DSCATT Literature Review – Summary of feedback

General comments

- Overall, the literature review needs to be consistent in regards to terminology about Lyme disease, other infectious diseases and DSCATT. The review needs to carefully differentiate between diagnosed classical Lyme disease and other diseases. It is important that terms are not used that are incorrect - for example, don't refer to 'chronic lyme borreliosis' as a condition, and don't use the term 'illness' when referring to DSCATT.
- More rigour about the hierarchy of evidence would be valuable– for example, statements and self-reported information from the senate enquiry must still meet the same criteria for inclusion as all other evidence.
- Each section should be linked to how that impacts the design of the clinical pathway.
- Be really careful with statements that attribute cause and effect. For example - Pg 3, Lit review report, second last paragraph "*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 diseases*".
    - Just because a person may have similar non-specific symptoms, it may not be appropriate to apply Lyme disease treatment evidence. Non-specific symptoms may be indicative of many different diseases.
- Don't focus on treatment for Lyme disease or any of its complications, as this is already covered in *An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis* and other international guidelines.

Specific comments regarding Chapter 4

- The questions should be structured much more like a literature review, with a question and then the evidence against that question, with it being very clear what the quality of that evidence is. Alternatively, turn the evidence and grading into recommendations for the pathway. For example "*there are many different conditions that may cause chronic non-specific symptoms. It is recommended that a full history, examination and targeted tests be undertaken as a first step. If no cause is found, referral to a relevant specialist is recommended*."
- 4.1 – This information is from sources that are self-reported and in some cases not supported by evidence that meets the literature review criteria. For the purpose of the clinical pathway, the identification of a list of other tick borne pathogens has a place, however these can be found in the existing clinical pathway.
- 4.2 – This could be a long list of other conditions that have been diagnosed in people with these symptoms. Perhaps include a statement about how symptoms of these conditions may have significant overlap, and that a good history and examination with judicious testing can help diagnose which of these may be causing the symptoms.
  The major problem here is the fundamental difference in opinion between some DSCATT sufferers and their medical professional.

- 4.2.3 – Rather than refer to experts' evidence at the inquiry, wherever possible use of the papers used to reach the opinions presented by these experts would give stronger evidence. This would also better support the criteria outlined in the literature review ToR.
- 4.2.4 – There are currently 4 different lists of Australian tick pathogens in this chapter. We suggest that this be tidied up to either:
    - match each disease with the evidence available; or
    - batch them into categories, matched with the appropriate evidence. For example, "*proven to be in Australia*", "*could be transmitted if introduced but no cases yet seen*", and "*zoonosis of unknown potential*".
- 4.2.5 – Suggest this be removed as it does not appear to be relevant to the clinical pathway and may cause confusion.
- 4.2.6 – This is why the "check for other tick borne diseases" is an important inclusion in the current plan for the diagnostic pathway. The known infections that can have a chronic manifestation from this section would more readily fit in the differential diagnosis section of this chapter.
- 4.2.7 – As above. This information is about longer lasting or chronic infections and would more readily fit into a differential diagnosis section.
- 4.2.8 – It is unclear how this should be used. As an alternative, another table could be used instead. For example, Table 30 in this chapter, with alternative diagnoses matched to supporting evidence.

Specific comments regarding Chapter 5

- Is the NRL report listed in the initial table of evidence?
- It needs to be clear when comments and evidence are applicable to acute, classical Lyme disease (e.g. the NICE guidelines), and when people are using the tests in situations for which it wasn't designed (e.g. years or decades after symptoms began).

From:	s47F
To:	s22
Cc:	s47F
Subject:	FW: DSCATT Clinical Pathway literature review information [SEC=No Protective Marking]
Date:	Wednesday, 29 May 2019 3:14:29 PM
Attachments:	image001.jpg Allen + Clarke - DSCATT Clinical Pathway Literature Review - Research Questions.pdf

FYIO distributed to all TT attendees

s47F

Manager, Policy + Regulatory | Allen + Clarke | s47F

From: s47F
Sent: Wednesday, 29 May 2019 5:05 PM
To: s47F
Subject: DSCATT Clinical Pathway literature review information

Good afternoon,

Further to the DSCATT Clinical Pathway Think Tank in Sydney earlier this month, please find attached further information about the literature review, including the research questions and search parameters.

Kind regards,
s47F

s47F

Project Lead, DSCATT Clinical Pathway

e: s47F

LITERATURE REVIEW TO INFORM AN EVIDENCE-BASED CLINICAL PATHWAY FOR DSCATT IN AUSTRALIA

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) that can be flexibly applied in both private and public health settings.

The Clinical Pathway must be informed by relevant literature and key documents. The literature review will focus on published evidence that can inform an evidence base to underpin the development of the Clinical Pathway.

Research questions

Allen + Clarke is using five research questions as the basis for conducting a search of published literature and websites with date inclusion of literature being 1 January 2008 to current. In the 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'.

Research questions
1. What is the clinical epidemiology of DSCATT in Australia? *Supplementary Questions* What information is available on the prevalence, demographics and geographic distribution of patients experiencing DSCATT in Australia? What information is available on the symptoms and clinical signs that have been associated with DSCATT as reported by Australian patients and treating physicians?
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?
3. What are the issues associated with diagnostic testing for Lyme disease both in Australia and by overseas laboratories?
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?
5. What current guidelines and approaches to investigation and ongoing syndromic management of symptoms associated with DSCATT have been found effective internationally?

Search parameters, criteria and critical appraisal

The following databases will be searched: 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. Official literature will be sourced using full text Google Scholar.

From the results of the search, literature will be prioritised for inclusion in the review 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.

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.

Allen + Clarke will use a range of critical appraisal tools to assess the quality of publications sourced through the search, as appropriate for the methodologies employed. These will include the GRADE Systematic Review Checklist; the CASP Randomised Controlled Trials checklist; the CASP Case Control Study Checklist and the CASP Diagnostic Checklist (for quantitative research); the COREQ (COnsolidated criteria for REporting Qualitative research) Checklist (for qualitative research); the AACODS Checklist (for grey literature); and the AGREE Checklist (for clinical guidelines).

Timeframes

As at May 2019, the literature review, including consideration of material for inclusions and exclusions, is a work in progress.

The literature review will be peer reviewed by the project team's expert technical advisors before being finalised later in 2019.

PROJECT STATUS REPORT

Project name: DSCATT Clinical Pathway

Prepared by: s47F

Prepared for: s22

ALLEN+CLARKE AUSTRALIA

Period covered: 1/5/19 - 31/5/19

Client: Department of Health (Australia)

Main activities this period

s22

Literature search and review

- Completed draft Literature Search report, for discussion at 4 June meeting.
- Completed working draft of Literature Review Summary Report, for discussion at 4 June meeting.
- Developed and iterated skeleton of literature review report.

Draft Clinical Pathway development

- Developed initial working concept ("strawman") for a Clinical Pathway, for discussion at 4 June meeting.

s22

Main activities next period

Draft Clinical Pathway development

- Refine Draft Clinical Pathway based on discussion of the initial concept ("strawman") at Customer Workshop on 4 June.
- Develop accompanying material (as agreed) to support Draft Clinical Pathway stakeholder consultation

s22

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PROJECT STATUS REPORT

Project name: DSCATT Clinical Pathway

Prepared by: s47F

Prepared for: s22

ALLEN+CLARKE AUSTRALIA

Period covered: 1/6/19 - 30/6/19

Client: Department of Health (Australia)

Main activities this period

Stakeholder engagement via Think Tank

- Discussed draft Think Tank report at 4 June workshop.
- Drafted a Summary Think Tank Report based on the Draft Think Tank Report content and sent to DoH on 28 June.

Literature search and review

- Discussed draft Literature Search report and working draft of Literature review report at 4 June meeting.
- Teleconference with DoH to discuss Literature review report and DoH feedback on 18 June.

Draft Clinical Pathway development

- Discussed initial working concept ("strawman") for a draft Clinical Pathway at June 4 meeting.
- Provided updated draft Clinical Pathway diagrams for adult and child patients to DoH on 19 June.
- Teleconference to discuss DoH feedback on draft Clinical Pathway diagrams on 26 June.

s22

Main activities next period

Draft Clinical Pathway development

- Get agreed Draft Clinical Pathway diagram professionally designed by in house graphic designer, send to DoH for approval and finalise based on DoH feedback.
- Develop accompanying material (as agreed) to support Draft Clinical Pathway stakeholder consultation.

s22

Phase 1 and 2 deliverables

- Finalise Summary Think Tank report incorporating DoH feedback and refine larger Think Tank report based on DoH feedback.
- Respond to DoH comments on the literature review and organise a teleconference to discuss comments and proposed approach.
- Refine Literature Search report and Literature Review Summary Report based on DoH feedback and teleconference discussions.

s22

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s22

From: s47F
Sent: Thursday, 18 July 2019 12:58 PM
To: s22
s22
Cc: s47F
Subject: RE: Literature Review feedback from DoH [SEC=OFFICIAL]

Hi s22 and s22
Thank you again for your helpful feedback on the working draft of the literature review. Over the last three weeks we have been somewhat consumed with the Think Tank summary report, Draft Clinical Pathway, stakeholder consultation documents and emailing and responding to stakeholders.
For the literature review, I had put together a response to your comments on our working draft and our proposed approach fairly soon after I received your comments. I just needed time to tidy the document up. Now is a very opportune time to discuss our mutual comments as the literature review evidence will inform the documents accompanying the Draft Clinical Pathway diagram.

We have some questions in the document which are really quite critical to how we proceed. These are particularly around how the self-reported evidence and anecdotal evidence is included when it is the only evidence that exists, particularly on symptomology. The answers will also help inform what evidence we include in the evidence-based Draft Clinical Pathway documents about DSCATT clinical epidemiology. Most of the information available comes from the Senate Inquiry and the Think Tank.

We would welcome your thoughts on the comments we have made in the attached document and a discussion about proposed approaches.

Thank you, in advance.

Kind regards
s47F

Senior Consultant

s47F

www.allenandclarke.co.nz

s22

DSCATT Literature Review (Working draft) Summary of Feedback and A+C comments and proposed approach

GENERAL COMMENTS		
DOH comments	A+ C comment	Our suggested/proposed approach
Overall, the literature review needs to be consistent in regards to terminology about Lyme disease, other infectious diseases and DSCATT. The review needs to carefully differentiate between diagnosed classical Lyme disease and other diseases.	We agree that there is a wide range of terminology used in the literature. We highlight this in section 1.5 Interdependencies, where we also raised the issue/disagreement about chronic Lyme disease and the Australian Government's position on chronic Lyme disease. Most of the Australian literature (which we have included irrespective of quality but quality appraised) refers to Australian Lyme-like cases and Lyme-like illness. This is the case in the high quality review by Chalada et al. and these terms are used heavily in the Senate Inquiry. We didn't change the terms used by authors in the Working Draft. We also noted in the working draft that the patient advocacy groups, especially LDAA use several terms and use these interchangeably, leading to confusion.	For clarity and consistency, we can change the terms used in papers and the Senate Report to DSCATT, with a statement up front saying we have done that. Happy to discuss.
It is important that terms are not used that are incorrect - for example, don't refer to 'chronic lyme borreliosis' as a condition, and don't use the term 'illness' when referring to DSCATT.	Regarding the use of the term chronic Lyme borreliosis, this was the exact term used by Chalada et al. so we retained it. Chalada et al. wrote "Since diffuse arthralgia, cognitive difficulties and fatigue are common in chronic Lyme borreliosis, it is possible for fibromyalgia to be mistaken for Lyme borreliosis and *vice versa* [147,148]"	We can make it clear that chronic Lyme borreliosis was the term used by Chalada et al, not us. Happy to discuss the best way forward to avoid confusion.

GENERAL COMMENTS		
	We wrote: • It is possible for fibromyalgia to be mistaken for Lyme Borreliosis and *vice versa* as diffuse arthralgia, cognitive difficulties and fatigue are common in chronic Lyme Borreliosis.	
More rigour about the hierarchy of evidence would be valuable– for example, statements and self-reported information from the senate enquiry must still meet the same criteria for inclusion as all other evidence.	We have done the quality review of papers but this hasn't been articulated in the working draft of literature review yet. The Senate Inquiry reports were provided as key documents which were to be used to inform the development of the Clinical Pathway (irrespective of their quality). As grey literature the reports will be assessed using AACODS. However, within those reports all of the evidence presented to the Inquiry about symptoms and co-morbidities was by patients and was self-reported or was anecdotal evidence from Lyme literate doctors. Regarding what is included from the Senate Inquiry we understood from the workshop conversation that no quotes or specific references attributed to submitters, irrespective of whether they were experts/expert bodies or by patient advocacy	We will assess the Senate Inquiry reports using AACODS as stated in the ToR, however, within those reports as much of the evidence presented to the Inquiry was by patients and was self-reported It would be really helpful to discuss the inclusion/exclusion of information from the Senate Inquiry/DSCATT Forum reports given that these documents are key documents. Also how we respectfully acknowledge the self-reported and anecdotal evidence provided by patients and patient advocacy groups to the Senate Inquiry (where it is the only information available, while also acknowledging the level of evidence does not reach the level of quality to inform an evidence based pathway). We can either only have dot points on issues raised at the Senate Inquiry with no specific submissions attributed to those dot points OR

GENERAL COMMENTS		
	groups were to be included; rather any issues raised were to be as dot points.	If submissions are to be acknowledged, and if there is a reference cited in the submission to support the statement in the submission we can note the reference that was cited. If there was no reference cited we can note that too.
Each section should be linked to how that impacts the design of the clinical pathway.	Noted.	This was not in the ToR but we can include a statement(s) about this.
Be really careful with statements that attribute cause and effect. For example - Pg 3, Lit review report, second last paragraph "*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 diseases*". ▪ Just because a person may have similar non-specific symptoms, it may not be appropriate to apply Lyme disease treatment evidence. Non-specific symptoms may be indicative of many different diseases.	That statement is included in the Literature search draft report and is taken directly from the agreed ToR. We included the systematic reviews that underpin the NICE guidelines on non-specific symptoms of Lyme disease and on-going symptoms of Lyme disease because they were symptoms reported by ACIIDS to be similar to DSCATT. But we agree DSCATT is not Lyme disease so even though the symptoms are similar this could cause confusion.	We need to agree the best way to articulate this given it is in the finalised ToR.
Don't focus on treatment for Lyme disease or any of its complications, as this is already covered in *An*	We mentioned in the working draft of the literature review we had included the Lyme disease treatment	We can remove all of the treatment guideline reviews. However, if we remove all of the

GENERAL COMMENTS		
Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis and other international guidelines.	guidelines because Lyme-literate doctors and ACIIDS state they use Lyme disease guidelines to treat patients with Lyme-like illness (based on their view and in the ACIIDS submission that the symptoms are very similar to European Lyme disease). We included the NICE treatment guidelines for Lyme disease to demonstrate the latest guidance (NICE 2018) on Lyme disease does not support long term antibiotic therapy, or multiple courses of antibiotics for people with on going symptoms of Lyme disease (symptoms which are similar to those reported by patients who identify as having DSCATT). However, we realise that this could be confusing as DSCATT is not classical Lyme disease, and DSCATT is associated with symptoms and symptom complexes. The major concern about long term antibiotic treatment prescribing and AMR was raised in the Senate Report and by papers such as Collignon et al. So we thought including the latest guidance on antibiotic prescribing for Lyme disease made sense and addressed the concerns about prescribing practices of Lyme literate doctors made by medical professional bodies to the Senate Inquiry and in published papers. We also included the other international treatment guidelines to show similarity in guidance, except for	international treatment guidance on Lyme disease the PICO questions will also go to. We included PICO questions in the ToR because we knew that the NICE guidelines had specifically done PICO questions on antibiotic treatment and we intended to report these in our literature review. OR We will note that guidelines X, Y and Z do not support long term antibiotic therapy. Happy to discuss.

GENERAL COMMENTS		
	the ILADS and German Borreliosis Society guidelines that ACIIDS uses – which are in contrast to IDSA (2006) guidelines that the Australian Government uses. Regarding the discussion at the workshop about complementary treatments, it was raised that we could look to include the evidence base on treatments such as herbs and supplements if it were given to us by patients during the consultation. We had previously agreed with DOH that we would not review the complementary therapies and have included the advice provided by DoH that DOH had given previously to patients.	We use the advice provided by DOH on other treatment modalities as already included in the literature review OR If DoH want the evidence on complementary therapies reviewed, this will need to be considered as a new scope in the literature review. Happy to discuss.

SPECIFIC COMMENTS REGARDING CHAPTER 4		
DOH comments	A+C comment	Our suggested/ proposed approach
The questions should be structured much more like a literature review, with a question and then the evidence against that question, with it being very clear what the quality of that evidence is.	We agreed the research questions with DOH. The question "What information is available on diseases and disorders Australian patients experiencing DSCATT have been diagnosed with and what are the most likely differential diagnoses" can be answered in two ways. For the first part of the question we have answered the question by including lists/graphs of diseases and disorders as reported in submissions	We can certainly reorganise the information in the chapter and have more discrete headings, and as above include the grading of evidence which we have not included in the working draft.

SPECIFIC COMMENTS REGARDING CHAPTER 4		
	to the Senate Inquiry. We recognise these are self-reported and therefore of low reliability. However, this is the information available. Alternatively, the question could be answered from the perspective that there is no published epidemiological or clinical evidence to answer this question. The only information available comes from the Senate Inquiry, and submissions to the Senate Inquiry, all of which is self-reported and anecdotal and of low reliability and we therefore have not included any of information. If we take this approach we will have no list of diseases/disorders to be considered when patients with debilitating symptoms present to the GP.	
Alternatively, turn the evidence and grading into recommendations for the pathway. For example *"there are many different conditions that may cause chronic non-specific symptoms. It is recommended that a full history, examination and targeted tests be undertaken as a first step. If no cause is found, referral to a relevant specialist is recommended."*		Happy to discuss which approach works best to inform the Clinical Pathway.
4.1 – This information is from sources that are self-reported and in some cases not supported by evidence that meets the literature review criteria. For the purpose of the clinical pathway, the identification of a list of other tick borne pathogens	We have answered the question by including lists of self-reported diseases and disorders as reported in submissions to the Senate Inquiry. We recognise these are self-reported and therefore of low reliability. However, this is the information available.	As above, we are happy to discuss the best way forward regarding the level of evidence and what is included.

SPECIFIC COMMENTS REGARDING CHAPTER 4		
has a place, however these can be found in the existing clinical pathway.	The Senate Inquiry reports are key documents that had to be included in the literature review irrespective of the quality.	
4.2 – This could be a long list of other conditions that have been diagnosed in people with these symptoms. Perhaps include a statement about how symptoms of these conditions may have significant overlap, and that a good history and examination with judicious testing can help diagnose which of these may be causing the symptoms. The major problem here is the fundamental difference in opinion between some DSCATT sufferers and their medical professional.	Do you mean including a list of conditions (e.g MNS, MS) that people (not DSCATT patients) have been diagnosed as having based on similar symptomology to DSCATT? For example, the MAYO Clinic provides a range of conditions commonly associated with ongoing fatigue. See https://www.mayoclinic.org/symptoms/fatigue/basics/causes/sym-20050894ue	Happy to discuss
4.2.3 – Rather than refer to experts' evidence at the inquiry, wherever possible use of the papers used to reach the opinions presented by these experts would give stronger evidence. This would also better support the criteria outlined in the literature review ToR.	We refer our question above about the decision that needs to be made about what is included from the Senate Inquiry and the level of detail- dot points of issues with no attribution, or if attribution is given whether there is evidence to support the statement.	
4.2.4 – There are currently 4 different lists of Australian tick pathogens in this chapter. We suggest that this be tidied up to either:	We agree there is a lot of detail and some overlap in this working draft.	We will make this more succinct and divide into headings DoH suggests.

SPECIFIC COMMENTS REGARDING CHAPTER 4		
○ match each disease with the evidence available; or ○ batch them into categories, matched with the appropriate evidence. For example, "*proven to be in Australia*", "*could be transmitted if introduced but no cases yet seen*", and "*zoonosis of unknown potential*".		
4.2.5 – Suggest this be removed as it does not appear to be relevant to the clinical pathway and may cause confusion.	We included this information because we understood that while symptoms of DSCATT may be attributed to ticks, the cause is yet unknown and, as mentioned in the Senate Inquiry reports there may be other causes for the symptoms in some patients that need to be investigated in a Clinical Pathway, e.g, parasitic and viral causes and environmental toxins	We can remove this section if DOH considers it is confusing. Happy to discuss if it fits better elsewhere, or not at all.
4.2.6 – This is why the "check for other tick borne diseases" is an important inclusion in the current plan for the diagnostic pathway. The known infections that can have a chronic manifestation from this section would more readily fit in the differential diagnosis section of this chapter.		We can move this and make it more clear and succinct
4.2.7 – As above. This information is about longer lasting or chronic infections and would more readily fit into a differential diagnosis section.		We can move this

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SPECIFIC COMMENTS REGARDING CHAPTER 4		
4.2.8 – It is unclear how this should be used. As an alternative, another table could be used instead. For example, Table 30 in this chapter, with alternative diagnoses matched to supporting evidence.	This section includes the information reported by ACIIDS doctors and patients on conditions that have or should be considered in patients with symptoms that have led to a diagnosis of Lyme-like illness DSCATT. We acknowledge this is all anecdotal and no evidence has been provided to support the anecdotal evidence. Again this is a discussion about how much is included from the /Senate Inquiry and the DSCATT Forum reports.	It will be easier to address this once we have a clear way forward about inclusion of Senate Inquiry evidence.

SPECIFIC COMMENTS REGARDING CHAPTER 5		
DOH comments	A+C comment	Our suggested/proposed approach
Is the NRL report listed in the initial table of evidence?	Noted.	It will definitely be included.
It needs to be clear when comments and evidence are applicable to acute, classical Lyme disease (e.g.	Noted.	Happy to discuss the best approach for inclusion.

SPECIFIC COMMENTS REGARDING CHAPTER 5		
the NICE guidelines), and when people are using the tests in situations for which it wasn't designed (e.g. years or decades after symptoms began).	We included all of the NICE guidelines including the findings of their PICO questions in the chapter on treatment modalities and the evidence for those modalities. Do you see some of the guidelines and evidence-based reviews including PICO questions fitting more appropriately in this section?	

PROJECT STATUS REPORT

Project name: DSCATT Clinical Pathway

Prepared by: s47F

Prepared for: s22

Period covered: 1/8/19 - 30/8/19

Client: Department of Health (Australia)

Main activities this period

s22

Literature search and review

• Discussion at 6 August meeting on direction of draft literature review. Agreement to pause while developing Draft Clinical Pathway, then revisit direction. Confirmed at 29 August meeting the direction to take (including incorporating literature on stepped care model that is part of the Draft Pathway).

Draft Clinical Pathway development

• Development of Draft Clinical Pathway, provided to DoH for comment on 19 August. Co-development and/or testing with expert advisors.

• Interim feedback from DoH (22 August) and verbal feedback (29 August), ahead of written comments.

s22

Main activities next period

Draft Clinical Pathway development

• Revise Draft CP following receipt of DoH written feedback (expected by 6 Sep), verbal discussion 10 Sep to confirm any material and stakeholder engagement approach, including consultation materials (if any in addition to Draft CP).

s22

From:	Boyley, Matthew
To:	s47F
Cc:	s22 NORRIS, Sarah; s22
Subject:	Update on the DSCATT Clinical Pathway - Think Tank Report [SEC=OFFICIAL:Sensitive]
Date:	Monday, 2 September 2019 8:43:42 AM
Attachments:	DSCATT Summary Think Tank report FINAL.PDF FW FOR CLEARANCE Email to MO re DSCATT SECOFFICIAL.msg image001.png

Hi s47F

I have previously provided you with information regarding projects related to Debilitating Symptom Complexes Attributed to Ticks (DSCATT) – refer email of 12 July 2019 attached.
It is timely that I provide you with an update on the project to develop an evidenced-based clinical pathway for patients suffering from DSCATT, as we've reached a milestone deliverable.
s22

Allen + Clarke has now provided a report (refer attached) which summarises the key discussion points and outcomes of the Think Tank discussion. The report captures the discussion at an outcome based level and as such does not delve into identifying individual comments or contributions from stakeholders. As I have previously noted, the Think Tank was designed to provide stakeholders with opportunities for input however some stakeholders have continued to express concerns regarding the consultation process and their ability to actively influence the inputs into the clinical pathway – particularly in relation to stating the existence of Lyme disease in Australia and the use of unapproved therapies.
s22

Regards
Matt

Matthew Boyley
First Assistant Secretary

Office of Health Protection Division | Chief Medical Officer Group
Australian Government Department of Health
02 6289 7330 | s22 | matthew.boyley@health.gov.au
GPO Box 9848, Canberra ACT 2601, Australia
Executive Assistant
s22
Executive Officer
s22

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present

DSCATT Think Tank

8 May 2019, Sydney

SUMMARY REPORT

21 August 2019

ALLEN+CLARKE

ACKNOWLEDGEMENTS

Allen + Clarke sincerely acknowledges all the stakeholders who took the time to attend the Think Tank. Their input, experience, knowledge and personal stories were much appreciated, and will be used to inform the development of relevant sections of the Clinical Pathway.

Document status:	FINAL
Version and date:	21/8/2019
Author(s):	Dr Robyn Haisman-Welsh and Marion Clark
Filing Location:	DSCATT Clinical Pathway - Documents\04b Deliverables Phase 2\Think Tank\Think Tank Report
Peer / technical review:	Dr Robyn Haisman-Welsh, Catherine Marshall
Verification that QA changes made:	Marion Clark
Proofread:	May Guise
Formatting:	May Guise
Final QA check and approved for release:	Paul Houliston

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

CONTENTS

Tables

Figures

GLOSSARY

ACA	Acrodermatitis chronica atrophicans
ACIIDS	Australian Chronic Infectious and Inflammatory Disease Society
ALS	Amyotrophic lateral sclerosis
CFS	Chronic fatigue syndrome
DSCATT	Debilitating Symptom Complexes Attributed to Ticks
GI	Glycaemic Index
GP	General Practitioner
LDAA	Lyme Disease Association of Australia
MCAD	Mast Cell Activation Disorder
ME	Myalgic encephalomyelitis
MS	Multiple sclerosis
MSIDS	Multiple Systemic Infectious Disease Syndrome
NHMRC	National Health and Medical Research Council
PFAPA	Periodic Fever, Aphthous stomatitis, Pharyngitis, Adenitis
STI	Sexually transmitted infection
VZV	Varicella-Zoster Virus

1. INTRODUCTION

The Australian Department of Health (the Department) has contracted 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 purpose of the Clinical Pathway is 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, which cannot be attributed to another condition (acute or chronic).

The Clinical Pathway will be designed specifically for the Australian health care context in order for it to be generally accepted by the Australian medical and other health professions and patient groups as part of their clinical management.

The Clinical Pathway will be informed by the relevant literature and key documents. It will be developed in consultation with key stakeholders, including medical and other health professionals, government health authorities and patient groups.

On 8 May 2019, as the first stage of key stakeholder consultation on the Clinical Pathway, *Allen + Clarke* convened a Think Tank with key stakeholders at the Rydges International Airport Hotel in Sydney to discuss the nature of DSCATT and future support pathways.

1.1. Purpose

The purpose of this report is to capture the key discussion points and outcomes of the DSCATT Think Tank. *Allen + Clarke* will use the Think Tank discussions, a literature review and other input captured through the consultation process, to inform the development of the Clinical Pathway.

1.2. Stakeholders at the Think Tank

A list of the organisations represented at the Think Tank is provided in Appendix 1. Over 60 stakeholders were invited to attend the Think Tank. Of these, 41 attended: 25 in person and 16 online. Slightly more than half of stakeholders in attendance represented patient groups. Representatives from the Department of Health attended as observers.

Reference to stakeholders in this report relates **only** to those stakeholders who attended the Think Tank.

2. THINK TANK PROGRAMME

Venue: Hercules Room, Rydges Sydney Airport Hotel, Sydney International Airport
Date: Wednesday 8 May 2019
Time: 10am – 4pm

Time	Item	Lead
09.00	Coffee and tea on arrival	
10.00	**Opening of the Think Tank** • Welcome to country • Introduction to the project • Purpose of today	Mr Paul Houliston Uncle Chicka Madden Dr Robyn Haisman-Welsh
10.45	**Session 1: Symptoms and clinical signs attributed to DSCATT**	Dr Virginia Hope
11.30	Morning break	
11.45	**Session 2: Diagnosable diseases and disorders to be excluded before a patient is considered for DSCATT referral pathway**	Dr Virginia Hope
13.00	Lunch	
13.40	**Session 3: What does the ideal patient journey look like?**	Ms Catherine Marshall
14.50	Afternoon break	
15.10	**Session 4: Who and when: Regulated health professions and skills that best meet the clinical needs of patients considered for the DSCATT referral pathway**	Ms Marion Clark
15.45	**Closing of the Think Tank** • Next steps from here	Mr Paul Houliston
16.00	Think Tank close	

3. METHODS OF CONTRIBUTION

This report summarises the key themes and discussions presented by stakeholders, including state and territory health officials, medical professionals and patient groups who participated in the Think Tank in person or online.

Department officials present at the Think Tank and *Allen + Clarke* facilitators did not contribute responses to the questions posed for the discussion outputs detailed in this report.

The Think Tank was designed to be very participative, providing opportunities for maximum input from stakeholders. Feedback from stakeholders was captured in several different ways throughout the day, including:

- using *Sli.do* – a website designed to "crowd-source" questions and ideas;
- writing on sticky notes or large pieces of paper on the walls during the sessions;
- speaking directly to the facilitator at their table;
- speaking directly to the room during plenary sessions; and
- contributing through Zoom videoconferencing, for those who were unable to attend in person.

A number of technical issues with the provision of the online aspect of the workshop limited online stakeholders' ability to meaningfully engage with some sessions throughout the day. Given these issues, relevant contributions were captured as best as possible, and collated. Following the Think Tank, the online forum was kept open for a week with stakeholders invited to contribute any further feedback through this means.

4. INTRODUCTION TO THE PROJECT

4.1. Welcome to country – Uncle Charles (Chicka) Madden

The day opened with a welcome to country by Uncle Charles (Chicka) Madden who is a respected Gadigal Elder in Sydney.

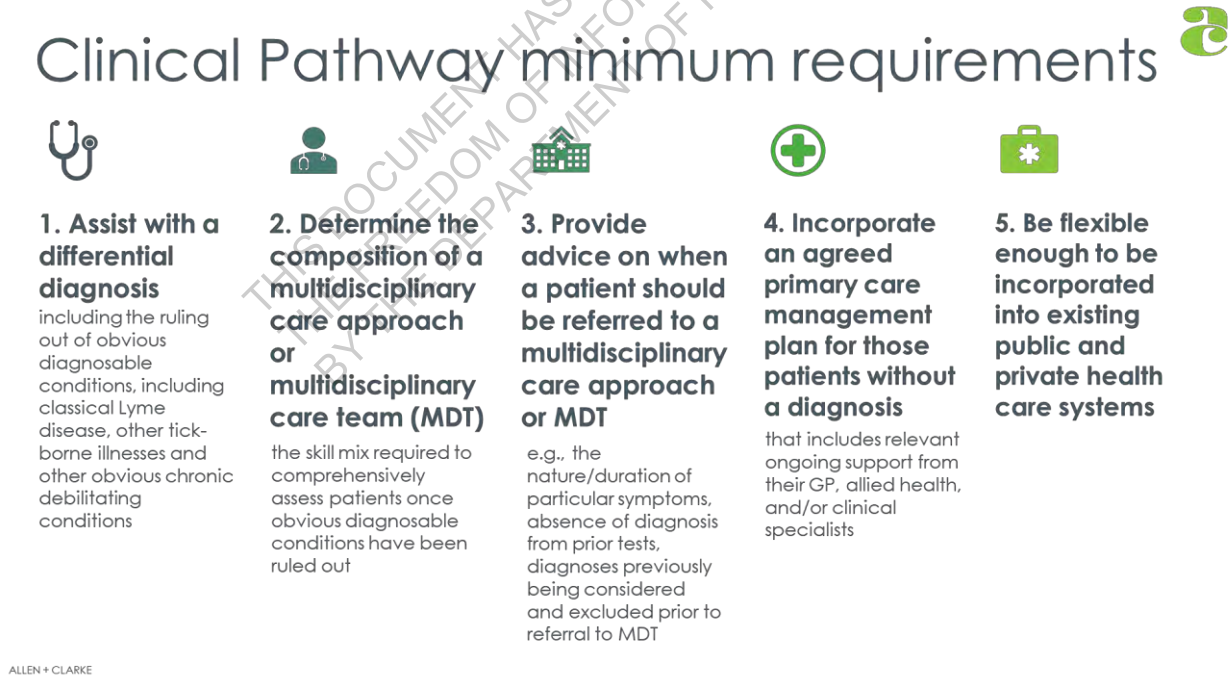
4.2. Opening remarks – Mr Paul Houliston, *Allen + Clarke* Facilitator

Mr Paul Houliston welcomed stakeholders in the room and online, and outlined the key structure of the day. Sessions were planned to address the overall Clinical Pathway development, including an explanation of how the Think Tank fits into the development process, the discussion topics as presented in the agenda and a brief overview of the next steps in the DSCATT Clinical Pathway development. He emphasised that the format of the day was designed to provide the opportunity for perspectives to be heard.

4.3. Project overview – Dr Robyn Haisman-Welsh, *Allen + Clarke*, Project Lead

Dr Haisman-Welsh introduced the purpose of the DSCATT project and the Think Tank and outlined the key stages of the project and the five minimum requirements for the Clinical Pathway as presented below in Figure 1. She noted that the project aligns with the Australian Government's commitment to implement Recommendation 5 of the Senate Inquiry Report. [1]

Figure 1: Clinical pathway minimum requirements



[1] 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

The topics for discussion at the Think Tank were designed to collect stakeholder input to inform the requirements of a Clinical Pathway.

The aim of the Think Tank was to:

- understand the issues and perspectives of stakeholders to inform a draft Clinical Pathway which would be subject to further consultation; and
- provide stakeholders with a better understanding of the project, provide an opportunity for stakeholders to contribute ideas on key components of a Clinical Pathway, and outline the timing of future consultation opportunities.

The six principles underpinning discussions throughout the Think Tank were:

- inclusivity,
- receptivity,
- reciprocity,
- respect,
- timeliness, and
- transparency.

5. DISCUSSION OUTPUTS

5.1. Session 1: Signs and symptoms attributed to DSCATT

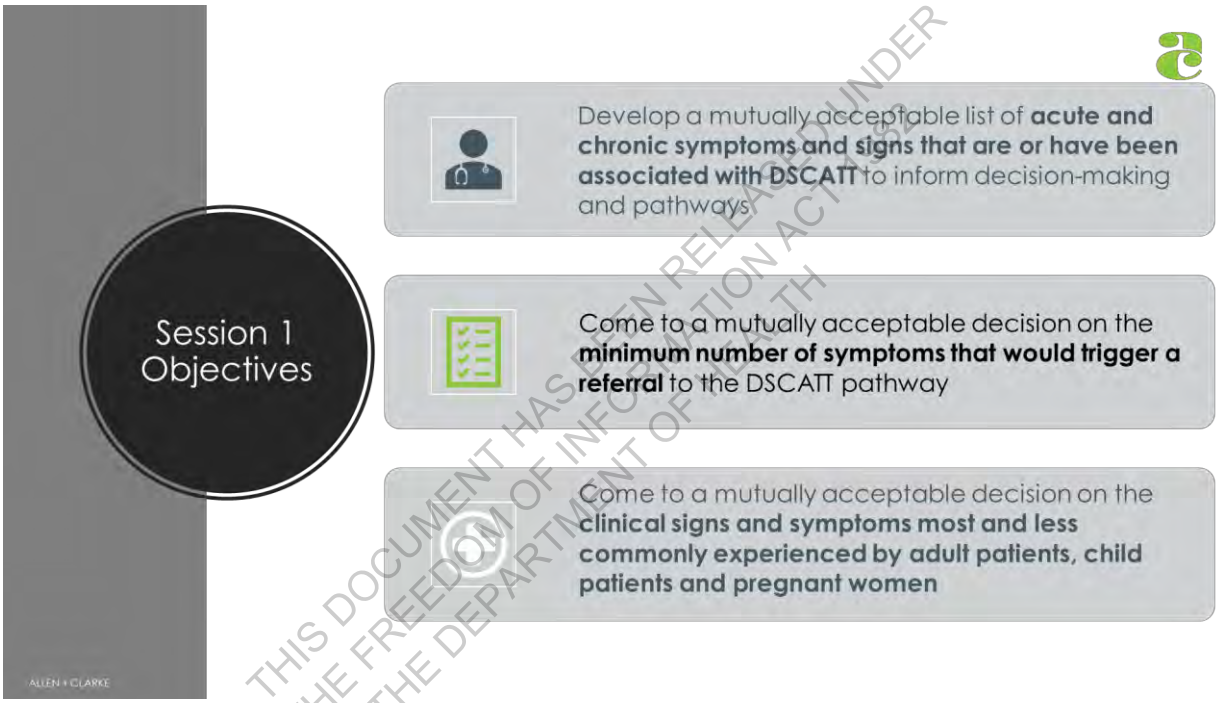
This session was presented and led by Dr Virginia Hope, Institute of Environmental Science and Research, and Expert Medical Technical Advisor on the *Allen + Clarke* project team.

5.1.1. Overview and objectives of this session

Dr Hope began by describing the clinical definition of signs and symptoms. She explained that symptoms are subjective and experienced by patients; signs are objectively observable; and that the terms are often used interchangeably.

Dr Hope introduced the objectives of the session, as in Figure 2 below.

Figure 2: Objectives of Session 1



She acknowledged the lack of peer-reviewed scientific literature describing Australian clinical studies investigating the symptoms and clinical signs of DSCATT. To support the discussion, Dr Hope talked to a series of slides[2] produced from publicly available information on self-reported signs and symptoms attributed to DSCATT, including from the Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS) submission to the Senate Inquiry and the published paper by Brown (2018)[3].

[2] Presented on pages 31-32 of this report.

[3] Brown, J.D (2018). A description of 'Australian Lyme disease' epidemiology and impact: an analysis of submissions to an Australian senate inquiry. *Internal Medicine Journal, 48(4),* 422-426. https://doi.org/10.1111/imj.13746

5.1.2. Stakeholder views on symptoms and signs they attribute to DSCATT most frequently in adults

Stakeholders were asked to use *Sli.do* to identify the symptoms and signs they attribute to DSCATT most frequently. There were 111 responses received from Think Tank stakeholders as presented in Table 1 below. Note that some of those identified were not signs or symptoms, rather specific diagnoses (for example, cluster headaches, Irritable Bowel Syndrome, myocarditis, Bell's Palsy, osteomyelitis).

Table 1: Signs and symptoms attributed to DSCATT as identified by Think Tank stakeholders

Sign or symptom identified	Responses
Neurological issues, including brain fog; cognitive dysfunction; memory loss; fine motor impairment and reduced verbal fluency	20
Chronic fatigue	15
Headaches/Migraine, including cluster headaches; pressure behind eyes; sinus pain	9
Heart problems, including palpitations; bradycardia; myocarditis; Lyme carditis and chest pain	8
Joint pain and inflammation	8
Gut disorders, including IBS; food intolerance; Glycaemic Index (GI) issues; severe malabsorption and abdominal pain	7
Neuropathy or dysesthesia	7
Myalgia	7
Visual disturbances, including random blindness and eye floaters	7
Rash including erythema migrans	6
Reduced stamina, weakness and post-exertional malaise	5
Arthritis	4
Sensitivity, including to sounds, smells, temperature and/or chemicals	4
Chronic pain syndromes	4
Flu-like symptoms	3
Nausea/vomiting	3
Paralysis	3
Migrating pain	3
Bell's palsy	3
Swollen lymph nodes	3
Sleep impairment, including insomnia	3
Shortness of breath	3
Personality change, including out-of-character anger outbursts; seizures; tremors; stiff neck; bone pain; fever; encephalitis; light-headed or dizziness	2 each

Sign or symptom identified	Responses
Neuro-muscular issues; ME/CFS; irregular temperature; Multiple sclerosis (MS); Amyotrophic lateral sclerosis (ALS); Lyme psychosis; thyroid issues; paraesthesia; osteomyelitis; numbness; bladder irritability; cycling symptoms; night sweats; atypical seronegative autoimmune disease; striae, involuntary limb movement; cherry angiomas; tinnitus; disorientation; balance issues; Borrelia Lymphocytoma; chromesthesia; coated tongue; cold hands and feet; increased levels of Quinolinic Acid; increased levels of ammonia; extracellular glutamate excitotoxicity; death	1 each

5.1.3. Stakeholder views on the number of symptoms to trigger referral

Stakeholders were asked their views on the minimum number of symptoms that should trigger referral to the DSCATT Clinical Pathway, again using *Sli.do*. 25 responses were received.

