelines Australian overseas acquired
2015	McManus, M; Cincotta, A	Effects of Borrelia on host immune system: Possible consequences for diagnostics	Advances in Integrative Medicine	Good narrative review
2015	Perronne, C	Critical review of studies trying to evaluate the treatment of chronic Lyme disease	La Presse Médicale	High quality narrative review
2015	Stenos, JV, et al	No evidence of lyme disease in Australia yet	Pathology	Australia reference lab short report - not possible to review against CASP diagnostics checklist
2015	Subedi, S; Dickeson, DJ; Branley, J M	First report of Lyme neuroborreliosis in a returned Australian traveller.	The Medical Journal of Australia	Case report poor quality by CASP
2016	Australia CMO	Statement	Official	
2016	Australia; Parliament; Senate; Community Affairs References Committee; Siewert, Rachel	Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients: interim report	Official	
2016	Australian Government	Response to Senate Inquiry Interim report	Official	
2016	Beaman, M H	Lyme disease: why the controversy?	Internal Medicine Journal	High quality Narrative review. Australian and authoritative

Year	Author	Title	Publication Title	Quality Review
2016	Berende, A; et al	Randomized Trial of Longer-Term Therapy for Symptoms Attributed to Lyme Disease	New England journal of medicine	High quality CASP RCT checklist review. Superseded by NICE
2016	Cadavid, D; Auwaerter, PG; Rumbaugh, J; Gelderblom, H	Antibiotics for the neurological complications of Lyme disease	Cochrane database of systematic reviews (online)	High quality Cochrane Systematic Review AMSTAR compliant superseded by NICE
2016	Chalada, MJ; Stenos, J; Bradbury, RS	Is there a Lyme-like disease in Australia? Summary of the findings to date	One Health	Narrative review. Not AMSTAR compliant but comprehensive and Australian
2016	Collignon, P J; Lum, G D; Robson, J MB	Does Lyme disease exist in Australia?	The Medical Journal of Australia	Opinion but Australian
2016	Dickeson, DJ; Chen, SC-A; Sintchenko, V G	Concordance of four commercial enzyme immunoassay and three immunoblot formats for the detection of Lyme borreliosis antibodies in human serum: the two-tier approach remains.	Pathology	High quality Reviewed using CASP for diagnostics
2016	Graves, et al	Ixodes holocyclus Tick-Transmitted Human Pathogens in North-Eastern New South Wales, Australia	Tropical Medicine and Infectious Disease	Case study CASP checklist. Medium quality but Australian
2016	Halperin, J J.	Nervous system Lyme disease, chronic Lyme disease, and none of the above	Acta Neurologica Belgica	High quality Narrative review /Authoritative opinion
2016	Horton, DB et al	Clinical and treatment factors associated with antibiotic-refractory LYME arthritis in children	Arthritis and rheumatology. Conference: ACR/ARHP 2016. United states.	Superseded by NICE
2016	LDAA	A patient Perspective		Also in Senate Inquiry

Year	Author	Title	Publication Title	Quality Review
2016	Loh, SM et al	Novel Borrelia species detected in echidna ticks, Bothriocroton concolor, in Australia	PARASITES & VECTORS	High quality Animal, Australian
2016	NCT02687165	Uncovering Neural and Immune Mechanisms of Chronic Pain in Post Treatment Lyme Syndrome	Https://clinicaltrials.gov/show/nct02687165	Superseded by NICE
2016	Parliament of the Commonwealth of Australia	Inquiry into chronic disease prevention and management in primary health care	Official	
2016	Senate Community Affairs reference Committee	Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients	Official	
2016	Steurer, J	Months of antibiotic therapy in persistent symptoms of Lyme disease without effect	Praxis	Superseded by NICE
2016	Whiley, H. et al	Rickettsia Detected in the Reptile Tick Bothriocroton hydrosauri from the Lizard Tiliqua rugosa in South Australia	Pathogens	High quality Animal, Australian
2016	Yeung, C. H. T. et al	Integrated multidisciplinary care for the management of chronic conditions in adults: an overview of reviews and an example of using indirect evidence to inform clinical practice recommendations in the field of rare diseases	Haemophilia	Very high-quality review (AMSTAR)
2016	Cook and Puri	Commercial test kits for detection of Lyme borriliosis: a meta-analysis of test accuracy	International Journal of general medicine	High quality Reviewed using CASP for diagnostics tests
2017	Australian Government	Response to Senate Inquiry Final report	Official	
2017	Australian Government	Ministerial Statement Govt response senate inquiry final report	Official	
2017	Brunton	Lyme disease stakeholder experiences	DoH (UK) Health Reviews Facility	Very High-quality review (AMSTAR)
2017	Citera, Maryalice; Freeman, Phyllis R; Horowitz, Richard I	Empirical validation of the Horowitz Multiple Systemic Infectious Disease Syndrome	International Journal of General Medicine	