The majority view of stakeholders was that entry into the Clinical Pathway should rely on clinical assessment by an experienced health professional and individual treatment requirements, rather than the number of symptoms manifested.

5.1.4. Stakeholder views on symptoms and signs attributed to DSCATT most commonly experienced by children

Dr Hope noted that the limited self-reported information available on DSCATT related mostly to adults and little is known about children.

Stakeholders were asked their views on the symptoms and signs most commonly experienced by children (15 years and younger) presenting with systemic symptoms, with or without a history of tick bite and that are or have been attributed to DSCATT. There were 37 responses.

A common view expressed by stakeholders present at the Think Tank was that many of the symptoms and signs identified as experienced by children vary but are the same, or similar, as those identified in Table 1 above.

The following table (Table 2) presents a list of signs and symptoms identified by stakeholders as most commonly experienced among children, noting that some of those identified were not signs or symptoms (for example, asthma, autism).

Table 2: Signs and symptoms experienced by children as identified by Think Tank stakeholders

Sign or symptom identified	Responses
Pain, including joint pain; muscle pain; bone pain and wrist pain	11
Extreme fatigue or lethargy	9
Behaviour changes, including depression; rage; poor behaviour and attention issues	9
Gut disorders, including abdominal pain; malabsorption; food allergies or intolerances and constipation	7
Rash, including petechial; lines; bull's eye and acrodermatitis chronica atrophicans (ACA)	5
Headaches	4
Seizures, including febrile convulsions and twitching	4
Insect bite	3

Sign or symptom identified	Responses
Cognitive disorders, including memory loss	3
Bladder issues	2
Autism	2
Fever	2
Black eyes	2
Neck stiffness	2
Heart problems; skin reactions; paralysis; orthostatic hypotension; neuropathies; enlarged lymph nodes; insomnia; cytokine storm; failure to thrive; asthma; sore eye; vision changes; leg weakness	1 each

5.1.5. Stakeholder views on symptoms and signs of DSCATT experienced by pregnant women

Stakeholders were asked their views on the symptoms and signs most commonly experienced by pregnant women presenting with systemic symptoms, with or without a history of tick bite and that are or have been attributed to DSCATT. There were 30 *Sli.do* responses.

A common view expressed by stakeholders at the Think Tank was that symptoms experienced by pregnant women are usually very similar to those identified in Tables 1 and 2.

The following table (Table 3) lists the responses identified by stakeholders present at the Think Tank as the signs and symptoms experienced by pregnant women, noting that some of those identified by stakeholders were not signs or symptoms. Some of the signs or symptoms identified affect babies rather than pregnant women.

Table 3: Signs and symptoms identified by stakeholders as being experienced by pregnant women

Sign or symptom reported	Responses
Fatigue	3
Congenital transmission without treatment	3
Miscarriages	3
Onset of extreme allergies	2
Birth defects	2
Immune suppression	2
Muscle weakness	2
Insomnia; bladder issues; candida overgrowth in gut; tachycardia; onset of "atypical" immune disorders; children born with autism; joint pain; neuropathy; higher risk of caesarean birth due to neonate encephalitis	1 each

5.2. Session 2: Diagnosable diseases and disorders to be excluded before a patient is considered for DSCATT Clinical Pathway

This session was presented and led by Dr Virginia Hope, Expert Medical Technical Advisor.

5.2.1. Overview and objectives of session 2

Dr Hope introduced the session by explaining that a minimum requirement for the Clinical Pathway is to assist with a differential diagnosis, including the ruling out of obvious diagnosable conditions, such as Lyme disease, other tick-borne illnesses and other obvious chronic debilitating conditions. The health professional has a duty of care to ensure that other illnesses are not overlooked.

Dr Hope presented the objectives of the session as in Figure 3 below.

Figure 3: Objectives of Session 2

To inform the discussion Dr Hope presented publicly available information[4], including guidance on persistent non-specific symptoms to be considered in differential diagnosis of Lyme disease reported by Public Health England in the UK, submissions by ACIIDS and Lyme Disease Association of Australia (LDAA) to the Senate Inquiry, and information from papers by Brown (2018)[5] and Chalada et al. (2016)[6].

[4] Presented on pages 35-38 of this report.
[5] Brown, J.D (2018). A description of 'Australian Lyme disease' epidemiology and impact: an analysis of submissions to an Australian senate inquiry. *Internal Medicine Journal, 48(4),* 422-426. https://doi.org/10.1111/imj.13746
[6] Chalada, M. J., Stenos, J., & Bradbury, R. S. (2016). Is there a Lyme-like disease in Australia? Summary of the findings to date. *One Health*, *2*, 42–54. https://www.sciencedirect.com/science/article/pii/S2352771416300039?via%3Dihub

5.2.2. Stakeholder views on diagnosable diseases and disorders to exclude

All stakeholders were asked to identify the diagnosable diseases and disorders that should be **excluded** after a patient presents with systemic symptoms, with or without a history of tick bite, and to add any additional diseases or disorders if they need to be considered further.

Many stakeholders at the Think Tank expressed the view that DSCATT should **not** be considered by exclusion of other diagnoses because co-morbidities are common and diagnosis of one disease should not exclude DSCATT.

Many stakeholders wanted to ensure that patients with other diseases are not misdiagnosed as having a tick-borne disease, and equally important, that patients with tick-borne illnesses are not misdiagnosed as having other diseases.

5.2.3. Stakeholder views on the diseases and disorders most commonly experienced by adult patients, child patients and pregnant women

Stakeholders made the following additions to the list of infections reported by LDAA[7]: Periodic Fever, Aphthous stomatitis, Pharyngitis, Adenitis (PFAPA), Autoimmune disease, Legionella, Sexually transmitted infections (STIs), Varicella-Zoster Virus (VZV), and Mast Cell Activation Disorder (MCAD) – often brought on by inflammation due to long term infection or chronic inflammatory response syndrome/mould issues as well as ongoing allergy and underlying immune system dysfunction.

Stakeholders also added Syphilis and Leptospirosis to the list of other diagnoses by ACIIDS[8].

There was no consensus on the diseases and disorders most commonly experienced by adult patients, child patients and pregnant women, apart from those identified in the questions on signs and symptoms, including: cluster headaches; myocarditis; Lyme carditis; erythema migrans; Bell's palsy; encephalitis; multiple sclerosis; amyotrophic latera sclerosis (ALS); Lyme psychosis, osteomyelitis; atypical seronegative autoimmune disease; cherry angiomas; Borrelia Lymphocytoma; acrodermatitis chronica atrophicans (ACA); and autism.

[7] See list on page 35 of this report.
[8] See list on page 37 of this report.

5.3. Session 3: The ideal patient journey

This session was presented and led by Ms Catherine Marshall, Independent Guideline Advisor and Expert Guidelines Technical Advisor on the *Allen + Clarke* project team.

5.3.1. Overview and objectives of session 3

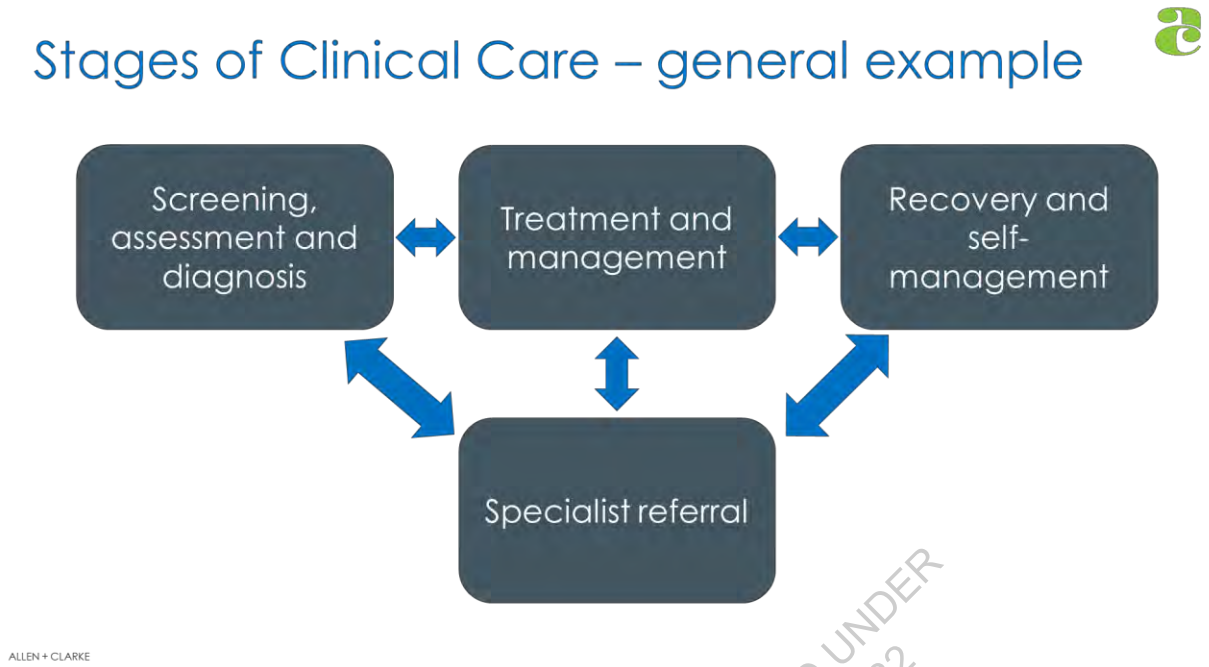
Ms Catherine Marshall presented an overview of the common elements of clinical pathways, and a brief overview of what is already known about what patients want from a pathway. She presented the objectives of the session as presented below in Figure 4.

Figure 4: Objectives of Session 3

The session was organised in a café style rotation. A designated leader for each part of the pathway rotated around the tables to collect views on the identified topic to add to those contributed by groups at previous tables. Online stakeholders were invited to participate in a group discussion facilitated by one of the *Allen + Clarke* project team facilitators (Ms May Guise). Views were then presented back in a plenary session with a summary of key messages from online discussion communicated via Ms Guise.

All stakeholders present were asked to discuss the core primary care and specialist services that the DSCATT Clinical Pathway should cover at each of the four stages of clinical care as presented in Figure 5 below (in public and private settings) and identify any differences in services required for children, pregnant women or people living in rural and remote areas.

Figure 5: Stages of Clinical Care



The key points raised by stakeholders are presented below.

5.3.2. Stakeholder views on assessment, screening and diagnosis

Assessment

Stakeholders expressed the view that the preferred first point of contact was the patient's General Practitioner (GP) for a person presenting with new onset or unresolved debilitating symptoms (with or without a history of tick bites.)

Diagnostic testing

While there were many views expressed about diagnostic testing during acute and chronic illness, and among children and pregnant women, there was no consensus reached by stakeholders about diagnostic testing.

Diagnosis

Stakeholders acknowledged that diagnoses by medical practitioners needed to be based on consideration of patient history and pathology. Some stakeholders expressed concerns that, in their view, they doubt the reliability of pathology testing.

5.3.3. Stakeholder views on treatment and management

While there were many views expressed about treatment, stakeholders at the Think Tank expressed the view that any treatment pathway should be underpinned by a clear diagnosis.

Regarding treatment plans for patients with chronic symptoms attributed to DSCATT, many stakeholders expressed the view that:

- patients should be treated specifically for symptoms and conditions using an appropriate treatment for the underlying causative organism, disease process or symptomatology, which may not be bacterial; and
- regular check-ups to monitor progress should be provided.

Most stakeholders at the Think Tank felt that it is important to recognise chronic illness as a long-term disability and that the treatment goal is to minimise disability and maximise function in order to improve patient outcomes.[9]

Many stakeholders also felt that any treatment pathway should consider the ability of patients living in rural and remote areas to travel and access treatment and management programs; and the focal point must be working with GPs to recognise and treat DSCATT.

5.3.4. Stakeholder views on specialist referral

The majority of stakeholders at the Think Tank expressed the view that:

- the GP is best placed to lead the care, with specialists brought in ancillary to the GP when they need advice on particular areas;
- referral to specialists should not be automatic and should only be done where the GP needs specialist advice;
- appropriate referral will depend on the particular signs and symptoms experienced by each patient; and
- any multi-disciplinary team should not be restricted to conventional specialists. Alternative practitioners may also be useful.

5.3.5. Stakeholder views on recovery and self-management

Stakeholders noted that it is important to define what successful treatment and care might include, as success may not be full recovery/remission. The goal may just be to maximise function and look for ways that people can reintegrate and manage their own lives as much as possible. Defining success will be very personal for each patient. For most patients, the goal will be to improve their quality of life as much as possible.

The majority of stakeholders expressed the view that a personalised integrated self-management plan may be useful, and the planning may need to involve supporters, carers or families. Stakeholders expressed concern about access to some treatments, including the cost of some treatments.

5.3.6. Further stakeholder views on the patient journey

Generally, stakeholders expressed the view that there needs to be more information on DSCATT, and that research can be informed by data capture and surveillance from each stage of the clinical journey. Monitoring of patient outcomes will also provide useful information going forward.

Stakeholders felt that education of medical practitioners is important, as is public education, including parents and schools, regarding dealing with tick bites and how to remove ticks safely.

[9] See https://www.who.int/news-room/fact-sheets/detail/disability-and-health for more information on the World Health Organisation (WHO) position on health and disability.

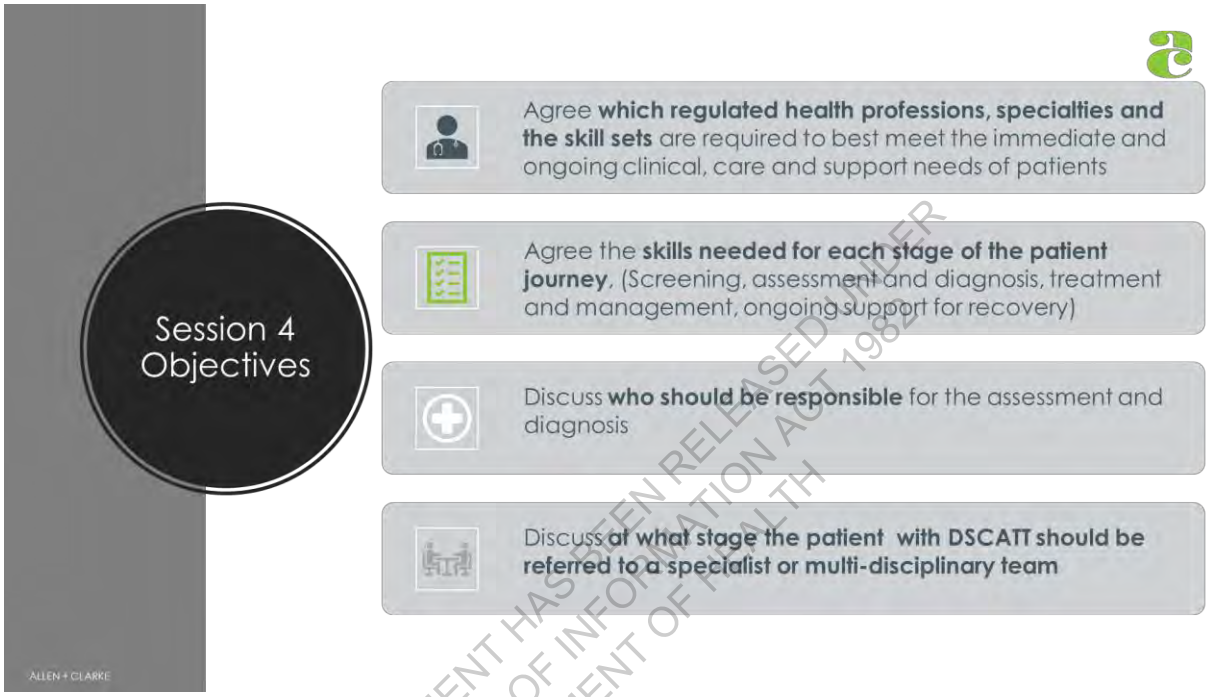
5.4. Session 4: Health practitioners and skills required

Ms Marion Clark from the *Allen + Clarke* project team presented and led this session.

5.4.1. Overview and objectives of the session

The session was significantly reduced in length to reflect the fact that most of the objectives, presented below, had already been well canvassed. Ms Clark introduced the objectives of this session as in Figure 6 below.

Figure 6: Objectives of Session 4



5.4.2. Stakeholder feedback

Commonly expressed views among the stakeholders were:

- responsibility for initial diagnosis should be with the GP or emergency care physician with referral or advice from relevant medical specialists when necessary;
- treatment and management should be led by the patient's GP with referral or advice from medical specialists or other health practitioners as necessary; and
- in general, a GP should look after the patient throughout the treatment / care journey and refer to specialists as needed.

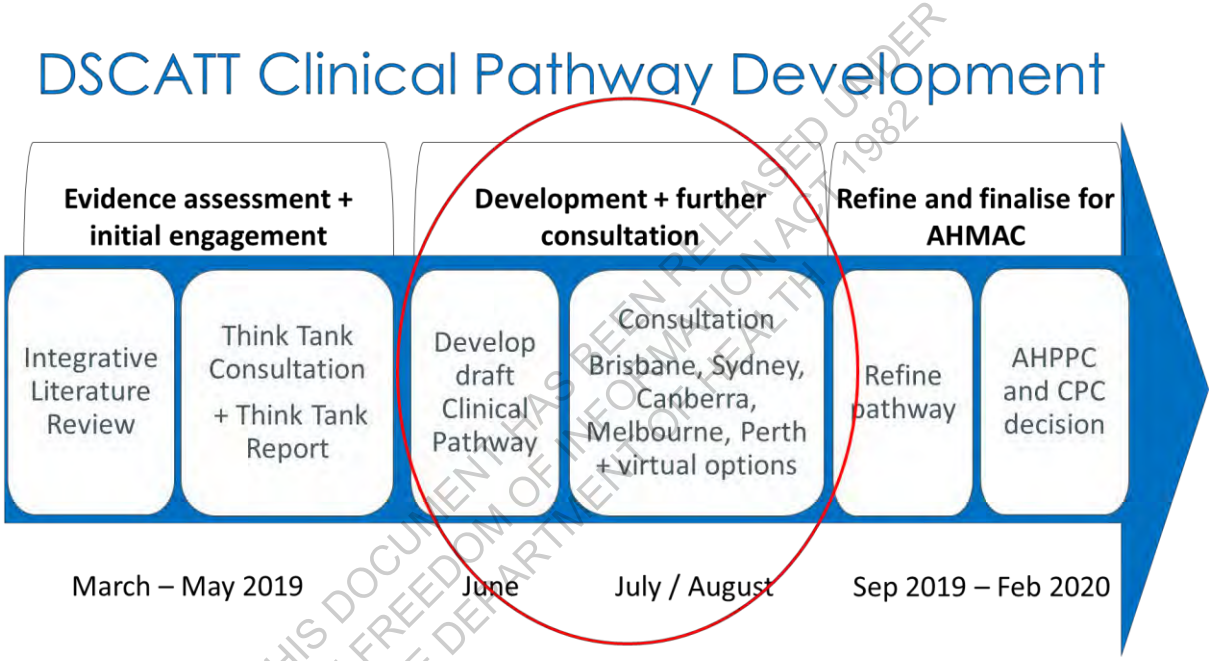
5.5. Closing session

Before the Think Tank closed, stakeholders were invited to comment further on DSCATT and the Clinical Pathway in an open plenary session.

It was noted that the National Health and Medical Research Council (NHMRC) has recently approved funding for research into DSCATT. Stakeholders discussed the research and raised issues relating to testing methods with some of the researchers who were present. They supported a collaborative approach across the studies to ensure that resources were used efficiently to gain the most information from the research.

Finally, Mr Paul Houliston from *Allen + Clarke* outlined the process for the development of the Clinical Pathway following the Think Tank, including plans for a further consultation round with stakeholders, with the opportunity to provide feedback.

Figure 7: Process for development of DSCATT Clinical Pathway



The Think Tank closed at 4.30 pm.

APPENDIX 1: LIST OF THINK TANK PARTICIPANT ORGANISATIONS

Table 4: Stakeholder organisations represented (in person)

Organisation
Australian College of Nutritional and Environmental Medicine
Australian Infectious and Inflammatory Disease Society (ACIIDS)
Canberra Area Lyme Disease Support Group
Chrysalis CFS/ME and Lyme Support
Gold Coast Patient Support
Hunter Region MSIDS
Karl McManus Foundation
Lyme Australia Recognition and Awareness
Lyme Disease Association of Australia (LDAA)
LDAA/ NSW Far South Coast Lyme Group
Lyme Victoria
MS/CFS/FM Support Association QLD
National Health and Medical Research Council (NHMRC)
NSW Far South Coast Lyme Group
NSW Riverina Lyme Support Group
Private individual – health practitioner
Royal Australian and New Zealand College of Psychiatrists
Royal College of Pathologists of Australasia
Royal North Shore Hospital
Sarcoidosis Lyme Australia
Therapeutic Guidelines Limited

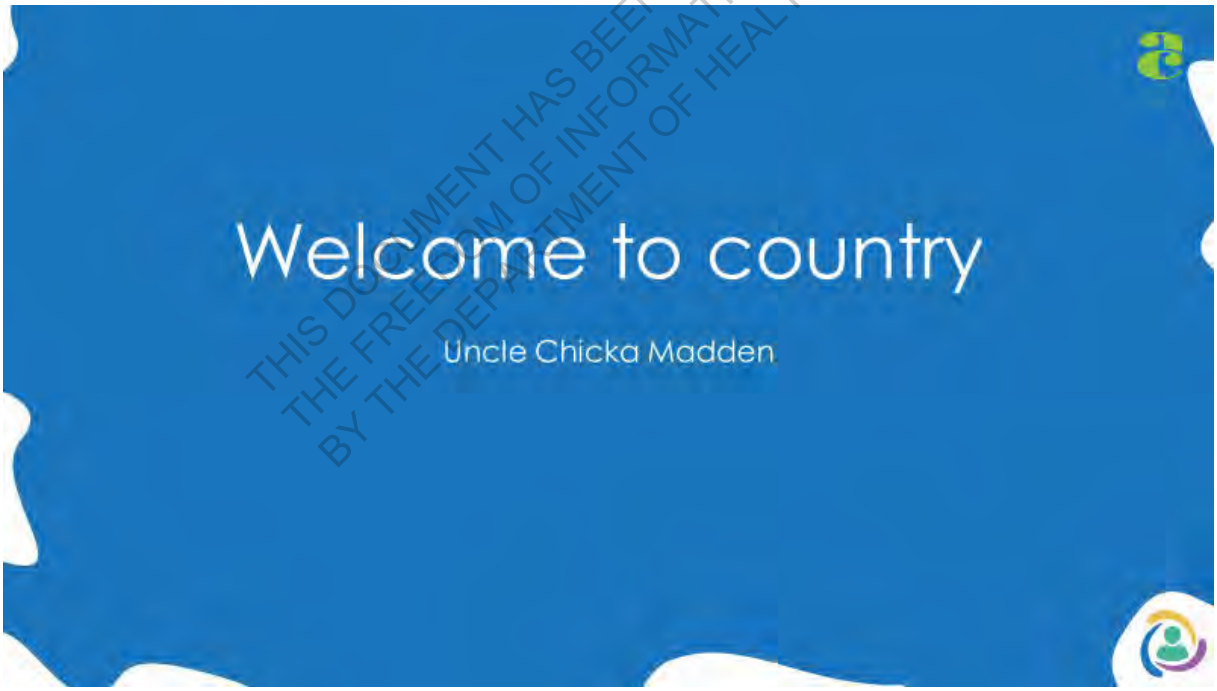
Table 5: Stakeholder organisations represented (online)

Organisation
ACT Health Directorate
Consumers Health Forum of Australia
Department of Health Tasmania
Health Pathways Capital Health Network
Independent Patient Advocate
Lyme Australia and Friends Group
ME/CFS and Lyme Association of WA Inc
Medical practitioner, Perth
Multiple Systemic Infectious Disease Syndrome Inc. (MSIDS Inc.)
The Kojonup Lyme Supporters Association Inc.
Tick Awareness Australia
Toxic Mould Support Australia
VIC Lyme Support

Four Department of Health representatives attended in person, as observers.

Nine *Allen + Clarke* representatives attended in person as facilitators. Speakers representing *Allen + Clarke* at the Think Tank are listed in the agenda.

APPENDIX 2: THINK TANK PRESENTATION



Opening address

DSCATT Clinical Pathway Think Tank

Introducing Allen + Clarke

Allen + Clarke is a public policy consulting firm with offices in Melbourne, and Wellington New Zealand.

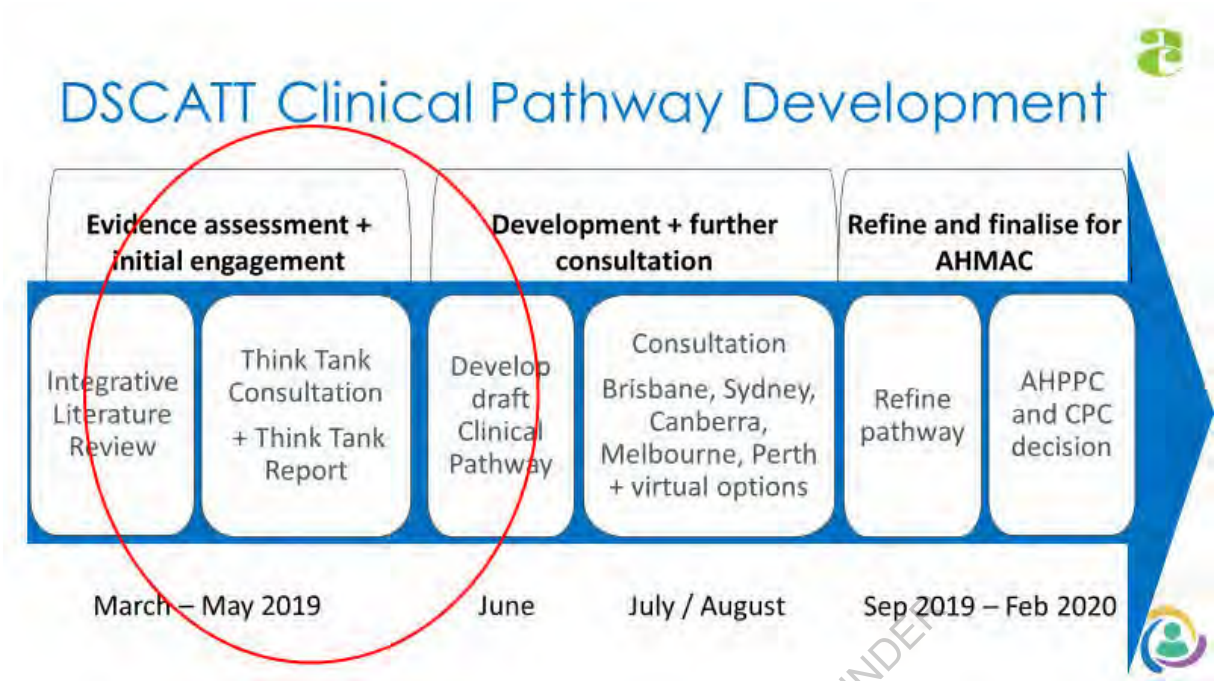
We are trusted advisors to the public sector, business and NGOs, and have extensive experience working in public health.

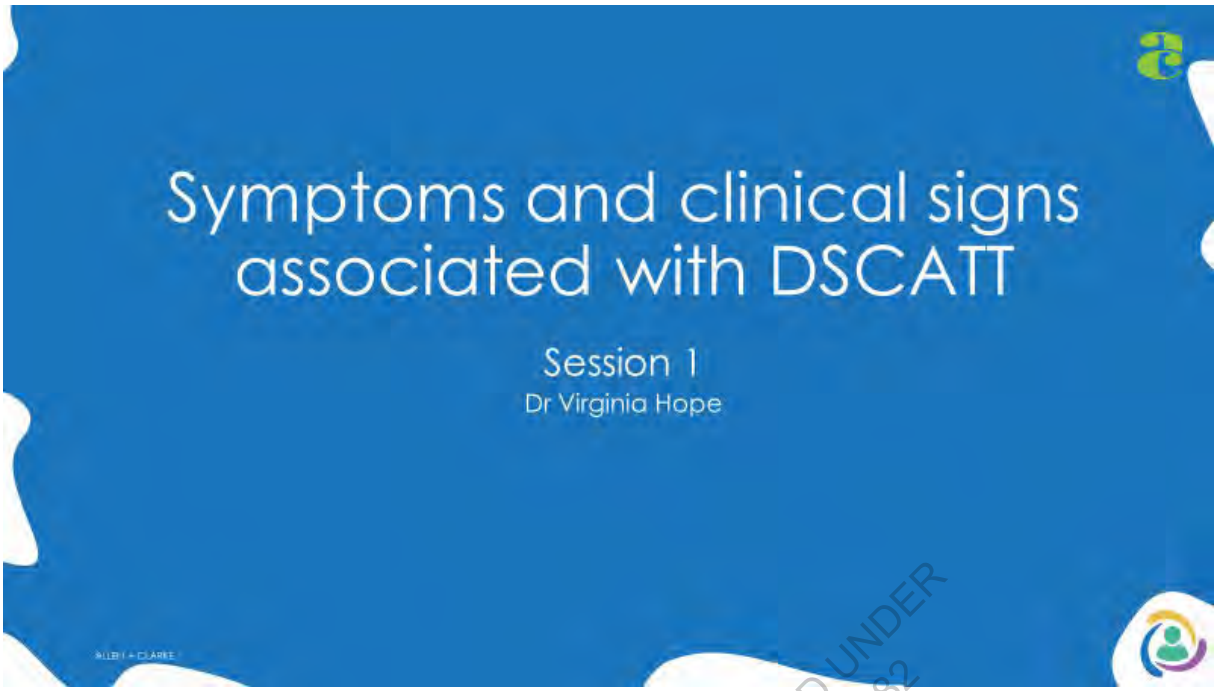
ALLEN+CLARKE

DSCATT Clinical Pathway project team

- **Paul Houliston**, MPhil
  - Project Sponsor
- **Dr Robyn Haisman-Welsh**, PhD (Oral Microbiology), BDS
  - Project Lead
- **Dr Virginia Hope**, MNZM BHB, MBChB, Dip Comm H, MPhil (Hons), FAFPHM, FNZCPHM, FRACMA
  - Medical Expert Advisor
- **Catherine Marshall**, BA, Post Grad Cert H Econ
  - Guidelines Expert Advisor
- **Marion Clark**, RN, BA (Soc.Sci), MPP
  - Lead Analyst
- **May Guise**, GradCert (Management), BA (Hons)/BCA
  - Project Manager
- **Stephanie James**, BSC (Biotechnology), LLB
  - Analyst

Sli.do #DSCATT





Symptoms reported by patients to Senate Inquiry

>45%*	20-45%*	<20%*
Fatigue -66.6%	Headache -44.5%	Palpitations -18.3%
Disordered thinking ('brain fog', 'memory loss' or loss of mental acuity -55.2%)	Myalgias- 36.6%	Insomnia -18.0%
Sensory disturbance- 49.1%	Rash -34.1%	Seizures -16.0%
	Mood disturbance-29.7%	Diarrhoea -13.1%
	Visual disturbance 27.7%	Tremor -13.0%
	Dizziness -26.4%	Personality change -4.1%
	Pain -25.6%	
	Fever -24.8%	
	Nausea- 22.4%	

18 symptoms identified as described by the patient

*** % of patients who reported at least one symptom (*n* = 656)**

698 submissions (Brown, 2018)

ALLEN + CLARKE

Sli.do #DSCATT

Symptoms of Australian Lyme-like Illness (ACIIDS)

Acute Lyme-like Illness	Chronic Lyme-like Illness
Typically includes: • Fever • fatigue • headache • joint pain and muscle pain	Most common symptoms: • fatigue • headache • muscle and joint pain • cognitive impairment ("brain fog"), poor memory and concentration
• Some patients develop erythema migrans rash (EM) • Occasionally encephalitis or meningitis	Other symptoms can include: • sharp pains, numbness or pins and needles in the limbs, sensitivity to light and sound, sore throat, swollen glands, sleep disturbance, palpitations, limb weakness, muscle twitching, non-epileptic seizures, anxiety, depression, panic attacks, constipation, dizziness, vertigo, fainting episodes, double vision and tinnitus

Source: ACIIDS submission to Senate Inquiry

Sli.do #DSCATT

Signs of Australian Lyme-like Illness (ACIIDS)

Acute Lyme-like Illness	Chronic Lyme-like Illness
Can include: • fever • skin rash • signs of acute neurological involvement, encephalitis or meningitis (occasionally)	• cranial and peripheral nerve signs • ECG changes and arrhythmias, POTS • acrodermatitis chronic atrophicans • enlarged liver or spleen, gastroparesis, loaded colon due to slow transit constipation • swollen joints, muscle weakness, muscle tenderness and trigger points

Source: ACIIDS submission to Senate Inquiry

Sli.do #DSCATT

Diagnosable diseases and disorders to be excluded before a patient is considered for DSCATT referral pathway

Session 2

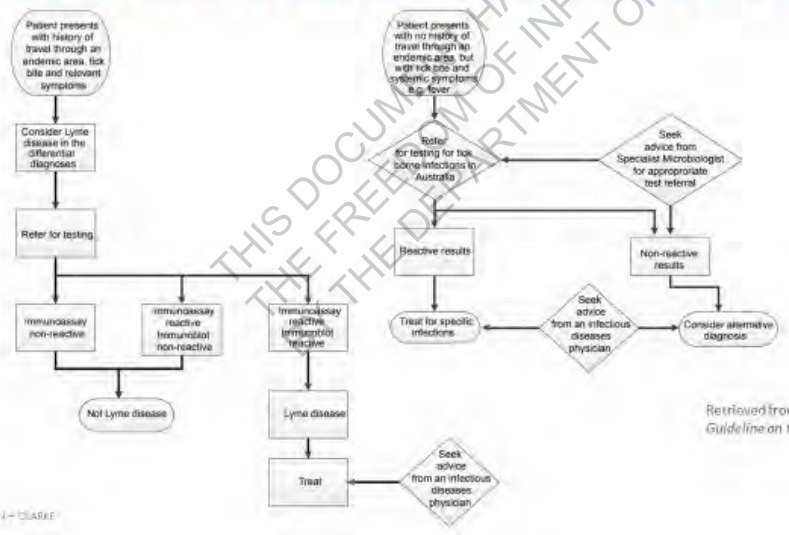
Dr Virginia Hope

Differential diagnosis

The Clinical Pathway will assist with a differential diagnosis; including the ruling out of obvious diagnosable conditions, including classical Lyme disease, other tick-borne illnesses and other obvious chronic debilitating conditions

Sli.do #DSCATT

Australian diagnostic guideline for overseas acquired Lyme disease



Retrieved from Gary D Lum, Jennie B Hood, Phil Wright *An Australian Guideline on the Diagnosis of Overseas-acquired Lyme Disease/Borreliosis*

Differential diagnosis – persistent non-specific symptoms

- CMV
- EBV
- hepatitis B or C
- HIV
- Syphilis
- toxoplasmosis
- unusual infections e.g. anaplasmosis, rickettsial disease, tick-born encephalitis, Q fever
- auto-immune diseases including rheumatoid arthritis
- malignancy
- primary psychiatric disorders
- chronic fatigue syndrome, myalgic encephalomyelitis or fibromyalgia

https://www.gov.uk/guidance/lyme-disease-differential-diagnosis

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Infections reported (LDAA)

- *Borrelia*
- *Bartonella*
- *Babesia*
- *Rickettsia*
- *Mycoplasma spp*
- Ross River Virus (RRV) Disease
- Chlamydia Pneumoniae (CPN)
- Epstein-Barr Virus (EBV)
- Ehrlicha
- Typhus
- Barmah Forest Virus (BFV)
- Cytomegalovirus (CMV)
- Q Fever
- Coxsackie
- Blastocystis
- HSV/Zoster
- Parvovirus
- *Streptococcus*
- Toxoplasmosis
- *Diantomeoba fragilis*
- Anaplasma
- *Brucella*
- Equine Morbillivirus Disease (EMV)
- Other

Based on data from LLDA Submission 528, May 2016

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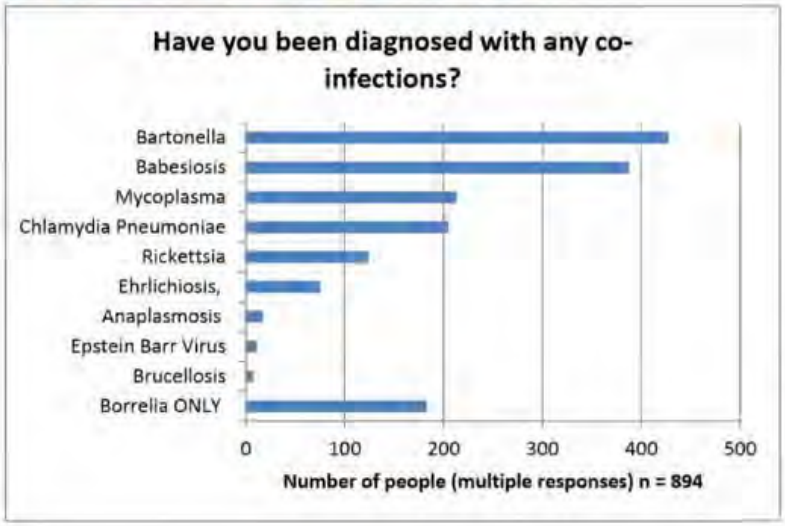
Infections - LDAA



Based on data from LDAA Submission 528, May 2016

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Co-existing disease

...one in ten (73, 10.5%) of the total patients reported another diagnosis that could explain their physical symptoms including

- 23 who reported **multiple sclerosis** (MS)
- 19 who reported **rheumatoid arthritis** (RA)
- 10 who reported **systemic lupus erythematosus** (SLE)
- 7 who reported **Crohn's disease**
- 4 who reported **motor neurone disease** (MND), and
- 14 patients who reported 'Other'.

Four patients reported more than one diagnosis.

- Brown's analysis of first-person submissions made to the Senate Inquiry by people who self-identified as having Lyme disease in Australia

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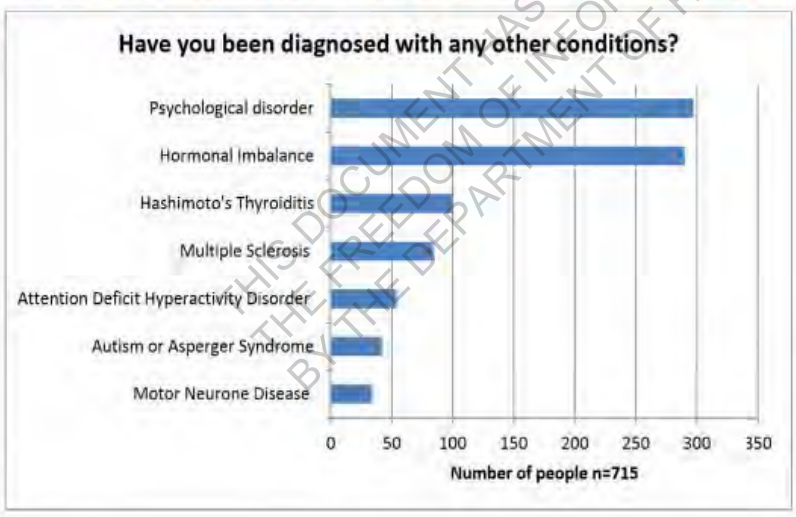
ACIIDS – other diagnoses

- Multiple sclerosis
- Amyotrophic lateral sclerosis (ALS)
- Parkinson's disease
- Alzheimer's disease
- Chronic Fatigue Syndrome
- Fibromyalgia
- Rheumatoid arthritis
- Polymyalgia rheumatica
- Polymyositis
- Autism
- Complex regional pain syndrome

ACIIDS, Submission 370, May 2016

Sli.do #DSCATT

Other illnesses and disorders - LDAA



Based on data from LDAA Submission 528, May 2016

Sli.do #DSCATT

Diagnoses provided by medical professionals from 349 submissions

- Depression – 42
- Fibromyalgia – 42
- Multiple Sclerosis – 28
- Anxiety – 21
- Mental disorder – 18
- Epstein-Barr Virus (EPV) – 16
- Adrenal fatigue – 13
- Chronic fatigue syndrome / myalgic encephalomyelitis – 8 (CFS/ME)

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Chalada, Stenos and Bradbury

- Infections
  - Australian Rickettsioses
  - Babesiosis
  - Q Fever (*Coxiella burnetti*)
  - *Bartonella*
  - *Candidatus neoehrlichia*
- Other
  - Fibromyalgia
  - CFS
  - Multiple sclerosis
  - Delusional parasitoses

Chalada, Stenos and Bradbury. Is there Lyme-like disease in Australia? Summary of the findings to date. One Health 2 2016 42-54.

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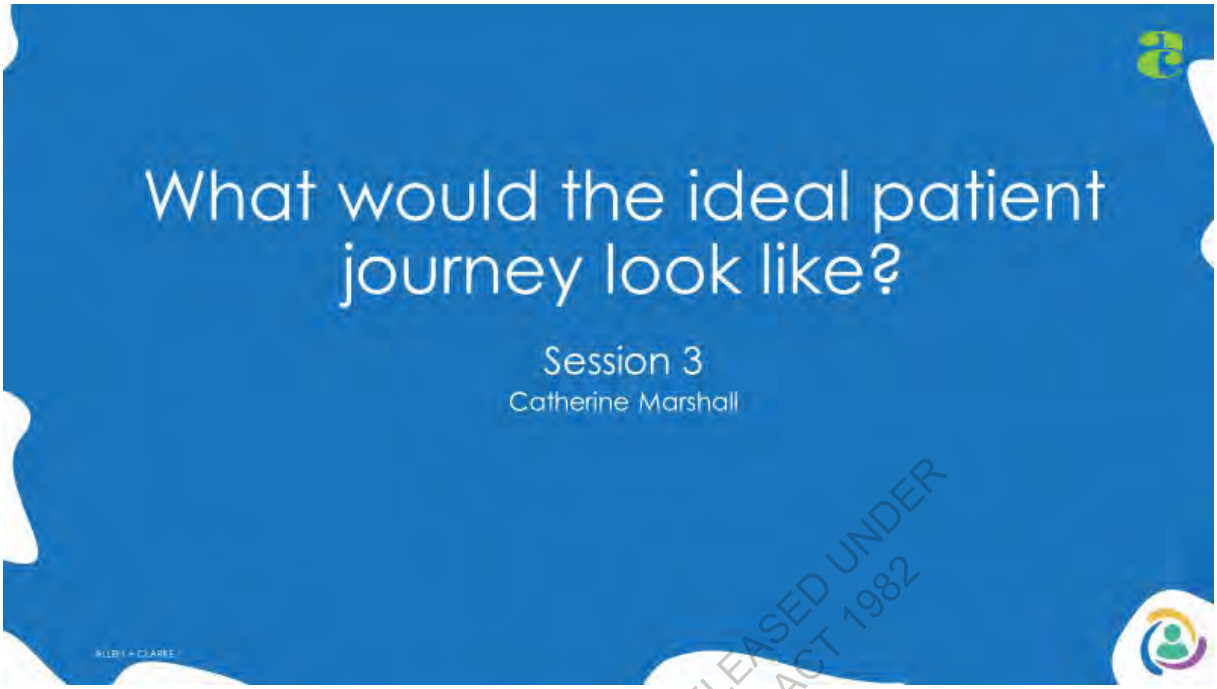

What are Clinical Pathways?

- **Evidence-based** tool – care map
- Aimed at **standardising** care
- Describes the standard **clinical decisions** along the patient journey
- Identifies where **different pathways** are required (eg adults/ children)
- Translates the evidence in a way that reflects **local services** (eg public/ private – rural/urban)

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ACSQHC Definition of Person-centred Care

*"Person-centred care is **respectful of, and responsive to, the preferences, needs and values of patients and consumers.***

Key dimensions include:

- *respect*
- *emotional support*
- *physical comfort*
- *information and communication*
- *continuity and transition*
- *care coordination*
- *access to care and*
- *partnerships with patients, carers and family in the design and delivery of care".*

https://www.safetyandquality.gov.au/wp-content/uploads/2018/06/Fact-sheet-1-Achieving-great-person-centred-care.pdf

Sli.do #DSCATT

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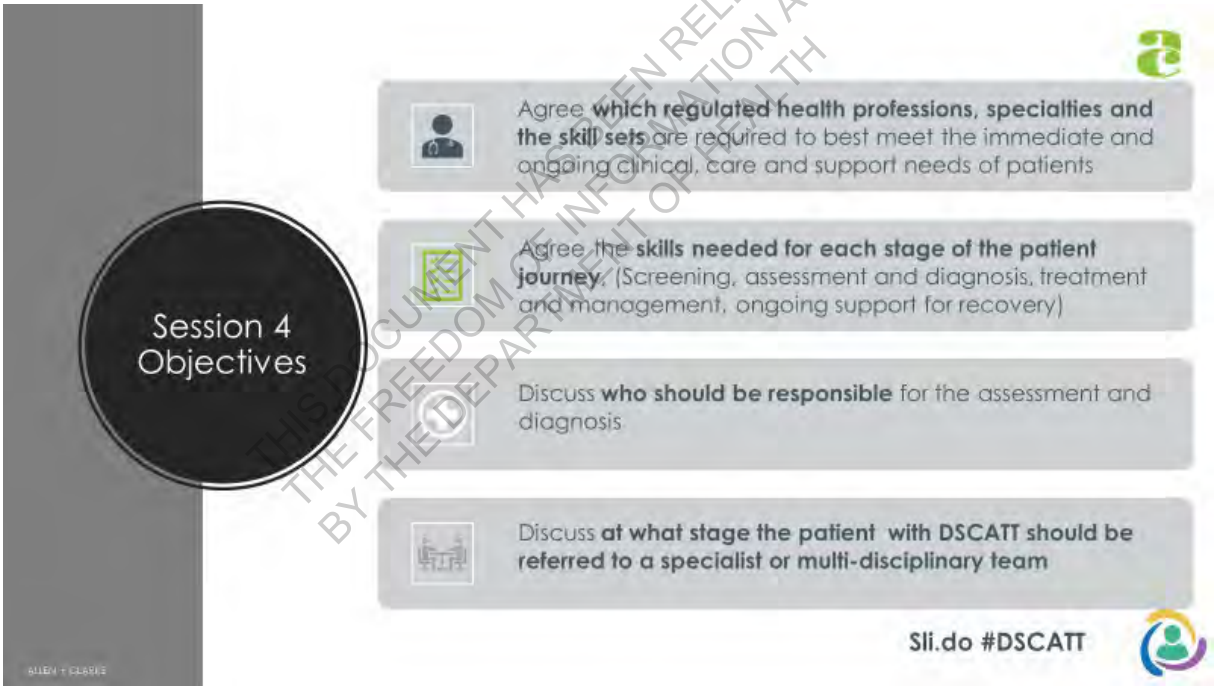
What consumers and their representatives have said they want (Senate Enquiry and previous Forums)

Sli.do #DSCATT

Stages of Clinical Care– general example

Sli.do #DSCATT



Key points

- The scope of this session is on considering regulated professions in the multi-disciplinary team
- This session builds on the discussions on the range of **signs and symptoms** experienced by patients with DSCATT (discussed earlier in Sessions 1 and 2) and the **services and care** required (discussed in Session 3).

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Symptoms reported by patients to Senate Inquiry

>45%*	20-45%*	<20%*
Fatigue -66.6%	Headache -44.5%	Palpitations -18.3%
Disordered thinking ('brain fog', 'memory loss' or loss of mental acuity -55.2%)	Myalgias- 36.6%	Insomnia -18.0%
Sensory disturbance- 49.1%	Rash -34.1%	Seizures -16.0%
	Mood disturbance-29.7%	Diarrhoea -13.1%
	Visual disturbance 27.7%	Tremor -13.0%
	Dizziness -26.4%	Personality change -4.1%
	Pain -25.6%	
	Fever -24.8%	
	Nausea- 22.4%	

18 symptoms identified as described by the patient

*** % of patients who reported at least one symptom (*n* = 656)**

698 submissions (Brown, 2018)

Sli.do #DSCATT

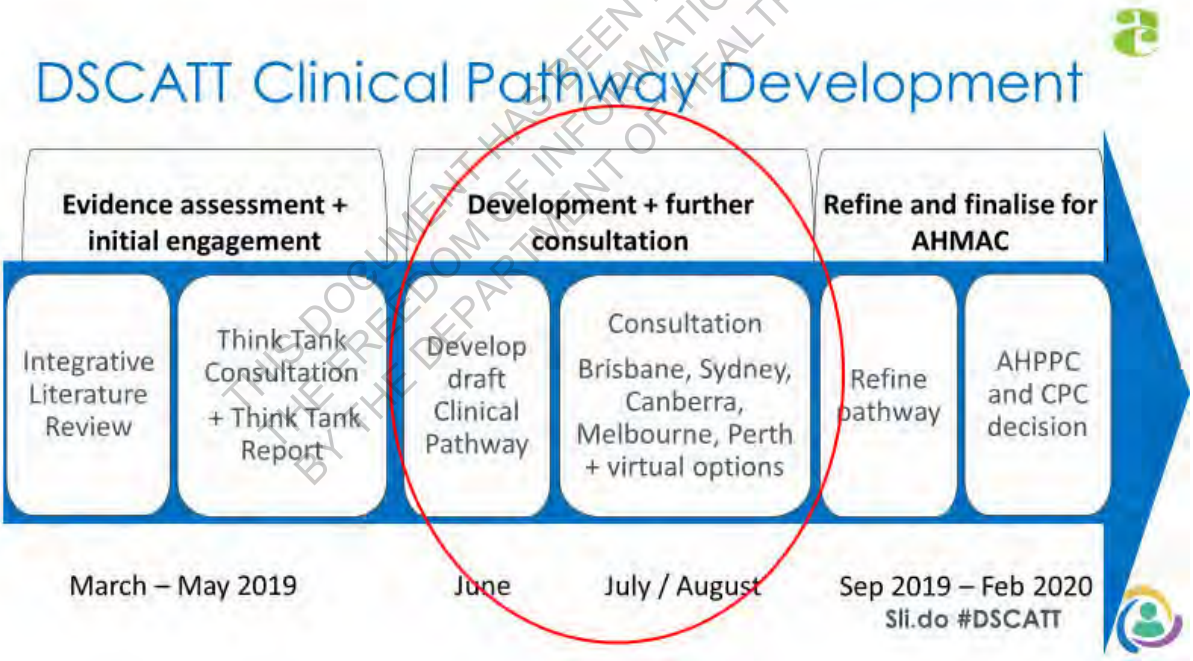
What skills and practitioners are needed to deliver the services?

1. Primary care?
2. Care coordination/case management?
3. General medicine?
4. Pathology (laboratory testing)?
5. Neurology?
6. Rheumatology?
7. Psychological/mental health support for long term chronic illness?
8. Physiotherapy?
9. Paediatrics?
10. Obstetrics/Midwifery?
11. Other?

Sli.do #DSCATT

Closing address

DSCATT Clinical Pathway Think Tank



From: NORRIS, Sarah
To: s22
Subject: FW: FOR CLEARANCE: Email to MO re DSCATT [SEC=OFFICIAL]
Date: Monday, 15 July 2019 8:24:11 AM
Attachments: image001.jpg

FYI

From: Boyley, Matthew <Matthew.Boyley@health.gov.au>
Sent: Friday, 12 July 2019 4:39 PM
To: s47F
Cc: NORRIS, Sarah <Sarah.Norris@health.gov.au>
Subject: FW: FOR CLEARANCE: Email to MO re DSCATT [SEC=OFFICIAL]

Hi s47F

As promised from our catch-up meeting below is an update on work we are undertaking in relation to Debilitating Symptom Complexes Attributed To Ticks (DSCATT).

As you are aware, in late 2018, Minister Hunt approved two projects to assist with the Australian Government response to the Senate Inquiry in to Lyme and Lyme-like disease. Work on the projects has now commenced, particularly the development of an evidence-based clinical pathway and s22 It is timely I provide you with an update on the work.

Clinical Pathway

The contractor for this work, Allen + Clarke, has been working closely with advocacy groups, including Lyme Disease Association of Australia (LDAA), as well as key health profession organisations such as the Royal Australian College of General Practitioners (RACGP) and the Australian Medical Association (AMA). Discussions to date with Lyme disease advocates continue to focus on the existence of Lyme disease in Australia, as well as concerns regarding work being undertaken by the Medical Board of Australia to curtail the use of non-evidence based treatment options. Unfortunately, the clinical pathway is being seen by many groups as a mechanism for easier access to non-evidence based treatments such as vitamin infusions and ozone therapy.

Given continued agitations by some of these advocates, it is important that I work with you to ensure that this important work does not become derailed into a discussion of the existence/non-existence of Lyme disease or access to particular treatment options. For both of these issues, the evidence is very clear and well documented.

Whilst key stakeholders have been consulted throughout the process, irrespective of engagement, any materials produced are unlikely to be accepted by the patient groups due to the need to pass the 'evidence test'. From a health perspective, the best outcome for patients is to be considered thoroughly in a multidisciplinary medical approach that makes the best use of clinical acumen and available diagnostic skills and technology. Ultimately, my concern remains the evidence based nature of the pathway and its acceptance by the medical profession. The Government cannot risk producing a pathway without key buy in from RACGP, the AMA and other key medical groups. To go against the evidence, would be too a high a risk for the medical groups and likely lead to concerns about the Government's ability to produce evidence based policy, well targeted programs and best practice regulation for health professionals.

s22

s22

Matt

Matthew Boyley | First Assistant Secretary
Office of Health Protection (OHP) | Department of Health
02 6289 7330 | s22 | Matthew.Boyley@health.gov.au
Executive Assistant
s22
Executive Officer
s22

I acknowledge the traditional custodians of the land on which I live and pay my respects to the Elders, past, present and future

PROJECT STATUS REPORT

Project name: DSCATT Clinical Pathway

Prepared by: s47F

Prepared for: s22

s22

ALLEN+CLARKE AUSTRALIA

Period covered: 6/1/20 - 31/1/20

Client: Department of Health (Australia)

Literature review and Clinical Pathway

- No specific work on either product anticipated, but drafting the Stakeholder Consultation Report will inform and shape next products for next period of work.

s22

Australian Government
Department of Health

s22

Correspondence Background Brief
Minister Hunt

Subject DEBILITATING SYMPTOM COMPLEXES ATTRIBUTED TO TICKS (DSCATT)

Summary of Issues

- The Department of Health (the Department) is progressing a number of activities in response to the 2016 Senate Inquiry into the Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients. This includes the development of an evidence-based clinical pathway for patients suffering from Debilitating Symptom Complexes Attributed to Ticks (DSCATT) and a suite of tick-related education materials.
- Both the clinical pathway and the tick-related education materials are expected to benefit a large number of stakeholders, so it is important that these projects remain evidence-based and reflect current best practice within the Australian context.
- Consistent with the Department's approach to the development of materials for publication, peak representative bodies (for both health professionals and patient groups) were selected for consultation on both projects to ensure the majority of affected stakeholders views were adequately considered.
- During the consultation period, the draft Clinical Pathway was well accepted and viewed as a valuable resource by the following authoritative medical and government health authorities. These organisations generally supported the Clinical Pathway, noting that many also provided advice and recommendations on aspects of the draft pathway and how it may be improved:
    - Royal Australian College of General Practitioners
    - Royal College of Pathologists of Australasia
    - ACT Health
    - Australasian College for Emergency Medicine (ACEM)
    - Australasian Society for Infectious Diseases (ASID)
    - Australian College of Nursing
    - Australian Psychological Society (APS)/College of Health Psychologists
    - Australian Rheumatology Association (ARA)
    - Pain Australia
    - Private Healthcare Australia (PHA)
    - South Australia Health
    - Therapeutic Guidelines Ltd (TGL)
    - Victoria Department of Health and Human Services
    - Western Australia Health
    - Westmead Hospital
- The best outcome for patients is to be considered thoroughly in a multidisciplinary medical approach that makes the best use of clinical acumen and available diagnostic skills and technology.
- Any non-evidence based approach presents a risk for the relevant medical professionals and likely lead to concerns about the Government's ability to produce evidence based policy, well targeted programs and best practice regulation for health professionals.

- There is a risk to both the delivery of the projects, as well as their likely acceptance by the broader medical colleges, if a moratorium is granted until **all** patient community stakeholder feedback is provided and incorporated into revisions.
    - The key concern from patient groups remains the existence of Lyme disease in Australia, the inclusion of the 'patient experience', the perceived lacking of acknowledgment within the pathway, and access to non-evidence based treatments.
- Many claims in the letter are misrepresented and founded on circumstantial evidence, rather than peer-reviewed scientific publications. An overview of the projects, including specific issues raised in the letter, is provided at Attachments A and B.

s22

Contact Officer:	s22	*A/g Assistant Secretary, Health Protection Policy Branch, Office of Health Protection*	Ph: (02) 6289 s22 Mobile: s22
Clearance Officer:	*Sarah Norris*	*A/g First Assistant Secretary, Office of Health Protection*	Ph: (02) 6289 s22 Mobile: s22

DSCATT CLINICAL PATHWAY PROJECT

- Allen and Clarke Policy and Regulatory Specialists (Allen and Clarke) was engaged in March 2019 to develop an evidence-based clinical pathway and multidisciplinary care model for patients presenting with DSCATT.

s22

Information regarding specific issues raised in correspondence:

- The draft clinical pathway is consistent with the statement of requirement for the project, which stipulates that the pathway be an evidence based multidisciplinary medical approach.
- The clinical pathway is underpinned by a comprehensive literature review that is being updated in response to additional references provided during the consultation process. The review is expected to be published at the same time as the final clinical pathway.
- The Australian Government supports the use of only accredited Australian laboratories. An evaluation commissioned by the Department in 2015, following community concern regarding tests used to diagnose Lyme disease, did not indicate any problems with the quality of testing performed by accredited medical testing laboratories in Australia.
- As with all clinical guidelines, the end treatment remains at the discretion of the treating physician in line with their assessment of the patient and their needs.

PROJECT STATUS REPORT

Project name: DSCATT Clinical Pathway

Prepared by: s47F

Prepared for: s22

ALLEN+CLARKE AUSTRALIA

Period covered: 2/2/20 - 28/2/20

Client: Department of Health (Australia)

Main activities this period

s22

Main activities next period

s22

• Complete table of feedback received by stakeholder type, and proposed response in relation to the final Clinical Pathway. Discuss contentious items / uncertainties with project team, expert advisors, and DoH to agree approach.
• Agree proposed approach to refining the Clinical Pathway with DoH and proceed with revisions (may be a March activity).

Literature review

• Agree way forward with DoH, considering initial 2019 draft, literature included in the Draft Pathway, and literature received (may be a March activity).

s22

PROJECT STATUS REPORT

Project name: DSCATT Clinical Pathway

Prepared by: s47F

Prepared for: s22

ALLEN+CLARKE AUSTRALIA

Period covered: 2/3/20 - 31/3/20

Client: Department of Health (Australia)

Main activities this period

s22

Final Clinical Pathway

- Developed sample of table of feedback received by stakeholder type, with proposed response in relation to the final Clinical Pathway.
- Discussed table and next steps with DoH (19 Mar).
- Completed full table of feedback received by stakeholder type, and proposed response in relation to the final Clinical Pathway, provided table to DoH ahead of discussion(27 Mar).

s22

Main activities next period

s22

Final Clinical Pathway

- Discuss table of feedback, particularly codes 3 and 4s, with DoH (7 Apr). Further discussion with project team as required.
- Determine form of final Clinical Pathway (e.g. same length document or shorter version with reference material) and proceed with agreed amendments.

Literature review

- Agree way forward with DoH, considering initial 2019 draft, literature included in the Draft Pathway, and literature received.

Project management

- April monthly teleconference scheduled for 7 April, to discuss table of coded feedback.

s22

PROJECT STATUS REPORT

Project name: DSCATT Clinical Pathway

Prepared by: s47F

Prepared for: s22

ALLEN+CLARKE AUSTRALIA

Period covered: 1/4/20 - 30/4/20

Client: Department of Health (Australia)

Main activities this period

s22

Final Clinical Pathway

• Received initial verbal feedback from the Department (7 and 21 Apr), including discussion of the final form of the Clinical Pathway as being a short document (3-15 pages), with an accompanying ~30 page document presenting the evidence for the Pathway.

• Provided additional information on ILADS vs ISDA guidelines issue.

Literature review

• Discussed status of May 2019 working draft, DoH comments received in August 2019, confirmation the report is intended to be published, and how to progress the literature review now given the evidence provided in the Draft Pathway (21 Apr).

• Sought advice from DoH on several specific queries, to inform revisions to the literature review report (23 Apr).

s22

Main activities next period

s22

Final Clinical Pathway

• Receive written feedback from DoH on the coded table of feedback, to inform final Clinical Pathway.

• Receive list from DoH of tick-borne illnesses that will be covered in detail in the other educational materials project and therefore do not need to be included in the Pathway.

• Develop final Clinical Pathway (short doc + evidence doc), based on advice from DoH and with input from tecnical advisors (noting potential availability issues given Covid19). *Target delivery date of 15 June depends on receiving DoH advice by 18 May at latest, as well as the amount of additional work required, the decision about IDSA 2006/2019 Lyme disease guideline status with respect to finalising the Clinical Pathway, and the availability of our technical advisors to provide input .*

Literature review

• Receive advice from DoH in response to queries to inform revisions to the literature review report.

• Once feedback received, discuss and agree an appropriate revised delivery date to allow for technical advisor review prior to provision to DoH. *Given covid19 environment we will need to provide sufficient notice to our technical advisors to receive their input, to ensure a sound report for publication.*

• Proceed with revising literature review report.

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Stakeholder Consultation

Australian Department of Health Draft DSCATT Clinical Pathway

November 2019 – January 2020

SUMMARY REPORT

April 2020

ALLEN+CLARKE

ACKNOWLEDGEMENTS

Allen + Clarke sincerely acknowledges all the stakeholders who participated in the Australian Department of Health Draft DSCATT Clinical Pathway consultation and gave us their valuable time, feedback, advice and recommendations on the Draft Pathway. Feedback was greatly valued and will be used to refine, further develop and finalise the DSCATT Clinical Pathway.

Document status:	Draft for Departmental review
Version and date:	V 5.0 08/05/2020
Author(s):	s47F
Filing Location:	Allen and Clarke\DSCATT Clinical Pathway - Documents\04c Deliverables Phase 3\04 Stakeholder Consultation report
Peer / technical review:	s47F
Verification that QA changes made:	
Proofread:	
Formatting:	
Final QA check and approved for release:	

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

Telarc. Registered ™ Quality ISO 9001

ALLEN+CLARKE

CONTENTS

TABLES

FIGURES

GLOSSARY

ACNEM	Australian College of Nutritional and Environmental Medicine
ACEM	Australian College for Emergency Medicine
ACIIDS	Australian Chronic Infectious and Inflammatory Disease Society
ACN	Australian College of Nursing
AMA	Australian Medical Association
ANZMES	Associated New Zealand ME Society
APA	Australian Physiotherapy Association
ASID	Australasian Society for Infectious Diseases
CDC	Centers for Disease Control and Prevention
CFS	Chronic Fatigue Syndrome
CDNA	Communicable Diseases Network Australia
DSCATT	Debilitating Symptom Complexes Attributed to Ticks
DHHS	Department of Health and Human Services
EM	Erythema Migrans. Bull's Eye Rash
GP	General Practitioner
ID	Infectious Disease
IDSA	Infectious Disease Society of America
ILADS	International Lyme and Associated Diseases Society
LDAA	Lyme Disease Association of Australia
MUS	Medically Unexplained Symptoms
NATA	National Association of Testing Authorities, Australia
NICE	National Institute of Health and Care Excellence (UK)
NHMRC	National Health and Medical Research Council
NRL	National Serology Reference Laboratory
PHA	Public Health Association of New Zealand
RACGP	Royal Australian College of General Practitioners
RACP	Royal Australasian College of Physicians
RCPA	Royal College of Pathologists of Australasia
RCT	Randomised Controlled Trial
TGL	Therapeutic Guidelines Limited
QTT	Queensland Tick Typhus

1. INTRODUCTION

1.1. Project overview and background

In 2019, the Australian Department of Health (the Department) contracted Allen and Clarke Policy and Regulatory Specialists (*Allen + Clarke*) to develop an evidence-based clinical pathway and multidisciplinary care model for patients suffering from debilitating symptom complexes attributed to ticks (DSCATT), which can be flexibly applied in both private and public healthcare settings.

This project contributes 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*. The Australian Government agreed to consult with key stakeholder groups to develop a cooperative multidisciplinary framework accommodating patient and medical needs and building on the consultation in April and July 2018 with medical professionals, state and territory health authorities and patient groups about the concept of multidisciplinary care.

1.2. Development of the Clinical Pathway

As part of the development of the Australian Department of Health DSCATT Clinical Pathway (the Pathway), *Allen + Clarke* developed a Draft Pathway for consultation with stakeholders. The Draft Pathway was informed by a review of published evidence and views presented by stakeholders at a Think Tank held in Sydney on 8 May 2019. The Think Tank was a full day focus group discussing the nature of DSCATT and future support pathways.[1]

The Draft Pathway aims to support decision-making on differential diagnosis and referral pathways for patients presenting with either new on-set or unresolved debilitating symptoms with or without a history of tick bites and that cannot be attributed to another condition (acute or chronic). It was designed specifically for the Australian health care context.

1.3. Consultation on the Draft Pathway

Allen + Clarke consulted on the Draft Pathway with key stakeholders, including medical professionals, government health authorities and patient groups between 13 November 2019 and 24 January 2020. The purpose of consultation was to seek feedback on the Draft Pathway to inform refining and finalising the Clinical Pathway. Nominated representatives of key stakeholder organisations were identified with the Department at the beginning of the project, and these people were invited to contribute to the consultation. These organisations were mainly identified from related prior work and the Think Tank. Stakeholders from the original agreed list were invited to participate in the consultation on the Draft Pathway irrespective of whether they had participated in the Think Tank.

This Stakeholder Consultation Summary Report describes the consultation document (the Draft Pathway); the consultation process and stakeholder participation rates; and a summary of stakeholder feedback against the key consultation questions.

[1] A report of stakeholder views expressed at the Think Tank was published in August 2019 available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/4594AB5B9B2A90D4CA257BF0001A8D43/$File/DSCATT-Think-Tank-2019.pdf.

2. DRAFT PATHWAY

The Draft Pathway for consultation was a comprehensive document of 56 pages. It was informed by a review of published scientific literature, which focused on an integrative review of the published peer-reviewed literature and grey literature on and relevant to DSCATT. Information was drawn from systematic reviews, narrative literature reviews, Randomised Controlled Trials (RCTs), case-control studies, prospective studies, observational studies, official Australian reports and government inquiries including submissions within relevant Senate Inquiry reports, (inter)national authority and intergovernmental reports and guidelines and international and Australian guidelines produced by clinical and professional bodies over the past 10 years.

The Draft Pathway for consultation included:

- an algorithm (diagram)
- a three-page summary of the key points in the document
- over 40 pages of text with the supporting evidence base provided as footnotes
- two case studies to illustrate how the Clinical Pathway could be applied in practice, and
- a bibliography of references cited in the footnotes.

The Clinical Pathway is being developed to support decision-making on differential diagnosis and referral pathways for patients presenting with either new on-set or unresolved debilitating symptoms with or without a history of tick bites and that cannot be attributed to another condition (acute or chronic). The Draft Pathway was created for this round of stakeholder consultation, with stakeholder feedback used to inform refinement and finalisation of the Clinical Pathway.

Acknowledging the attribution to ticks in the term DSCATT, the Draft Pathway considered tick-borne diseases in the differential diagnosis, and included comprehensive information on overseas-acquired Lyme disease, known Australian tick-borne diseases, and relevant referral pathways and management approaches for patients for whom a diagnosis cannot be established and medically unexplained symptoms (MUS) persist.

The target population for the Draft Pathway was patients of all ages who presented at primary care with new onset (for example, fever, rash) or unresolved debilitating symptoms and who have or may have had a history of tick bites.

2.1. Algorithm

The algorithm to support clinical decision making was based on designs used in published Australian and international clinical pathways and guidelines.

The algorithm was organised into clinically sequential stages starting with initial assessment and support of a patient presenting to primary care who meets the criteria of the target population for the Clinical Pathway, through to decisions about when it was appropriate for the patient to exit the Clinical Pathway, or remain within it.

Layered across each stage and depending on the history, clinical examination and exclusion of obvious acute or chronic diagnosable conditions undertaken in the initial assessment stage symptoms, was the consideration of overseas acquired Lyme disease, other Australian and international tick-borne and vector-borne diseases, or alternative diagnoses if tick or vector-borne diseases were not indicated.

The stages in the Draft Pathway were:

- initial assessment and support at primary care
- differential diagnosis
- diagnostic testing for overseas acquired Lyme disease, international and known Australian tick-borne and vector-borne diseases and for non-infectious alternative diagnoses
- diagnosis +/- referral
- initial management for patients for whom a diagnosis or diagnoses was confirmed through appropriate diagnostic testing, for patients who have no confirmed diagnosis but who have unresolved or persistent symptoms, and for patients who have no diagnosis and where medically unexplained symptoms persist (using a person-centred stepped care approach), and
- ongoing management for patients for whom a diagnosis or diagnoses was confirmed through appropriate diagnostic testing, for patients who have no confirmed diagnosis but who have unresolved or persistent symptoms, and for patients who have no diagnosis and where medically unexplained symptoms persist.

For each box in the algorithm containing a recommendation to the treating clinician, the reader was referred to the relevant section(s) in the document where the full information and evidence base was provided. It was highlighted above the algorithm diagram that patients may be on multiple parts of the pathway simultaneously. In this Clinical Pathway, a patient would exit when their symptoms resolved.

2.2. Three-page summary of the key points

The Summary Information included key information for clinicians covering:

- Initial assessment
- Lyme disease (only in patients who have travelled to Lyme disease endemic areas)
- Australian and international vector-borne (including tick-borne) diseases, and
- Management of patients who have persistent symptoms and who remain undiagnosed.

2.3. Supporting evidence base underpinning the Draft Pathway

The remainder of the Draft Pathway included comprehensive information, maps where known Australian tick-borne diseases have been found, and the supporting evidence base for the advice and recommended approach relevant to each box in the algorithm for the Draft Pathway. Supporting evidence was referenced in footnotes.

While *Allen + Clarke* acknowledges the Draft Pathway document was lengthy, it was important for stakeholders to see and have the opportunity to comment on the evidence base underpinning the advice and recommendations in the Draft Pathway. Including the evidence base in the document also enabled stakeholders at consultation to recommend other peer-reviewed published evidence that they considered relevant in further refining the Clinical Pathway.

3. CONSULTATION PROCESS AND STAKEHOLDER PARTICIPATION RESULTS

This section describes both the planned and actual consultation process.

3.1. Consultation timing and document development

Consultation on the Draft Pathway was initially scheduled for July and August 2019, with the subject of consultation intended to be a brief diagrammatic overview of a Draft Pathway. In the course of developing the Draft Pathway, *Allen + Clarke* and the Department agreed that a more comprehensive consultation document that included the evidence base supporting a diagrammatic overview would be more useful to the development of the pathway and make better use of stakeholders' time and expertise. Stakeholders were notified in July that consultation would be postponed while this documentation was developed.

The *Allen + Clarke* project team and independent expert technical advisors developed documentation and received approval of the Draft Pathway for consultation from the Department in November 2019.

In anticipation of the consultation period opening, invited stakeholders were re-contacted in October 2019 to thank them for their patience, advise them that consultation would run from 13 November to 18 December 2019, and ask them to indicate their interest in receiving the consultation documents and participating in the consultation. Almost 90 stakeholder groups or organisations were invited to participate, which included both groups which had and had not attended the 2019 Think Tank.

From 6 November onwards, consultation documents were provided by email to those stakeholders who advised us they wished to participate and *Allen + Clarke* proceeded to schedule meetings. Stakeholders were advised that the document was for consultation purposes only and not for further distribution. In instances where stakeholder groups requested to forward the document to others in their organisation for input, contact details were requested (to ensure that the number and type of stakeholders involved in the consultation process could be captured).

Following feedback from stakeholders, and in recognition of the Christmas period, an extension to the consultation timeframe was initially granted to 10 January 2020 and then further extended to 24 January 2020. All stakeholders who had agreed to participate were notified of extensions to the consultation timeframe. Taking into account these two extensions, and in fairness to all stakeholders who had participated and provided their feedback by 24 January 2020, any submissions received after 24 January 2020 were not considered in this report.[2]

Some stakeholders also commented publicly on the Draft Pathway and consultation process during the consultation period.

[2] Two emails were received after the deadline by patient support groups stakeholders. One of these stakeholders had previously attended a focus group, completed the online survey and sent an email before the deadline. The other email contained substantially the same information as other emails from patient stakeholders, so the views expressed in it are generally, although not explicitly, represented in this Summary Report.

3.2. Consultation approach and Key Consultation Questions

The consultation format was designed primarily to discuss the Draft Pathway with stakeholders, to better understand stakeholder views and inform the final version of the Clinical Pathway. Consultation on the Draft Pathway involved a mix of one-on-one and group meetings, conducted face-to-face and virtually using the Zoom technology platform. SurveyMonkey was also offered as a response platform as well as written feedback via email.

An Information and Consent form was provided to all consultation participants. The form provided information about the project and the consultation, and then asked for participants' consent to take part. The form varied slightly depending on the type of meeting (whether one-on-one or group, and face-to-face or virtual). This form outlined the Key Consultation Questions.

The Key Consultation Questions were:

1. What do you think are the most important elements of the Draft Pathway?
2. In what specific ways do you think the Draft Pathway could be improved?
3. Do you have any other feedback to offer on the Draft Pathway?
4. How do you see the Draft Pathway working in practice, taking into account the current Australian health framework and resourcing?

Interviewers followed a protocol of checking at the beginning of each meeting that the stakeholder(s) had received the consultation documents, including the form. They confirmed that participants gave consent to participate in the consultation and to use their feedback to further refine and develop the Draft Pathway. Interviewers took hand-written notes of the feedback at meetings, for the purposes of developing this report and informing development of the Pathway.

Face-to-face meetings were not audio recorded. *Allen + Clarke* did not electronically record virtual meetings to enable all participants to talk freely and to protect participants' privacy.

3.3. Summary of participation

Table 1\Figure 1 summarises, by stakeholder group, the number of stakeholders invited to participate in the consultation, and the number who actually participated and how. This detail is further explained in the following subsections. Note that:

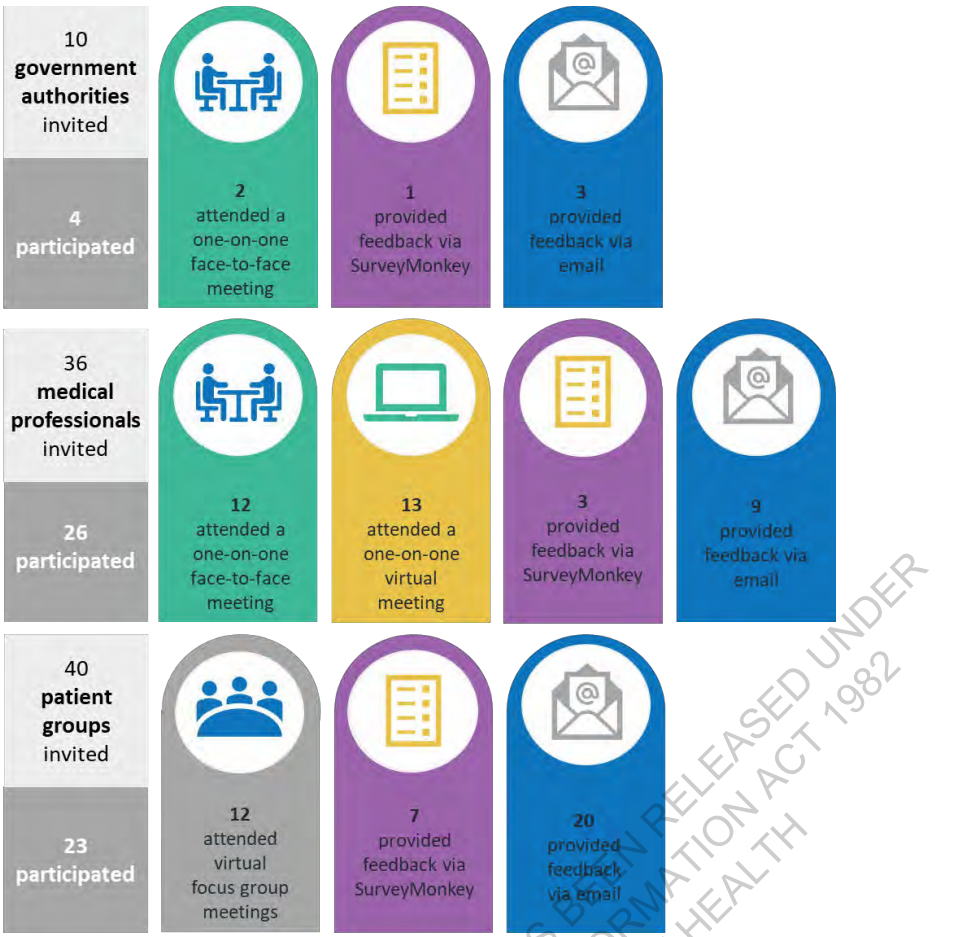
- Stakeholders invited were not necessarily those who participated: for example, some stakeholders delegated or referred participation to others; and some stakeholders invited other members of their organisation to participate. Therefore there is no direct relationship between the number of invited versus actual participants.
- Many participants contributed via multiple means of participation (for example, some sent an email containing their feedback and attended a focus group). Therefore, the actual number of total participants is less than the total from each means of participation.
- One patient stakeholder group forwarded the consultation documents to other stakeholder groups who were not on the original invitation list. Feedback was received from three new groups to which the consultation documents were sent by the patient stakeholder.
- Two members of the public who were not on the original list also provided feedback on the consultation documents.

Table 1: Summary of participation by stakeholder group and means of participation

	Number invited	Number of actual participants and means of participation					
		One-on-one face-to-face	One-on-one virtual	Virtual focus group	Feedback via survey	Feedback via email	TOTAL participants
Government	10	2	-	-	1	3	**4**
Medical	36	12	13	-	3	9	**26**
Patient	40	-	12	7	20[3]		**23**
Total	**86**	**14**	**13**	**12**	**11**	**32**	**53**

[3] Of these, five were not invited.

Figure 1: Summary of participation by stakeholder group and means of participation



3.3.1. One-on-one meetings (face-to-face)

Allen + Clarke extended invitations for 60-minute face-to-face meetings in Brisbane, Sydney, Canberra, Melbourne and Perth. These meetings were primarily focussed on receiving feedback from government and medical stakeholder groups, given limited engagement with these stakeholder groups up to this point. Stakeholders could choose a virtual meeting if the meeting dates did not suit.

Nine face-to-face meetings were held between 13 and 22 November 2019. The Project Lead s47F and Lead Analyst s47F attended all face-to-face meetings:

- one in Melbourne (government authority)
- five in Sydney (medical professionals), and
- three in Perth (two medical professionals and a group interview with several people from WA Health, including a public health physician, pathologist and ID physician).