Year	Author	Title	Publication Title	Quality Review
		Questionnaire for suspected Lyme disease		
2017	Graves, Stephen R; Stenos, John	Tick-borne infectious diseases in Australia	The Medical Journal of Australia	High quality Narrative review Australian
2017	Irwin, PJ et al.	Searching for Lyme borreliosis in Australia: results of a canine sentinel study.	Parasites & Vectors	Animal Australian
2017	Loh, SM et al	Molecular characterization of 'Candidatus Borrelia tachyglossi' (family Spirochaetaceae) in echidna ticks, Bothriocroton concolor	International Journal of Systematic and Evolutionary Microbiology	Animal Australian
2017	Lorenc	Lyme disease surveillance	London: Department of Health Reviews Facility.	Very high-quality review (AMSTAR)
2017	Panetta, JL et al.	Reptile-associated Borrelia species in the goanna tick (Bothriocroton undatum) from Sydney, Australia	PARASITES & VECTORS	Animal Australian
2017	Stokes	Lyme disease evidence map	DoH (UK) Health Reviews Facility	Very High-quality review (AMSTAR)
2017	Sutcliffe	Lyme disease treatment	DoH (UK) Health Reviews Facility	Very High-quality review (AMSTAR)
2017	Mackenzie, John S	Scoping study to develop a research project(s) to investigate the presence or absence of lyme disease in australia	Official	Australian Official
2018	Berende, A; et al.	Cost-effectiveness of longer-term versus shorter-term provision of antibiotics in patients with persistent symptoms attributed to Lyme disease	Plos one	High quality review AMSTAR
2018	Brown, Jeremy D.	A description of Australian Lyme disease epidemiology and impact	Internal Medicine Journal	Senate Inquiry submissions
2018	DOH	Position Statement Lyme	Official	
2018	DSCATT Forum Melborne	Final report	Official	

Year	Author	Title	Publication Title	Quality Review
2018	DSCATT Forum Sydney	Final report	Official	
2018	Garg, K; et al.	Evaluating polymicrobial immune responses in patients suffering from tick-borne diseases	Scientific reports	Evaluated high quality using CASP for diagnostics
2018	Gofton, AW et al.	Genome-wide analysis of Borrelia turcica and 'Candidatus Borrelia tachyglossi' shows relapsing fever-like genomes with unique genomic links to Lyme disease Borrelia.	Infection, Genetics And Evolution: Journal Of Molecular Epidemiology And Evolutionary Genetics In Infectious Diseases	Animal Australian
2018	Horowitz, R I.; Freeman, P R.	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	
2018	Izzard, L. et al	Isolation of a divergent strain of Rickettsia japonica from Dew's Australian bat Argasid ticks (Argas (Carios) dewae) in Victoria, Australia	TICKS AND TICK-BORNE DISEASES	Animal Australian
2018	Kwak, M L.	The first records of human infestation by the hard tick Ixodes (Endopalpiger) australiensis (Acari: Ixodidae), with a review of human infestation by ticks in Australia	Experimental and Applied Acarology	Single case study but Australian
2018	LDAA	Ministerial Forum addendum	Official	
2018	Maine CDC	Report to Maine Legislature Lyme and other Tickborne Illnesses	Official	
2018	Middelveen, M. et al	Persistent Borrelia Infection in Patients with Ongoing Symptoms of Lyme Disease	Healthcare	Reviewed using CASP for diagnostics. Good quality though not directly applicable to the review?
2018	NICE	Lyme disease	NICE	
2018	National Serology Reference Laboratory	Investigation of the performance of the Assays for Lyme Disease in Australia	Official	High level official

Year	Author	Title	Publication Title	Quality Review
2018	NICE	a,b,c,d,e,f,g,h,I,j,k suite of background papers	NICE	NICE
2019	Dehhaghi, M. et al	Human Tick-Borne Diseases in Australia	Frontiers in Cellular and Infection Microbiology	High quality Animal Australian
2019	Doolan, BJ; Christie, M; Dolianitis, C	A ticking time bomb: A case of Lyme disease	Australasian Journal of Dermatology	Case report CASP review low quality returned traveller
2019	Harvey, ER et al.	Extensive Diversity of RNA Viruses in Australian Ticks.	Journal of Virology	Animal Australian
2019	Horowitz, Richard I; Freeman, Phyllis R	Precision medicine: retrospective chart review and data analysis of 200 patients on dapsone combination therapy for chronic Lyme disease/post-treatment Lyme disease syndrome: part 1	International Journal of General Medicine	Post NICE
2019	Dehhaghi M. et al	Human Tick-Borne Diseases in Australia	Frontiers in Cellular and Infection Microbiology	Animal Australian
2019	Eldin, C., et al	Review of European and American guidelines for the diagnosis of Lymeborreliosis	Med Mal Infect	Review of Guideline's quality.

(APA convention used: for 5 or more authors - et al)

Table 3: Papers excluded in final check and reasons for exclusion

Year	Authors	Title	Journal	Reason
2007	Feder, H M; Shapiro, E D	A Critical Appraisal of "Chronic Lyme Disease"	New Engl J med	High quality narrative review but old
2007	Harris, M F; Zwar, N A	Care of patients with chronic disease: the challenge for general practice	Medical Journal of Australia	High quality Australian narrative review but old
2007	Oksi, J; et al.	Duration of antibiotic treatment in disseminated Lyme borreliosis: a double-blind, randomized, placebo-controlled, multicenter clinical study	European journal of clinical microbiology & infectious diseases	Superseded by NICE
2008	Cameron, D	Severity of Lyme disease with persistent symptoms. Insights from a double-blind placebo-controlled clinical trial	Minerva medica	CLD
2008	Skogman, BH; et al	Lyme neuroborreliosis in children: a prospective study of clinical features, prognosis, and outcome	Pediatric infectious disease journal	CLD old
2009	Grosse, S. D.; et al	Models of Comprehensive Multidisciplinary Care for Individuals in the United States With Genetic Disorders	PEDIATRICS	Genetic only
2010	Cerar, D; et al	Subjective symptoms after treatment of early Lyme disease	American journal of medicine	CLD
2010	Dillon, R.; O'Connell, S.; Wright, S.	Lyme disease in the UK: clinical and laboratory features and response to treatment	Clinical Medicine	Superseded by NICE
2010	Johnson, Michael; Feder, Henry M.	Chronic Lyme Disease: A Survey of Connecticut Primary Care Physicians	The Journal of Pediatrics	USA
2011	Eikeland, R; Mygland, A; Herlofson, K; Ljostad, U	European neuroborreliosis: quality of life 30months after treatment	Acta neurologica scandinavica	CLD
2011	NCT01368341	Comparing 3 Antibiotic Regimes for Erythema Migrans in General Practice	Https://clinicaltrials.gov/show/nct01368341	Superseded by NICE