3.3.2. One-on-one meetings (virtual)

Allen + Clarke offered 60-minute one-on-one virtual meetings to government stakeholders in the States and Territories to which the project team were not travelling (Northern Territory, South Australia and Tasmania); medical professional stakeholders located outside Australia; and stakeholders invited to face-to-face meetings who elected for virtual meetings.

Thirteen virtual meetings were held between 28 November and 13 December 2019. The Project Lead s47F attended all meetings. The Lead Analyst s47F attended most meetings. The *Allen + Clarke* Expert Medical Advisor s47F attended the two meetings with international stakeholders. The *Allen + Clarke* Expert Guidelines Advisor s47F s47F attended the meetings with representatives from the College of Health Psychologists (CHP), Therapeutic Guidelines Limited (TGL) and the Australian College of Nursing (ACN).

3.3.3. Focus group meetings (virtual)

Many patient groups had attended the May 2019 Think Tank physically or virtually. For this consultation round, *Allen + Clarke* offered patient groups four 90-minute virtual focus group meetings. Invitations were emailed to representatives of 40 patient stakeholder groups with six possible dates and times in November 2019 for focus groups. The four most popular times were selected based on responses received. Stakeholders could participate in more than one session.

The Project Lead s47F attended all patient stakeholder focus groups. The Lead Analyst s47F attended three of the meetings, with the *Allen + Clarke* Expert Guidelines Advisor s47F attending the other one (29 November). Interviewers aimed to ensure all participants in the focus group meetings had the opportunity to share their feedback. A member of the *Allen + Clarke* DSCATT team s47F was virtually present for all meetings to assist in case of technical issues.

Of the 40 patient groups invited to participate in the virtual patient focus groups, twelve patient groups participated. The number of individual participants in each patient focus group was:

- Patient focus group 1: 2 participants
- Patient focus group 2: 1 participant
- Patient focus group 3: 4 participants
- Patient focus group 4: 9 participants

- **Total patient groups = 12***

  ** the two participants at the first focus group attended again in later group sessions, with one participant attending three focus groups, the other attending two focus groups. Two of the participants in focus group 4 were from the same organisation.*

3.3.4. SurveyMonkey

All stakeholders were advised that they could also provide feedback via SurveyMonkey and were given the link to the SurveyMonkey. The survey was set up to receive structured feedback from stakeholders according to the four Key Consultation Questions and was open to all invited stakeholders from 8 November 2019 to 24 January 2020.

Eleven stakeholders provided feedback this way:

- seven patient group stakeholders*
- three medical professionals, and
- one government authority.

  ** two of these stakeholders were from the same organisation.*

3.3.5. Feedback via email

All stakeholders were advised they could also provide feedback via email to the s47F address.

Thirty-two stakeholder groups provided feedback via email. In some instances, more than one representative from a group provided email feedback. Some stakeholders included links to papers and further research that they felt *Allen + Clarke* should consider as part of the evidence base.

Emails were received from:

- twenty patient group stakeholders
- nine medical professionals, and
- three government authorities.

4. STAKEHOLDER FEEDBACK

This section reports stakeholder feedback and key themes structured according to the Key Consultation Questions. Most participants preferred to provide their feedback on the Draft Pathway loosely, but as the Key Consultation Questions were open questions, participants' feedback usually fell within their broad parameters. If a participant had not provided feedback on a particular Key Consultation Question, the interview team drew attention to the question and asked the participant's view.

At three of the one-on-one meetings, participants provided feedback on what they thought were important elements and what should be included in the Clinical Pathway but stated they had not read the Draft Pathway document at that time.

In written feedback received via email, some stakeholders answered the Key Consultation Questions directly, while others chose to present their feedback in a more narrative manner.

Eleven stakeholders submitted direct answers to the Key Consultation Questions through the survey tool SurveyMonkey. Many of these stakeholders also sent accompanying emails, further detailing their thoughts.

Some of the feedback received from stakeholders was relevant to more than one Key Consultation Question, and this is reflected in the occasional duplication of content in the sections below.

4.1. General comments on the Draft Pathway

To preface the following feedback: many stakeholders recognised the difficulty in balancing:

- the information that needs to be included in the Draft Pathway that guides diagnosis and treatment
- the literature about the different issues regarding diagnosis of Lyme disease, diagnostic testing and treatment
- the recommendations based on current evidence and practice, and
- a useable, comprehensive document for practicing General Practitioners (GPs), which does not include the entire literature on all issues and various held views.

Most medical professional stakeholders commented that the Draft Pathway was balanced, while also reflecting the ongoing controversies.

4.2. Key Consultation Question 1: What do you think are the most important elements of the Draft Pathway?

4.2.1. Supporting views

The Draft Pathway was well accepted and viewed as a valuable resource by the vast majority of medical and allied health professionals and government health authorities (with some recommended minor changes). These stakeholders saw it as a useful and important resource for the clinical management of patients.

Comments about the Draft Pathway included that:

- it was good to see an evidence-based clinical pathway
- the pathway was based on best practice as it currently stands
- the document was of high quality, comprehensive and well organised
- the algorithm and maps were of a high quality, and
- it would be a useful resource for GPs (particularly new clinicians), who it was agreed need more education on tick borne diseases.

Most of these groups made some minor suggestions for how the Draft Pathway could be improved.

A few medical professional stakeholders – mostly those who diagnose and treat 'chronic Lyme'/DSCATT patients, and who had strongly held views about many aspects the Pathway in general (as outlined in Section 4.3 below) – did acknowledge that it raised the profile of tick-borne diseases, had some good information about tick-borne diseases and may be useful for new doctors.

4.2.2. Differential diagnosis

A few medical professional stakeholders expressed approval for the clarification that Lyme disease cannot be contracted in Australia. They considered that this would be useful in supporting GPs when dealing with patients. Two government authorities also commented that the discussion of alternative tick-borne diseases was useful.

Other medical professional stakeholders recommended keeping the diagnostic section on Lyme disease and other tick-borne diseases simple (as in the Draft Pathway) rather than referring to all the possible vector-borne diseases, and relying on the referral to and expertise of ID Physicians to diagnose any additional infections, based on the patient's travel history.

4.2.3. Evidence base

The majority of medical professional stakeholders were highly complimentary about the evidence base in general and commented that it was helpful to see it all in one place.

Several medical professional stakeholders emphasised that the science clearly shows that there is no Australian-acquired Lyme disease, and commented that the finalised Clinical Pathway must explicitly state this. Many medical professional stakeholder groups noted they are aware of the variation in views between themselves and patient support and advocacy groups.

IDSA/NICE guidelines

Most medical professionals supported the use of the Infectious Diseases Society of America (IDSA) or the National Institute for Health and Care Excellence (NICE) guidelines, particularly the IDSA guidelines for the diagnosis and management of overseas-acquired Lyme disease.

4.2.4. Laboratory diagnostic testing

NATA/RCPA accredited laboratories in Australia

The majority of medical professionals and government authorities strongly supported the recommendation in the Draft Pathway to only use National Association of Testing Authorities, Australia (NATA)/Royal College of Pathologists of Australasia (RCPA) accredited laboratories.

While some stakeholders were concerned that Australian laboratories could not do the comprehensive range of tests done overseas (discussed below in Section 4.3.4), in fact pathologists commented that they were able to do all these tests in NATA/RCPA accredited laboratories and would do if they thought them necessary. These stakeholders commented that NATA/RCPA accredited laboratories will send samples to other NATA/RCPA accredited laboratories if a wider range of testing is needed, and samples which need testing for particularly rare diseases may be sent to the CDC.

Travel history

Stakeholders strongly supported the need to include travel history in the initial assessment of the patient; however, feedback varied on the duration of travel histories. One medical professional stakeholder stated that travel history is particularly relevant for acute cases, with the focus being on travel that has happened in the last three or four weeks. However, patient groups stated strongly that this timeframe was not sufficient; their feedback is outlined in further detail in Section 4.3.5. below.

4.2.5. Involvement of ID Physicians

The majority of medical professional stakeholders and government health authority stakeholders supported the involvement of ID Physicians in the finalised Clinical Pathway, however, there were concerns that waiting for this could delay the commencement of antibiotics where timing is critical.

Some of these medical professionals acknowledged that this process would be difficult to implement for patients who are already in the pathway with chronic conditions and believe that they have Lyme disease.

4.2.6. Patient-centred stepped care approach

The majority of medical professional stakeholders and government health authorities supported the proposed person-centred stepped care approach for patients with ongoing symptoms who remain undiagnosed.

4.2.7. Treatment modalities

Many medical professional and government authority stakeholders expressed their approval that the treatment modalities not recommended for Lyme disease had been included and highlighted, as they thought this would be helpful for GPs (and health authorities) when patients ask, and

would help reduce harm to patients. This included support for the recommendation not to use long-term antibiotics.

4.3. Key Consultation Question 2: In what specific ways do you think the Draft Pathway could be improved?

The majority of feedback received sits under Key Consultation Question 2. This does not detract from the high level of support for the Draft Pathway from the medical professional and government authority stakeholders, but rather speaks to the purpose of the consultation being to prompt discussion about the Clinical Pathway and potential improvements.

A minority of medical professionals (mostly those who diagnose and treat 'chronic Lyme'/DSCATT patients, and patient stakeholder groups) did not support the Draft Pathway in its current form. Their feedback is presented in this section. This section also contains minor recommendations from stakeholders who did support the Draft Pathway in general.

4.3.1. General comments

There was considerable feedback that the finalised Clinical Pathway needed to be short and concise, and easily accessible for GPs, not as dense as the current Draft document. Suggestions for achieving this included:

- removing any political or controversial references and focusing on the facts
- removing references to coinfections, as they are very rare, and it is not necessary to complicate the document by including them, and
- making the final document pictographic, and essentially a summary of the large Draft document.

A few stakeholders made suggestions in relation to publishing the final Pathway:

- GPs are likely to focus on the algorithm, so it needs to be detailed and comprehensive.
- Create one or two pages for doctors with the most important information, and a document for patients, or a good podcast for GPs by the Royal Australian College of General Practitioners (RACGP).
- The Pathway should be available electronically with links to the supporting evidence-based information in each of the boxes in the algorithm.
- The Clinical Pathway should be a living document, with changes being made as new research develops, as well as links to Chronic Fatigue Syndrome (CFS) guidelines where relevant. Some stakeholders expressed the view that there are clearly research gaps which need to be filled, and there must be ongoing funding for research. The final Pathway needs to ackowledge these gaps, and be adaptable to new findings.

Other general recommendations included:

- include in the introduction the fact that the National Health and Medical Research Council (NHMRC) is doing research in Australia. This would be particularly given the discrepancies in the belief of a tick-borne illness
- include pictures where appropriate to assist doctors, for example the EM rash, would be useful as it can be variable and atypical QTT has a particular rash. This would help guide

doctors and be sure that they can distinguish between certain kinds of rashes and cellulitis and other infections

- DSCATT should be made a notifiable disease, and
- create a registry of patients which GPs can follow to see what has happened and what has worked in previous cases, for example structured biofeedback and interventions, and the standard set of tests. This could also include updated research.

Stakeholders also suggested other specific additions to the Draft Pathway to aid GPs:

- more information around timeframes and payments
- timeframes are particularly important with reference to Lyme, because antibiotics must be taken within the first two weeks
- more information on signs and symptoms, and matrices of how these could cross-relate in order to reduce the risk of misdiagnosis
- guidelines on how to manage the symptoms for MUS patients
- language guidelines about how to talk about pain and have difficult conversations with patients, and
- further information on the safe removal of ticks.

4.3.2. Differing views

The Draft Pathway was not well received by a minority of medical professional stakeholders, mostly those who diagnose and treat 'chronic Lyme'/DSCATT patients in Australia or internationally. Many of this group of stakeholders were very focussed on the concerns they had about the Lyme disease section of the Draft Pathway.

One medical professional expressed concern that the Draft Pathway, by not including therapies that have been found to be beneficial is not useful for the modern treatment of patients with tick-borne illnesses. One integrative practice stakeholder did not think that the Clinical Pathway was fit for purpose.

One of the medical professional stakeholders expressed strong concerns about the Draft Pathway for many reasons ranging from the pathway being perceived as a closed pathway with no room for improvement for patients with tick-borne diseases and undiagnosable patients, to the narrow focus on Lyme disease rather than the range of tick-borne diseases and zoonotic infections internationally and in Australia, that diagnostics that use antibody response assume the patient is immunocompetent, current testing methods are inadequate for diagnosis of DSCATT, through to the perceived lack of a multidisciplinary care model. This stakeholder was of the view that the one constant was that DSCATT is transmitted by ticks, that DSCATT is a multi-systemic disease, and as such, it is multidisciplinary, needs the team work of all colleges of physicians, with data collection being an integral part of the multidisciplinary team.

Some of these stakeholders did acknowledge that it raised the profile of tick-borne diseases, had some good information about tick-borne diseases and may be useful for new doctors, as identified in Section 4.2.1.

While only 12 patient stakeholder representatives (11 groups) out of 40 invited groups participated in the four focus group consultation meetings, none of the groups who participated supported the Draft Pathway, for various reasons. The negative views presented in the focus groups were mirrored in the strongly worded emails and online surveys received by patient

groups (with the exception of one patient group representative who completed the online survey and did support the Draft Pathway).

Patients expressed strong views about the Draft Pathway in its current form, including that it was not fit for purpose, was scientifically unsound, and would lead to continued suffering of patients in Australia. Patient stakeholders also raised concerns that the Draft Pathway in its current form would result in them being labelled "*MUS*", and not being able to get out of the Pathway, because GPs would likely not consider or test for other tick-borne illnesses that they may have contracted. Patients felt that this model would not improve the care available to patients, many of whom report being misdiagnosed with CFS and psychological problems.

Most patient groups expressed the view that the Draft Pathway in its current form is too flawed to continue.

4.3.3. Differential diagnosis

Some stakeholders thought other diseases should be mentioned in the finalised Clinical Pathway include:

- Anaplasma, Babesia, Neoerhlichia (according to two medical professionals, these are rare co-infections that patients may have if they acquired Lyme disease overseas)
- Relapsing fever
- Bartonella (flea-borne disease which can be transmitted by cats in Australia)
- Mammalian meat allergy
- Tick paralysis, and
- Epstein-Barr Virus.

Two medical professionals who approved of the clarification that Lyme disease cannot be contracted in Australia went on to say that the use of the term "yet" when referring to Lyme disease (i.e. that Lyme disease had not yet been identified in Australia) was potentially dangerous, and should be removed from the Clinical Pathway.

Rickettsia diseases

While the information on Australian tick-borne diseases was generally considered helpful, including the maps, some medical stakeholders and government authorities asked for more information (rather than just links to other resources) on Rickettsial and other diseases, including:

- Australian Spotted Fever
- Flinders Island Spotted Fever
- Rickettsia felis, and
- Queensland Tick Typhus (QTT).

MUS or psychological problems

Patient stakeholders repeatedly expressed concern about having been told that their symptoms are 'in their head' and being referred to mental health practitioners. They expressed the view that GPs should be responsible for completely ruling out tick-borne diseases before referring patients to mental health practitioners.

Medical professional stakeholders also commented on MUS and psychological problems.

- Secondary wounding can often be even more harmful, when patients feel that they are not being heard.
- Psychological help can be used as treatment (alongside other medical interventions) to prevent patients with long-term symptoms developing depression.
- For some, lifestyle and psychological approaches to management are not an indication that it is 'all in the mind' but a useful and necessary component of managing persistent (chronic) symptoms which have no diagnosis.
- Patients with MUS should be referred to a clinical psychologist who can assess if the symptoms are psychological or physical (to rule out/dismiss psychological involvement)- this would empower the patients and help reduce the number of patients presenting with depression/anxiety being categorised by GPs/psychiatrists as 'psychological'.
- Mental health strategies should be described further, to allay the concerns of patients.

4.3.4. Evidence base

Most patient stakeholder groups expressed the view that the full body of evidence was not considered in developing the Draft Pathway. In particular, many patient groups and some medical professionals who treat 'chronic Lyme'/DSCATT patients were concerned that Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS) doctors were not referenced in the Draft Pathway. Some stakeholders also expressed concern about the 10-year time limit for inclusion of literature to inform the evidence base and commented that there are some good peer-reviewed animal studies and other papers that should be included (which were published more than 10 years ago).

Patient groups also commented that if there is not enough peer-reviewed evidence available, then patient evidence should be used, along with medical experience. Patients considered that there is an issue about what constitutes evidence: in their view, this underpins the weakness of the pathway, and results in a diagnosis of MUS.

Patient groups expressed concern about a conflict of interest in some of the research papers used in the Draft Pathway (as they felt that the owners of recommended lab tests had been over-referenced). Patients also expressed concern about studies included as evidence being behind a paywall (that is, not free to access) and wanted to see the full literature review.

The few medical professional stakeholders who diagnose and treat 'chronic Lyme'/DSCATT patients and who did not support the Draft Pathway, did acknowledge that there is no published research on DSCATT and the treatments that they provide, and that this needs to be addressed.

IDSA/NICE guidelines

A small minority of medical professional stakeholders in Australia and internationally, and most patient stakeholder groups, did not support the recommendation in the Draft Pathway that the IDSA or NICE guidelines on Lyme disease be used in Australia. Concerns expressed by these stakeholders included that IDSA guidelines do not have appropriate treatment recommendations for 'chronic Lyme disease' patients through to views regarding the organisations' political affiliations.

These stakeholders preferred the International Lyme and Associated Diseases Society (ILADS) guidelines for Lyme disease. One patient stakeholder suggested using the Centers for Disease Control and Prevention (CDC) guidelines rather than the NICE guidelines.

4.3.5. Laboratory diagnostic testing

NATA/RCPA accredited laboratories in Australia

As mentioned above in Section 4.2.4., the majority of medical professional stakeholders approved of the recommendation to use NATA/RCPA accredited laboratories. These stakeholders also commented that the importance of using NATA/RCPA accredited laboratories should be stressed more in the document, with additional information added about the quality assurance (QA) and accreditation process that sits around these laboratories as well as their international recognition. These stakeholders considered that more information about the NATA/RCPA accreditation process would reassure GPs and patients that there is no need to send blood tests/pathology to overseas laboratories or unaccredited laboratories in Australia.

Some medical professionals commented that a list of NATA/RCPA accredited laboratories should be included in the final Pathway to assist GPs. A government authority suggested developing ready-made tools for clinicians, so that they know exactly which tests to order.

While the cause of the DSCATT symptom complex remains unknown, many patient stakeholder groups claimed that they knew what the cause was, as they had had the tests done internationally. There was a very strong focus within the patient stakeholder group feedback on Lyme disease/Borrelia (and the co-infections) they had been diagnosed with and these stakeholders questioned why results from 'reputable' international laboratories are not recognised in Australia.

A minority of medical professionals, mostly who treat 'chronic Lyme'/DSCATT patients, and most patient stakeholder groups, strongly did not support recommending/limiting testing to NATA/RCPA accredited laboratories. Some expressed concern that the focus on recommending NATA/RCPA accredited Australian laboratories was anti-competitive and restricted patient choice.

A minority of medical professional stakeholders and many patient groups expressed the view that the Australian NATA/RCPA accredited laboratories were incapable of detecting all relevant diseases (for example, Babesia), and were extremely critical of the 2-tier testing protocol for Lyme disease in particular. Feedback from these stakeholders included that:

- when the tests are done in Australia, they sometimes get negative results, which is often at odds with the clinical diagnosis
- false negatives are more common than false positives (particularly in chronic Lyme cases), and
- a case cannot be ruled out because there are negative test results, and
- the information about diagnosis of Lyme disease in Australia contained in the Draft Pathway is wrong; in this stakeholder's opinion it does not conform to CDC advice that Lyme disease is a firstly clinical diagnosis, with supporting pathology.

There was significant concern from these stakeholder groups about the limitations and accuracy of the two-tier test for Lyme disease both in Lyme disease endemic areas and in Australia. Feedback from patient stakeholder groups included that patients are spending thousands of dollars on overseas testing because they consider the laboratories offer a broader range of testing.

Additional comments from medical professionals regarding diagnostic testing included:

- the need to include a sentence in the Summary Information about practising harm minimisation by avoiding repeated diagnostic testing, and

- the need to include more nuance about test limitations for clinicians and patients, for example, serology, which involves testing for the presence of antibodies known to be associated with certain infections and does not simply provide a 'positive' or 'negative' result-serology tests can have indeterminate or false results.

Specification and range of diagnostic tests

Medical professional stakeholder groups had mixed views about listing diagnostic tests for GPs to consider supporting diagnosis of a patient who has entered the DSCATT Clinical Pathway.

Some medical professional stakeholders commented that GPs need to be confident about what tests to order, and the Pathway should give clear guidelines about which tests to order, and when. They considered that the role of the ID Physician is to interpret the results of the tests. Others felt that providing a list was too prescriptive, the list may not include a test that is relevant for a particular patient and that it was best to highlight the need for GPs to include travel history and clinical symptoms on the laboratory request form to inform the pathologist who could then decide on the appropriate test.

One medical professional stakeholder expressed the view that when conducting laboratory tests, the pathologist is guided by what is written on the test form. If the GP has stated that they would like to test for Lyme disease only, then the pathologist cannot test for anything else.

Patient groups suggested including a decision tree in the Pathway for GPs on what testing to order.

Travel and other history

As outlined above in Section 4.2.4., although most patient stakeholders agreed with the recommendation for GPs to ask patients about their travel history, they strongly stated that going back six to 12 months is not sufficient, because diseases can lie dormant for longer than that. Many patient stakeholders expressed the view that history should be taken from where the patient has worked, lived and travelled for a few years prior to developing symptoms.

One government authority stakeholder commented that as well as an accurate travel history, the GP should note any relevant activities undertaken during travel so that the history can be stratified for risk. This government authority went on to say that for those who do not have a travel history, the investigations need to be kept broad, and possibly wider than vector-borne disease.

One medical professional considered that there is some evidence that transmission can be passed on genetically, through blood transfusions and through sexual transmission, and this should be included in the finalised Clinical Pathway, as it will be an important feature of questioning.

Stakeholders also suggested including maps of areas where tick-borne illnesses are common internationally.

4.3.6. Involvement of ID Physicians

Most stakeholders agreed that GPs should be at the centre of patient care. There was concern among a small number of medical professionals (who generally supported the Draft Pathway) as to whether there would be sufficient ID Physicians with expertise in tick-borne illness to cover all the referrals, with fears of delays in getting referrals and diagnoses (which could delay treatment and increase complications). In contrast to this concern, one medical professional pointed out that the number of ID physicians has doubled in the last decade, and that patients in rural and remote areas have access to Telehealth.

A few medical professionals who provide care to patients with 'chronic Lyme'/DSCATT/tick-borne illnesses did not support the referral of patients to ID Physicians. They were concerned about ID Physicians' knowledge of tick-borne diseases and ID Physicians' apparent previous dismissal of patients who were concerned they have Lyme disease.

One medical professional stakeholder stated that the involvement of ID Physicians was not consistent with modern treatment of patients.

Patient stakeholder groups very strongly disagreed with referring patients to ID Physicians. These stakeholder groups generally expressed the view that referral to ID Physicians would not help patients at all and were very strongly opposed to this section of the Draft Pathway.

These groups expressed the view that a Clinical Pathway needs flexibility to respond to individual patients' needs, and that it should be GPs leading the cases.

In addition, patients were concerned that rural patients would struggle to access ID Physicians.

One medical professional (who supported the referral of adult patients to ID Physicians) commented that unresolved symptoms in children should always be led by a paediatrician, as children are different and need specialised care.

4.3.7. Patient-centred stepped care approach

Two medical professional stakeholders considered that patients in any step of the stepped care model would benefit from access to the interdisciplinary team, including psychologists where necessary.

One government health authority stakeholder suggested that there should be resources available to assist GPs, both in general about the stepped care approach, and specifically about how the stepped care approach would work effectively for patients who have entered the DSCATT Clinical Pathway and for whom no diagnosis has been established and who have ongoing symptoms. This stakeholder also pointed out that although the stepped care model comes from the mental health space, not all patients require psychological treatment.

Medical professional stakeholders recommended including more advice on stepped care to educate GPs, including a comprehensive case study describing the use of the stepped care approach.

One medical professional suggested including a recommendation that all patients under stepped care can be referred to an Interdisciplinary team (not restricted to Step 2 or 3 patients) as Step 1 patients would benefit from referral if appropriate.

Some medical professionals commented that more information could be included about the stepped care concept, as some practitioners may not know much about it.

4.3.8. Multidisciplinary care

Several stakeholders (across stakeholder groupings) raised the need for the pathway to better highlight consideration of a multidisciplinary/interdisciplinary team approach. Stakeholders stressed the need for psychiatric/mental health support to help patients who have had long-term symptoms, as well as a rehabilitation approach to maximise function.

4.3.9. Treatment modalities

A few medical professionals who diagnose and treat 'chronic Lyme'/DSCATT patients in Australia and internationally expressed significant concern about the exclusion of certain treatment

modalities. These stakeholders argued these therapies can be useful in some circumstances. One medical professional pointed out that treatment modalities should be patient specific.

There was also strong concern from patient groups and some medical practitioners that complementary therapies they use are noted as 'Not recommended' and therefore would be considered to be 'outlawed' or 'banned' by the Draft Pathway. Many patients expressed they got benefit from using these therapies to some extent and they were also supported by some practitioners who recommend them to their patients and reported having seen the benefit.

Patient groups provided several arguments as to why this aspect of the pathway is wrong:

- there is a need to use safe natural therapies and a holistic approach to care and treatment
- the position is biased towards Medicare-funded treatments
- conventional models of care often do not work
- there is a difference between integrative medicine (which involves a medically trained practitioner) and alternative therapies
- some doctors have had good results with supplements, infrared therapy and herbs, and
- there is no reason to forbid therapies that are low risk and low cost.

One patient stakeholder who attended three out of four focus groups acknowledged that most of the literature on complementary therapies for treatment of chronic Lyme disease comes from Germany or Russia (and is not in English) and therefore would not meet evidence base parameters set for developing the Draft Pathway.

These medical professionals and patients also expressed concern about recommendations to do with antibiotics. They commented that antibiotics should be used as early as possible to prevent further harm, even if test results have not come back. Some stakeholders also commented that the Draft Pathway was incorrect in only recommending one course of antibiotics for treatment.

One medical professional (who supported the position of the Draft Pathway) suggested including advice and caution about the harms that could be caused by complementary remedies, as consistent with NHMRC guidance. This would help to address patient and some medical practitioner concerns about not recommending complementary therapies.

4.4. Key Consultation Question 3: Do you have any other feedback to offer on the Draft Pathway?

4.4.1. DSCATT terminology

Some medical professional stakeholders commented that the term "*DSCATT*" should not have been invented and applied to patients, as it implies that there is a chronic tick-borne cause for symptoms, and no such disease has been demonstrated to exist. Medical professionals and government authorities were very concerned that it should be emphasised further that patients cannot be "diagnosed" with DSCATT.

Patient stakeholder groups generally expressed their dislike for the term DSCATT. Patient groups considered that the term DSCATT is insulting and will not assist in reducing the stigma and getting the illness recognised in the mainstream. They considered that it is not helpful for those patients who have a genuine illness.

This term was carefully considered and adopted by the Australian Government in 2018 and is beyond the scope of the consultation on the Draft Pathway.

4.4.2. Differential diagnosis

Some stakeholders suggested that the finalised Clinical Pathway should include other international and domestic vector-borne diseases, which are beyond the scope of the DSCATT Clinical Pathway.

One patient group stakeholder commented that there is evidence that the migratory patterns of birds are spreading some international diseases into Australia, and this evidence should also be considered.

4.4.3. Evidence base

Further inclusions

Government authorities, medical professional stakeholder groups and patient stakeholder groups made suggestions for consideration of additional research, books, webpages and guidelines to improve the evidence base and inform the finalised Clinical Pathway (a full list is included in Appendix 2).

One medical professional stakeholder suggested including evidence-based grades to the Clinical Pathway to support the recommendations made.

4.4.4. Patient-centred stepped care approach

A minority of medical professionals who treat 'chronic Lyme'/DSCATT patients did not provide substantial comment on the stepped care approach, instead providing information on their own treatment regimens and modalities. However, some did support involvement of psychologists and provision of psychotherapy to manage disability.

Patients expressed concern that in their opinion the stepped care approach leaves no room for patients to negotiate with doctors. Moreover, patient groups were concerned that the stepped care approach would lead to a MUS diagnosis.

Continuity of care

Two government authorities emphasised the importance of avoiding fragmented patient care and over-investigation through patients seeing multiple practitioners. Feedback included that:

- any specialist or GP should try to continue their care with a patient as far as possible so that they can manage all the complexities of the case and benefit everyone, and
- for patients, seeing multiple practitioners and having to repeat their experiences over again can potentially re-traumatise patients.

4.4.5. Education on tick-borne illnesses

Most medical professional and patient stakeholders agreed that more education is needed for GPs and other health professionals on recognising and treating tick-borne disease.

One patient stakeholder agreed that there should be a DSCATT education component in medical schools, with junior doctors being taught to check the bite site and the whole body. This stakeholder considered that this type of education would also help overcome some of the stigma. However, there was also concern from some medical professional stakeholders about DSCATT being considered a named disease in its own right, and that it should not be a diagnosis given by a medical professional.

One medical professional stakeholder commented that the multidisciplinary team should be specifically trained and educated on tick-borne illnesses, possibly even with one person on the team having a PhD in tick-borne diseases.

Medical professional and patient stakeholders also agreed that there needs to be a focus on public awareness.

Some medical professionals expressed concern about requiring ticks to be removed at a hospital facility, as they did not feel that this was realistic for all patients, particularly those in rural or remote areas and requiring this would delay the removal of the tick with potential negative consequences. Stakeholders from all groups considered that information on removing ticks in the Draft Pathway was incorrect.[4]

4.4.6. Comments about the consultation process

There was considerable feedback from patient groups about the consultation process.

Patient groups expressed a strong preference to provide further input before decision and finalisation of the Pathway. They pointed out that guidelines produced by other agencies, such as the NHMRC guideline on CFS, had multiple drafts. Patient groups consider that the drafting process of the Clinical Pathway needs to have a longer, more staged approach, with more iterations. Some patient groups would like to see another Think Tank-style meeting to go over the Draft Pathway.

Patients felt that the Draft Pathway should have been open for public consultation to include all stakeholder groups and avoid the potential of anti-competitive issues, and the chance given to representatives of organisations to disseminate it widely. They strongly questioned the request not to distribute the consultation document. Some patient groups felt that the timeframe given for

[4] NB: The Department's factsheet on preventing and removing ticks is currently being reviewed [add reference once published].

the consultation was unacceptable. Patient groups also questioned the decision not to record focus groups.

Some patient groups also felt that the matters which were discussed at the Think Tank in May 2019 were not apparent in the Draft Pathway. Patient groups considered that the experience of ILADS-trained practitioners and the CDC were excluded, and these views need to be taken into account.

Patient stakeholders considered that the level of certainty claimed in the Draft Pathway was too high for what is known. Patient groups considered that in chronic and complex disease, the studies are small, and do not always come up with a clear solution.

Patient groups requested that the Clinical Pathway be put on hold until the research has been complete and would rather have the development of the Pathway take a long time than be rushed, and wrong for patients.

4.5. Key Consultation Question 4: How do you see the Draft Pathway working in practice, taking into account the current Australian health framework and resourcing?

4.5.1. Further input

Many medical professionals and government authorities commented that they wanted to see patients get access to appropriate care for their diseases/conditions/symptoms and would like to be further involved in providing feedback and wording to improve the Draft Pathway. They offered to help promulgate the pathway through established clinical networks, provide links to it on their websites or incorporate information from the Pathway into their work or training resources.

One medical professional commented that the Clinical Pathway should try to do anything it can to prevent long-term institutionalisation of patients.

Another medical professional stakeholder (who supported the Draft Pathway in general), questioned whether the Clinical Pathway would provide much value to current clinical practice.

A minority of medical professionals, and most patient groups, did not comment on how the Clinical Pathway will work in practice, as they did not support it in its current form.

4.5.2. Multidisciplinary care

Some patient groups suggested the creation of free clinics in each state utilising multidisciplinary teams, including pathologists, psychiatrists, and occupational therapists working together. These clinics were seen as being able to fill a growing gap and take pressure off emergency services.

One medical professional stakeholder did acknowledge that these clinics would be costly to set up and would need specialists who have an interest in this area.

Two medical professional stakeholders considered that referral to specialists should be kept broad.

4.5.3. Funding issues

Stakeholders from all groups were concerned about some aspect of funding in the Draft Pathway.

One medical professional (who supported the Pathway) commented that the time required for patients to access mental health support will not be adequately funded by Medicare.

Patients repeatedly mentioned that full immunology studies are not funded in Australia.

One government authority stakeholder questioned how the stepped care model would be funded and suggested that there might be a potential funding void.

Patient stakeholder groups were concerned that the tests needed were not funded by NATA/RCPA accredited laboratories, which is why they need to go overseas. As stated in Section 4.3.5., patients were also concerned about the perceived lack of quality of tests in NATA/RCPA accredited laboratories in Australia.

APPENDIX 1: STAKEHOLDERS INVOLVED IN THE CONSULTATION

The table below sets out the forms of consultation undertaken by each stakeholder group.

** indicates where a specific form of consultation was offered to, and declined by, a stakeholder (with a reason provided).*

 # indicates where a specific form of consultation was offered to a stakeholder and another form of consultation was requested by the stakeholder.

+ indicates where a specific form of consultation was offered to a stakeholder, and no response was received.

Table 2: Consultation undertaken by each stakeholder group

Stakeholder	Type of stakeholder	Invitation sent	Face-to-face	Virtual interview	Focus group	Survey	Email feedback
Adult Infectious Diseases, Westmead Hospital	Medical professional	✓	✓				
Armin Labs (member of German Borreliosis Society)	Medical professional	✓		✓			✓
Associated New Zealand ME Society (ANZMES)	Patient group	✓				✓	
Austin Health Department of Medicine, University of Melbourne	Medical professional	✓	*				
Australasian College for Emergency Medicine (ACEM)	Medical professional	✓		✓			✓
Australasian Integrative Medicine Association (AIMA)	Patient group	✓					
Australasian Society for Infectious Diseases (ASID)	Medical professional	✓		✓			✓
Australian Biologics[5]	Patient group						✓
Australian Capital Territory (ACT) Health	Government	✓	*				✓
Australian Capital Territory (ACT) ME/CFS Society Inc., ACT	Patient group	✓					
Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS)	Medical professional	✓		✓			
Australian College of Nursing (ACN)	Medical professional	✓		✓			

[5] Received the consultation documents via a patient stakeholder group.

Stakeholder	Type of stakeholder	Invitation sent	Face-to-face	Virtual interview	Focus group	Survey	Email feedback
Australian College of Nutritional and Emergency Medicine (ACNEM)	Medical professional	✓	✓			✓	
Australian College of Rural and Remote Medicine (ACRRM)	Medical professional	✓	*				
Australian Indigenous Doctors Association (AIDA)	Medical professional	✓		*			
Australian Medical Association (AMA)	Medical professional	✓	*				
Australian Physiotherapy Association (APA)	Medical professional	✓		+			
Australian Primary Health Care Nurses Association (APNA)	Medical professional	✓		*			
Australian Psychological Society (APS) (referred us to the College of Health Psychologists)	Medical professional	✓		*			
Australian Rheumatology Association (ARA)	Medical professional	✓		✓		✓	✓
Bridges and Pathways Institute (ME/CFS and Fibromyalgia research centre)	Patient group	✓					
Canberra Area Lyme Disease Support Group	Patient group	✓			✓		✓
Chrysalis CFS/ME and Lyme Support	Patient group	✓			✓	✓	✓
College of Health Psychologists (CHP)	Medical professional	✓		✓			
Consumers Health Forum	Patient group	✓					Received after 24 January
Emerge Australia	Patient group	✓					
Equity Trustees, Mason Foundation	Patient group	✓					
Gold Coast Lyme Group	Patient group	✓					
Great Southern Specialist Centre	Medical professional	✓	✓				
HealthPathways	Medical professional	✓	✓				
Hollywood Private Hospital	Medical professional	✓	✓				

Stakeholder	Type of stakeholder	Invitation sent	Face-to-face	Virtual interview	Focus group	Survey	Email feedback
Hunter Region Multiple Syndrome Infectious Disease Society (MSIDS)	Patient group	✓			✓	✓	✓
IGenX Laboratory (via LARA)	Patient group						✓
Independent GP	Medical professional	✓	✓				✓
Independent GP	Medical professional	✓	✓				✓
Independent GP	Medical professional	✓	✓				
Independent member of public[6]	Patient group						✓
Independent member of public[7]	Patient group						✓
Independent patient advocate	Patient group	✓					✓
Karl McManus Foundation	Medical professional	✓	✓				✓
Lyme Australia and Friends Group	Patient group	✓				✓[8]	
Lyme Australia Recognition and Awareness (LARA)/Global Lyme and Invisible Illness Organisation (GLIIO)	Patient group	✓					✓
Lyme Disease Association of Australia (LDAA)	Patient group	✓	*	#			✓
Lyme Disease Association of Australia (LDAA) Patron	Medical professional	✓		✓			
Lyme Disease Awareness and Support for East Gippsland	Patient group	✓					
Lyme Victoria	Patient group	✓			✓[9]		✓
#MEAction	Patient group	✓			✓		✓

[6] Not on the original invitation list- it is unclear where the consultation documents were sourced from.
[7] Not on the original invitation list- it is unclear where the consultation documents were sourced from.
[8] Two individuals from this group completed surveys.
[9] Two individuals from this group attended one of the focus groups.

Stakeholder	Type of stakeholder	Invitation sent	Face-to-face	Virtual interview	Focus group	Survey	Email feedback
ME Association	Patient group	✓					
ME/CFS & FM Association of NSW	Patient group	✓					
ME/CFS and Lyme Association of WA Inc	Patient group	✓					
ME/CFS Australia	Patient group	✓					
ME/CFS South Australia	Patient group	✓			✓		✓
Mid North Coast Lyme Awareness and Support Group	Patient group	✓					
MS/CFS/FM Support Association QLD	Patient group	✓					
Multiple Systemic Infectious Disease Syndrome (MSIDS) Inc.	Patient group	✓		*			✓
National Health and Medical Research Council (NHMRC)	Government	✓	*			#	#
New South Wales (NSW) Health	Government	✓					
Northern Territory Department of Health	Government	✓		*			
NSW Agency for Clinical Innovation	Government	✓	*				
NSW Far South Coast Lyme Group	Patient group	✓			✓		✓
NSW Riverina Lyme Support Group	Patient group	✓			✓		✓
NutriPATH[10]	Patient group						✓
Paediatric Infectious Diseases, The Children's Hospital at Westmead	Medical professional	✓	✓				
Pain Australia	Medical professional	✓	*	✓			✓
Paradigm Change	Patient group	✓					
Private Healthcare Australia (PHA)	Medical professional	✓		✓			

[10] Received the consultation documents via a patient stakeholder group.

Stakeholder	Type of stakeholder	Invitation sent	Face-to-face	Virtual interview	Focus group	Survey	Email feedback
Queensland Health	Government	✓	*				
Royal Australasian College of Physicians (RACP)	Medical professional	✓	*			#	#
Royal Australian and New Zealand College of Psychiatrists (RANZCP)	Medical professional	✓		✓			
Royal Australian College of General Practitioners (RACGP)	Medical professional	✓				✓	
Royal College of Pathologists of Australasia (RCPA)	Medical professional	✓		✓			
Sarcoidosis Lyme Australia	Patient group	✓			✓		✓
Solve ME/CFS Initiative	Patient group	✓					
South Australia (SA) Health	Government	✓		*		✓	
South Australia (SA) Lyme Support	Patient group	✓			✓	✓	✓
South Australian Health and Medical Research Institute (SAHMRI)	Medical professional	✓		*			
Southwest Coastal MSIDS Support Group	Patient group	✓					
Tasmania Department of Health and Human Services (DHHS)	Government	✓		*			
The Associated NZ ME Society	Patient group	✓					
The Kojonup Lyme Supporters Association Inc.	Patient group	✓					
Therapeutic Guidelines Limited (TGL)	Medical professional	✓		✓			
Tick Awareness Australia	Patient group	✓					
Tickborne Illness Community Network Australia (TICNA)	Patient group	✓			✓		✓
Toxic Mould Support Australia	Patient group	✓				✓	
Tweed Coast CFS/ME/FMS Support Group Inc.	Patient group	✓					
University of Sydney / North Shore Private Hospital	Medical professional	✓		*			
Veterinary Clinical Science, Murdoch University	Medical professional	✓	✓				✓

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Stakeholder	Type of stakeholder	Invitation sent	Face-to-face	Virtual interview	Focus group	Survey	Email feedback
Victoria Department of Health and Human Services (DHHS)	Government	✓	✓				✓
WA Primary Healthcare Alliance	Medical professional	✓	✓				
Western Australia (WA) Health	Government	✓	✓				✓
Wollongong ME/CFS/FM Support Group	Patient group	✓					

APPENDIX 2: SUGGESTED ADDITIONAL EVIDENCE

Below is a list of additional resources recommended by stakeholders for inclusion in the evidence base.