Year	Authors	Title	Journal	Reason
2011	Stricker, RJ	Lyme disease: the next decade	Infection and Drug Resistance	CLD USA
2012	NCT01635530	Study of Lyme Neuroborreliosis	Https://clinicaltrials.gov/show/nct01635530	CLD
2013	Maud, C; Berk, M	Neuropsychiatric presentation of Lyme disease in Australia.	The Australian And New Zealand Journal of Psychiatry	low quality case report
2013	Deanehan, JK; et al	Distinguishing Lyme from septic knee monoarthritis in Lyme disease-endemic areas	Pediatrics	CLD
2013	Jacek, E et al	Increased IFNα activity and differential antibody response in patients with a history of Lyme disease and persistent cognitive deficits	Journal of neuroimmunology	CLD
2013	Solano, PL; Mcduffie, MJ; Fagan, HB; Gifford, K	Evaluation of educational interventions for three lesser-known illnesses	Delaware medical journal	Out of scope
2013	Vayssier-Taussat, M. et al	Next Generation Sequencing Uncovers Unexpected Bacterial Pathogens in Ticks in Western Europe	PLoS ONE	NICE
2013	Wressnigg, N; et al.	Safety and immunogenicity of a novel multivalent OspA vaccine against Lyme borreliosis in healthy adults: a double-blind, randomised, dose-escalation phase 1/2 trial	The lancet. Infectious diseases	vaccine
2013	Yazdany, J; et al.	Choosing wisely: the American College of Rheumatology's Top 5 list of things physicians and patients should question	Arthritis care & research	Superseded NICE
2014	Bockenstedt, L K.; Wormser, GP.	Review: Unravelling Lyme Disease: Lyme Disease	Arthritis & Rheumatology	Narrative review fails AMSTAR excluded in NICE due to "incorrect analysis"

Year	Authors	Title	Journal	Reason
2014	Lantos, P. M.; Auwaerter, P. G.; Wormser, G. P.	A Systematic Review of Borrelia burgdorferi Morphologic Variants Does Not Support a Role in Chronic Lyme Disease	Clinical Infectious Diseases	Excluded by NICE - "incorrect analysis"
2014	Blanc, F;; et al.	Lyme neuroborreliosis and dementia	Journal of alzheimer's disease	CLD
2014	Lindsay, Lr; Bernat, K; Dibernardo, A	Laboratory diagnostics for Lyme disease	Canada Communicable Disease Report	Superseded NICE
2014	Tokarska-Rodak, M; et al	Significance of circulating immune complexes (CIC) in the diagnosis of infections with Borrelia burgdorferi	Wiadomosci lekarskie (Warsaw, Poland	Superseded NICE
2014	Wressnigg, N; et al.	A Novel multivalent OspA vaccine against Lyme borreliosis is safe and immunogenic in an adult population previously infected with Borrelia burgdorferi sensu lato	Clinical and vaccine immunology	vaccine
2014	Bockenstedt, L K.; Wormser, GP.	Review: Unravelling Lyme Disease: Lyme Disease	Arthritis & Rheumatology	Narrative review fails AMSTAR excluded in NICE due to "incorrect analysis"
2015	Feldman, KA; et al	Abundance and infection rates of Ixodes scapularis nymphs collected from residential properties in Lyme disease-endemic areas of Connecticut, Maryland, and New York	Journal of vector ecology	USA ticks
2015	Kuchynka, P; et al.	Recent-onset dilated cardiomyopathy associated with Borrelia burgdorferi infection	Herz	CLD
2015	Moore, Karen S.	Lyme Disease: Diagnosis, Treatment Guidelines, and Controversy	The Journal for Nurse Practitioners	Low Quality Journal
2015	NCT02553473	Six Versus Two Weeks Treatment With Doxycycline in Lyme Neuroborreliosis	Https://clinicaltrials.gov/show/nct02553473	superseded by NICE
2015	NCT02613585	Tick-borne Illness and Clothing Study of Rhode Island	Https://clinicaltrials.gov/show/nct02613585	superseded by NICE

Year	Authors	Title	Journal	Reason
2016	Beaujean, DJ; et al	Comparing the effect of a leaflet and a movie in preventing tick bites and Lyme disease in The Netherlands	BMC public health	Out of scope prevention
2016	Faller, M et al	EU-wide external quality assessment study to establish performance characteristics of different amplification protocols for detection of Borrelia burgdorferi sensu lato	International journal of medical microbiology. Conference: 68th annual meeting of the german society for hygiene and microbiology, DGHM 2016. Germany.	Superseded by NICE
2016	Horton, DB et al	Clinical and treatment factors associated with antibiotic-refractory LYME arthritis in children	Arthritis and rheumatology. Conference: american college of rheumatology/association of rheumatology health professionals annual scientific meeting, ACR/ARHP 2016. United states. Conference start: 20161111. Conference end: 20161116	CLD
2016	Jowett, N; Gaudin, RA; Banks, CA; Hadlock, TA	Steroid use in Lyme disease-associated facial palsy is associated with worse long-term outcomes	Laryngoscope	CLD
2016	NCT03010228	Study Assessing the Safety, Immunogenicity and Dose Response of VLA15, A New Vaccine Candidate Against Lyme Borreliosis	Https://clinicaltrials.gov/show/nct03010228	vaccine
2016	Scott, JD; et al	Established population of blacklegged ticks with high infection prevalence for the lyme disease bacterium, borrelia burgdorferi sensu lato, on corkscrew island, kenora district, Ontario	International journal of medical sciences	Cochrane review but Ontario

Year	Authors	Title	Journal	Reason
2017	Basile, R. et al	Brazilian borreliosis with special emphasis on humans and horses	Brazilian Journal of Microbiology	Case report not high quality by CASP
2017	Bechtold, K T et al	Standardized Symptom Measurement of Individuals with Early Lyme Disease Over Time	Archives of Clinical Neuropsychology	Classical Lyme Disease (CLD)
2017	States, S.L. et al	Co-feeding transmission facilitates strain coexistence in Borrelia burgdorferi, the Lyme disease agent	Epidemics	animal US
2017	Eliassen, KE et al	Symptom load and general function among patients with erythema migrans: a prospective study with a 1-year follow-up after antibiotic treatment in Norwegian general practice	Scandinavian journal of primary health care	CLD
2017	Pacheco, A et al	The incidence of emergency department visits for bell's palsy peaked in summer in a lyme endemic area	Academic emergency medicine. Conference: 2017 annual meeting of the society for academic emergency medicine, SAEM 2017. United states	CLD
2018	Benders, M; et al	Incidence of type i sensitization to alpha-gal in patients with borreliosis	Allergy	Separate diagnosable syndrome meat allergy
2018	van Nunen, SA	Tick-induced allergies: mammalian meat allergy and tick anaphylaxis	Medical Journal of Australia	out of scope
2018	NCT03769194	Immunogenicity and Safety Study of a Vaccine Against Lyme Borreliosis, in Healthy Adults Aged 18 to 65 Years. Randomized, Controlled, Observer-blind Phase 2 Study	Https://clinicaltrials.gov/show/nct03769194	vaccine

APPENDIX X: DOCUMENTS PROVIDED BY THE DEPARTMENT

a. Interim Report - *Growing evidence of an emerging tick-borne disease that causes a Lyme like illness for many Australian patients* – 4 May 2016. https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lyme-like_Illness/Interim_Report

b. Australian Government response to the Senate - Community Affairs References Committee interim report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients* – Interim Report – 9 November 2016. https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lymelikeillness45

c. Final Report - *Growing evidence of an emerging tick-borne disease that causes a Lyme like illness for many Australian patients* – 30 November 2016. https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lymelikeillness45/Final_Report

d. Australian Government response to the Senate - Community Affairs References Committee interim report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients* – Final Report - 15 November 2017. https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lymelikeillness45/Government_Response

e. Department of Health – DSCATT Forum – 18 April 2018 – Melbourne. http://www.health.gov.au/lyme-disease#dscatt

f. Department of Health – DSCATT Patient Group Forum – 27 July 2018 – Sydney. http://www.health.gov.au/lyme-disease#dscatt_syd

g. Department of Health – DSCATT Position Statement. http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-lyme-disease.htm/$File/Posit-State-Debilitating-Symptom-Complexes-Attributed-Ticks-June18.pdf

h. Department of Health – Lyme disease in Australia Position Statement. http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-lyme-disease.htm/$File/Posit-State-Lyme-June18.pdf

i. An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis. (2015). Gary D. Lum, Jennie R. Hood, Phil Wright. Office of Health Protection, Australian Department of Health. http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-lyme-disease.htm/$File/Aust-guideline-diagnosis-overseas-acquired-Lyme-disease.pdf

[to add: citations for additional Departmental resources on guidelines, as well as Therapeutic Guidelines limited]

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Terms of Reference for Literature Search

Supporting an evidence-based approach to developing a clinical pathway and multidisciplinary care model for Australian patients suffering from debilitating symptom complexes attributed to ticks (DSCATT)

23 April 2019

ALLEN+CLARKE

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Allen + Clarke has been independently certified as compliant with ISO9001:2015 Quality Management Systems

CONTENTS

1. INTRODUCTION

1.1. Purpose of this document

The Australian Department of Health (the Department) has commissioned Allen + Clarke Policy and Regulatory Specialists Limited (*Allen + Clarke*) 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 health settings. The purpose of the pathway will be to support decision making on differential diagnosis and referral pathways for patients presenting with systemic symptoms with or without a history of tick bite and that cannot be attributed to diagnosable overseas-acquired Lyme disease or vector-borne illnesses in Australia.

The Department requires the Clinical Pathway to be informed by relevant evidence-based literature and key documents. The Department has provided a set of key documents to be included in the literature review (see Annex 1). *Allen + Clarke* will also undertake a supplementary online search to identify additional Australian and international evidence-based research and best practice/guideline documents relevant to DSCATT and to developing the Clinical Pathway.

This document sets out the terms of reference for a search strategy to identify and appraise published literature and describe the process and methodology for a robust integrative review.

Allen + Clarke will use this as the basis for conducting the search of published literature and websites. *Allen + Clarke* will use a range of critical appraisal tools (see Annexe 2) to assess the quality of publications, as appropriate for the methodologies employed.

Annexe 2 contains the critical appraisal tools designed for particular literature types that will be systematically applied in order to rate the level of evidence for identified outcomes presented across the included research.

1.2. Why is this literature review important?

The Australian Government acknowledges that there is a group of Australian patients suffering from the chronic debilitating symptom complexes, which many associate with a tick bite. The Australian Government has chosen to collectively describe this varied patient group as suffering from Debilitating Symptom Complexes Attributed to Ticks (DSCATT). The term DSCATT was carefully considered to appropriately acknowledge this patient group and the multifaceted illness they are experiencing, whilst moving away from the stigma and controversy associated with the use of "Lyme disease", "Lyme disease-like illness" and "chronic Lyme disease" that have previously and erroneously been used to describe this patient group.

Many of these patients experiencing debilitating symptom complexes are living in turmoil as their illness is poorly understood, making accurate diagnosis and treatment difficult. It is imperative for government health authorities, clinicians and patients alike to remain open minded as to the causes of these symptoms and work together to achieve a patient-centred multidisciplinary approach to their care.