Books

1. Dr Richard I. Horowitz, "Why Can't I Get Better? Solving the Mystery of Lyme and Chronic Disease"
2. Warrel, "Infectious Diseases 3rd Edition," in Infectious Diseases 3rd Edition, Morley, 2010, pp. 1243-1246
3. Burrascano, Dr Joseph J. Jr., "Advanced Topics in Lyme Disease. Diagnostic Hints and Treatment Guidelines for Lyme and other tick borne illnesses", 16th Edition, 2008 (ebook) https://lymediseaseassociation.org/wpcontent/uploads/2009/08/BurrGuide200810.pdf
4. Miodrag Ristic, "Babesiosis of Domestic Animals and Man", 1988

Academic journals

1. Lancet Infectious Diseases, "Antiscience and ethical concerns associated with advocacy of Lyme disease": https://www.ncbi.nlm.nih.gov/pubmed/21867956
2. Aging and Disease, "Vitamin D and Chronic Diseases": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5440113/
3. Healthcare, "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": https://www.ncbi.nlm.nih.gov/pubmed/30400667
4. Neurotherapeutics, "Ketogenic Diets for Adult Neurological Disorders": https://www.ncbi.nlm.nih.gov/pubmed/30225789
5. A link to over 1500 studies on ketogenic epilepsy: https://www.ncbi.nlm.nih.gov/pubmed/?term=ketogenic+epilepsy
6. International Journal of General Medicine, "Application of Bayesian decision-making to laboratory testing for Lyme disease and comparison with testing for HIV": https://www.ncbi.nlm.nih.gov/pubmed/28435311
7. American Neurological Association, "Post-Lyme syndrome and chronic fatigue syndrome. Neuropsychiatric similarities and differences": https://www.ncbi.nlm.nih.gov/pubmed/9362985
8. Clinical Infectious Diseases, "Functional brain imaging and neuropsychological testing in Lyme disease": https://www.ncbi.nlm.nih.gov/pubmed/9233666
9. Peer J, "Severity of chronic Lyme disease compared to other chronic conditions: a quality of life survey": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3976119/

10. Pediatrics & Therapeutics, "From Research Subgroup to Clinical Syndrome: Modifying the PANDAS Criteria to Describe PANS (Pediatric Acute-on-set Neuropsychiatric Syndrome)": https://www.longdom.org/open-access/from-research-subgroup-to-clinical-syndrome-modifying-the-pandas-criteria-to-describe-pans-pediatric-acute-onset-neuropsychiatr.pdf

11. International Journal of General Medicine, "Commercial test kits for detection of Lyme borreliosis: a meta-analysis of test accuracy": https://www.ncbi.nlm.nih.gov/pubmed/27920571

12. International Journal of General Medicine, "Application of Bayesian decision-making to laboratory testing for Lyme disease and comparison with testing for HIV": https://www.ncbi.nlm.nih.gov/pubmed/28435311

13. Clinical Infectious Diseases, "Detection of IFN-γ Secretion by T Cells Collected Before and After Successful Treatment of Early Lyme Disease": https://www.ncbi.nlm.nih.gov/pubmed/26936671

14. Clinical and Experimental Immunology, "The outer surface proteins of Lyme disease borrelia spirochetes stimulate T cells to secrete interferon-gamma (IFN-^y): diagnostic and pathogenic implications": https://www.ncbi.nlm.nih.gov/pubmed/7664493

15. The New England Journal of Medicine, "Seronegative Lyme disease": https://www.nejm.org/doi/full/10.1056/NEJM198812013192203

16. Indian Journal of Dermatology, "Borrelial Lymphocytoma Cutis: A Diagnostic Dilemma": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4248499/

17. Ticks and Tick-borne Diseases, "A minority of children diagnosed with Lyme disease recall a preceding tick bite": https://www.sciencedirect.com/science/article/abs/pii/S1877959X18304965

18. Journal of Health Psychology, "'PACE-Gate': When clinical trial evidence meets open data access": https://journals.sagepub.com/doi/full/10.1177/1359105316675213

19. BMC Psychology, "Rethinking the treatment of chronic fatigue syndrome—a reanalysis and evaluation of findings from a recent major trial of graded exercise and CBT": https://www.ncbi.nlm.nih.gov/pubmed/29562932

20. Antibiotics, "The Long-Term Persistence of Borrelia burgdorferi Antigens and DNA in the Tissues of a Patient with Lyme Disease": https://www.mdpi.com/2079-6382/8/4/183/htm?utm_campaign=Kresser%20Institute&utm_source=hs_email&utm_medium=email&utm_content=79168458&_hsenc=p2ANqtz-8VJP7i35GjAfkeMaN_Bxow8fOwmRdpEW79zseQ2jkxkMrHCjn5bv28V4dXF8mvOO_dDM9fpM1FuF-rAZGO6YRSzVSp6A&_hsmi=79168458

21. The Medical Journal of Australia, "Estimating non-billable time in Australian general practice": https://www.mja.com.au/journal/2016/205/2/estimating-non-billable-time-australian-general-practice

22. Ticks Tick Bourne Dis, "Borrelia spirochetes in Russia: Genospecies differentiation by real-time PCR": https://www.ncbi.nlm.nih.gov/pubmed/25108777

23. Parasite Vectors, "Distribution of tick-borne diseases in China": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3640964/

24. PLoS One, "Tick surveillance for relapsing fever spirochete Borrelia miyamotoi in Hokkaido, Japan": https://www.ncbi.nlm.nih.gov/pubmed/25111141

25. M. A. D. D. M. O. e. a. Kalmár Z, "Geographical distribution and prevalence of Borrelia burgdorferi genospecies in questing Ixodes ricinus from Romania: a countrywide study.," *Ticks Tick Borne Dis.,* vol. 4(5), no. September. doi: 10.1016/j.ttbdis.2013.04.007., pp. 403-8., 2013

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27. Healthcare, "Under-Detection of Lyme Disease in Canada": https://www.ncbi.nlm.nih.gov/pubmed/30326576

28. Internal Medicine Journal, "A Description of 'Australian Lyme Disease' Epidemiology and Impact: An Analysis of Submissions to an Australian Senate Inquiry: Australian Lyme from Senate inquiry": https://www.researchgate.net/publication/322685589_A_Description_of_'Australian_Lyme_Disease'_Epidemiology_and_Impact_An_Analysis_of_Submissions_to_an_Australian_Senate_Inquiry_Australian_Lyme_from_Senate_inquiry

29. BMC Public Health, "Characteristics and patient pathways of Lyme disease patients: a retrospective analysis of hospital episode data in England and Wales (1998–2015)": https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-7245-8

30. PLoS One, "Gender Disparity between Cutaneous and Non-Cutaneous Manifestations of Lyme Borreliosis": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3667797/

31. Emerging Infectious Diseases, "Incidence of Clinician-Diagnosed Lyme Disease, United States, 2005–2010": https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article

32. APA, "Highlights of Changes from DSM-IV to DSM-5: Feeding and Eating Disorders": https://focus.psychiatryonline.org/doi/abs/10.1176/appi.focus.120408?journalCode=foc

33. BMJ, "The new somatic symptom disorder in DSM-5 risks mislabeling many people as mentally ill": https://www.ncbi.nlm.nih.gov/pubmed/23511949

34. Healthcare, "Line Immunoblot Assay for Tick-Borne Relapsing Fever and Findings in Patient Sera from Australia, Ukraine and the USA" (with the key data summarised in Table 4): https://www.mdpi.com/2227-9032/7/4/121/htm

35. Microbiology Reviews, "Biology of Borrelia species": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC373079/?page=1

36. Scientific Reports, “Evaluating polymicrobial immune responses in patients suffering from tick-borne diseases”: https://www.ncbi.nlm.nih.gov/pubmed/30374055

37. Healthcare, “Line Immunoblot Assay for Tick-Borne Relapsing Fever and Findings in Patient Sera from Australia, Ukraine and the USA”: https://www.mdpi.com/2227-9032/7/4/121

38. One Health, “Is there a Lyme-like disease in Australia? Summary of the findings to date”: https://www.ncbi.nlm.nih.gov/pubmed/28616477

39. Link to Dr Mayne’s published research on Lyme disease [22 links]: http://www.drmayne.com/research.htm

40. Immunopathological Diseases and Therapeutics, “A Brief Chronicle of CD4 as a Biomarker for HIV/AIDS: A Tribute to the Memory of John L. Fahey”: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4864990/

41. International Journal of General Medicine, “Empirical validation of the Horowitz Multiple Systemic Infectious Disease Syndrome Questionnaire for suspected Lyme disease”: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5590688/

42. Expert Review of Anti-infective Therapy, “Evidence assessments and guideline recommendations in Lyme disease: the clinical management of known tick bites, erythema migrans rashes and persistent disease”: https://www.tandfonline.com/doi/full/10.1586/14787210.2014.940900

43. Emerging Infectious Diseases, “Candidatus Bartonella mayotimonensis and endocarditis”: https://www.ncbi.nlm.nih.gov/pubmed/20202430

44. Clinical Microbiology Reviews, “Bartonella Species, an Emerging Cause of Blood-Culture-Negative Endocarditis”: https://www.ncbi.nlm.nih.gov/pubmed/28490579

45. PLoS One, “Molecular prevalence of Bartonella, Babesia, and hemotropic Mycoplasma species in dogs with hemangiosarcoma from across the United States”: https://www.ncbi.nlm.nih.gov/pubmed/31923195

46. Infectious Disease Clinics of North America, “Human babesiosis”: https://www.ncbi.nlm.nih.gov/pubmed/18755385

47. International Journal of General Medicine, “Clinical determinants of Lyme borreliosis, babesiosis, bartonellosis, anaplasmosis, and ehrlichiosis in an Australian cohort”: https://www.ncbi.nlm.nih.gov/pubmed/25565883

48. Immunopathological Diseases and Therapeutics, “A Brief Chronicle of CD4 as a Biomarker for HIV/AIDS: A Tribute to the Memory of John L. Fahey”: https://www.ncbi.nlm.nih.gov/pubmed/27182452

49. Molecular and Cellular Probes, “Emerging borreliae - Expanding beyond Lyme borreliosis”: https://www.ncbi.nlm.nih.gov/pubmed/27523487

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53. Culture and identification of Borrelia spirochetes in human vaginal and seminal secretions
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55. Erosive Vulvovaginitis Associated With Borrelia burgdorferi Infection: https://www.ncbi.nlm.nih.gov/pubmed/31043089

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57. Marianne J Middelveen, Cheryl Bandoski, Jennie Burke, Eva Sapi, Katherine R Filush, Yean Wang, Agustin Franco Peter J Mayne, and Raphael B Stricker BMC Dermatol. 2015; 15(1): 1. Published online 2015 Feb 12.doi: 10.1186/s12895-015-0023-0

58. Granulomatous hepatitis associated with chronic Borrelia burgdorferi infection: a case report
http://www.labome.org/research/Granulomatous-hepatitis-associated-with-chronic-Borrelia-burgdorferi-infection-a-case-report.html

59. Marianne J Middelveen1, Steve A McClain2, 3, Cheryl Bandoski4, Joel R Israel3, Jennie Burke5, Alan B MacDonald1, Arun Timmaraju3, Eva Sapi4, Yean Wang5, Agustin Franco5, Peter J Mayne1, Raphael B Stricker1 International Lyme and Associated Diseases Society, Bethesda, MD, USA. 2 Departments of Dermatology and Emergency Medicine, State University of New York, Stony Brook, NY, USA. 3 McClain Laboratories LLC, Smithtown, NY, USA. 4 Department of Biology and Environmental Science, University of New Haven, West Haven, CT, USA. 5 Australian Biologics, Sydney, NSW, Australia:
DOI http://dx.doi.org/10.13070/rs.en.1.875 Date 2014-06-09 Cite as Research 2014;1:875 License CC-BY

60. Morgellons: a novel dermatological perspective as the multisystem infective disease borreliosis
https://f1000research.com/articles/2-118

61. Peter Mayne , John S English , Edward J Kilbane , Jennie M Burke , Marianne J 1 2 3 4 Middelveen , Raphael B Stricker 1:
http://f1000r.es/116

62. Persistent Borrelia Infection in Patients with Ongoing Symptoms of Lyme Disease:
https://f1000research.com/articles/2-118

63. Marianne J. Middelveen, Eva Sapi, Jennie Burke, Katherine R. Filush, Agustin Franco, Melissa C. Fesler, and Raphael B. Stricker. Published online 2018 Apr 14.doi:
10.3390/healthcare6020033

64. Borrelia detection and Lyme disease. Published on November 27, 2019 Chris Newton Research Director CIMMBER (Center for Immuno-Metabolism, Microbiome and Bio-Energetic Research):
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1195970/

Misc. sites/attachments/links:

1. EMA "Tick bite anaphylaxis: Incidence and management in an Australian emergency department"
2. Asia Pacific Allergy "Tick killing in situ before removal to prevent allergic and anaphylactic reactions in humans: a cross-sectional study"
3. TIARA "Allergic Conditions caused by Tick Bites" pamphlet
4. TIARA prevention and management pamphlet
5. Asia Pacific Allergy "Tick-induced allergies: mammalian meat allergy, tick anaphylaxis and their significance"
6. ILADS guidelines (website):
https://www.ilads.org/patient-care/ilads-treatment-guidelines/
7. The tick disease toolkit by the Royal College of General Practitioners UK (website):
https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/lyme-disease-toolkit.aspx
8. National Health and Medical Research Council (NHMRC) Guidelines for Guidelines (website):
https://www.nhmrc.gov.au/guidelinesforguidelines/review/public-consultation
9. Tick Induced Allergies Research & Awareness (TIARA) website:
https://www.tiara.org.au/
10. ACIIDS Guidelines:
https://www.google.com/search?client=firefox-b-d&q=aciids+lyme&spell=1&sa=X&ved=0ahUKEwiHmvyJ5-DlAhWItI8KHb6pD2IQBQgsKAA&biw=2859&bih=1456 [incorrect link, cannot access]
11. MSIDS questionnaire:
https://docs.google.com/viewer?a=v&pid=sites&srcid=ZGVmYXVsdGRvbWFpbnxjYW5nZXRiZXR0ZXIyfGd4OjViM2FhOTFjYWViY2RmNzI

12. Antibodies Inaccuracy
13. Basic science (mostly) Lyme Borrelia references referring to chronic or persistent infection disease
14. ArminLabs, "Statement about Borrelia-Elispot"
15. "Lyme Borreliosis – A short overview about symptoms, diagnostic tests and therapies" PowerPoint
16. Seronegativity in Lyme borreliosis and Other Spirochetal Infections
17. Centers for Disease Control and Prevention, "Lyme disease rashes and look-alikes" website: https://www.cdc.gov/lyme/signs_symptoms/rashes.html
18. Centers for Disease Control and Prevention, "Case Definition and Report Forms" website: https://www.cdc.gov/lyme/stats/forms.html
19. Drexel University, College of Medicine profile – Gareth D. Ehrlich, PhD: https://drexel.edu/medicine/faculty/profiles/garth-ehrlich/
20. 22/11/2019 WA Health et al. DSCATT Consultation meeting notes and actions
21. HealthPathways, "Fibromyalgia"
22. KMF's Multidisciplinary teams Model, A solution to some of the current DSCATT/TBD issues
23. Dr Richard Schloeffel OAM, CV
24. Dr Richard Schloeffel – Transcript of Sharon Whiteman's interview, 29 January 2020
25. "Dr Richard Schloeffel - Australian Lyme, a global view" (YouTube video): https://youtu.be/9dZYJHGTN24
26. Department of Health, pp. 2, 5, "Stakeholder Engagement Framework": https://www.health.gov.au/sites/default/files/stakeholder-engagement-framework_0.pdf
27. Parliament of Australia, "Final report: Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients": https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Lymelikeillness45/Final_Report?fbclid=IwAR08c5jydlklmr5E9Mj5jo1P9jw55H0T1JTPaF0kHrtxuqk3bdnnim0aMWs
28. The Spoon Theory: https://www.scarymommy.com/wp-content/uploads/2017/12/spoon-theory-feature.jpg
29. Spoon theory (Wikipedia page): https://en.wikipedia.org/wiki/Spoon_theory
30. RACGP, General Practice Health of the Nation 2018 (annual report): https://www.racgp.org.au/download/Documents/Publications/Health-of-the-Nation-2018-Report.pdf
31. U.S. Government Printing Office, "Health Insurance Coverage in the United States: 2018" Current Population Reports:

https://www.chn.org/wp-content/uploads/2019/09/2018-Health-Insurance-Coverage.pdf

32. PhD Thesis by Michelle Wills in 1995 '*Lyme Borreliosis, an Australian Perspective'*: https://pdfs.semanticscholar.org/47b1/4806da6ee45838beea98c1bbb1b46013a030.pdf

33. ACCC on cartels (website): https://www.accc.gov.au/business/anti-competitive-behaviour/cartels

34. ACCC on anti-competitive behaviour (website): https://www.accc.gov.au/business/anti-competitive-behaviour

35. Dr Horowitz MSIDS questionnaire is available online at: https://www.lymedisease.org.au/horowitz-msids-38-point-symptom-checklist/

36. In the United States, a federal lawsuit is in progress: *'Torrey, et al v. Infectious Diseases Society of America et al'*. In this case seven architects of the ISDA Guidelines (one now deceased) along with eight private health insurers are being prosecuted under the Racketeer Influenced and Corrupt Organisations (RICO) Act; The lawsuit essentially charges that the defendants have been working with the insurance companies to deny appropriate medical treatment to patients with Lyme disease, including through the development of the IDSA guidelines; and On 26 November, it was announced that one of the defendants, Kaiser Permanente, Inc had settled and mediation continues with the other parties: https://www.lymedisease.org/wp-content/uploads/2019/12/Torrey-et-al-Kaiser-settles.pdf

37. Treat Lyme, "Lyme Disease Treatments" website: https://www.treatlyme.net/

38. Lyme borreliosis in Australia – 1986

39. Australian Curriculum, Assessment and Reporting Authority (ACARA): https://www.acara.edu.au/

40. ILADS Guidelines on Lyme disease: 'Evidence assessments and guideline recommendations in Lyme disease: the clinical management of know tick bites, erythema migrans rashes and persistent disease': https://www.tandfonline.com/doi/full/10.1586/14787210.2014.940900

41. Australian Rickettsial Reference Laboratory tests offered (2017). Retrieved from https://www.rickettsialab.org.au/tests-performed

42. Medicine: Science or Art? https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3190445/

43. IDSA Guidelines Deny Diagnosis https://www.lymedisease.org/guidelines-deny-lyme-diagnosis/

44. Backlash to the 2019 IDSA guidelines. Organisations that have signed https://www.lymedisease.org/wp-content/uploads/2019/11/89-groups-in-12-countries.pdf

45. The Ad Hoc committee recommendations against the IDSA guidelines https://www.lymedisease.org/wp-content/uploads/2019/08/Ad-Hoc-Patient-Physician-Coalition-Comments.pdf

s47F

23 January 2020

Minister Hunt,

We write to urge you to intervene in the DSCATT Clinical Pathway Project and its proposed approval process. We ask that you **call an immediate moratorium** on further progression of the draft Clinical Pathway through formal channels of endorsement until all patient community stakeholder feedback is provided and incorporated in revisions of the draft document.

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Furthermore, the Pathway is unlikely to be acceptable to the scientific community, with international medical experts advising the document is incomplete, misleading and will contribute to ongoing patient suffering in Australia.

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Patient community stakeholders are unified in their rejection of the Pathway and are appalled that their considerable body of work established over a decade is completely disregarded within this document. The ultimate purpose of the Pathway is to serve the interim health needs of people affected by debilitating illness, not for patients to be made unwell meeting timelines set for the convenience of your Department or its contracted consultants.

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Yours sincerely

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ATTACHMENT A

Patient community concerns includes, but is not limited to, the following points:

The Clinical Pathway (Allen & Clarke):

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- There are multiple contradictions, flaws, inconsistencies and omissions in the Pathway, with evidentiary bias in the research articles referenced and the selective use of the referenced content. The bibliography provides secondary references that perpetuate scientific error, to the detriment of personal and public health. The poor state of referencing and bibliography error raises serious credibility questions.
- The Pathway assumes that laboratory testing means antibody testing serology, and this is the only method that should be used in the detection of the aetiological agent of this syndrome in Australia. The consultants have missed the critical fact that we don't yet have a serology test for an 'unknown' aetiological agent/s for this syndrome. In respect to Lyme disease, the reliability of serology testing as the basis for diagnosis is highly contested.
- The Pathway is anti-competitive in its stance on pathology testing and in prescribing and restricting the laboratories permitted to test for tick-borne pathogens. This is likely to be interpreted as collusion and necessitates legal review.
- The Pathway obstructs the clinical autonomy of medical practitioners by requiring specialist advice prior to ordering tests or prescribing treatment. This is in stark opposition to clinical advice provided in other countries with considerably more experience in tick-borne illness, where prophylactic use of antibiotics is routinely recommended. In fact, this requirement imposes on all Australian practitioners the same restrictive conditions as were applied to Lyme doctors disciplined by AHPRA.
- The Pathway aims to support decision-making only from a medical perspective and fails to recognise individual patient needs or choice. The immediate requirement for specialist advice establishes a dangerous precedent for patients, imposes delays that could have serious adverse health implications, and adds significantly to their burden of illness with a time delay and unnecessary cost. Delays in testing and treatment can cause totally avoidable harm; such delays place medical practitioners in a precarious situation in respect to non-maleficence. This issue should have been legally and ethically investigated before dissemination of such a document.
- The Pathway is predicated on biased and arbitrary views, arguably unscientific, that ignore multiple pieces of critical contemporary evidence regarding the persistence of Lyme and Borrelia and it completely ignores the role of complementary and comorbid infections; known to affect more than 60% of Australian patients.
- The notion and use of 'medically unexplained symptoms' (MUS) terminology in a Pathway designed to support patients is an embarrassment. Naming a disease DSCATT and allowing the commissioned Pathway to place DSCATT under the MUS banner is a demonstration of the tokenistic efforts by the Department of Health to 'tick boxes' in their handling of Australian Lyme-like illness and Multiple Systemic Infectious Disease Syndrome.

PROJECT STATUS REPORT

Project name: DSCATT Clinical Pathway

Prepared by: s47F

Prepared for: s22

ALLEN+CLARKE AUSTRALIA

Period covered: 1/5/20 - 31/5/20

Client: Department of Health (Australia)

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Final Clinical Pathway

• Nil. Awaiting response from DoH on coded table of feedback, to inform final Clinical Pathway.

Literature review

• Continued to revise the draft literature review to 1) bring across and more closely align the information in the Draft CP with the research questions, while also providing, in many areas, greater detail and discussion of the evidence than is in the Draft CP, and 2) include information from the Senate Community Affairs References Committee May and November 2016 reports and other evidence from the Draft CP which was not in the Working Draft of the literature review in accordance with the verbal feedback and decisions provided by DoH in the teleconference of 21 April.

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Main activities next period

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Final Clinical Pathway

• Receive written feedback from DoH on the coded table of feedback, to inform final Clinical Pathway.

• Receive list from DoH of tick-borne illnesses that will be covered in detail in the other educational materials project and therefore do not need to be included in the Pathway.

• Develop final Clinical Pathway (short doc + evidence doc), based on advice from DoH and with input from tecnical advisors (noting potential availability issues given Covid19). *New delivery date to be agreed following receipt of DoH advice and taking into account the amount of additional work required, the decision about IDSA 2006/2019 Lyme disease guideline status with respect to finalising the Clinical Pathway, and the availability of our technical advisors to provide input .*

Literature review

• To continue to advance the literature review, we seek decisions from DoH on any additional content (and therefore research) that was suggested/recommended by stakeholders during the consultation.

• Discuss and agree an appropriate revised delivery date to allow for technical advisor review prior to provision to DoH. *Given covid19 environment we will need to provide sufficient notice to our technical advisors to receive their input to ensure a sound report for publication*

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	A	B	C	D	E	F
1	**Submitter**	**Text**	**Feedback received/recommended change**	**Proposed response in relation to Final Clinical Pathway**	**Code**	**DoH proposed response in relation to A+C comments**
2	**Notes on document as a whole**					
3	Medical professional	Supporting evidence for the recommendations	The grades of evidence to support recommendations are not included so all recommendations seem to be non-stratified. It would be useful to add evidence-based grades.	A+C team will discuss and consider including evidence-based grades, where possible and appropriate. This will have to be done in conjuction with the literature review.	3	The literature review / evidence summary should mention the hierarchy of evidence sources, such as published international government reports > Australian government reports > peer-reviewed scientific literature. It should also delineate between grey and white literature.
4	Medical professional	Data collection	Data collection should be an integral part of the Pathway. Data collected from patients via Medicare number and medical history in the database can be used to be part of big data so that differences and commonalities can be explored and analysed to provide better ways of diagnosing and treating	Out of scope for the Clinical Pathway	2	Out-of-scope. The biobank case study project is looking into possible common biomarkers which will assist in linking patient data.
5	Government authority	Whole document	There were a few grammatical and typographical errors throughout the Pathway that need correcting	A+C team will undertake a comprehensive Q+A process, including proof read and peer review before finalising the Clinical Pathway	1	Review spelling and grammar prior to finalisation.
6	Medical professional	History	Travel history shouldn't go back further than a year- it is really only relevant for acute cases, with the concentration on travel that occurred in the last 3 or 4 weeks	A+C team will discuss whether to include more information about how far back the travel history should be taken- this will be based on best practice and evidence available. Discussion with DoH will be valuable.	4	Based on available evidence and best practice. Strengthen wording around need to look at other possible aspects of a patient's history, for example, hobbies such as bushwalking. However for new presentations only recent travel history likely to be relevant.
7	Patient groups		There should be an education component for DSCATT in medical schools	Out of scope for the Pathway development	2	Out-of-scope. Distribution of the published clinical pathway will be considered as part of a broader communication strategy.
8	Medical professional		DSCATT should be made a notifiable disease	Out of scope- DSCATT is not a diagnosable disease, and this is out of scope of the Pathway development. Needs clarification in Clinical Pathway.	2	Out-of-scope. DSCATT is not a diagnosable disease.
9	Medical professional		There are research gaps which need to be filled. The Pathway should acknowledge these gaps and be adaptable to new findings	Agree, incorporate. Links to recommendation that the NHMRC research grants into DSCATT should be highlighted.	1	Please include text re NHMRC and CSIRO projects and that the clinical pathway is expected to be reviewed as significant new evidence emerges.
10	Patient groups	History	12 months is not sufficient for a travel history because diseases can lay dormant for longer than that. History should be taken from where the patient has worked, lived and travelled for a few years prior to developing symptoms	A+C team will discuss whether to include more information about how far back the travel history should be taken- this will be based on best practice and evidence available. Discussion with DoH will be valuable.	4	Base on available evidence and best practice. Strengthen wording around need to look at other possible aspects of a patient's history, for example hobbies such as bushwalking. However for new presentations only recent travel history likely to be relevant.
11	Government authority		The final document should be pictographic, and should essentially be a summary of the current large document	A+C team will discuss and consider how to achieve this	3	The final output should be a concise guideline that includes a decision tree diagram and supporting overview. This would be supported by a supplementary document that provides greater detail regarding the evidence base and reasoning behind the approach.
12	Medical professional		GPs are likely to focus on the algorithm, so it needs to be detailed and comprehensive	A+C team will discuss and consider how to achieve this	3	The final output should be a practical guideline that includes a decision tree diagram and concise overview. This would provide sufficient information for a treating medical practitioner but still link to further information if required.
13	Government authority		Create one or two pages for doctors with the most important information, and a document for patient information	A+C team will discuss this recommendation and consider how this can be done	3	A plain english summary highlighting the key points of the pathway can be added for use by patients and clinicians. This will compliment more detailed fact sheets for patients that are pending.
14	Government authority		Another useful tool would be, for example, a good podcast for GPs by RACGP	Possibly out of scope for the Clinical Pathway. Could be developed by DoH or authoratative medical organisation/ Government Health Department	2	Out-of-scope. Distribution of the published clinical pathway will be considered as part of a broader communication strategy. Audio-visual resources are being developed as part of another departmental project.
15	Patient groups		Remove all references to MUS ('Medically Unexplained Symptoms') from the document as it is unhelpful and inappropriate term, and will lead to patients not being treated	Discuss with DoH	4	Suggest keeping MUS as it is a term used by clinicians. Suggest spelling out where possible to soften.
16	Medical professional		Develop a registry of patients, which GPs can follow to see what has happened and what has worked in previous cases, for example structured biofeedback and interventions, and the standard set of tests. This can also include updated research	Out of scope for the Clinical Pathway	2	Out-of-scope. The biobank case study project is looking into possible common biomarkers which will assist in linking data.
17	Various submitters		Multiple submitters also sent through further evidence that they wanted to be considered as part of the evidence base for the Clinical Pathway and Literature Review	A+C team will spend up to 2 hours assessing the evidence (titles and abstracts) as to whether it is in scope for the development of the Pathway to determine whether to examine that evidence	3	Suggest triaging references by first ensuring that any further evidence submitted meets the requirements/criteria for inclusion under the literature review.
18	**Notes on algorithm**					

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19	Medical professional	Pathway on page 4	Most GPs will only ever look at the Pathway section (i.e. pg. 4) and not the detailed text. Thus include a bit more detail here, including the names of diagnostic tests, and the type and dose of antibiotics for treatment.	A+C team will discuss this as a team and consider ways of making the Algorithm more comprehensive.	3	Suggest developing a simplified guideline (refer line 11 above). Further detail can be linked to appropriate section of the supporting document. The algorithm does provide a function as a quick refence guide to locate information .
20	**Initial assessment and support**					
21	Medical professional	Clinical examination - specifically check presence of tick bite and rash	Add "enlarged lymph notes" (infection from ticks can cause this a hard sign that cannot be faked).	Accept and incorporate into Final	1	Ok, as it is an indicator of the presence of illness, infection or stress that should be investigated further.Also an indicator of underlying malignancy.
22	Medical professional	Initial assessment	If patients present at a psychologist before going to the GP, include a recommendation for referral to GP when symptoms are not explained by psychological reasons. Include another box for clarity.	A+C team will discuss this as a team- it may be that adding a box prior to this is out of scope.	3	Agree, additional box is out of scope. However suggest adding text to describe that patients entering the pathway may come from various entry points and other pathways.
23	Patient group		A standard consultation with a GP is not long enough to get through the 6 steps- a better approach would be to give a one-month prescription of doxycycline to any patient with a tick bite or EM rash	Out of scope- not consistent with best practice	2	Agree - needs to be based on best practice and appropriate use of antibiotic treatments.
24	**Differential diagnosis**					
25	Medical professional	If relevant symptoms but no travel overseas through a Lyme disease endemic area, then suspect tick-borne disease	If relevant symptoms but no travel overseas through a Lyme disease endemic area, then suspect other tick-borne disease	Accept and incorporate into Final	1	Agree with the addition of the word 'other'. If history of tick bite then yes, if no tick bite history then investigate further.
26	Medical professional	If history of travel to a Lyme disease endemic area and relevant symptoms, then suspect Lyme	If history of travel to a Lyme disease endemic area and relevant symptoms, then suspect Lyme disease or other diseases such as Rickettsial diseases	Accept and incorporate into Final	1	Ok.
27	Medical professional	If erythema migrans (EM) rash confirmed, start appropriate antibiotic treatment	If likely erythema migrans (EM) rash present start appropriate antibiotic treatment (a rash cannot be 'confirmed')	Accept and incorporate into Final	1	Disagree. EM is NOT pathognomonic in Australia. An EM rash must be investigated. An experienced medical practitioner who has seen acute Lyme disease in patients with a recent travel history from an area endemic for classical Lyme disease can start therapy, but there are other causes of annular rashes.
28	Medical professional	If suspect Queensland tick typhus (QTT), start antibiotic treatment	If suspect Queensland tick typhus (QTT), Flinders Island Spotted Fever (FISF) or Australian Spotted Fever (ASF), start antibiotic treatment OR If suspect Rickettsia disease start antibiotic treatment	Accept and incorporate into Final	1	Ok.
29	Medical professional	Lyme endemic area	There is no explanation for what a 'Lyme endemic' area means for Australia and all its territories. It is known that there are ticks in many locations but unknown what is 'Lyme endemic'	Out of scope- there is no 'Lyme endemic' area in Australia. Perhaps we can clarify that these are referring to overseas areas only	3	Agree - clarify that Lyme disease is not endemic to Australia.
30	Medical professional	Lyme endemic area	Restricting the pathway to patients only from 'Lyme endemic' areas may miss many other patients who are affected by ticks or 'Lyme-like' vector borne illnesses	Out of scope- there is no 'Lyme endemic' area in Australia. Pathway is only restricted to Lyme endemic areas in terms of diagnosing Lyme disease. The Pathway allows for diagnosis of other tick-borne diseases that can be contracted in Australia	2	Agree - pathway is not restrictive to diagnosis of other tick-borne diseases
31	Medical professional	The NICE guideline covers diagnosing and managing Lyme disease, and aims to raise awareness of Lyme disease should it be suspected, and ensure people have prompt and consistent	CDC guidelines should be used rather than NICE guidelines	Discuss with team- possibly not for us to decide?	4	Stick with the NICE guidelines as they are the most recent evidence-based guidelines. The CDC TICKBORNE DISEASES OF THE UNITED STATES Reference Manual for Healthcare Providers (2018) would have a narrower evidence base to that required to develop the NICE clinical practice guidelines.
32	Medical professional		ILADS guidelines should be used rather than IDSA guidelines	Discuss with team- possibly not for us to decide?	4	The NICE guidelines should be used as much as possible. The ILADS guidelines are controversial; due to a poor evidence-base.NICE, CDC, and IDSA can be used for reference, as these are evidene-based robust guidelines.
33	Medical professional	The NICE guideline covers diagnosing and managing Lyme disease, and aims to raise awareness of Lyme disease should it be suspected, and ensure people have prompt and consistent	There seems to be a preference for the NICE guidelines in this document. It would be more appropriate to have a focus on the IDSA guideline	Discuss with team- possibly not for us to decide?	4	The IDSA guidelines are still in draft and potentially will change. Given there is no timeframe for the IDSA guideines completetion it would be sensible to use NICE were possible. If a recommendation is used from the draft guideline it would be advisable to refer back to the underlying evidence base of that recommendation.
34	Government authority	History	For those who do not have a travel history, the investigations need to be kept broad, and possibly wider than vector-borne disease	While the Pathway development focuses on tick-borne illnesses, this recommendation pertains to other conditions that could be considered under differential diagnoses	3	Agreed, a thorough subjective and objective examination will assist in forming a differential diagnosis.
35	Medical Professional	History	There is some evidence that transmission can be passed on genetically, through blood transfusions and through sexual transmission, and this should be included in the Clinical Pathway, as it will be an important feature of questioning	A+C team to discuss including other forms of transmission according to the evidence available. Discussion with DoH will be valuable.	3	Reference to modes of transmission must be based on reputable scientific evidence. Not aware of any other forms of transmission.
36	**Diagnostic testing**					

	A	B	C	D	E	F
37	Medical professional	Diagnostic testing	Referring all patients with possible DSCATT needing tick infection testing or treatment is unrealistic and has long wait times for patients, adding burdens on their health care costs, when GPs can be educated as to which tests can be done with NATA accredited labs for initial screening and simple treatment	No change- majority of medical professionals agreed with the recommendation in the Draft (subject to the changes above)	2	Ok, base on best practice.
38	**Diagnosis +/- referral**					
39	Medical professional	Refer for testing for tick-borne diseases	Refer for testing for other tick-borne diseases	Accept and incorporate into Final	1	Ok.
40	**Initial management**					
41	Medical professional	Seek advice from a specialist pathologist or ID Physician in regards ...	Seek advice from a medical microbiologist (pathologist) or ID physician in regards ...	Accept and incorporate into Final	1	Ok.
42	Medical professional	Seek advice from a specialist pathologist or ID Physician in regards ...	Rather than restricting this group of patients to specialist ID physicians, and there being insufficient ID physicians (my patients have not been able to get in to see them in the past, in good time), this pathway is not realistic. More GPs need to be educated in this rather than have the autonomy and expertise taken away from them.	No change- majority of medical professionals agreed with the recommendation in the Draft (subject to the changes above)	2	Agree The CPP intends to increase GP awareness and assist decision making on the most approapriate care.
43	Government authority		Include more advice on Stepped Care to educate GPs, including a comprehensive case study describing the use of the Stepped Care approach.	A+C team will discuss and consider adding more information here	3	Some additional text may be useful however GPs should be familiar with the general use of a stepped care approach.
44	**Ongoing management**					
45	Medical professional		Include a recommendation to involve health psychologists in ongoing management	A+C team will discuss and consider including a recommendation to this effect	3	Suggest inclusion of general recommendation that additional patient support, such as mental health support [and other specialty areas], be considered if required.
46	**SUMMARY INFORMATION**					
47	Government authority	Follow usual clinical assessment practice including a travel history	Follow usual clinical assessment practice including a travel and activity (e.g. bushwalking) history	Accept and incorporate into Final	1	Ok.
48	Government authority	For patients presenting with a bulls'-eye rash (Erythema migrans) and a relevant travel history ...	Include a photo of a typical EM rash	Accept and incorporate into Final	1	Suggest use of images be consistent throughout pathway - note that images may not be necessary as the guidance material under development contains significant descriptions and images with respect to the different conditions.
49	Medical professional	For patients presenting with a bulls'-eye rash (Erythema migrans) and a relevant travel history ...	For patients presenting with a bulls'-eye rash (erythema migrans) ...	Accept and incorporate into Final	1	Ok.
50	Medical professional	Diagnostic testing for Lyme disease should only be initiated following advice from appropriate experts such as a consultant physician practising in his or her speciality of infectious disease or a specialist pathologist in his or her speciality of microbiology and should only be undertaken in Australia in a pathology laboratory accredited by	Diagnostic testing for Lyme disease should only be initiated following advice from appropriate experts such as a consultant physician practising in his or her speciality of infectious disease or a specialist pathologist in his or her speciality of microbiology and should only be undertaken in Australia in a pathology laboratory accredited by National Association and Testing Authorities (NATA) or Royal College of Pathologists of Australasia (RCPA) to conduct such testing.	Accept and incorporate into Final	1	Ok.
51	Medical professional	Diagnostic testing for Lyme disease should only be initiated following advice from appropriate experts such as a consultant physician practising in his or her speciality of infectious disease or a specialist pathologist in his or her speciality of microbiology and should only be undertaken in Australia in a pathology laboratory accredited by National Association or Testing Authorities (NATA) or Royal College	Change to College of Pathologists	Accept and incorporate into Final	1	Ok, as above.
52	Medical professional	For patients with ongoing symptoms after one course of antibiotics ...	Define a 'course' of antibiotics	Accept and incorporate into Final	1	Please include course duration as definied according to best practice.