In addition, overseas travellers to Lyme disease-endemic areas may return to Australia before becoming symptomatic and/or being diagnosed. In Australia, Lyme disease should be considered in patients presenting with a travel history to Lyme disease-endemic areas along with supporting

symptoms and/or a known tick bite. However, due to the controversy and stigma attached to Lyme disease in Australia some of these patients have also not received an appropriate assessment of their symptoms.

The literature review, which will be peer-reviewed by *Allen + Clarke's* Expert Medical Technical Advisor and Expert Guidelines Technical Advisor and published, will inform the development of an evidence-based approach to developing a draft Clinical Pathway. The draft Clinical Pathway will then be further developed in consultation with key stakeholders to ensure it is fit for purpose and acceptable to the majority of stakeholders, including the Australian Health Ministers' Advisory Council (AHMAC) and its subcommittees, the Australian Health Protection Principal Committee (AHPPC) and Clinical Principal Committee (CPC).

The Clinical Pathway will contribute to fulfilling the Australian Government's response to Recommendation 5 of the Senate Community Affairs References Committee Final Report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients,* where the Australian Government agreed to consult with key stakeholder groups to develop a cooperative multidisciplinary framework which can accommodate patient and medical needs. The development of the Clinical Pathway will build on the consultation about the concept of multidisciplinary care previously undertaken through consultation forums with medical professionals, state and territory health authorities and patient groups in April and July 2018.

2. SCOPE AND TOPICS

As discussed above, the Australian Government has chosen to describe this patient group as people suffering from Debilitating Symptom Complexes Attributed to Ticks (DSCATT) with this term being only very recently adopted in Australia. A preliminary PubMed search revealed there is no published academic literature using this term.

The literature review will focus on published evidence that can inform an evidence-base to underpin the development of a clinical pathway for patients experiencing symptoms or a complex of symptoms now referred to collectively as DSCATT.

However, the situation with DSCATT is complex and a number of factors and limitations must be considered regarding the scope and topics for this literature review. Regarding being able to distinguish between the illnesses classical Lyme disease, an infectious disease, and DSCATT, the Australian Government Position Statement: Lyme Disease in Australia notes that while some Australians and healthcare providers believe that classical Lyme disease can be acquired from ticks in Australia or that a form of 'chronic Lyme disease' exists, the Australian Government cannot support the diagnosis of locally acquired Lyme disease in Australia without the causative organism of classical Lyme disease (*Borrelia burgdorferi* sensu lato) or a competent vector being identified in Australia. With respect to DSCATT, the Australian Government Position Statement: Debilitating Symptom Complexes Attributed to Ticks notes that the illnesses experienced by patients with debilitating symptom complexes is poorly understood, making accurate diagnosis and treatment difficult and that because of the imprecise nature of the symptom complexes some patients will remain undiagnosed. The Position Statement therefore stresses it is imperative for government health authorities, clinicians and patients to remain open minded as to the causes of these symptoms.

To overcome the lack of published evidence on the term 'DSCATT' we will need to revert to the terminology most commonly used to describe this set of symptoms in the literature both in

Australia and internationally, including Lyme disease-like disease, Lyme disease-like illness, chronic Lyme disease and Australian Lyme disease. Other terms are also used internationally to describe similar symptoms or complexes of symptoms including chronic multiple systemic infectious diseases syndrome, chronic arthropod-borne neuropathy and Baggio-Yoshinari syndrome.

Regarding the available literature, while extensive literature and literature reviews exist for classical Lyme disease (particularly from Europe and North America), for DSCATT and terminology used to describe it in Australia, the literature is more limited and less restricted to peer-reviewed medical and scientific literature.

This literature review will therefore not be a literature review on overseas-acquired Lyme disease or recognised tick-borne disease in Australia. Indeed, an Australian guideline on the diagnosis of overseas-acquired Lyme disease/Borreliosis was published in 2015, including a flow chart to guide clinicians when a patient presents with a tick bite.

It will; however, include evidence and guidelines on overseas-acquired or classical Lyme disease and recognised tick-borne diseases, where relevant and where that evidence assists in informing aspects of a clinical pathway for this group of Australian patients. Specifically, we propose to identify and review Australian (as a priority) and international peer reviewed research and evidence-based practice/guideline documents and literature (including primary studies and secondary research) to support the development of the Clinical Pathway.

We propose a robust integrative review methodology that will include clearly defined Australia-specific research questions, a thoroughly documented search strategy (including key Australian material from multiple official sources, summaries from forums and material included in the Senate Inquiry reports) and the use of suitable frameworks to guide synthesis of evidence. While we acknowledge the Australian Government's position that debilitating symptom complexes described as DSCATT is not overseas-acquired (classical) Lyme disease we will find and summarise appropriate systematic reviews and meta-analyses for Lyme disease, particularly where these have been used in the development of clinical guidelines internationally and are relevant to the development of a clinical pathway for Australian patients experiencing debilitating symptom complexes that are, for example, similar to non-specific symptoms associated with Lyme disease. A systematic and transparent peer review process will assess the quality of evidence, give confidence in the validity of the analysis, and enable the evidence to be presented in summary of evidence tables, supplemented with detailed commentary.

3. RESEARCH QUESTIONS

In the following research questions, the term 'DSCATT' is intended to cover the range of terms formerly used to describe this set of symptoms including 'Lyme disease-like disease', 'Lyme disease-like illness', 'chronic Lyme disease', 'Australian Lyme disease' and 'Lyme'.

Table 1: Research questions

Research questions
Research Question 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?
Research Question 2 What information is available on diseases or disorders Australian patients experiencing DSCATT symptoms have been diagnosed with and what are the most likely differential diagnoses?
Research Question 3 What are the issues associated with diagnostic testing for Lyme disease both in Australia and by overseas laboratories?
Research Question 4 What are the treatment modalities that have been provided to patients (including subgroups of patients) with DSCATT in Australia and what is the evidence base to support these treatment modalities?
Research Question 5 What current guidelines and approaches to investigation and ongoing syndromic management of symptoms associated with DSCATT have been found effective internationally?

4. TERMS OF REFERENCE FOR THE LITERATURE SEARCH

4.1. Breadth of search (Databases)

- Discover (CINAHL Complete, Medline and PsycINFO)
- Cochrane Library database
- National Institute for Health and Clinical Excellence
- PubMed
- ProQuest (including Sociological Abstracts)
- Guidelines International Network (www.g-i-n.net) guideline library.

4.2. Inclusions

From the results of the search, literature will be prioritised according to the following criteria:

- Published, peer-reviewed literature
- Official Australian reports and government inquiries including submissions within relevant Senate Inquiry reports
- (Inter)national authority and intergovernmental reports and guidelines
- Guidelines (International and Australian) produced by clinical and professional bodies
- Currency (published between 1 January 2008 and current)
- Relevance to primary research questions, and
- Full article available in English language.

4.3. Exclusions

The literature review will exclude non-peer reviewed material (other than that associated with the Senate Inquiry and 2018 DSCATT forum reports), any material that does not relate to the research questions, non-English language sources, and material published before 31 December 2007. Misidentified, irrelevant papers and duplicates will be removed.

4.4. Search terms

Subject to the flexibility of individual database search functions, examples of the keywords and search strings included in the search strategy are outlined below. Exact terms and strings will be informed by findings as the work progresses.

4.5. Sources

4.5.1. Academic / medical literature

Example of a search string: each initially AND Australia *(ti.ab = words in title and abstract)*

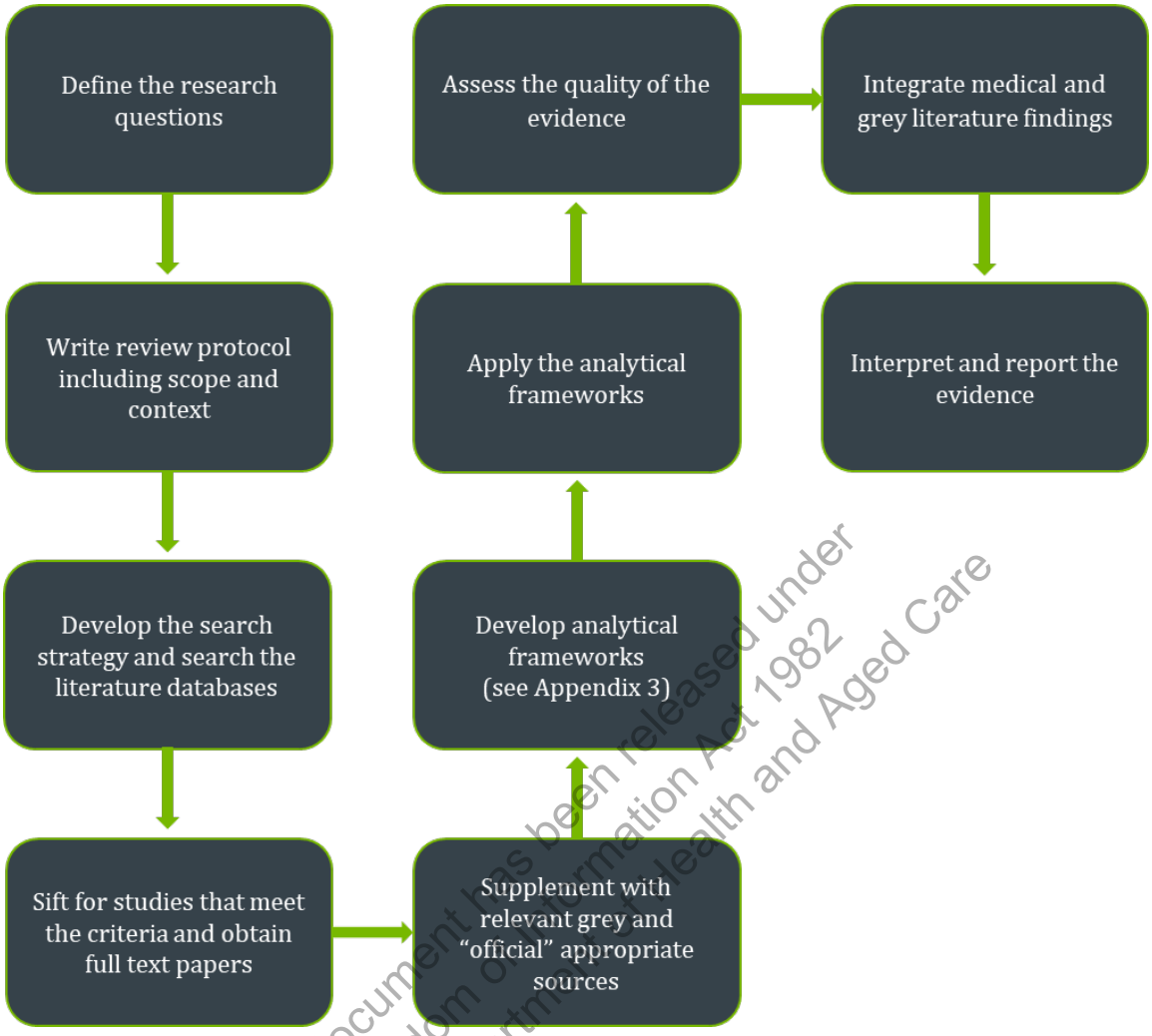
1. exp Borrelia infection/
2. Lyme*.ti.ab. (this should also pick up Lyme like and chronic Lyme and 3rd stage Lyme)
3. Lyme* and guidelines;
4. Lyme*.ti.ab. (this should also pick up Lyme like and chronic Lyme and 3rd stage Lyme)
5. Erythema Chronicum Migrans/
6. (tick* adj2 (bite* or bitten or biting or borne)).ti.ab.