	A	B	C	D	E	F
53	Medical professional	For patients with ongoing symptoms after one course of antibiotics, only one additional course of antibiotics may be recommended as there is no evidence of benefit of longer courses. An additional course of antibiotics will be determined on case by case basis. Full resolution of symptoms may take some time	For patients with ongoing symptoms after one course of antibiotics, only one additional course of antibiotics may be recommended as there is no evidence of benefit of longer courses. An additional course of antibiotics should be determined on case by case basis. Full resolution of symptoms may take some time but does not require further antibiotics. (including the word "will" opens up the risk that patients will expect another course).	Accept and incorporate into Final	1	Ok.
54	Government authority	Therapeutic modalities not recommended for treatment of patients with any manifestation of Lyme disease include ...	Therapeutic modalities *not recommended* for treatment of patients with any manifestation of Lyme disease include ... (put in **bold** and *italics* to indicate emphasis)	Accept and incorporate into Final	1	Ok, if consistent with formatting used in other sections of pathway.
55	Government authority	In patients who have not travelled overseas to a Lyme endemic area, AND who have or may have been recently bitten by a vector, such as a mosquito or tick ...	If we are including those who may have been bitted by a vector (e.g. the patient suspects it but there is no objective evidence), then the pathway should not only explore Australian vector-borne disease because the symptoms actually intersect with many other clinical diagnoses ... influenzas, other viral infections, arthritis etc.	Out of scope- the Clinical Pathway is focused on tick-borne illnesses	2	The pathway emphasises the importance of a thorough subjective and objective examination will assist in forming a differential diagnosis.
56	Medical professional	Mosquito borne disease	Mosquito and flea-borne disease (ADD: consider Bartonella - in Australia, *Bartonella clarridgeiae* and *Bartonella henselae* are found in cats, cat fleas and humans - acknowledges that Australian patients who have not left Aus but report they have been diagnosed with Bartonella could have contracted it from cat fleas).	Accept and incorporate into Final	1	Suggest paring this back if possible to only touch on other vectors and not describe in any detail.
57	Medical professional	Some types of mosquitoes can transmit viruses such as Ross River and Barmah Forest in most parts of Australia and, rarely, the virus that causes Murray Valley encephalitis. Some parts of northern Queensland have a type of mosquito (Aedes aegypti) that are capable of transmitting dengue fever, chikungunya and zika infections. Dengue outbreaks have known to occur from time to time	Some types of mosquitoes can transmit viruses such as Ross River and Barmah Forest in most parts of Australia and, rarely, the virus that causes Murray Valley encephalitis. Some parts of northern Queensland have a type of mosquito (Aedes aegypti) that are capable of transmitting dengue fever, chikungunya and zika infections. Dengue outbreaks have known to occur from time to time in Queensland while chikungunya and zika are only seen in imported cases.	Accept and incorporate into Final	1	Refer above - suggest not going into any significant detail. Ross River virus is usually in arid areas rather than urban areas and there are other mosquito species that can carry dengue, although mostly contained in Queensland.
58	Medical professional		Consider Bartonella in the differential diagnosis as this disease is common in Australia, is transmitted by fleas (cats)and presents as fever, enlarged lymph nodes	Accept and incorporate into Final	1	Refer below and above - suggest paring this back to avoid detail.
59	Medical professional	Diagnosis of tick-borne disease known to exist in Australia is challenging. Symptoms may overlap with other infectious diseases including those that are transmitted by non-tick vectors as well as a number of chronic	It is important to also mention tick-induced paralysis here for completeness	Accept and incorporate into Final	1	Ok. There is value in mentioning mosquito vectors here, which should address the above points, i.e. Symptoms may overlap with other infectious diseases including those that are transmitted by non-tick vectors such as mosquitoes as well as a number of chronic dieases.
60	Medical professional	Diagnosis of tick-borne disease known to exist in Australia is challenging (...) Apart from the occasional local bacterial infectious at the tick bite site (eschar) the only two systemic infections that are definitely known to be transmitted by tick bites in	I think this is a bit misleading	A+C team will consider this comment and reword if necessary	3	Agree, consider rewording perhaps softening to say that only Rickettsia spp are known to transmit systemic infections in Australia.
61	Medical professional	Diagnosis of tick-borne disease known to exist in Australia is challenging (...) (Queensland tick typhus, Flinders Island spotted fever and Australian spotted fever) and Q fever ...	Mention the likelihood that there are others, such as *neoehlirichia* spp. Also a single case of babesiosis	Accept and incorporate into Final	1	Suggest using a "catch all" and say some examples include...
62	Medical professional	**Tick-borne encephalitis (TBE)** is a human viral infectious disease, transmitted by the bite of infected ticks in woodland habitats, and involves the central nervous	What about soft ticks? Add tick-borne relapsing fever	Accept and incorporate into Final	1	Other tick-borne illnesses will be described in detail by the suite of guidance notes and fact sheets under development, which are external to the clinical pathway, therefore suggest keeping descriptions minimal in pathway and perhaps pointing to fact sheets.

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63	Medical professional	If a tick has embedded in the patient's skin and remains ***in situ***, enquire whether the patient suffers from allergies to ticks before attempting to remove the tick. Removing a tick must occur in a medical facility with capacity to initiate advanced life support in the event of anaphylaxis.	Not sure that this is practical or needed. **Freezing the tick is recommended if possible.**	Either accept and incorprate or link to latest DoH advice on removal of ticks, if available.	3	This needs to be in line with the fact sheet under development, which outlines that freezing the tick is best practice. Please clarify within the document that the requirement to remove a tick in a medical facility is only if there is a risk of anaphylaxis.
64	Government authority	Insecticides containing either diethyl-meta-toluamide (DEET) or picaridin should be applied to the skin prior to entering a tick-infested area.	Insecticides containing either diethyl-meta-toluamide (DEET) or picaridin should be applied to the skin prior to entering a tick-infested area. **Higher concentrations of DEET are not necessarily more effective but are longer lasting.**	Either accept and incorprate or link to latest DoH advice on removal of ticks, if available.	3	Accept, noting that the fact sheet (still under development) also states that you can also use protective clothing or clothing impregnated with insecticide instead. Other insecticides, such as p-methane-3,8-diol (36%) also sold as oil of lemon eucalyptus, can also be effective against Australian ticks.
65	Government authority	Practice harm minimisation by avoiding repeated diagnostic testing, use of non-accredited laboratories for diagnostic testing and use of unconventional diagnostic techniques, unnecessary referrals and interventions, and	Practice harm minimisation by avoiding **fragmented care from multiple different practitioners;** repeated diagnostic testing**;** use of non-accredited laboratories for diagnostic testing**;** and use of unconventional diagnostic techniques, unnecessary referrals and interventions, and treatments with known harm and**/or** no benefit.	Accept and incorporate into Final	1	Ok.
66	Government authority	End of summary information	Generally with a clinical pathway, it is wise to make a recommendation that periodic review of the pathway is needed and when that might occur e.g. no longer than 3 years or sooner should new evidence emerge. I think this is especially important in a space where further research may uncover more and ensures that the need to undertake review is acknowledged up front and can be referenced in business cases, etc. It would also be heartening for patients to see that this does not assume how it is now will be the end of the story.	Accept and incorporate into Final	1	Agree, please include that the pathway will be reviewed in light of significant new evidence (for example, current NHMRC and CSIRO projects likely to contribute to current evidence base).
67	Medical professional		Include a recommendation that patients with MUS be referred to a clinical psychologist who can assess if the symptoms are psychological or physical (rule out/dismiss any psychological involvement). Advice was that this would empower the patients and help reduce the number of patients presenting with depression/anxiety being categorised by GPs/psychiatrists as 'psychological'.	A+C team will discuss and consider adding a recommendation to this effect	3	Suggest recommendation be based on best clinical practice and relevant evidence.
68	**GLOSSARY**					
69	Medical professional		ID physicians using IDSA guidelines does not work in clinical practice. IDSA guidelines only work in acute cases of Lyme disease and are no good for chronic Lyme patients. Persistent infections/biofilms. There are benefits for long courses of antibiotics. Persistor drugs and biofilm agents are needed- see research from last 7 years. Therapeutic modaliaited not recommended: persistor drugs helps him stop using long term antibiotics; hyperbaric oxygen therapy helpful; IV Ig helpful with Lyme patients with neuropathy; vitamins and nutritional - depends on patient; chelation therapy can be useful.	The Majority of medical professionals approved of using the IDSA guidelines. Discuss with team- possibly not for us to decide? Consider evidence sent by stakeholder about biofilms etc. Discussion with DoH	4	Refer line 32. Note chronic lyme disease is globally considered a disputed diagnosis which lacks supporting evidence.
70	**1. INTRODUCTION**					
71	Medical professional		More of an introduction, including that the NHMRC is doing research in Australia would be useful, particularly given the discrepancies in the belief of a tick-borne illness	A+C team will discuss including this	3	Suggest concise text to capture Australian context and how current gaps are being addressed, incldiuing NHMRC research, and projects underway in the Department.
72	**Section 1.2 DSCATT**					
73	Medical professional	Debilitating symptom complexes attributed to ticks (DSCATT) is the term used by the Australian Government to describe the group of Australian patients suffering from the symptoms of a chronic debilitating illness, which many associate with a tick bite, to appropriately acknowledge this	It is dangerous to have **tick** in the name as it gives credence to the thought that ticks are responsible.	Changing/not using the term is out of scope, however, the Final Pathway will clarify that patients cannot leave a medical practice with a diagnosis of DSCATT	3	Out of scope. Agree, clarify that DSCATT is not a diagnosable disease.
74	Medical professional	The Australian Government acknowledges that many of these patients experiencing debilitating symptom complexes are living in turmoil. With the causes of DSCATT as yet unknown, the Australian Government urges patients and health professionals to keep an	This comment in not based in fact	This is official text. Consider removing, particularly the first sentence.	3	It is important that the clinical pathway does reflect the message that patients and health professionals are urged to keep an open mind about the cause's of a patient's symptoms. Revisions may be made, but that focus and message should remain. Allen and Clarke may find the following statement from the Chief Medical Officers statement (in useful in revising this text, incldiuing paragraph 3) refer https://www1.health.gov au/internet/main/publishing.nsf/Content/ohp-lyme-disease.htm/$File/statement-cmo-October2016.pdf

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75	Medical professional	The symptom complexes to which the name DSCATT has been given incorporates a wide range of non-specific symptoms. Some people may have a diagnosis that has not yet been identified and that explains these symptoms while others may have a cluster of	Most of the patients do have an alternative diagnosis and are just unwilling to accept it. This document has the potential for harm by justifying this belief.	Changing/not using the term is out of scope, however,the Final Pathway will clarify that patients cannot leave a medical practice with a diagnosis of DSCATT	3	Out of scope. Agree, clarify that DSCATT is not a diagnosable disease.
76	**2. INITIAL ASSESSMENT AND SUPPORT**					
77	**2.1.1. Usual clinical practice including travel history**					
78	Medical professional	The inclusion of a travel history as part of the clinical history is important, as the organism that causes Lyme disease ahs not yet been identified in Australia, but is endemic in parts of the USA, Europe and Asia	Implies that it will be. Has never been or has not been would be more accurate.	Accept and incorporate into Final	1	Agree
79	Medical professional		Include blood transfusion and maternal foetal transmission in history	A+C team will discuss and consider whether to include	3	Not aware of any other forms of transmission - would need to be based on reputable scientific evidence. Recommend not including. The evidence exists for congenital transmission and infection but not for disease or signicant poor outcomes. If it was an efficient method of transmission we'd see many more cases and reports. The same is true for blood transfusion. It's possible to transmit but most blood donation organisations defer if the person has a history or if the person has a febrile illness with a rash because other blood borne pathogens can be a cause.
80	Medical professional	The inclusion of a travel history as part of the clinical history is important, as the organism that causes Lyme disease ahs not yet been identified in Australia, but is endemic in parts of the USA,	Remove the word "yet"	Accept and incorporate into Final	1	The word 'yet' reflects while there is currently no evidence, there may be in the future.
81	Patient groups		All of the treatment modalities should not be banned by the Clinical Pathway	Discuss with DoH- A+C technical Advisory will draft clarification to address this point and to also bring alignment with NHMRC guidelines on complementary and alternative therapies	4	Agree - add text to describe NHMRC position on complementary and alternative medicines and that the pathway is likely to be reviewed as significant new evidence emerges.
82	**2.1.2. Consult with appropriate experts**					
83	Medical professional	Tick bite diagnoses are challenging as clinical features can be similar to many other diseases (infectious and non-infectious). Consult with appropriate experts in vector-borne diseases including specialist pathologists with diagnostic experience and infectious disease (ID) physicians for treatment of	Replace the term specialist pathologist with microbiologist throughout the whole document	Accept and incorporate into Final	1	The term "specialist microbiologist" is preferred. Under the AHPRA designations a pathologist with a speciality field in microbiology is a specialist microbiologist.
84	Medical professional		If use ID physicians, this will go nowhere.	Involving ID physicians in diagnosis and treatment was supported by the majority of medical stakeholders	3	Specialists are essential to diagnosis and treatment.
85	Medical professional	Tick bite diagnoses are challenging as clinical features can be similar to many other diseases (infectious and non-infectious). Consult with appropriate experts in vector-borne diseases including specialist pathologists with diagnostic	Replace the term specialist pathologist with microbiologist throughout the whole document	Accept and incorporate into Final	1	See line 83.
86	**3. DIFFERENTIAL DIAGNOSIS**					
87	**3.1. Lyme disease**					
88	Medical professional	A tick bite can be followed by an 'erythema migrans' rash (EM), a circular target-like rash which is considered pathognomonic for Lyme disease but can sometimes be mistaken for cellulitis or ringworm, delaying effective treatment	The differential for such a rash also indicates allergic or post viral phenomena (e.g. erythema multiforme) or acute rheumatic fever (erythema marginatum)	A+C team will discuss and consider whether to add this	3	Detail regarding specifics of each symptom may be best referred to the tick guidance notes under development.

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89	Medical professional	Lyme disease is customarily divided into three stages, with clinical manifestation varying in their occurrence and incidence depending on the infecting species and whether the infection was acquired in Eurasia or North America. Approximately 4-8 percent of patients develop cardiac findings, 11 percent develop neurologic findings and 40-60 percent of patients manifest arthritis, although surveillance data over the last 15 years documents a	This paragraph is misleading. It would be better to characterise early, early disseminated and late Lyme disease	A+C team will discuss and consider whether to add this	3	It is important to stick to accepted descriptions and classifications. The three stages are acute, early disseminated and late disseminated. The "early disseminated" can be broken up into three broad manifestations, viz., cardia, neurological and joint. Often the manifestation depends on the quasi species in the group Borrelia burgdorferi sensu lato is geographically dependent as well.
90	Medical professional	In children with developmental, behavioural or psychiatric disorders, there is no evidence to support a causal relationship between Lyme disease and developmental or behavioural disorders. Low probability testing is expected to produce disproportionate false positive results, potentially causing harm. However, as with many acute medical illnesses, Lyme disease could worsen behav oural or	This is a big statement. Where is the evidence to back it up? Provide evidence and define "predisposed to these"	Provide clarification of the evidence to back up this statement, and define what we mean by "predisposed". Evidence was from 2019 IDSA draft guideline.	3	Agree, base on published guidelines. Suggest including a descriptor before 'evidence', for example, 'no confirmed evidence'.
91	Medical professional	The organism that causes Lyme disease has not yet been identified in Australian ticks nor any other vector that could transmit the disease to humans.	Again use of the term yet is misleading and inflammatory	Remove the term "yet" throughout the document when referring to Lyme disease	3	Suggest altering text slightly to 'to date, the organism that causes Lyme Disease has not been found in Australia'.
92	Medical professional	The organism that causes Lyme disease has not yet been identified in Australian ticks nor any other vector that could transmit the disease to humans.	It is also important to say "despite multiple studies which have thoroughly searched for it in Australian ticks and patients"	Include this wording to improve the statement	3	The feedback is correct.
93	Medical professional	A course of antibiotic treatment for Lyme disease should only be initiated based on the expert advice of either a consultant physician practising in his or her speciality of infectious disease or a specialist pathologist in his or her	Should probably only be an ID physician. Microbiologists do not have training in treating patients.	Accept and incorporate into Final	1	Disagree. Specialist Microbiologists do have training in providing treatment advice to referring medical practitioners. This is a core element of the work of a Specialist Microbiologist.
94	Medical professional		Please provide for atypical bulls eye rashes. For GPs it is not always clear what bulls eye rashes look like in different variations, and they need to be informed about it. There is also no word about lymphocytoma and different variations of that.	A+C team will consider adding more information about the potential for atypical rashes following tick bites	3	While some detail could be added, it is not strictly necessary as detail regarding the specifics of each symptoms may be best referred to the tick guidance notes which are under development.
95	Medical professional		Around 18% of infected Lyme patients remember a former tick bite and this needs to be respected in any clinical pathway.	A+C team will consider including the findings of this paper- it aligns with infomration that patients don't always remember being bitten by a tick.	3	Agree.
96	Medical professional		Lyme disease is a subset of tick borne diseases, so an over-focus on Lyme disease will not solve the problem we have in Australia	No action required	N/A	Agree
97	Patient groups		The Pathway is too "Lyme-centric" and should include the full range of tick-borne illness, borrelia and co-infections should be included whether the patient has travelled or not	A+C team will consider adding more about other potential pathogens	3	Other tick-borne illnesses will be described in detail by the suite of guidance notes and fact sheets under development, therefore suggest keeping descriptions minimal in pathway and perhaps pointing to fact sheets.
98	Medical professionals		Other diseases which can be co-infections that patients may have if they acquired Lyme disease overseas should also be included: Anaplasma, Babesia, neoerlichia	Accept and incorporate into Final	1	Other tick-borne illnesses will be described in detail by the suite of guidance notes and fact sheets under development, therefore suggest keeping descriptions minimal in pathway and perhaps pointing to fact sheets. Coments received during public consultation should assist in informing the content of the fact sheets
99	Government authority		Include maps of international Lyme endemic areas	Accept and incorporate into Final	1	Disagree - this information will be captured in the other guidance material currently under development.
100	Medical professional		Include the rash associated with Rheumatic fever in the list of rashes that are not EM	Accept and incorporate into Final	1	Agree
101	**3.2. Tick-borne disease known to be acquired in**					

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102	Medical professional		Should also include the recently described Rickettsia gravesii (WA) to the list in this section	Include [check with others on this one as I am not sure]	3	Suggest keeping species name. The species is named after Stephen Graves who has been a significant stakeholder in the DSCATT process. However can be simplified by saying other Rickettsial species.
103	Medical professionals		Also include pictures of other rashes to help guide doctors and be sure that they can distinguish between different rashes, cellulitis and other infections (e.g. QTT has a specific rash)	Include some relevant pictures or links to pictures	3	Suggest use of images be consistent throughout pathway - note that images may not be necessary as the guidance material under development contains significant descriptions and images with respect to the different conditions.
104	Medical professional	Seek further expert opinion as necessary depending upon the nature of the patient's clinical presentation from appropriate experts in vector-borne diseases including specialist pathologists with diagnostic experience and ID physicians for diagnosis and	All references to specialist pathologists should be microbiologists.	Accept and incorporate into Final	1	See line 83.
105	Medical professional		Tick borne diseases commonly include bartonella, babesia, rickettsia, anaplasma, ehrlichia, borrelia, and the list does not preclude any other pathogens that may be transferred from reservoir animals to humans. A tick is just a carrier. This must be emphasised so that an assumption does not develop that these are the only pathogens that can be transmitted from a tick bite.	A+C team will consider adding more about other potential pathogens	3	Other tick-borne illnesses will be described in detail by the suite of guidance notes and fact sheets under development, therefore suggest keeping descriptions minimal in pathway and perhaps pointing to fact sheets.
106	Medical professional		The Clinical Pathway should include more information about other Australian and international vector-borne diseases (that is, transmitted by mosquitos or fleas)	A+C team will consider this - see line 55 about including flea-borne diseases such as Bartonella (RCPA)	3	Pathway should be focussed on tick-borne illnesses with only a brief mention of other possible vector-borne illnesses.
107	Patient groups		Include more information around timeframes and payments. Timeframes are particularly important with reference to Lyme, because antibiotics must be taken within the first 2 weeks.	A+C team will discuss and consider adding more information. Discussion with DOH will also be valuable.	4	Needs to be based on best practice and appropriate use of antibiotic treatments.
108	Medical professional		Bartonella should be included on the list- this is a flea-borne disease which can be transmitted by cats in Australia and often presents in adolescents	A+C team will consider this - see line 55 about including flea-borne diseases such as Bartonella	3	Pathway should be focussed on tick-borne illnesses with only a brief mention of other possible vector-borne illnesses.
109	Medical professional		Mammalian meat allergy should be included	A+C team will discuss and consider adding	3	Other tick-borne diseases, including MMA, will be covered in detail in the education materials which are external to the clinical pathway, therefore suggest only briefly mentioning here.
110	Government authority		EB Virus should be included	A+C team will discuss and consider adding	3	Other tick-borne diseases will be covered in detail in the education materials, therefore suggest only briefly mentioning here.
111	Medical professional		For patients who haven't travelled overseas to Lyme-endemic areas, maybe consider Bartonella	Accept and incorporate into Final	1	Ok. Please also note the text should state "lyme disease endemic areas" rather than "lyme-endemic".
112	**3.3. Tick-borne disease not acquired in Australia**					
113	Medical professional	There is no evidence it exists in Australia outside from those who have been infected overseas, but TBE has been characterised in an Australian man following a six-week trip through Russia.	Why is this statement relevant? Of course Australians can get it if we go to endemic areas. Why is an example needed?	Remove this example, as no example is given to demonstrate any of the other points in this section, and it is not necessary	3	Remove example for consistency.
114	Medical professional		The Clinical Pathway should include more information about other Northern Hemisphere tick-borne diseases	A+C team will discuss and consider adding more information	3	Other tick-borne diseases will be covered in detail in the education materials, therefore suggest only briefly mentioning here.
115	Medical professionals		Keep the Clinical Pathway simple, and rather than referring to all of the possible diseases, rely on the referral to ID Physicians to cover any additional infections, based on the patient's travel history	A+C team will consdier adding in more information about collecting travel history information, to ensure approprite information is conveyed on referral to ID physician	3	Suggest it would be useful to have a high level recommendation rather than go into each disease in detail (the detail will be provided in the education materials).
116	**3.4. Patients presenting with persistent debilitating**					
117	Government authority	Develop a differential diagnosis with consideration of the following causes ...	Add neurological and possibly also cardio-respiratory conditions to the list.	Accept and incorporate into Final	1	Ok.
118	Government authority	Take care to identify any potentially treatable illness.	Consider the important components of care necessary to manage those in whom no potentially treatable illness is identified - acknowledgement of symptoms/suffering/genuine experience. Emphasise that for some, lifestyle and psychological approaches to management are not an indication that it's 'all in the min' but are a useful and necessary component of managing persistent symptoms with no diagnosis.	Add some more wording into this section to reflect the need for doctors to acknowledge this.	3	Agree.
119	Medical professional	The diagnosis of MUS, including DSCATT, is a diagnosis of exclusion and requires ongoing review as new symptoms arise or treatments are trialled. A full history and exam nat on are c t cal	DSCATT is **not** a diagnosis. It is a term you have invented. It should not be considered a diagnosis as there is no literature to support its existence.	Changing/not using the term is out of scope, however, the Final Pathway will clarify that patients cannot leave a medical practice with a diagnosis of DSCATT	3	Agree - please clarify DSCATT is not a diagnosis, rather it is a term used to describe symptoms of a chronic debilitating illness, often associated with a tick bite.

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120	Medical professional	Autoimmune - including rheumatoid arthritis, motor neurone disease, multiple sclerosis	Inflammatory arthritis would be a better term	Accept and incorporate into Final	1	Ok.
121	Medical professional	Vascular	Would the vascular diseases not be autoimmune?	A+C team will discuss and consider this recommendation	3	In the context of maintaining a broad view for differential diagnosis consideration of vascular origin is reasonable.
122	Medical professional	Genetic	What diseases are you trying to cover with this term? Many of the above have genetic components	Maybe clarify what we mean by genetic, if there is anything different that is not already covered by the other terms in this list, and consider removing it if it is not necessary	3	Ok remove.
123	Government authority		Take care to identify any potentially treatable illness: consider important components of care necessary to manage those in whom no potentially treatable illness is identified- acknowledgement of symptoms/suffering/genuine experience. Emphasise that for some, life-style and psychological approaches to management are no an indication that it's all in the mind but a useful and necessary component of managing persistent symptoms with no diagnosis	Include more information on these points	3	Agree
124	**4. DIAGNOSTIC TESTING**					
125	Government authority		This whole section is a little repetitive and could potentially be synthesised.	A+C team will consider rewording the section to make it more synthesised	3	Agree
126	Government authority		The section contained a lot of detail for some diseases (e g. QTT) but very little detail for others (e.g. other Rickettsia infections). A bit of description on Rickettsia infections is probably warranted.	A+C team will consider adding more detail around Rickettsia diseases	3	Suggest paring back information on other diseases as detailed information will be developed as part of the guidance material project.
127	Medical professional		Diagnostic testing for Lyme disease keeps changing and people are working on it. 2-tier lacks sensitiviey and specificity. The new two tier ELISA still has low sensitivity and specificity. Need to develop a country-sspecific Western blot and senstivie PCR. Lyme disease is hyperendemic world wide. Patentis with chronic fatique, musculo skeletal and cognitive deficits should be tested for the full range of infections including Anaplasma, Erhlichia and relapsing fever. Need to change the model in Australia.- needs to be a paradigm shift. One cause/one disease is not appropriate.	A+C team will consider adding more detail around limitations and issues with diagnostic testing of Lyme disease and diagnostic tests. Rest is out of scope.	3	Out-of-scope. Pathway can only recommend current testing methods. Prescribing unecessary tests is not consistent with best practice.
128	Medical professional		There are seronegativity problems of antibody testing and lacking standardisation of ELISA and Westernblot testing. There is lots of evidence-based paperwork about and lots of reasons why you will not find antibodies in chronic infections	A+C team to discuss and consider	3	Consider the published evidence evidnece regarding the reliability of ELISA and Westernblots for chronic infections
129	Medical professional		Differentiate what you want to express in testing methods like LTT. The test we are doing in European labs is not LTT as this is not certified and accredited test method, but inhouse testing - why isn't IGRA mentioned in the draft?	A+C team to discuss and consider	3	The Pathway can only utilise existing resources available in Australia
130	Medical professional		The current methods of testing are inadequate in diagnosis of DSCATT. The limitations of diagnostics should be understood and also utilised to explore alternative diagnosis. ELISA and other antibody-based diagnostics assume a competent immune system and many DSCATT patients are not, so testing immuno-competence would be helpful.	Out of scope	2	Disagree with comment - laboratory testing in NATA accredited labs can detect tick-borne illnesses.Medical testing laboratories conforming to NPAAC standards as assessed by NATA/RCPA can perform Lyme disease testing.
131	Medical professionals and Government		The recommendation to use only accredited testing labs is good, but there should be more emphasis on this, including more information about the QA and accreditation process as well as the international recognition	A+C team will consider adding more detail about the QA/accreditation process	3	Information regarding the QA and accreditation process is beyond the scope of this project. However, it is worthwhile briefly mentioning international recognition and importance of using accredited facilities.
132	Patient group		There needs to be more focus on proper testing for all pathogens for everyone- the bias of not testing for certain things if someone has not been overseas is not scientific.	Out of scope- this is not a "bias" and is based on the research	2	Disagree with comment - prescribing unnecessary tests is not consistent with best practice. The patient's history and presenting symptoms will stimulate the need for additional test of other pathogens if clinically indicated. Diagnostic stewardship is vital and over-referring patients to pathologists for testing is inappropriate unless there is a sound clinical indication.
133	Government authority		Include a list of accredited labs in the Clinical Pathway to assist GPs. Develop ready-made tools for GPs so that they know what tests to order	Could include a list of accredited labs	3	Disagree - a list of accredited laboratories can be accessed through NATA.
134	**4.1. Lyme disease**					
135	Government authority	Tests for Lyme disease have limitations and that false-positive and false-negative results	This needs more nuance, both for clinicians and for patients. E.g. serology, which involves testing for the presence of certain antibodies known to be associated with certain infections, does not simply provide a 'positive' or 'negative' result. All serology tests can have indeterminate results or fake results. A false positive result is when the serology is positive, but the disease is not present. This happens for all tests, and is more likely to occur when testing individuals with a low likelihood of actually having the infection/illness.	A+C will discuss	3	The reasons for limitations on test results should be clearly explained.
136	Medical professional	NICE recommends clinicians provide the following information to patients being tested for Lyme disease.	There needs to be a better explanation of false positives here given the expected PPV <4%.	Provide more explanation of what we mean by false positives.	3	Agree.

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137	Medical professional		There is no Australian Lyme disease, and this should be emphasised in the Clinical Pathway	A+C team will consider making it even clearer that there is no Australian Lyme disease	3	Agree - clarify that Lyme disease is not endemic to Australia.
138	**4.2. Tick-borne disease known to be acquired in**					
139	Medical professional	For patients presenting with tick bite and systemic symptoms (e.g. fever) consult with an appropriate expert in tick-borne diseases such as a pathologist or microbiologist with diagnostic expertise for appropriate test referral and follow advice for requests for testing for known Australian tick-borne infections and treatment of infections found.	Should just be microbiologist	Change all references to microbiologist only	3	The term "specialist microbiologist" is preferred. Under the AHPRA designations a pathologist with a speciality field in microbiology is a specialist microbiologist. This feedback is being semantic. Disagree with changing reference to microbiologist only. Microbiology is simply a subspeciality of pathology but other pathology testing is also needed in the patient work up where clinically relevant. In Australia we also have general pathologists who are familiar with the major aspects of all branches of laboratory medicine. These type of patholgists are usually trained in anatomical pathology, cytology, chemical pathology, microbiology, haematology and transfusion serology/medicine. Some may also choose to subspecialise in one area as well such as microbiology. Therefore keep existing wording.
140	**4.3. Tick-borne disease not acquired in Australia**					
141	Medical professional	Seek advice from appropriate experts in vector-borne disease including pathologists with diagnostic experience and ID physicians	Should be microbiologist	Change all references to microbiologist only	3	See comment above.
142	**5. DIAGNOSIS**					
143	**5.1. Lyme disease**					
144	Medical professional	The difficulties in interpreting diagnostic tests for Lyme disease as described above, coupled with the difficulties clinicians in Lyme endemic countries experience in diagnosing Lyme disease underpin the recommendations that medical professionals seek advice from appropriate experts in infectious diseases or pathology.	Change to microbiology	Accept and incorporate into Final	1	See line 139.
145	**6. INITIAL MANAGEMENT**					
146	**6.1. Lyme disease**					
147	Medical professional	Initial statements	The initial statements have a +/- related to tick bites being necessary to be clinically considered as part of the Pathway, but the guidelines are specific to tick-borne illnesses- so it appears to be discordant with the intention of creating this document	Need to discuss this with DoH -this has been pointed out by a medical stakeholder who reporesents primary care, and it indicates that there needs to be further clarification and explanation.	4	Not all those bitten by ticks have a history of a known tick bite. They may have been unaware of this. Suggest reordering of content to emphasise management of tick borne disease in Australia and Lyme disease suspected of being acquired overseas to feature afterwards. It is almost as if Section 3 2 should become 3.1 then section 3.4 become section 3.2 as the third column in the pathway needs to be immediately considered if tick bite not suspected and no overseas travel. The current Section 3.1 and 3.3 on Lyme Disease and overseas acquired tick disease should come after the text about known tick borne disease in Australia and the text related to a patient presenting with a debilitating illness but no diagnosis and tick borne illness is not suspected. Also it should say in the flow chart and text for this last cohort "tick borne disease is not suspected" rather than "tick borne disease is not indicated".
148	Government authority	Key dimensions include respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination, access to care, and partnerships	Patient-centred care is necessary, but not sufficient in addressing the specific needs of people who feel they are acknowledged believed or experiencing 'real' suffering. This does not address acknowledgement or authentic engagement.	Discuss- not sure how we can improve on this in a Clinical Pathway.	4	The information around person centred care is sufficient. The pathway notes the importance of ensuring that person centred care is provided that validates, addresses and manages their symptoms, and further to this, outlines what person centered care involves.
149	Patient group		Ensure that there is scope to constantly update the guidelines	This will be discussed with DoH- how the Clinical Pathway will ultimately be published	4	The clinical pathway is expected to be published as a PDF on the department's website. It is anticipated that the pathway will be reviewed as significant new evidence emerges.
150	Government authority		The Clinical Pathway should be electronically available with links to the supporting evidence-based information in each of the boxes. It should be a living document with changes being made as new research develops, as well as links to CFS guidelines where relevant	This will be discussed with DoH- how the Clinical Pathway will ultimately be published	4	The clinical pathway is expected to be published as a PDF on the department's website. It is anticipated that the pathway will be reviewed as significant new evidence emerges.
151	**6.4. Management of patients with persistent**					
152	Patient groups		All references to ticks should be replaced with arthropods to include diseases transmitted by fleas and mosquitos	Discussion with DoH. While the focus is on tick-borne illnesses the Summary includes infomration on other vector-borne diseases	4	Out-of-scope. The pathway should focus on tick-borne diseases only.

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153	Medical professional	Patients should be treated symptomatically and are also encouraged to consider the potential for harm with complementary medicines for which there is no evidence in those with comorbidities. All people with medically unexplained symptoms, (including those given the title DSCATT) can be assisted to have an	DSCATT is not a diagnosis. It is a term you have invented. It should not be considered a diagnosis as there is no literature to support its existence.	Changing/not using the term is out of scope, however, the Final Pathway will clarify that patients cannot leave a medical practice with a diagnosis of DSCATT	3	Agree
154	Medical professional	International and Australian guidelines provide evidence-based, practical and consistent recommendations for people that can be applied to patients with DSCATT. Good communication and empathy are important. Patients' concerns need to be taken seriously and their symptoms	DSCATT is not a diagnosis. It is a term you have invented. It should not be considered a diagnosis as there is no literature to support its existence.	Changing/not using the term is out of scope, however, the Final Pathway will clarify that patients cannot leave a medical practice with a diagnosis of DSCATT	3	Agree.
155	Medical professional	An analysis of the Senate submissions noted patients that identified as having DSCATT experience social and financial harms and are at risk of nosocomial harms and may also have sought alternative and potentially non-evidence-based diagnoses and	This does NOT indicate that any disease is responsible for these social and financial harms. There is NO evidence for this.	More nuance around DSCATT not being a diagnosis, as above	3	Agree
156	Medical professional	An analysis of the Senate submissions noted patients that identified as having DSCATT experience social and financial harms and are at risk of nosocomial harms and may also have sought alternative and potentially non-evidence-based diagnoses and	The reference to DSCATT as a disease is dangerous wording and should not be used	More nuance around DSCATT not being a diagnosis, as above	3	Agree
157	Medical professional	Repeated diagnostic testing. Harms include worry that there is still something to be found that hasn't been tested for yet, increased likelihood of false positives, and the finding of minor, non-significant abnormalities in test results that increase anxiety	Harm also includes complications of investigations	Accept and incorporate into Final	1	Agree
158	Medical professional	Use of non-accredited laboratories for diagnostic testing and use of unconventional diagnostic techniques e g. kinesiology. Harms include false positives and wrong diagnosis	And harms of investigations/treatment	Accept and incorporate into Final	1	Agree
159	Government authority	International evidence indicated patients with MUS are at risk of potentially harmful additional testing and are often subjected to repeated diagnostic investigations, and unnecessary and costly referrals and interventions.	And multiple primary care practitioners to this list of harms	Accept and incorporate into Final	1	Agree
160	Medical professional	Having a chronic medical condition of any cause increases the likelihood of mental health conditions, which in turn can lead to poorer outcomes. Acknowledging the difficulty of chronic symptoms and supporting the important mental health strategies is vital to person centred	The document has not discussed that mental health problems can manifest as pain, fatigue and other symptoms listed here. Often it is the mental health causing symptoms rather than the other way around. This needs to be acknowledged in the document.	Can include more about the difficulty of physical manifestations	3	Agree.
161	Medical professional	People experiencing debilitating symptoms attributed to ticks, without any definitive diagnosis could be considered to fall within the definition of MUS	Attributed to ticks by whom? Infectious disease specialists and rheumatologists do not attribute these symptoms to ticks	Perhaps we include more evidence here?	3	The term DSCATT is used by the Australian Government in the context of these range of symptoms. Please leave as is.
162	Government authority	List of recommendations related to MUS	These points need to be rolled into the patient-centred care section	Discuss with team- is this a reasonable rec?	3	The recommendations provide the principles that underpin the development of an individualised care plan in discussion with the patient so this information should preceed

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163	Government authority		Consider whether the overlap between MUS and chronic fatigue type symptoms needs to be described further	Discuss with team- is this a reasonable rec?	3	Strengthening the messaging around the evidence of chronic health issues and its impact on mental health is warranted.
164	Government authority		Consider whether the utility or benefit of multi-disciplinary (non-medical) services may be under-emphasised.	Consider adding more information about multidisciplinary management- this is a rec suggested by a number of submitters	3	Agree. More information on development of an individualised care plan in discussion with the patient that may involve a multidisciplinary team is important.
165	Medical professional		The most important aspect of the Pathway is that it is multidisciplinary. It needs the teamwork of all colleges of physicians, because DSCATT is a multi-systemic disease.	Consider adding more information about multidisciplinary management- this is a rec suggested by a number of submitters	3	Agree. More information on development of an individualised care plan in discussion with the patient that may involve a multidisciplinary team is important.
166	Patient group		Natural treatment is best for those that weren't recognised straight away. Detox and immune boosting protocol needs to be administered.	Out of scope- A+C will include more information about the reasoning behind not recommending alternative treatments	3	Agree. Treatments need to be supported by peer-reviewed evidence.
167	Medical professional		Psychological help can be used as treatment (alongside other medical interventions) to prevent patients with long-term symptoms developing depression	A+C will discuss and consider how this recommendation can be incorporated	3	Acknowledgement of the existing evidence of chronic health issues and its impact on mental health is warranted .
168	Medical professional		Unresolved symptoms in children should always be led by a paediatrician, as children require specialised care	A+C will consider adding a section about the treatment of children	3	It would be appropriate to mention children may require paediatric care.
169	Medical professional	ALLI Australian Lyme-like Illness	It is dangerous to have this as a term. We do NOT have Lyme disease in Australia. Remove this term from the document.	Discuss with DoH- this is not a term that A+C have made up, but has been used for a while	4	Strongly suggest avoiding. This term seems to appear only in the Glossary, suggest removing. Senate Inquiry recommended against the use of 'Lyme-like' terms.
170	Medical professional		The multidisciplinary team should be specifically trained and educated on tick-borne illnesses, possibly even with one person on the team having a PhD in tick-borne diseases	Out of scope for the Pathway development	2	Agree, out-of-scope, the Pathway can only utilise existing resources and structures.
171	Medical professional		Include best practice guidance on how to safely remove ticks (i.e. by freezing them before removal)	A+C will include links to the Department guidance on this once it has finished development	3	This will be covered in the education material, noting these are still under development.
172	Medical professional		Interdisciplinary teams/clinics (look at Pain Clinic model) should ideally be developed at tertiary hospitals (Brisbane, Sydney, Melbourne, Perth) to manage complex cases and provide support to GPs.	Out of scope for the Pathway development	2	Agree, out of Scope, the pathway can only utilise existing resources and structures.
173	Medical professional	Consideration of mental health strategies	There needs to be further description in this section to allay the concerns of patients	A+C will discuss and consider adding more detail	3	Ok.
174	Patient groups		Include guidelines on how to manage symptoms for MUS patients	A+C will discuss and consider adding more detail	3	Ok.
175	Patient group		Include guidelines on how to talk about pain, and have difficult conversation with patients. This would help bridge the gap between the evidence-base and learned patient experience.	A+C will discuss and consider adding more detail	3	Ok.
176	**7. ONGOING MANAGEMENT**					
177	Patient group		There should be a free clinic in every state with a team of people working together, pathology, MD, psychiatry, OT and natural medicine	Out of scope for the Pathway development	2	Agree, out-of-scope, the Pathway can only utilise existing resources and structures.

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1	**Submitter**	**Text**	**Feedback received/recommended change**	**Proposed response in relation to Final Clinical Pathway**	**Code**	**Completed?**	**Discussion with DoH - 7 April/21 April**	**DoH proposed response in relation to A+C comments**
2	**Notes on document as a whole**							
3	Patient group	Lyme	All discussion of 'Lyme' should be changed to the broader 'Borreliosis' and the document be amended accordingly. This permits flexibility in the document as existing research is acknowledged, new research emerges and new species and strains are discovered. There is a disconnect between the infections the Pathway is discussing, the infections A+C believe patient groups are discussing, and the infections that patient groups and treating doctors are discussing. Patient groups and treating doctors are concerned with Borreliosis, Baronellosis, Babesiosis and a wide range of other infections.	A+C team will discuss- value DoH input?	3			Please leave it as Lyme disease. Other tick-borne illnesses will be described in detail by the suite of guidance notes and fact sheets under development.
4	Patient group		Widen the discussion of potential vectors- all referneces to 'ticks' in the Pathway should be amended to the broader 'arthropods'. More research is required on vectors. Science doesn't support the assumption that ticks are the primary vector for VBD in Australia or overseas.	Out of scope?	4	As at April 22- We will wait until we have heard more from DoH about the education sheets/list of diseases that they are including before we strip anything out	DoH expressed a preference for stripping out this information and linking to other educational resources on tick-borne diseases.	Out-of-scope. The pathway should focus on tick-borne diseases only.
5	Patient group		Remove all eferneces to "Lyme". It is unclear what the word Lyme means in the draft doc- presumably refers to just B31 strain North American 'Classical Lyme Disease'. It could also refer to Lyme Group bacteria, Borreliosis, or the broader definition that patients and treating doctors are familiar with, which is Borreliosis and co-infections.	A+C to discuss	3			Pleave leave it as Lyme disease. Other tick-borne illnesses will be described in detail by the suite of guidance notes and fact sheets under development.
6	Patient group		ACIIDS doctors develop Australian guidelines based on existing guidelines for diagnosing and treating patients with multiple infections such as Borreliosis, Baronellosis and Babesiosis. There are several guides that could be adapated for the purposes of making a clinical diagnosis in Australian patients. Suggest that Drs47F document is the most adaptable to the current Australian environment, but there are many options.	A+C to discuss	3			The clinical pathway has been formed using the (draft 2019) IDSA/AAN/ACR Lyme disease clinical practice guideline as they are evidence based. The Guidelines by the Australian Chronic Infectious and Inflammatory Disease Society are extremely controversial and should not be referenced.
7	Patient group		Remove all opinions and assumptions from the Pathway- the Department and A+C have conclued that there is no Borreliosis in humans by exlcluding research on humans and only considering research on ticks, some dogs, an echidna and a lizard. There are many unsubstantiated opinions and assumptions in the document and its supporting research papers. It could be greatly simplified by removing anything not supported by evidnece. The opinions put forward in the draft Clinical Pathway do not accord with the experience of patient groups or treating doctors.	A+C will discuss and ensure/confirm that each piece of information in the Clinical Pathway is backed up by evidence.	3			The Clinical Pathway document has both fairly and dispassionately reflected the available scientific evidence on this topic.
8	Patient group		Discuss research on humans that is relevant to the Australian context and add it to the bibiography. Remove the 'published research' and 10 year timeframe limitations of the literature review. This limit has excluded some of the most important and comprehensive research into Borreliosis and other VBD in humans in Australia.	A+C to discuss	3			The most up to date scientific literature should be used. Generally, it is good practice to use literature published in the last ten years as it refelects the most recent evidence.
9	Patient group		Research on other species does not prove the absence of VBD in humans. The literature review and Pathway excluded all research on humans in Australia and replaced it with limited research on other species and a range of opinion pieces that have not employed scientific methods or provided any new science.	A+C will discuss and ensure/confirm that each piece of information in the Clinical Pathway is backed up by evidence.	3			The Clinical Pathway document has both fairly and dispassionately reflected the available scientific evidence on this topic. The comment refers to s47F PhD thesis which was acceptable but not published. It's never been verified.
10	Patient group		Conflicts of interest in the Literature Review, bibliography and annotations need to be disclosed in the Pathway document. Conflicts of interest exist between authors and the positions they are taking in journal articles should be dislcosed in the Pathway document and persons with a conflict of interest should be xcluded from further participation in the process.	A+C to discuss	3			It is unclear what this comment is referring to. No real or perceived conflicts of interest have been declared in relation to the project. It is not standard practice to include a list of conflicts of interest in such documents. These are generally considered when assessing the reliabiity of the studies for inclusion into a report.
11	Patient group		IDSA related guidelines and journal articles should be excluded from the Clinical Pathway. Seven authors of the IDSA guidelines and eight private health insurers are currently being sued in the US.	A+C to discuss, possibly with DoH?	4	As at April 22- We will wait until we have heard more from DoH about how they would like us to approach	DoH asked us to send through some information about this controversy **(SENT 21 APRIL)**. Waiting to hear back on DoH's view on this	NICE, CDC, and IDSA can be used for reference. The NICE guidelines should be used as much as possible, as the IDSA are still in draft format and may change. Given there is no timeframe for the IDSA guideines completetion it would be sensible to use NICE where possible. If a recommendation is used from the draft guideline it would be advisable to refer back to the underlying evidence base of that recommendation.

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12	Patient group		Make the Pathway compliant with Australian Competition and Consumer Law. It is recommended that legal advice be sought on the compliance of the Clinical Pathway with ACCL, as it may be seen as endorsing anti-competitive conduct.	A+C to discuss, possibly with DoH?	4			Evidence-based recommendations will always move business away from supplements, complementary and alternative medicine services. That is not anticompetitive, it's good medical practice. Medical services already are answerable to competition laws.
13	Patient group		Gaslighting of patients should be removed from the document. It has discounted patient and treating doctor involvement in the Senate Inquiry, Patient Forum and Think Tank, as if these events did not happen. Patients and treating doctors are being gaslit through having their illness dismissed as MUS or psychological when there are proven and valid explanations for their symptoms. The Pathway in its present form systematically gaslights patients.	A+C to discuss	3			The Department notes that Allen and Clarke has undertaken stakeholder engagement, including engaging with consumers, to finalise the stakeholder pathway. The clinical pathway is intended to be an evidence-based pathway, which engages consumers, and supports the best possible outcomes for consumers.
14	Patient group		Further consultation with patient groups and medical professionals is required, including a face to face meeting where all stakeholders can work cooperatively through the final draft of the Pathway. It should be distributed to stakeholders at least 6 weeks prior to the event.	Out of scope	2	No action		The Department will engage with stakeholders prior to the finalisation of the pathway. A face to face meeting to review document prior to finalisation will not be possible in this climate, however the Department will continue enagaging with stakeholders on this work. COVID-19 has proven the benefit of telemedicine.
15	Patient group		ILADS practitioners need to be consulted and listened to- the Pathway discounted the experience of the ILADS trained practitioners who are best placed to deal with this emerging epedemic. These doctors need to represent the bulk of the medical professionals involved in further consultation. They are the only ones with an appropriate experience and knowledge base in the Australian context. They are the only group of doctors that patient groups will support and trust.	A+C to discuss, possibly with DoH?	4			The Clinical Pathway is intended to be evidence-based, and informed by consultation. Equal consideration has been given to all feedback received through the process.The ILADS guideline lacks credible evidence-based protocols.
16	Patient group		The Pathway is too restrictive in terms of which practitioners are allowed to assess/diagnose/treat patients. There are experienced/knowledgeable practitioners in the marketplace who should not be disadvantaged.	A+C to discuss	3			The pathway must be clinically relevant and generally accepted by the Australian medical profession including who provides such services in terms of training etc. The advice must be consistent with accepted medical practice and must be accepted by the broad medical profession until real evidence requires change in practice.
17	Patient group		The Pathway provides no process for pracititoner upskilling/training/education int his area to develop in this area of medicine. Either the local experts train the practitioner market or international experts should be brought in to do this.	Out of scope	2	No action		Out of scope. The clinical pathway is a tool for identifying appropriate treatment for patients, it is not a professional development tool. Individual practitioners are responsible for their professional development.
18	Medical professional		The Pathway must be MULTIDISCIPLINARY - it needs the team work of all colleges of physicians because DSCATT is a multi-systemic disease	A+C to discuss	3			The management of symptoms would be a multidisciplinary effort, and the clinical pathway should reflect this approach.

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19	**Differential diagnosis**							
20	Patient group	History	Borrelia, bartonella and babesia have also been proved to be able to be transferred vertically (from mother to child).	A+C team to discuss including other forms of transmission according to the evidence available. Discussion with DoH will be valuable.	3	Comment added- 8 April 2020		Base on the available scientific evidence.Vertical transmission does not necessarily result in symptomatic disease and if it does, the expression may vary. The evidence used must be firm and clear if this is going to be included.
21	**Initial management**							
22	Medical professional		Useful link explaining stepped care: https://www.chnact.org.au/what-is-stepped-care	A+C team will discuss potentially adding links to useful information- may depend on how DoH chooses to publish the Pathway	3			Some additional text may be useful however GPs should be familiar with the general use of a stepped care approach.
23	**1.4. Management of patients with persistent symtpoms or who remain undiagnosed**							
24	Patient group	it is especially important to esnure that patient or person-centred care is provided that validates, addresses and manages their symptoms as well as possible	Natural remedies have helped immensely as I have multiple allergies to many pharmaceutical medications and many more now with the Alpha/Gal allergy, I must be careful even with natural remedies making sure they do not contain mammalian ingredients. This point is discriminative when one has limited options and even more so when they do help.	Discuss with DoH- A+C technical Advisory will draft clarification to address this point and to also bring alignment with NHMRC guidelines on complementary and alternative therapies	3	Comment added- 8 April 2020		Note and support Allen and Clarke's recommended response. The Clinical Pathway should be evidence based.
25	**3.1. Lyme disease**							
26	Patient group	TITLE and throughout this section	Lyme disease an tick-borne relapsing fever. This is because Borrelia miyamotoi that causes TBRF is transmitted by the same hard ticks that transmit Borrelia burgdorferi, the causative agent of Lyme disease. TRBF caused TRBF borrelia transmitted by soft ticks are prevalent in the Americas, Europe, Asia and Africa.	A+C to discuss, possibly with DoH?	4	As at April 22- We will wait until we have heard more from DoH about the education sheets/list of diseases that they are including before we strip anything out	DoH expressed a preference for stripping out this information and linking to other educational resources on tick-borne diseases.	Lyme disease should not be described as a relapsing fever just because one species varies in its presentation. The variation can be called out, but Lyme disease should not be classified as a relapsing fever. It creates further confusion when it can be made clear. Other tick-borne illnesses will be described in detail by the suite of guidance notes and fact sheets under development (including Relapsing Fever Borreliosis).
27	Patient group		Diagnosis and treatment should be by local GPS. Patients want to be treated by their GP. This is the most efficient and cost-effective way to deliver care for both patients and the taxpayer. In a large country like Australia, it makes no sense to require seriously ill patients to travel unnecessarily. Specialist Pathologists and ID doctors have failed to deliver adequate diagnosis, treatment and ongoing support for over 30 years.	A+C to discuss	3			While GPs can use the pathway, diagnosis is challenging, thus it is important to seek opinons of experts in vector-borne diseases including specialist pathologists with diagnostic experience. The management of these complex patients must be a collaborative approach between GP and specialists. GPs alone are not sufficently trained to look after patients just by themselves. Telehealth may alleviate some of these issues.
28	Patient group		The Clinical Pathway ignores relapsing fever Borrelia. There is no testing of this in Australia, and it assumes that Lyme disease Borrelia cannot be acquired in Australia and "cases of overseas acquired Lyme disease are very rare." These assumptions are without suppoting evidence and a significant body of evidence to the contrary exists. There is a notable boabsence of discussion on Bartonella, mycoplasma and chlamydia which form part of the disease profile globally recognised in patients with tick-borne infection.	A+C will discuss and ensure/confirm that each piece of information in the Clinical Pathway is backed up by evidence.	3			There is no evidence of relapsing fever in Australia and the diagnosis of relapsing fever is microscopy because the species which cause relapsing fever preferentially live in the vascular system rather than soft tissue.

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29	Patient group		Add 3.1.2- Transmission and Distribution of Tick- Borne Relapsing Fever Tick-borne Relapsing Fever is endemic in parts of USA, South America, Europe, Asia and Africa. A person visiting TBRF-endemic area may become infected with Tick-Borne Relapsing Fever Borrelia though a tick bite and subsequently develop Tick-borne Relapsing Fever. Overseas travellers to TBRF-endemic areas may return to their home country before becoming symptomatic and/or being diagnosed. TBRF disease is an infectious disease that can be transmitted to humans who are bitten by a tick carrying different species of Borrelia bacteria (spirochaetes) collectively known as Tick-Borne Relapsing fever Borreliae. There are two types of Tick-borne relapsing fever. (1) Tick-borne relapsing fever (TBRF) (2) B. miyamotoi disease (sometimes called hard tick relapsing fever). TBRF is transmitted by soft ticks of the genus Ornithodoros. The TBRF Borrelia species that are best known to cause TBRF in the USA are B. hermsii, B. miyamotoi, B. parkeri, and B. turicatae.A1 However, other TBRF Borrelia species that cause TBRF continue to be identified, for example, a patient infected with B. johnsonii-like species, previously found only in bat ticks, was recently identified in humans. TBRF has also been reported in Central and South America.A3 Borrelia hispanica,A4 B. persica, are important causes of TBRF in Europe and Asia, and B. hispanica, B. crocidurae, and B. duttonii are important causes of TBRF in Africa.A6 Borrelia miyamotoi disease is transmitted by the same hard ticks of the genus Ixodes that transmit Lyme Disease Borreliae.A7, A8 Therefore Lyme and B. miyamotoi disease occur in overlapping localities where their vectors are present. A7-A9	A+C to discuss	3			Lyme disease should not be described as a relapsing fever just because one species varies in its presentation. The variation can be called out, but Lyme disease should not be classified as a relapsing fever. It creates further confusion when it can be made clear. Other tick-borne illnesses will be described in detail by the suite of guidance notes and fact sheets under development (including Relapsing Fever Borreliosis).
30	Patient group	Transmission in pregnancy, sexual contact or blood products	However, TBRF contracted during pregnancy can cause spontaneous abortion, premature birth, and neonatal death. The maternal-fetal transmission of Borrelia is believed to occur, either transplacentally or while traversing the birth canal. In one study, perinatal infection with TBRF was associated with lower birth weights, younger gestational age, and higher perinatal mortality.A10	A+C to discuss	3			Relapsing fever doesn't occur in Australia. This is when any traveller who is pregnant and who develops a fever should be referred to an infectious diseases physician who are trained in global health and almost always have training albeit often not certified in tropical medicine.
31	Patient group	Situation in Australia in considering a differential diagnosis of Lyme disease	However, the TBRF Borrelia, Candidus Borrelia tachyglossi closely related to B. crocidurae has been identified in echina ticks but not in patients. A11	A+C to discuss	3			This has no relevance to the pathway because transmissibility and pathogenicity has not yet be demonstrated.
32	**3.2. Tick-borne disease known to be acquired in Australia**							
33	Patient group		There is no mention of the Alpha/Gal mammalian meat allergy that is transmitted by tiucks or anything about testing for this condition/allergy by doctors or making people aware of this allergy.	A+C to discuss	3			Other tick-borne illnesses will be described in detail by the suite of guidance notes and fact sheets under development (including MMA).
34	**4. DIAGNOSTIC TESTING**							
35	Patient group		Acknowledge that patients will have multiple infections that require treatment. There is a very high probability that each patient will have multiple infections, and there is aso the possibility of patients being infected with multiple strains of the same pathogen. This high probability is recornised by ILADS and ILADS trained medical doctors. In practice, the old 2006 IDSA Guidelines only recognise 'Classical Lyme Disease' that is transmitted through only 2 species of ticks, as well as HGA and Babesiosis. They don't recognise the strain and species diversity of these pathogens and rely exclusively on serology. They do however recognise the need for clinical judgement, but this does not appear to be acknowledged in Australia under the prevailing dogma or within the Pathway document.	A+C to discuss	3			The probability of coinfections depends on the epidemiology of the diseases/infections in question. So far, there has not be clear evidence of coinfections with tick borne infections in Australia.
36	**4.2. Tick-borne disease known to be acquired in Australia**							
37	Medical professional		Current testing methods are inadeuqate in diagnosis of DSCATT. The limitations of diagnostics should be understood and also utilised to explore alterantive diagnosis e.g. ELISA or other antibody based diagnostics assume a competent immune system and many DSCATT patietns are not. So testing immuno-competence would be helpful. Current diagnostics are focused on Lyme rather than exploring pathogens outside the norm and focus on zoonosis not hype. We need to move away from mon-pathogenic, mono-systemic diseases.	A+C to discuss	3			The assumption that any degree of compromise to the immunological system impairs antibody production is incorrect. It may be true in severely immunocompromised people, e.g., after a bone marrow transplant or in aplastic anæmia.
38	**5.1. Lyme disease**							

	A	B	C	D	E	F	G	H
39	Patient group		Diagnosis will require judgement buy medical professionals and cannot rely on serology alone. There are at least 52 species of Borrelia with over 300 known strains. NATA labs test for 2 species of Borrelia, which is 4% of known species. It is unclear how diagnosis could be made purely on NATA or even overseas serology without Borrelia testing and research still being immature. This means that medical professionals need to be able to exercise jurdgment in making a diagnosis, rather than relying on serology alone. Medical professionals should not be restricted by guidelines or be required to comply with existing dogma. There are 45 known species of Bartonella, yet NATA labs only test for 1-2 species or 4.5%.	A+C to discuss	3			The clinical pathway should reflect that laboratory testing in NATA accredited labs can detect tick-borne illnesses.Clinical judgement by competent medical practitioners is always important.
40	Patient group		Remove the recommendation for two-tiered testing for Borreliosis. The use of two-tiered testing was developed for surveillance purposes. This approach uses n Elisa test initally, then the result is confirmed with a Western Blot. In Australia, we do not know all of the species and strains of Borrelia that are cuasing disease in humans. NATA labs currently use Western Blot tests designed for 2 species of Borrelia when there are over 52 known species. This means that for a Western Blot to be useful in Australia, we need to cover as many strains as commercial test kits will allow. We also need to recognise the signficance of test results that have 1 to 4 positive bands, are IgG or IgM positive, along with signs and symptoms of the patient.	A+C to discuss	3			The clinical pathway should reflect that laboratory testing in NATA accredited labs can detect tick-borne illnesses.
41	Patient group		Acknowledge the signficance of partially positive Western Blot testing for Borreliosis and that positive IgM may indicate long standing illness in Australian cases. The Pathway needs to ecognise the signficance of Western Blot results that have 1 to 4 positive bands and are IgM positive, as well as the clinical presentation of the individual patient. Medical professionals cannot explain the reasons for this occurring in some Australian patients. If the patient is symptomatic and has 1 or more positive bands or a positive IgM, they should be treated.	A+C to discuss	3			The clinical pathway should reflect that laboratory testing in NATA accredited labs can detect tick-borne illnesses. Reference should not be made to a 'partially positive western blot', as it is not medically correct.
42	Patient group		In the absence of a comprehensive Australian Western Blot panel for Borreliosis, the CD57 on NK cells is currently the most useful serological test. The CD57 on NK cells test can provide a clinician additional information to make their diagnosis. While there are differing opinions, the test is inexpensive, low risk and may also be used as a gauge of treatment progress.	A+C to discuss	3			The clinical pathway should reflect that laboratory testing in NATA accredited labs can detect tick-borne illnesses. CD57 is not specific and not a marker of Lyme disease.
43	Patient group		Send Borrelia tests to overseas labs that havea wider strain and species coverage and cover these tests under Medicare. Patient groups have no confidence that NATA labs have the knowledge, experience or resources to conduct Borreliosis, Bartonell or Babesia testing. Igenix, Arminlabs, Infectolab etc test for a broader range of Borrelia, Bartonella and Babesia speciesthan he NATA labs. Another option might be for NATA labs to use test kits from IGenix or Arminlabs after reciving training from these labs and ILADS trained doctors. If this option is used NATA lab staff should nto provide any advice to treating doctors but just run the tests. There is a long history of misleading advice being provided to doctors and patients by one lab.	Pathologists commented that they were able to do all these tests in NATA/RCPA accredited labs and would do them if they thought they were necessary. NATA/RCPA accredited labs will send samples to other accredited labs if a wider range of testing is needed, and samples which need testing for particularly rare diseases may be sent to the CDC.	3	No action		The clinical pathway should reflect that laboratory testing in NATA accredited labs can detect tick-borne illnesses.NATA/RCPA accredited laboratories using the NPAAC requirements with relevant testing listed in scope of accreditation is sufficient.
44	Patient groups		Acknowledge existing Australian Seroprevalence surveys. It is unclear to this group how the Pathway would exist without supporting broad strain/species seroprevalence surveys.	A+C to discuss	3			There are no good seroprevalence surveys yet.
45	Patient group		The Pathway presumes (incorrectly) that the only suitable diagnostic laboratory is a NATA accredited lab. Overseas labs are suitably accredited and also offer broader testing options than local Australian labs. They should not be ruled out for provision of diagnostic testing of DSCATT.	Pathologists commented that they were able to do all these tests in NATA/RCPA accredited labs and would do them if they thought they were necessary. NATA/RCPA accredited labs will send samples to other accredited labs if a wider range of testing is needed	3	No action		The clinical pathway should reflect that laboratory testing in NATA accredited labs can detect tick-borne illnesses.NATA/RCPA accredited laboratories using the NPAAC requirements with relevant testing listed in scope of accreditation is sufficient.

PROJECT STATUS REPORT

Project name: DSCATT Clinical Pathway

Prepared by: s47F

Prepared for: s22

ALLEN+CLARKE AUSTRALIA

Period covered: 1/6/20 - 30/6/20

Client: Department of Health (Australia)

Main activities this period

s22

Final Clinical Pathway

- Nil. Awaiting response from DoH on coded table of feedback, to inform final Clinical Pathway. Discussion with DoH on 23 June indicated feedback would be forthcoming shortly.

Literature review

- Continued to revise the draft literature review, consistent with information provided in the monthly report for May, with more detailed analysis of the evidence for the research questions 'Issues with diagnostic testing for Lyme disease in Australia and internationally' and 'What is the evidence-base for the treatments'. Awaiting response from DoH on any additional areas of research that might be required to inform the final Clinical Pathway.

s22

Main activities next period

Final Clinical Pathway

- Receive written feedback from DoH on the coded table of feedback, to inform final Clinical Pathway.
- Develop final Clinical Pathway (short doc + evidence doc), based on advice from DoH and with input from technical advisors s22

s22

Literature review

- Finalise literature review once approach agreed, to be informed by DoH feedback on the coded table of feedback.
- Discuss and agree an appropriate revised delivery date to allow for technical advisor review prior to provision to DoH. s22

s22

From:	s22
To:	s47F
Cc:	s47F s22 s22
Subject:	RE: DSCATT clinical pathway - DoH comments on stakeholder feedback [SEC=OFFICIAL]
Date:	Friday, 10 July 2020 5:21:59 PM
Attachments:	image001.png Table 2 of 2 - DSCATT Clinical Feedback Table - Second Table of Feedback - DoH comments - 120620.XLSX Table 1 of 2 - DSCATT clinical pathway feedback table - DoH comments - 100620.XLSX

Dear s47F ,

There have been a few staffing changes at the department, so while the section is being reorganised I am assisting the team with the DSCATT clinical pathway.

Attached are two tables containing the department's responses to Allen and Clarke's suggested actions in response to feedback received from stakeholders on the draft DSCATT clinical pathway.

In light of the feedback received from stakeholders we have provided the following comments for you to consider.

Overarching comments

- It would be useful to highlight the clinical pathway is not instructive but a tool, but a pathway to help structure assessments and management of patients that present with a wide variety of symptoms and severity of disability. The GP would develop the management plan in consultation with the patient so the patient can achieve their goals.
- That there should be a pictograph that is essentially be a summary of the current large document. This suggests that the current summary doesn't contain sufficient information for clinicians to pick up the summary/flow diagram and work through it. It will be good to hear Allen and Clarke's approach to how this will be achieved.

Summary information

- The focus on the patient in the summary of 'management of patients with persistent symptoms or remain undiagnosed' is missing patient engagement. The content in the clinical pathway highlights the importance of listening to the patient, and that where patient concerns are fully acknowledged, their satisfaction is greater, providing acceptable explanations, practical and constructive advice is essential.
- It would also be good to understand whether the literature on harm minimisation also reflected the above engagement, and whether that should be included as part of the harm minimisation here and in the related chapter.

Introduction

- While the primary audience for clinical pathway is clinicians, it is also focused on consumers, given the recommendations are for a patient-centred approach. This collaborative approach could be more strongly conveyed in the opening chapter, to set the tone of the document, for example including an emphasis on careful initial examination and detailed patient history being important, and working with the patient and the multi-disciplinary team to achieve patient goals. Some of the elements of patient centred care are included through the document (e.g. under the medically unexplained symptoms chapter, and would be good to introduce here).
- While there is talk of DSCATT, the introduction doesn't touch on Lyme disease. Given the sections of the clinical pathway are structured to include 1) Overseas Lyme disease 2)

Australian vector borne diseases, it is worthwhile having a section on Lyme disease in the introduction that highlights that there is a high degree of uncertainty as to the cause of these debilitating symptoms, the bacteria that causes Lyme disease overseas hasn't been detected in Australia, work is ongoing in this space, and other vectors may carry pathogens that cause illness in individuals that are susceptible – which is why it is essential to have an open mind to the causes of DSCATT.

- The pathway can state in its intro that there is ongoing research into DSACTT , including to identify its aetiology.
- There should also be a reflection that should the evidence base change significantly, then the clinical pathway may be reviewed.

Initial assessment

- The information should be presented more clearly for GPs on what signs and symptoms flag consideration of DSCATT. The summary section on this topic area acknowledges that clinical features can be similar to many other diseases (which would make this challenging). The more detailed 'initial assessment and support" refers to debilitating symptoms. Without some indication of the types of clinical features (i.e. some examples) of what 'debilitating' means, it may be unclear to the physician as to what factors suggest following this clinical pathway.

Differential diagnosis

- The differential diagnosis chapter would benefit from a summary table that compares and contrasts presenting signs and symptoms (could be split into acute and chronic); pathogenesis (suspected of known), possible vectors/exposures; geographical area; identification of at risk groups; and references to additional guidance could be presented in a easier format and, maybe a comparison table of signs and symptoms. (It could even be in as an appendix).
- 3.2.4 appears to be treatment.

Diagnostic testing

- NATA /RCPA accredited testing is important to as this builds a standardised clinical picture for Australia and clinicians understand what testing has been performed.
- It would be useful for clinicians to have a list of tests and their indicators, particularly if they are unfamiliar with these conditions.
- Also it would be good to state when consultation with multidisciplinary team eg, ID/ pathologist /microbiologist/ immunologists etc is indicated (based on results)

Management

- There is an emphasis on patient centred care, but there is also need to stress the multi-disciplinary approach for the management of the diverse range of chronic symptoms experienced by patients.
- It is not clear when referral to a specialist is required.

Please feel free to call the team if you require further clarification of any of the points raised. It would be good to schedule a time to discuss the timing for receipt of the two outstanding project deliverables – a Literature Review and the Final Clinical Pathway.

Kind regards

s22
Director – Antimicrobial Resistance Policy
Office of Health Protection Division | Chief Medical Officer Group
Health Protection Policy Branch
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amr.gov.au | Subscribe to AMR updates

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s47F
To: s22
Cc: s47F
Subject: DSCATT Clinical Pathway- revised Algorithm and monthly Progress Report [SEC=No Protective Marking]
Date: Monday, 10 August 2020 9:14:59 AM
Attachments: image002.png
image003.png
Clinical Pathway Diagram_7 August 2020 (three columns).pdf
DSCATT Clinical Pathway - Progress Report 7 Aug 20.pdf

Hi s22

Please find attached our monthly Progress Report.

A couple of key points to note:

- All the work we covered last week (and below) is underway at our end
- The revised Pathway will be back with you at the end of this week
- We have updated the algorithm as discussed (copy attached) and are keen to receive any additional feedback this week
- We are proposing to do no further work on the Lit Review (now that we understand the wider intention about how the guidance notes etc will work) – we recommend we reframe the existing A+C Lit Review into an "evidence review to support the development of the Clinical Pathway" and that it be retained in a non-published form – this would align with its current use and assist with completing this part of the work. We are interested in your thoughts on this approach?
- s22

Please let me know if you would like to discuss anything in further detail.

Kind Regards,

s47
s47F
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Allen + Clarke acknowledges the Traditional Custodians of the land we work on and the communities that we work with. We acknowledge their history, culture and Elders past, present and emerging.

From: s47F
Sent: Tuesday, 4 August 2020 1:00 PM
To: s22
s22
Cc: s47F
s47F
Subject: DSCATT Clinical Pathway- follow-up from teleconference with DoH and A+C - 3 August 2020

Hi everyone,

Thanks for making time for the call yesterday. It was great to discuss the work, feedback loop comments and next steps in some detail.

I noted down the following agreed actions:

Allen + Clarke:

- Wider scope of the Pathway - Include another box, if possible or change wording in the two current boxes related to tick-borne illness under differential diagnosis to accommodate other overseas acquired tick-borne diseases covered in the educational resources
- Algorithm - Retain the algorithm, add additional boxes where necessary for completeness
- Pictogram - Consider inclusion of a pictogram (see DoH actions below)
- Complimentary medicine - include additional paragraph(s) on alternative and complementary medicine
- Other DSCATT research - include additional paragraph on NHMRC funded research
- Minor changes - Make all agreed minor changes to wording throughout the document
- Mental Health/pain management – hold any further work in this area until a decision is made on the education resources and guidance notes

Department of Health:

- Pictogram – consider further the audience for the pictogram and share some examples of good pictograms with A+C.
- Evidence base for the Pathway – consider further whether the Pathway evidence base has primacy, or the guidance note evidence base.

Alignment of the fact sheets and resources with DSCATT CP evidence base

Allen + Clarke:

- Alignment of evidence sets - We have undertaken a quick comparison of a small number of the fact sheets/resources against the evidence base in the Pathway and the draft Lit Review. The rough and ready analysis (attached) shows that there is very little crossover in the evidence base between the two workstreams.

Review of the fact sheets and resources

Department of Health:

Review and finalisation of the resources – consider further the best approach to finalising the resources (possibly commissioning A+C through a change of scope)

Next steps with the Pathway

- A+C to make all the revisions outlined above and provide a new draft to the Department early next week (Word version, PDF with tracked changes, updated Excel of Feedback Loop).

Please let me know if I have missed anything off my list.

Kind Regards,

s47F

s47F

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Please consider the environment before printing this email

s22

PROJECT STATUS REPORT

Project name: DSCATT Clinical Pathway

Prepared by: s47F

Prepared for: s22

ALLEN+CLARKE AUSTRALIA

Period covered: 1 Jul - 7 Aug 20

Client: Department of Health (Australia)

Main activities this period

s22

Final Clinical Pathway

• Received and reviewed feedback from DoH on coded tabled of feedback, to inform final Clinical Pathway. Discussion with DoH on 3 August regarding feedback and our proposed response. Received draft versions of Factsheets and Guidance Notes for review. Undertook short comparison of evidence bases.

Literature review

• Nil. No further work expected on the Lit Review noting that alternative evidence will be included/alongside the Patway.

s22

Main activities next period

Final Clinical Pathway

• Revise final Clinical Pathway based on feedback from DoH and discussion on 3 August, with input from Technical Guidelines Advisor. Amend algorithm, add new paragraphs as discussed and make all agreed minor changes to wording throughout the document.

• Provide a new draft to DoH around 15 August (Word version, PDF with tracked changes, updated spreadsheet of feedback loop).

Literature review

• No further work scheduled.

s22

s22

From: s22
To: s47F
Cc: s22 s47F s22
Subject: RE: Revised DSCATT Clinical Pathway [SEC=OFFICIAL]
Date: Wednesday, 2 September 2020 6:53:00 PM
Attachments: image002.jpg
DSCATT Draft Clinical Pathway - 14 August2020 cleared.docx

Hello s47F and team.
Thank you for providing this draft and apologies in getting back to you a few days late.

The majority of our comments have been addressed in this draft and the majority of feedback relates to wording of some sentences, statements, recommendations. We have discussed the issue of TBE and it can be removed from the pathway given the complementary education material that will be available.

I think the pathway could be enhanced slightly with the inclusion of some text in key areas to consider mental health strategies as part of management of patients with Medically Undiagnosed Symptoms. There is a statement added on the link between chronic medical conditions and mental health (p.52) which is useful. Could consideration be given to the addition of mental health to the summary information section (as GPs may only look at this section).

I acknowledge that this had been discussed earlier but in looking back at the feedback from the medical professionals and they indicated the importance of considering mental health strategies as part of the ongoing management of patients presenting with DSCATT.

Please contact me if you have any other questions or queries.

Kind Regards

s22

From: s47F
Sent: Friday, 14 August 2020 3:59 PM
To: s22
Cc: s22
s22 s47F
s47F
Subject: Revised DSCATT Clinical Pathway [SEC=No Protective Marking]

Hi s22
It was lovely to talk yesterday and to meet you virtually. It was lovely to talk with you too s22 even though you were unable to join by video.

Thank you for the helpful discussion and for clarifying specific points about the deliverables.

As indicated in Paul's emails we have been working to revise the Draft Clinical Pathway. We have attached two versions- a pdf that shows all of the track changes, new text , comments and questions, and a clean Word version.

We have reverted to the original algorithm now we understand the 'other overseas acquired tick-borne diseases' are not to be included in this Clinical Pathway. We have retained the information on TBE (the only overseas acquired tick borne disease currently in the Draft Clinical Pathway), but welcome your thoughts on whether this disease is retained in the Clinical Pathway as were work towards finalising it.

We have made the approved text changes from the feedback tables and drafted new text, where requested. We have also added the references cited by the 2019 IDSA/AAN/ACR draft Lyme disease guidelines where we have included a recommendation of IDSA/AAN/ACR.

We have made some suggested changes to the order of subsections to help improve flow and clarity. We welcome your thoughts on these changes.

We have also addressed most of the points you raised in your email (overarching comments and comments on specific sections), except for three points where we would be grateful for further discussion about the department's expectations.

These are the following points in the DSCATT Clinical Pathway Feedback Table Control Sheet:

- ID 10 (the addition of a summary table that compares and contrasts presenting signs and symptoms)
- ID 13, 14 (Diagnostic testing)

Additionally, we have not as yet added in the findings of the paper, "A minority of children diagnosed with Lyme disease recall a preceding tick bite" as the paper is not freely accessible. We wonder if the department may be able to access it for us please?
https://www.sciencedirect.com/science/article/abs/pii/S1877959X18304965

We would be most grateful if you were able to provide your comments on this revised draft by the end of August so that we are able to progress to finalising the Clinical Pathway for you, including the peer review process by our Expert Medical and Guidelines Technical Advisors.

As always, we are more than happy to discuss any aspect of this work.

Kind regards
s47F

s47F

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From: s47F
To: s22
Cc: s22 s47F
Subject: DSCATT Literature review
Date: Monday, 21 September 2020 4:33:05 PM
Attachments: image003.jpg
Assessment of literature from DSCATT stakeholder consultation.docx

Hi s22

You asked for an update about the DSCATT literature review.

To progress the literature review, we are proposing to undertake the following steps:

- Review the latest version of the literature review and align this version of the literature review with the recent changes made during the finalisation process of the DSCATT Clinical Pathway (underway)
- Discuss with the Department the Inclusions/Exclusions in the attached tables (shared on in this email)
- Critically appraise additional literature (not yet started)
- Undertake internal QA and peer-review
- Provide second draft to the Department

At this stage we expect to provide a second draft to the Department on Friday 9 October.

I mentioned last week we had prepared a set of tables (attached to this email) that relate to the books, articles and websites that stakeholders had provided during the DSCATT Draft Clinical Pathway stakeholder consultation period (November 2019-January 2020) as they wished these to be considered for inclusion in the literature review. These books, articles and websites were included in Appendix 2: Suggested additional evidence of the Stakeholder Consultation Report we previously provided.

We have assessed the suggested literature against the ToR of the literature review, the finalised Clinical Pathway, and considerations around the hierarchy of evidence. In the attached document we have three sets tables of tables (for inclusion; for discussion with DoH; not for inclusion) which we seek the Department's decision on please.

As always, we are happy to discuss.

Kind regards

s47F

s47F

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Assessment of books, scientific articles and websites from stakeholder consultation

This document provides *Allen + Clarke's* assessment of books, scientific articles and websites that were provided to us by stakeholders during the stakeholder consultation phase (13 November 2019 to 24 January 2020) for the Draft DSCATT Clinical Pathway in the expectation that they would be considered for inclusion in the literature review. These books, articles and websites were included in Appendix 2: Suggested additional evidence of the Stakeholder Consultation Report we previously provided.

We assessed and critically appraised each source received according to our original search parameters and criteria where appliable, which were:

- 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.

This document consists of 3 parts:

1. Sources that have been or will be included in the literature review
2. Sources for discussion with the Department
3. Sources not to be included.