4.5.2. Official literature

Official literature will be sourced using full text Google Scholar.

Cross-checking for completeness (for example, following up authors and references listed in suitable reviews to check they appear in our capture strategy) will add rigour. A senior team approach will be taken to the review process to ensure consistency. The integrative review methodology is shown in Figure 1.

Figure1: Step by step review process



4.6. Documentation

Searches will be tabulated by source, search string, any inclusions and exclusions, and results will be illustrated using a standard review results flow chart (in Annexes).

4.7. Provision of materials

Allen + Clarke will perform the searches, and source the documents for which we require full-text. Citations will be managed with Zotero.

5. ANALYTICAL FRAMEWORKS

The analytical framework * will be a multi-stage, systematic approach:

- Systematic reviews and Randomised Controlled Trials will be described using a PICOT framework (Population, Intervention, Comparison, Outcome and Timeframe). Exact PICOT criterion will be informed by initial literature scans. An example is given below in Annexe 3.
- Reviews of diagnostic test accuracy will be analysed using a PTRT framework of population, index tests, reference standard and target condition.
- Qualitative reviews and reports will be analysed using a framework of population, setting and context.

This use of these frameworks will guide the literature searching process, critical appraisal and synthesis of evidence, and facilitate the development of recommendations by the pathway committee.

ANNEXE 1: KEY DOCUMENTS PROVIDED BY DEPARTMENT OF HEALTH

a. Interim Report - *Growing evidence of an emerging tick-borne disease that causes a Lyme like illness for many Australian patients* – 4 May 2016.
https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lyme-like_Illness/Interim_Report

b. Australian Government response to the Senate - Community Affairs References Committee interim report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients* – Interim Report – 9 November 2016.
https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lymelikeillness45

c. Final Report - *Growing evidence of an emerging tick-borne disease that causes a Lyme like illness for many Australian patients* – 30 November 2016.
https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lymelikeillness45/Final_Report

d. Australian Government response to the Senate - Community Affairs References Committee interim report: *Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients* – Final Report – 15 November 2017.
https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lymelikeillness45/Government_Response

e. Department of Health – DSCATT Forum – 18 April 2018 – Melbourne.
http://www.health.gov.au/lyme-disease#dscatt

f. Department of Health – DSCATT Patient Group Forum – 27 July 2018 – Sydney.
http://www.health.gov.au/lyme-disease#dscatt_syd

g. Department of Health – DSCATT Position Statement.
http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-lyme-disease.htm/$File/Posit-State-Debilitating-Symptom-Complexes-Attributed-Ticks-June18.pdf

h. Department of Health – Lyme disease in Australia Position Statement.
http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-lyme-disease.htm/$File/Posit-State-Lyme-June18.pdf

i. An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis. (2015). Gary D. Lum, Jennie R. Hood, Phil Wright. Office of Health Protection, Australian Department of Health.
http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-lyme-disease.htm/$File/Aust-guideline-diagnosis-overseas-acquired-Lyme-disease.pdf

ANNEXE 2: CRITICAL APPRAISAL (QUALITY TESTS)

Quantitative research

GRADE Systematic Review Checklist –

http://libguides.utoledo.edu/litreview/GRADE

CASP Randomised Controlled Trials Checklist –

https://casp-uk.net/wp-content/uploads/2018/01/CASP-Randomised-Controlled-Trial-Checklist-2018.pdf

CASP Case Control Study Checklist –

https://casp-uk.net/wp-content/uploads/2018/01/CASP-Case-Control-Study-Checklist-2018.pdf

CASP Diagnostic Checklist –

https://casp-uk.net/wp-content/uploads/2018/01/CASP-Diagnostic-Checklist-2018.pdf

Qualitative research

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist –

http://cdn.elsevier.com/promis_misc/ISSM_COREQ_Checklist.pdf

Grey literature

AACODS Checklist

https://dspace.flinders.edu.au/xmlui/bitstream/handle/2328/3326/AACODS_Checklist.pdf;jsessionid=F08E8268FA0E0E420B9ED73271A26258?sequence=4

ANNEXE 3: SAMPLE PICOT

For question: What is the evidence base for treatment modalities for patients diagnosed with DSCATT?

Criterion	Description
Population	• Adults over the age of 18 with documented symptoms defined in the literature as being associated with Lyme, Lyme-like or Chronic Lyme disease • Presenting symptoms • Australian, with or without history of travel to Lyme endemic areas • With or without known history of tick bite • With or without documented serology
Intervention	• Treatment
Comparator	• No treatment
Outcomes	• Symptom amelioration • Additional diagnostic tests undertaken and outcomes • Anxiety and depression • Additional costs incurred by patient
Timeframes	• Initial • Chronic
Study types	• Systematic reviews, randomised controlled trials (RCTs)

DSCATT CLINICAL PATHWAY

Page 1: Executive summary

Cover what, why, who for, evidence base, background – succinctly.

Explain

- The background to the Clinical Pathway,
- the purpose of the pathway
- that we are talking about overseas acquired Lyme disease and known Australian tick-borne illness, and other diagnoses, because they need to be ruled out before patients move to clinical management for undifferentiated illness (including DSCATT symptoms [or other appropriate wording]
- the limited knowledge of the clinical epidemiology of DSCATT – no published peer reviewed studies on clinical epidemiology but patients are likely to present with multiple symptoms with neurological issues including brain fog and memory loss and fatigue and chronic fatigue being the most common.
- Clinical management of patients with undifferentiated illness includes evidence-based approaches published by RACGP
- Note limitation of pathway- does not include international vector-borne disease and is restricted to known and treatable tick-borne diseases -overseas acquired Lyme disease and known Australian tick-borne diseases

[1 page max when desktopped]

Page 2: Overview of the Clinical Pathway

[insert diagram when agreed – likely to be a simpler version of the picture we have – make changes to picture AFTER we've done some thinking in the week beginning 22 July on what to include in this pathway document]

Glossary

xxx

[1 page max when desktopped]

Page 3: About DSCATT and the purpose of the Clinical Pathway

What is DSCATT? [or other title e.g. something about evidence base]

[genesis of the Clinical Pathway and its contribution to recommendation 5]

[succinct statements drawn from literature review, talking about e.g. epidemiological evidence (and that it's mainly self-reported), lack of case definition, symptomology]

Cause of DSCATT is as yet unknown and therefore the importance of medical professionals and patients to keep an open mind about the cause of a patient's symptoms.

Purpose of the Clinical Pathway

Using approved definition:

The purpose of the pathway will be to support decision-making on differential diagnosis and referral pathways for patients presenting with either new onset or unresolved debilitating symptoms with or without a history of tick bites and that cannot be attributed to another condition (acute or chronic).

The Clinical Pathway will also need to be applicable to the Australian health care context in order for it to be generally accepted by the Australian medical profession and patient groups as a part of their clinical management

[1 page max when desktopped]

Page 4: Starting point / what signs and symptoms patients who might be considered for the DSCATT Clinical Pathway may present with

Describe common presentations that a patient who might have DSCATT presents, e.g.:

No published studies of clinical epidemiology of DSCATT. From discussions at the Think Tank and anecdotally from patients, patients who might be considered for the DSCATT Clinical Pathway are likely to present with the following symptoms, with many patients reporting experiencing several symptoms.

- Insert list of signs and symptoms from TT (adults, children and pregnant women) and from Brown (2018).
- New onset and unresolved symptoms > 1 month consistent with overseas acquired Lyme disease – refer to e.g. RCPA Diagnostic Laboratory testing for Lyme Disease (or similar syndromes) in Australia and New Zealand (May 2019) + NICE 2018 guidelines.
- New onset and unresolved symptoms > 1 month consistent with known Australian tick-borne illnesses (evidence from lit review)

From discussions at the Think Tank and anecdotally from patients, the symptoms have been reported to mimic the following diagnosable diseases and conditions:

[1 page max when desktopped]

Page 5: Clinical and travel history assessment at initial presentation

[What should happen]

Explanation about how the patient enters the Clinical Pathway and the two initial decisions to consider:

- The patient (adult or child) is clinically stable and presents with new onset of symptoms that are consistent with tick-borne illness (particularly fever and/or rash) and a history of recent possible tick bite during overseas travel or in Australia
- The patient (adult or child) is clinically stable and presents with unresolved symptoms of more than one month and who may or may not have experienced a tick bite in a Lyme endemic area or in Australia

Initial assessment to consider the differential diagnoses and whether the

- patient fits the criteria for the tick-borne disease phase of the pathway
- patient has possible history of tick-bite and may require investigation through the tick-borne phase of the pathway
- patient has no history of tick-bite and does not fit the tick-borne disease pathway criteria and more appropriately should be assessed through the second phase of the pathway

Note the importance of an international travel history as this will determine whether investigation for overseas acquired Lyme disease should be considered or if Australian tick-borne diseases should be considered, or both.

Note the importance of a comprehensive clinical history for patients in both presenting groups

Evidence about Lyme disease- where the endemic areas are to inform decision-making about need to consider overseas-acquired Lyme disease.

Evidence about geographic distribution of known tick-borne diseases in Australia

Evidence-base to include RCPA Diagnostic Laboratory testing for Lyme Disease (or similar syndromes) in Australia and New Zealand (May 2019) + NICE 2018 guidelines + [others for Australian tick-borne diseases].

Page 6: Further testing and treatment for suspected tick-borne diseases

[What should happen]

For patients who are clinically suspected to have tick-borne disease following the clinical assessment, the following should be considered, based on the comprehensive clinical assessment and international travel history.

For this pathway

Consult with appropriate experts in tick-borne diseases including pathologists with relevant diagnostic expertise.

If diagnosis positive, treat accordingly.

If tests are negative, move to phase 2 of the Clinical Pathway

Exit point: if diagnosis positive, treat accordingly.

[Why we're saying this should happen – evidence base]

Explanation of the evidence that justifies the approach described

Page 7: Differential diagnosis in patients with no history of tick-bite or negative tests for tick-borne diseases

Description of what happens in the second phase of the pathway

Evidence base to include Jones (2015) esp 'Specific approaches to the management of elusive illnesses and Specific approaches to the management of contested illnesses

Criteria for exit of Clinical Pathway.

If no diagnosis of a specific disease (s) is established through this phase of the pathway and symptoms persist, move to next phase (i.e., undifferentiated illness)

Page 8: Undifferentiated illness – establishment and management

[What should happen]

Description of what happens in this third phase of the pathway, i.e. referral to specialist, develop care plan, ongoing management, etc (or other appropriate wording)

e.g. apply chronic pain guideline if x symptom

Exit point: ?? if they resolve?

Otherwise: ongoing management

[Why we're saying this should happen – evidence base]

Explanation of the evidence that justifies the approach described

Evidence base to include Jones (2015) 'Specific approaches to the management of chaotic illnesses and other guidelines for symptomatic management of unresolved symptoms e.g fatigue

Page 8: Bibliography

Add reference list – only those we've actually used to support the pathway design and description

Support during consultation: Case studies

Develop ~3 case studies to show how someone moves through the pathway – draw on Senate inquiry to define these – DoH happy to help