Contents

1. ALREADY INCLUDED OR TO INCLUDE

1.1. Scientific articles assessed as already included or for inclusion

Scientific articles (description of the material)	A+C assessment	Change required to Lit Review
Expert Review of Anti-infective Therapy, "Evidence assessments and guideline recommendations in Lyme disease: the clinical management of known tick bites, erythema migrans rashes and persistent disease": https://www.tandfonline.com/doi/full/10.1586/14787210.2014.940900	Aligns to 2014 ILADS Guidelines Already included in literature review.	No change
Internal Medicine Journal, "A Description of 'Australian Lyme Disease' Epidemiology and Impact: An Analysis of Submissions to an Australian Senate Inquiry: Australian Lyme from Senate inquiry": https://www.researchgate.net/publication/322685589_A_Description_of_'Australian_Lyme_Disease'_Epidemiology_and_Impact_An_Analysis_of_Submissions_to_an_Australian_Senate_Inquiry_Australian_Lyme_from_Senate_inquiry	Article by Brown (2018). Already included in literature review and Draft DSCATT Clinical Pathway.	No change
International Journal of General Medicine, "Clinical determinants of Lyme borreliosis, babesiosis, bartonellosis, anaplasmosis, and ehrlichiosis in an Australian cohort": https://www.ncbi.nlm.nih.gov/pubmed/25565883	2014 article Identified in literature review search. Reviewed by Chalada et al. under Lyme-like cases. Also includes information about anaplasmosis and erhlichiosis in Australia. Covered in literature review.	No change
International Journal of General Medicine, "Commercial test kits for detection of Lyme borreliosis: a meta-analysis of test accuracy": https://www.ncbi.nlm.nih.gov/pubmed/27920571	Cook & Puri (2016). Identified in literature search and included in lit review.	No change
Lancet Infectious Diseases, "Antiscience and ethical concerns associated with advocacy of Lyme disease": https://www.ncbi.nlm.nih.gov/pubmed/21867956	Recommended by ID Physician. Already included in the literature review A viewpoint article but evidence-based information on	No change

	• Symptomatology esp subjective symptomology and promotion long-term disease by Lyme literate medical doctors • Antiscience about transmission of Lyme disease • Background to ILADS guidelines • Use of long-term antibiotics and dangers – CDC/NIH trials that showed no improvement with long-term antibiotics • Deaths by other alternative medicines eg bismuth • Anitscience about diagnostic testing of Lyme disease • Diagnostic tests not recommended	
Mayne P, Song S, Shao R, Burke J, Wang Y, Roberts T "Evidence for Ixodes holocyclus (Acarina: Ixodidae) as a vector for human lyme Borreliosis infection in Australia.": https://www.ncbi.nlm.nih.gov/pubmed/25434042	Article already identified in literature review	No change
One Health, "Is there a Lyme-like disease in Australia? Summary of the findings to date": https://www.ncbi.nlm.nih.gov/pubmed/28616477	Chalada et al. (2016) Already included in lit review.	No change
Ticks and Tick-borne Diseases, "A minority of children diagnosed with Lyme disease recall a preceding tick bite": https://www.sciencedirect.com/science/article/abs/pii/S1877959X18304965	2019 article. A+C has included the findings in the revised DSCATT Clinical Pathway. This article is not free to the public. Abstract: Of 1770 children undergoing emergency department evaluation for Lyme disease, 362 (20.5%) children had Lyme disease. Of those with an available tick bite history, only a minority of those with Lyme disease had a recognized tick bite (60/325; 18.5%, 95% confidence interval 14.6–23.0%). Lack of a tick bite history does not reliably exclude Lyme disease.	Include in the Lit Review

1.2. Websites and other material assessed as already included or for inclusion

Websites	A+C assessment	A+C recommendation
22/11/2019 WA Health et al. DSCATT Consultation meeting notes and actions	These notes and recommendations have been taken into account in the stakeholder consultation feedback tables.	No change
Australian Rickettsial Reference Laboratory tests offered (2017). Retrieved from https://www.rickettsialab.org.au/tests-performed	Include. We have included the link to this website in the revised DSCATT Clinical Pathway and will include it in the literature review.	Include in the Lit Review
Centers for Disease Control and Prevention, "Case Definition and Report Forms" website: https://www.cdc.gov/lyme/stats/forms.html	This is covered in the literature review under the discussion about CDC surveillance of Lyme disease.	No change
ILADS Guidelines on Lyme disease: 'Evidence assessments and guideline recommendations in Lyme disease: the clinical management of know tick bites, erythema migrans rashes and persistent disease': https://www.tandfonline.com/doi/full/10.1586/14787210.2014.940900	Included in scientific articles (above). Included in literature review, under discussion on international guidelines for treatment of Lyme disease.	No change
ILADS guidelines (website): https://www.ilads.org/patient-care/ilads-treatment-guidelines/	Already included in literature review	No change
Parliament of Australia, "Final report: Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients":	Already included in literature review and DSCATT Clinical Pathway.	No change
The tick disease toolkit by the Royal College of General Practitioners UK (website): https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/lyme-disease-toolkit.aspx	Not included to date. We can include in the literature review as additional international guidance.	Include in the Lit Review

2. FOR DISCUSSION WITH THE DEPARTMENT

2.1. Scientific articles requiring discussion with DoH

Scientific articles	A+C assessment	A+C recommendation
BMC Public Health, "Characteristics and patient pathways of Lyme disease patients: a retrospective analysis of hospital episode data in England and Wales (1998–2015)": https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-7245-8	Prevalence data for England and Wales. Open access journal There is already high-level information about the geographical distribution of Lyme disease in the DSCATT Clinical Pathway. Beyond scope? UK is a Lyme disease endemic area- relevance to patient pathways Australia? 2019 article Abstract: Background: Lyme disease is a tick-borne disease of increasing global importance. There is scant information on Lyme disease patient demographics in England and Wales, and how they interact with the National Health Service (NHS). Our aims were to explore the demographic characteristics of Lyme disease patients within the Hospital Episode Statistics (HES) and Patient Episode Database for Wales (PEDW), and to describe patient pathways. Methods: Data from 1st January 1998 to 31st December 2015 was retrieved from the two administrative hospital datasets (HES and PEDW), based on patients coded with Lyme disease. Information was collected on demographic characteristics, home address and case management. Incidence rates were calculated, and demographics compared to the national population. Results: Within HES and PEDW, 2361 patients were coded with Lyme disease. There was a significant increase ($p < 0.01$) in incidence from 0.08 cases/100,000 in 1998, to 0.53 cases/100,000 in 2015. There was a bimodal age distribution, patients were predominantly female, white and from areas of low deprivation. New cases peaked annually in August, with higher	Discuss with DoH

	incidence rates in southern central and western England. Within hospital admission data (*n* = 2066), most cases were either referred from primary care (28.8%, *n* = 596) or admitted via accident and emergency (A&E) (29.5%, *n* = 610). This population entering secondary care through A&E suggest a poor understanding of the recommended care pathways for symptoms related to Lyme disease by the general population. Conclusions: These data can be used to inform future investigations into Lyme disease burden, and patient management within the NHS. They provide demographic information for clinicians to target public health messaging or interventions.	
Healthcare, "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": https://www.ncbi.nlm.nih.gov/pubmed/30400667	Dr Horowitz is an author Dr Horowitz also sent this article to A+C earlier in 2019.	Discuss with DoH
Clinical Infectious Diseases, "Detection of IFN-γ Secretion by T Cells Collected Before and After Successful Treatment of Early Lyme Disease": https://www.ncbi.nlm.nih.gov/pubmed/26936671	Relevant to issues for diagnostic testing of Lyme disease. A very small study. Consider for inclusion in section on future developments in diagnostic testing for Lyme disease Clin Infect Dis. 2016 May 15;62(10):1235-1241. doi: 10.1093/cid/ciw112. Epub 2016 Mar 1 Abstract: *BACKGROUND:* Current serodiagnostics for Lyme disease lack sensitivity during early disease, and cannot determine treatment response. We evaluated an assay based on QuantiFERON technology utilizing peptide antigens derived from Borrelia burgdorferi to stimulate interferon-gamma (IFN-γ) release as an alternative to serodiagnosis for the laboratory detection of Lyme disease. *METHODS:* Blood was obtained from patients with erythema migrans before (n = 29) and 2 months after (n = 27) antibiotic therapy. IFN-γ release was measured by enzyme-linked immunosorbent assay (ELISA) following overnight stimulation of whole blood	Discuss with DoH

	with the peptide antigens, and compared to the results of standard serological assays (C6, ELISA, and Western blot). *RESULTS:* IFN-γ release was observed in pretreatment blood of 20 of 29 (69%) patients with Lyme disease. Following antibiotic treatment, IFN-γ was significantly reduced (P = .0002), and was detectable in only 4 of 20 (20%) initially positive patients. By contrast, anti-C6 antibodies were detected in pretreatment sera from 17 of 29 (59%) subjects, whereas only 5 of 29 (17%) patients had positive Western blot seroreactivity. Antibody responses persisted and expanded following treatment. *CONCLUSIONS:* Our findings suggest that measurement of IFN-γ after incubating blood with Borrelia antigens could be useful in the laboratory diagnosis of early Lyme disease. Also, after antibiotic treatment, this response appears to be short lived. 	
Emerging Infectious Diseases, "Incidence of Clinician-Diagnosed Lyme Disease, United States, 2005–2010": https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article	Beyond scope? Provides estimated incidence data on Lyme disease in US. We have included evidence on geographical distribution of Lyme disease in the US in the DSCATT Clinical Pathway. 2015 paper from CDC. Abstract: National surveillance provides important information about Lyme disease (LD) but is subject to underreporting and variations in practice. Information is limited about the national epidemiology of LD from other sources. Retrospective analysis of a nationwide health insurance claims database identified patients from 2005–2010 with clinician-diagnosed LD using International Classification of Diseases, Ninth Revision, Clinical Modification, codes and antimicrobial drug prescriptions. Of 103,647,966 person-years, 985 inpatient admissions and 44,445 outpatient LD diagnoses were identified. Epidemiologic patterns were similar to US surveillance data overall. Outpatient incidence was highest among boys 5–9 years of age and persons of both sexes 60–64 years of age. On the basis of	Discuss with DoH

	extrapolation to the US population and application of correction factors for coding, we estimate that annual incidence is 106.6 cases/100,000 persons and that ≈329,000 (95% credible interval 296,000–376,000) LD cases occur annually. LD is a major US public health problem that causes substantial use of health care resources.	
Healthcare, "Under-Detection of Lyme Disease in Canada": https://www.ncbi.nlm.nih.gov/pubmed/30326576	Relevant to issues of diagnostic testing of Lyme disease. 2018 article Abstract: Lyme disease arises from infection with pathogenic *Borrelia* species. In Canada, current case definition for confirmed Lyme disease requires serological confirmation by both a positive first tier ELISA and confirmatory second tier immunoblot (western blot). For surveillance and research initiatives, this requirement is intentionally conservative to exclude false positive results. Consequently, this approach is prone to false negative results that lead to underestimation of the number of people with Lyme disease. The province of New Brunswick (NB), Canada, can be used to quantify under-detection of the disease as three independent data sets are available to generate an estimate of the true human disease prevalence and incidence. First, detailed human disease incidence is available for the US states and counties bordering Canada, which can be compared with Canadian disease incidence. Second, published national serology results and well-described sensitivity and specificity values for these tests are available and deductive reasoning can be used to query for discrepancies. Third, high-density tick and canine surveillance data are available for the province, which can be used to predict expected human Lyme prevalence. Comparison of cross-border disease incidence suggests a minimum of 10.2 to 28-fold under-detection of Lyme disease (3.6% to 9.8% cases detected). Analysis of serological testing predicts the surveillance criteria generate 10.4-fold under-diagnosis (9.6% cases detected) in New Brunswick for 2014 due to serology alone. Calculation of expected human Lyme disease cases based on tick and canine infections in New Brunswick indicates a minimum of 12.1 to 58.2-fold underestimation (1.7% to 8.3%	Discuss with DoH

	cases detected). All of these considerations apply generally across the country and strongly suggest that public health information is significantly under-detecting and under-reporting human Lyme cases across Canada. Causes of the discrepancies between reported cases and predicted actual cases may include undetected genetic diversity of *Borrelia* in Canada leading to failed serological detection of infection, failure to consider and initiate serological testing of patients, and failure to report clinically diagnosed acute cases. As these surveillance criteria are used to inform clinical and public health decisions, this under-detection will impact diagnosis and treatment of Canadian Lyme disease patients.	
International Journal of General Medicine, "Empirical validation of the Horowitz Multiple Systemic Infectious Disease Syndrome Questionnaire for suspected Lyme disease": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5590688/	Also sent to A+C by Dr Horowitz earlier in 2019. Dr Horowitz is an author.	Discuss with DoH
Parasite Vectors, "Distribution of tick-borne diseases in China": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3640964/	The only relevant section would be on Lyme disease. Other overseas acquired tick-borne diseases are not being included in the DSCATT Clinical Pathway. 2013 article. Abstract: As an important contributor to vector-borne diseases in China, in recent years, tick-borne diseases have attracted much attention because of their increasing incidence and consequent significant harm to livestock and human health. The most commonly observed human tick-borne diseases in China include Lyme borreliosis (known as Lyme disease in China), tick-borne encephalitis (known as Forest encephalitis in China), Crimean-Congo hemorrhagic fever (known as Xinjiang hemorrhagic fever in China), Q-fever, tularemia and North-Asia tick-borne spotted fever. In recent years, some emerging tick-borne diseases, such as human monocytic ehrlichiosis, human granulocytic anaplasmosis, and a novel bunyavirus infection, have been reported frequently in China. Other tick-borne diseases that are not as frequently reported in China include Colorado fever, oriental spotted fever and piroplasmosis. Detailed information regarding the history, characteristics, and current epidemic status of these human	Discuss with DoH

	tick-borne diseases in China will be reviewed in this paper. It is clear that greater efforts in government management and research are required for the prevention, control, diagnosis, and treatment	
PLoS One, "Gender Disparity between Cutaneous and Non-Cutaneous Manifestations of Lyme Borreliosis": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3667797/	Beyond scope? Wormser is an author. Large study population in Slovenia. Retrospective chart records. Finding was described as provocative with possible relevance to pathogenesis of Lyme disease. 2013 article Abstract: Cutaneous manifestations of Lyme borreliosis in Europe include erythema migrans (EM) and acrodermatitis chronica atrophicans (ACA); the most common non-cutaneous manifestations are Lyme neuroborreliosis (LNB) and Lyme arthritis. The purpose of this study was to evaluate the gender distribution of patients with these clinical manifestations of Lyme borreliosis. Data on gender were obtained from the clinical records of patients with Lyme borreliosis aged ≥15 years who had been evaluated at the University Medical Center Ljubljana, Ljubljana, Slovenia. Among 10,539 patients diagnosed with EM, 6,245 (59.3%) were female and among 506 ACA patients 347 (68.6%) were female. In contrast, among the 60 patients with Lyme arthritis only 15 (25%) were female ($p<0.0001$ for the comparison of gender with EM or ACA) and among the 130 patients with LNB only 51 (39.2%) were females ($p<0.0001$for the comparison of gender with EM or ACA). Although the proportion that was female in the LNB group was greater than that of patients with Lyme arthritis, this difference did not reach statistical significance ($p=0.10$). Although older individuals are more likely to be female in the general Slovenian population, the age of patients with cutaneous versus non-cutaneous manifestations was not the explanation for the observed differences in gender. In conclusion, patients with cutaneous manifestations of Lyme borreliosis were predominantly female, whereas those with non-cutaneous manifestations were predominantly male. This	Discuss with DoH

	provocative finding is unexplained but may have direct relevance to the pathogenesis of Lyme borreliosis.	
Scientific Reports, "Evaluating polymicrobial immune responses in patients suffering from tick-borne diseases": https://www.ncbi.nlm.nih.gov/pubmed/30374055	Beyond scope? Other overseas acquired tick-borne diseases are not being included in Clinical Pathway. Possible relevance to issues of diagnostic testing for Lyme disease. 2018 article Abstract: There is insufficient evidence to support screening of various tick-borne diseases (TBD) related microbes alongside Borrelia in patients suffering from TBD. To evaluate the involvement of multiple microbial immune responses in patients experiencing TBD we utilized enzyme-linked immunosorbent assay. Four hundred and thirty-two human serum samples organized into seven categories followed Centers for Disease Control and Prevention two-tier Lyme disease (LD) diagnosis guidelines and Infectious Disease Society of America guidelines for post-treatment Lyme disease syndrome. All patient categories were tested for their immunoglobulin M (IgM) and G (IgG) responses against 20 microbes associated with TBD. Our findings recognize that microbial infections in patients suffering from TBDs do not follow the one microbe, one disease Germ Theory as 65% of the TBD patients produce immune responses to various microbes. We have established a causal association between TBD patients and TBD associated co-infections and essential opportunistic microbes following Bradford Hill's criteria. This study indicated an 85% probability that a randomly selected TBD patient will respond to Borrelia and other related TBD microbes rather than to Borrelia alone. A paradigm shift is required in current healthcare policies to diagnose TBD so that patients can get tested and treated even for opportunistic infections.	Discuss with DoH

2.2. Websites and other material assessed as requiring discussion with DoH

Websites	A+C assessment	A+C recommendation
Dr Horowitz MSIDS questionnaire is available online at https://www.lymedisease.org.au/horowitz-msids-38-point-symptom-checklist/	This questionnaire was covered by the paper about the empirical validation of the MSIDS questionnaire.	Discuss with DoH
HealthPathways, "Fibromyalgia"	Beyond scope?	Discuss with DoH
MSIDS questionnaire:	Included in scientific articles table above.	Discuss with DoH

3. NOT FOR INCLUSION

3.1. Books assessed as not for inclusion

Books	A+C assessment	A+C recommendation
Burrascano, J. J. J., (16th ed.). (2008). *Advanced topics in Lyme disease. Diagnostic hints and treatment guidelines for Lyme and other tick borne illnesses*. Retrieved from https://lymediseaseassociation.org/wpcontent/uploads/2009/08/BurrGuide200810.pdf	Link goes to page not found. When putting the title into Google: ***Note:*** *These guidelines are written by Dr. Burrascano, who is regarded as being the grandfather of Lyme disease treatment. Although dated (last revised in 2008) and some of the information may be out of date, many patients and physicians continue to find them useful.* ***DISCLAIMER:*** *The information contained in this article is meant for informational purposes only. The management of tick-borne illnesses in any given patient must be approached on an individual basis using the practitioner's best judgment.*	Not included. DoH comment about ACIIDS guidelines and recommendation that Dr Burrascano's document is adaptable to the current Australian environment was: The clinical pathway has been formed using the (draft 2019) IDSA/AAN/ACR Lyme disease clinical practice guideline as they are evidence based. The Guidelines by the Australian Chronic Infectious and Inflammatory Disease Society are extremely controversial and should not be referenced.
Cohen, J., Opal, S. M., & Powderly, W. G. 2010. *Infectious diseases* (3rd ed.)(pp. 1243–1246). Edinburgh: Mosby.	Would have to be purchased. Unable to tell what this book covers without seeing the contents.	Not included
Horowitz, R. I. (2013). *Why can't I get better? Solving the mystery of Lyme and chronic disease*. New York: Macmillan.	Book would have to be purchased. Does not appear to be peer-reviewed.	Not included
Ristic, M. (1988). *Babesiosis of domestic animals and man*	Out of date range	Not included

3.2. Scientific articles assessed as not for inclusion

Scientific articles	A+C assessment	A+C recommendation
A link to over 1500 studies on ketogenic epilepsy: https://www.ncbi.nlm.nih.gov/pubmed/?term=ketogenic+epilepsy	Out of scope A+C has provided high-level guidance (including NHMRC) on the use of complementary and alternative therapies in Australia.	Not included
Aging and Disease, "Vitamin D and Chronic Diseases": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5440113/	Out of scope – Complementary medicines A+C has provided high-level guidance (including NHMRC) on the use of complementary and alternative therapies in Australia.	Not included
Antibiotics, "The Long-Term Persistence of Borrelia burgdorferi Antigens and DNA in the Tissues of a Patient with Lyme Disease": https://www.mdpi.com/2079-6382/8/4/183/htm?utm_campaign=Kresser%20Institute&utm_source=hs_email&utm_medium=email&utm_content=79168458&_hsenc=p2ANqtz-8VJP7i35GjAfkeMaN_Bxow8fOwmRdpEW79zseQ2jkxkMrHCjn5bv28V4dXF8mvOO_dDM9fpM1FuF-rAZGO6YRSzVSp6A&_hsmi=79168458	2019 article. Autopsy results of one patient with Lyme disease who had multiple antibiotic courses over 16 years. Research supported by Lyme advocacy groups. One case study. Low on the hierarchy of evidence. Abstract: Whether *Borrelia burgdorferi*, the causative agent of Lyme disease, can persist for long periods in the human body has been a controversial question. The objective of this study was to see if we could find *B. burgdorferi* in a Lyme disease patient after a long clinical course and after long-term antibiotic treatment. Therefore, we investigated the potential presence of *B. burgdorferi* antigens and DNA in human autopsy tissues from a well-documented serum-, PCR-, and culture-positive Lyme disease patient, a 53-year-old female from northern Westchester County in the lower Hudson Valley Region of New York State, who had received extensive antibiotic treatments during extensive antibiotic treatments over the course of her 16-year-long illness. We also asked what form the organism might take, with special interest in the recently found antibiotic-resistant aggregate form, biofilm. We also examined the host tissues for the presence of inflammatory markers such as CD3+ T lymphocytes. Autopsy tissue sections of the brain, heart, kidney, and liver were analyzed by histological and immunohistochemical methods (IHC), confocal microscopy, fluorescent in situ hybridization (FISH),	Not included

	polymerase chain reaction (PCR), and whole-genome sequencing (WGS)/metagenomics. We found significant pathological changes, including borrelial spirochetal clusters, in all of the organs using IHC combined with confocal microscopy. The aggregates contained a well-established biofilm marker, alginate, on their surfaces, suggesting they are true biofilm. We found *B. burgdorferi* DNA by FISH, polymerase chain reaction (PCR), and an independent verification by WGS/metagenomics, which resulted in the detection of *B. burgdorferi* sensu stricto specific DNA sequences. IHC analyses showed significant numbers of infiltrating CD3+ T lymphocytes present next to *B. burgdorferi* biofilms. In summary, we provide several lines of evidence that suggest that *B. burgdorferi* can persist in the human body, not only in the spirochetal but also in the antibiotic-resistant biofilm form, even after long-term antibiotic treatment. The presence of infiltrating lymphocytes in the vicinity of *B. burgdorferi* biofilms suggests that the organism in biofilm form might trigger chronic inflammation. Funding: The authors thank the Global Lyme Alliance, LivLyme Foundation, Lyme Warriors, and National Philanthropic Trust for their support of the research reported in this paper. Microscopes and cameras were donated by Lymedisease.org, the Schwartz Research Foundation, and the Global Lyme Alliance. We also thank Dr. Akiko Nishiyama (University of Connecticut) for the use of a Leica SP8 confocal microscope (NIH Shared and High Instrumentation Award #S10OD016435).	
American Neurological Association, "Post-Lyme syndrome and chronic fatigue syndrome. Neuropsychiatric similarities and differences": https://www.ncbi.nlm.nih.gov/pubmed/9362985	Outside of date range. Arch Neurol. 1997 Nov;54(11):1372-6	Not included
APA, "Highlights of Changes from DSM-IV to DSM-5: Feeding and Eating Disorders": https://focus.psychiatryonline.org/doi/abs/10.1176/appi.focus.120408?journalCode=foc	Out of scope. 2014 article.	Not included

Asia Pacific Allergy "Tick-induced allergies: mammalian meat allergy, tick anaphylaxis and their significance" Van Nunen Asia Pac Allergy. 2015 Jan;5(1):3-16. doi: 10.5415/apallergy.2015.5.1.3. Epub 2015 Jan 28.	Out of scope 2015 article Mammalian meat allergy is covered in the educational resources.	Not included
Asia Pacific Allergy "Tick killing in situ before removal to prevent allergic and anaphylactic reactions in humans: a cross-sectional study" Asia Pac Allergy. 2019 Apr 18;9(2):e15. doi: 10.5415/apallergy.2019.9.e15. eCollection 2019 Apr. Taylor BWP[1], Ratchford A[2,3], van Nunen S[3,4], Burns B[2,3].	Out of scope 2019 article	Not included
Association of spirochetal infection with Morgellons disease[v1; ref status: indexed, http://f1000r.es/8g] Marianne J Middelveen , Divya Burugu , Akhila Poruri , Jennie Burke , Peter J Mayne , Eva 1 2 2 3 1 Sapi , Douglas G Kahn , Raphael B Stricker 2 4	Out of scope. Link does not work. Found on googling title: Morgellons disease (MD) is an emerging multisystem illness characterized by skin lesions with unusual filaments embedded in or projecting from epithelial tissue. Filament formation results from abnormal keratin and collagen expression by epithelial-based keratinocytes and fibroblasts. Recent research comparing MD to bovine digital dermatitis, an animal infectious disease with similar skin features, provided clues that spirochetal infection could play an important role in the human disease as it does in the animal illness. Based on histological staining, immunofluorescent staining, electron microscopic imaging and polymerase chain reaction, we report the detection of *Borrelia* spirochetes in dermatological tissue of four randomly-selected MD patients. The association of MD with spirochetal infection provides evidence that this infection may be a significant factor in the illness and refutes claims that MD lesions are self-inflicted and that people suffering from this disorder are delusional. Molecular characterization of the *Borrelia* spirochetes found in MD patients is warranted.	Not included
BMC Psychology, "Rethinking the treatment of chronic fatigue syndrome—a reanalysis and evaluation of findings from a	Out of scope 2018 article	Not included

recent major trial of graded exercise and CBT": https://www.ncbi.nlm.nih.gov/pubmed/29562932		
BMJ, "The new somatic symptom disorder in DSM-5 risks mislabeling many people as mentally ill": https://www.ncbi.nlm.nih.gov/pubmed/23511949	Out of scope	Not included
Borrelia detection and Lyme disease. Published on November 27, 2019 Chris Newton Research Director CIMMBER (Center for Immuno-Metabolism, Microbiome and Bio-Energetic Research): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1195970/	Outside of date range 2005 article.	Not included
Clinical and Experimental Immunology, "The outer surface proteins of Lyme disease borrelia spirochetes stimulate T cells to secrete interferon-gamma (IFN-^y): diagnostic and pathogenic implications": https://www.ncbi.nlm.nih.gov/pubmed/7664493	Outside of date range Clin Exp Immunol. 1995 Sep;101(3):453-60	Not included
Clinical Infectious Diseases, "Functional brain imaging and neuropsychological testing in Lyme disease": https://www.ncbi.nlm.nih.gov/pubmed/9233666	Outside of date range Clin Infect Dis. 1997 Jul;25 Suppl 1:S57-63	Not included
Clinical Microbiology Reviews, "Bartonella Species, an Emerging Cause of Blood-Culture-Negative Endocarditis": https://www.ncbi.nlm.nih.gov/pubmed/28490579	Other vector-borne diseases are not being included in the DSCATT Clinical Pathway. 2017 article Bartonella	Not included
Culture and identification of Borrelia spirochetes in human vaginal and seminal secretions https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5482345/ Marianne J. Middelveen , Jennie Burke , Eva Sapi , Cheryl Bandoski , Katherine R. Filush , Yean Wang , Agustin Franco , Arun Timmaraju , Hilary A. Schlinger , Peter J. Mayne , Raphael B. Stricker *F1000Res*. 2014;3:309. Published 2014 Dec 18. doi:10.12688/f1000research.5778.3	NICE 2018 did a systematic review of person-to-person transmission of Lyme disease, which is higher level evidence. 2014 article Very small study of 4 controls and 13 patients diagnosed with Lyme disease by various methods. Conclusion states further studies are needed to evaluate this **hypothesis.** This paper was not mentioned as an inclusion or exclusion in the 2018 NICE evidence-based review of person-to-person transmission. **Background:** Recent reports indicate that more than 300,000 cases of Lyme disease are diagnosed yearly in the USA.	Not included

	Preliminary clinical, epidemiological and immunological studies suggest that infection with the Lyme disease spirochete *Borrelia burgdorferi* (Bb) could be transferred from person to person via intimate human contact without a tick vector. Failure to detect viable *Borrelia* spirochetes in vaginal and seminal secretions would argue against this hypothesis. **Methods:** Patients with and without a history of Lyme disease were selected for the study after informed consent was obtained. Serological testing for Bb was performed on all subjects. Semen or vaginal secretions were inoculated into BSK-H medium and cultured for four weeks. Examination of genital cultures and culture concentrates for the presence of spirochetes was performed using light and darkfield microscopy, and spirochete concentrates were subjected to Dieterle silver staining, anti-Bb immunohistochemical staining, molecular hybridization and PCR analysis for further characterization. Immunohistochemical and molecular testing was performed in three independent laboratories in a blinded fashion. Positive and negative controls were included in all experiments. **Results:** Control subjects who were asymptomatic and seronegative for Bb had no detectable spirochetes in genital secretions by PCR analysis. In contrast, spirochetes were observed in cultures of genital secretions from 11 of 13 subjects diagnosed with Lyme disease, and motile spirochetes were detected in genital culture concentrates from 12 of 13 Lyme disease patients using light and darkfield microscopy. Morphological features of spirochetes were confirmed by Dieterle silver staining and immunohistochemical staining of culture concentrates. Molecular hybridization and PCR testing confirmed that the spirochetes isolated from semen and vaginal secretions were strains of *Borrelia*, and all cultures were negative for treponemal spirochetes. PCR sequencing of cultured spirochetes from three couples having unprotected sex indicated that two couples had identical strains of Bb *sensu stricto* in their semen and vaginal secretions, while the third couple had identical strains of *B. hermsii* detected in their genital secretions.	

	Conclusions: The culture of viable *Borrelia* spirochetes in genital secretions suggests that Lyme disease could be transmitted by intimate contact from person to person. Further studies are needed to evaluate this hypothesis.	
EMA "Tick bite anaphylaxis: Incidence and management in an Australian emergency department" Emerg Med Australas. 2013 Aug;25(4):297-301. doi: 10.1111/1742-6723.12093. Epub 2013 Jul 21.	Out of scope. Tick bite anaphylaxis is covered in the DoH educational materials. 2013 article © 2013 Australasian College for Emergency Medicine and Australasian Society for Emergency Medicine.	Not included
Emerging Infectious Diseases, "Candidatus Bartonella mayotimonensis and endocarditis": https://www.ncbi.nlm.nih.gov/pubmed/20202430	Other vector-borne diseases not being included in the DSCATT Clinical Pathway. 2011 article Study from the US of one patient.	Not included
Erosive Vulvovaginitis Associated With Borrelia burgdorferi Infection: https://www.ncbi.nlm.nih.gov/pubmed/31043089	Out of scope. One case. Low in hierarchy of evidence. 2019 article Jenny Burke and Ralph Stricker are included as authors. Abstract: We describe a case of acute erosive vulvovaginitis accompanying Borrelia burgdorferi infection. The patient is a 57-year-old woman previously diagnosed with Lyme disease who presented with a painful erosive genital lesion. At the time of the outbreak, she was being treated with oral antibiotics, and she tested serologically positive for B burgdorferi and serologically negative for syphilis. Histological examination of biopsy tissue from the lesion was not characteristic of dermatopathological patterns typical of erosive vulvar conditions. Dieterle-stained biopsy sections revealed visible spirochetes throughout the stratum spinosum and stratum basale, and anti- B burgdorferi immunostaining was positive. Motile spirochetes were observed by darkfield microscopy and cultured in Barbour-Stoner-Kelly-complete medium inoculated with skin scrapings from the lesion. Cultured spirochetes were identified genetically as B burgdorferi sensu stricto by polymerase chain reaction, while polymerase chain reaction amplification of treponemal gene targets was negative. The condition resolved after treatment with additional systemic antibiotic therapy and topical	Not included

	antibiotics. In cases of genital ulceration that have no identifiable etiology, the possibility of B burgdorferi spirochetal infection should be considered.	
Granulomatous hepatitis associated with chronic Borrelia burgdorferi infection: a case report http://www.labome.org/research/Granulomatous-hepatitis-associated-with-chronic-Borrelia-burgdorferi-infection-a-case-report.html Marianne J Middelveen1, Steve A McClain2, 3, Cheryl Bandoski4, Joel R Israel3, Jennie Burke5, Alan B MacDonald1, Arun Timmaraju3, Eva Sapi4, Yean Wang5, Agustin Franco5, Peter J Mayne1, Raphael B Stricker1 International Lyme and Associated Diseases Society, Bethesda, MD, USA. 2 Departments of Dermatology and Emergency Medicine, State University of New York, Stony Brook, NY, USA. 3 McClain Laboratories LLC, Smithtown, NY, USA. 4 Department of Biology and Environmental Science, University of New Haven, West Haven, CT, USA. 5 Australian Biologics, Sydney, NSW, Australia: DOI http://dx.doi.org/10.13070/rs.en.1.875 Date 2014-06-09 Cite as Research 2014;1:875 License CC-BY	Out of scope. One case report. 2014 article Abstract: Although Lyme borreliosis has been linked to hepatitis in early stages of infection, the association of chronic Borrelia burgdorferi infection with hepatic disease remains largely unexplored. We present the case of a 53-year-old woman diagnosed with Lyme disease who developed acute hepatitis with elevated liver enzymes while on antibiotic treatment. Histological examination of liver biopsy tissue revealed spirochetes dispersed throughout the hepatic parenchyma, and the spirochetes were identified as Borrelia burgdorferi by molecular testing with specific DNA probes. Motile spirochetes were also isolated from the patient's blood culture, and the isolate was identified as Borrelia burgdorferi sensu stricto by two independent laboratories using molecular techniques. These findings indicate that the patient had active, systemic Borrelia burgdorferi infection and consequent Lyme hepatitis, despite antibiotic therapy.	Not included
Healthcare, "Line Immunoblot Assay for Tick-Borne Relapsing Fever and Findings in Patient Sera from Australia, Ukraine and the USA" (with the key data summarised in Table 4): https://www.mdpi.com/2227-9032/7/4/121/htm	Other overseas acquired tick-borne diseases are not being included in the DSCATT Clinical Pathway. 2019 article	Not included
Healthcare, "Line Immunoblot Assay for Tick-Borne Relapsing Fever and Findings in Patient Sera from Australia, Ukraine and the USA": https://www.mdpi.com/2227-9032/7/4/121	Duplicate. Tick-borne relapsing fever is not covered in the DSCATT Clinical Pathway.	Not included
Immunopathological Diseases and Therapeutics, "A Brief Chronicle of CD4 as a Biomarker for HIV/AIDS: A Tribute to the Memory of John L. Fahey": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4864990/	Out of scope – Not relevant to DSCATT Clinical Pathway– HIV/AIDS 2016 article.	Not included
Immunopathological Diseases and Therapeutics, "A Brief Chronicle of CD4 as a Biomarker for HIV/AIDS: A Tribute to the	Out of scope Duplicate	Not included

Memory of John L. Fahey": https://www.ncbi.nlm.nih.gov/pubmed/27182452		
Indian Journal of Dermatology, "Borrelial Lymphocytoma Cutis: A Diagnostic Dilemma": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4248499/	2014 article Case study of one patient in India. Lymphocytoma cutis (LC) is one of the most common types of cutaneous B cell pseudolymphoma. Borrelial LC occurs most commonly in areas endemic for *Ixodes ricinus* tick in Europe, and it is rare in North America. The disease is rarely seen in India and may cause diagnostic difficulties for dermatologist residing in parts of the world that are not endemic for Lyme disease. The diagnosis is critical as LC may present as the only early manifestation of Lyme disease. Herein, we have presented a case of borrelial LC in an 11-year-old boy of German descent, residing in India.	Not included
Infectious Disease Clinics of North America, "Human babesiosis": https://www.ncbi.nlm.nih.gov/pubmed/18755385	Other overseas acquired tick-borne diseases are not being included in DSCATT Clinical Pathway. 2008 article	Not included
International Journal of General Medicine, "Application of Bayesian decision-making to laboratory testing for Lyme disease and comparison with testing for HIV": https://www.ncbi.nlm.nih.gov/pubmed/28435311	Cook & Puri (2017) This article is theoretical modelling. A+C has included Cook and Puri's (2016) meta-analysis of diagnostic tests for Lyme disease in the literature review. Abstract: In this study, Bayes' theorem was used to determine the probability of a patient having Lyme disease (LD), given a positive test result obtained using commercial test kits in clinically diagnosed patients. In addition, an algorithm was developed to extend the theorem to the two-tier test methodology. Using a disease prevalence of 5%-75% in samples sent for testing by clinicians, evaluated with a C6 peptide enzyme-linked immunosorbent assay (ELISA), the probability of infection given a positive test ranged from 26.4% when the disease was present in 5% of referrals to 95.3% when disease was present in 75%. When applied in the case of a C6 ELISA followed by a Western blot, the algorithm developed for the two-tier test demonstrated an improvement with the probability of disease given a positive test ranging between 67.2% and 96.6%. Using an algorithm to determine	Not included

	false-positive results, the C6 ELISA generated 73.6% false positives with 5% prevalence and 4.7% false positives with 75% prevalence. Corresponding data for a group of test kits used to diagnose HIV generated false-positive rates from 5.4% down to 0.1% indicating that the LD tests produce up to 46 times more false positives. False-negative test results can also influence patient treatment and outcomes. The probability of a false-negative test for LD with a single test for early-stage disease was high at 66.8%, increasing to 74.9% for two-tier testing. With the least sensitive HIV test used in the two-stage test, the false-negative rate was 1.3%, indicating that the LD test generates ~60 times as many false-negative results. For late-stage LD, the two-tier test generated 16.7% false negatives compared with 0.095% false negatives generated by a two-step HIV test, which is over a 170-fold difference. Using clinically representative LD test sensitivities, the two-tier test generated over 500 times more false-negative results than two-stage HIV testing.	
Journal of Health Psychology, "'PACE-Gate': When clinical trial evidence meets open data access": https://journals.sagepub.com/doi/full/10.1177/1359105316675213	Out of scope – editorial 2017 article Of relevance to treatment modalities for patients with CFS. **Abstract** Science is not always plain sailing and sometimes the voyage is across an angry sea. A recent clinical trial of treatments for chronic fatigue syndrome (the PACE trial) has whipped up a storm of controversy. Patients claim the lead authors overstated the effectiveness of cognitive behavioural therapy and graded exercise therapy by lowering the thresholds they used to determine improvement. In this extraordinary case, patients discovered that the treatments tested had much lower efficacy after an information tribunal ordered the release of data from the PACE trial to a patient who had requested access using a freedom of information request.	Not included
Link to Dr Mayne's published research on Lyme disease [22 links]: http://www.drmayne.com/research.htm	Dr Mayne's research and review of his research is already covered in the literature review.	Not included

M. A. D. D. M. O. e. a. Kalmár Z, "Geographical distribution and prevalence of Borrelia burgdorferi genospecies in questing Ixodes ricinus from Romania: a countrywide study.," *Ticks Tick Borne Dis.,* vol. 4(5), no. September. doi: 10.1016/j.ttbdis.2013.04.007., pp. 403-8., 2013	Out of Scope. Information about Lyme disease in Romania and areas where people are more likely to contract Lyme disease. There is already high-level information about the geographical distribution of Lyme disease in the DSCATT Clinical Pathway. 2013 article. Abstract: The paper reports the prevalence and geographical distribution of Borrelia burgdorferi sensu lato (s.l.) and its genospecies in 12,221 questing Ixodes ricinus ticks collected at 183 locations from all the 41 counties of Romania. The unfed ticks were examined for the presence of B. burgdorferi s.l. by PCR targeting the intergenic spacer 5S-23S. Reverse line blot hybridization (RLB) and restriction fragment length polymorphism (RFLP) analysis were performed for identification of B. burgdorferi genospecies. The overall prevalence of infection was 1.4%, with an average local prevalence between 0.75% and 18.8%. B. burgdorferi s.l. was found in ticks of 55 of the 183 localities. The overall prevalence B. burgdorferi s.l. in ticks in the infected localities was 3.8%. The total infection prevalence was higher in female ticks than in other developmental stages. Three Borrelia genospecies were detected. The most widely distributed genospecies was B. afzelii, followed by B. garinii and B. burgdorferi sensu stricto (s.s.). The study is the first countrywide study and the first report of B. burgdorferi s.s. in Romania. The distribution maps show that higher prevalences were recorded in hilly areas, but Lyme borreliosis spirochetes were also present in forested lowlands, albeit with a lower prevalence.	Not included
Marianne J Middelveen, Gheorghe M Rotaru, Jody L McMurray, Katherine R Filush, Eva Sapi, Jennie Burke, Agustin Franco, Lorenzo Malquori, Melissa C McElroy and Raphael B Stricker "Canine Filamentous Dermatitis Associated with Borrelia Infection": https://www.researchgate.net/publication/311975095_Canine_Filamentous_Dermatitis_Associated_with_Borrelia_Infection	Out of scope – animal study on dogs Canine Filamentous Dermatitis Associated with Borrelia Infection Background: Although canine clinical manifestations of Lyme disease vary widely, cutaneous manifestations are not well documented in dogs. In contrast, a variety of cutaneous manifestations are reported in human Lyme disease caused by the spirochete Borrelia burgdorferi. A recently recognized dermopathy associated with tickborne illness known as	Not included

	Morgellons disease is characterized by brightly-colored filamentous inclusions and projections detected in ulcerative lesions and under unbroken skin. Recent studies have demonstrated that the dermal filaments are collagen and keratin biofibers produced by epithelial cells in response to spirochetal infection. We now describe a similar filamentous dermatitis in canine Lyme disease. Methods and Results: Nine dogs were found to have cutaneous ulcerative lesions containing embedded or projecting dermal filaments. Spirochetes characterized as Borrelia spp. were detected in skin tissue by culture, histology, immunohistochemistry, polymerase chain reaction (PCR) and gene sequencing performed at five independent laboratories. Borrelia DNA was detected either directly from skin specimens or from cultures inoculated with skin specimens taken from the nine canine study subjects. Amplicon sequences from two canine samples matched gene sequences for Borrelia burgdorferi sensu stricto. PCR amplification failed to detect spirochetes in dermatological specimens from four healthy asymptomatic dogs. Conclusions: Our study provides evidence that a filamentous dermatitis analogous to Morgellons disease may be a manifestation of Lyme disease in domestic dogs.	
Medicine: Science or Art? https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3190445/	Out of scope	Not included
Melissa C. Fesler, FNP-BC1, Marianne J. Middelveen, MDes2, Jennie M. Burke, MSc (Hons), and Raphael B. Stricker, MD1 Journal of Investigative Medicine High Impact Case Reports Volume 7: 1–5 "Exploring the association between Morgellons disease and Lyme disease: identification of *Borrelia burgdorferi* in Morgellons disease patients": https://www.ncbi.nlm.nih.gov/pubmed/25879673 Marianne J Middelveen, Cheryl Bandoski, Jennie Burke, Eva Sapi, Katherine R Filush, Yean Wang, Agustin Franco Peter J Mayne, and Raphael B Stricker BMC Dermatol. 2015; 15(1): 1. Published online 2015 Feb 12.doi: 10.1186/s12895-015-0023-0	Out of scope 2015 article Abstract: *BACKGROUND:* Morgellons disease (MD) is a complex skin disorder characterized by ulcerating lesions that have protruding or embedded filaments. Many clinicians refer to this condition as delusional parasitosis or delusional infestation and consider the filaments to be introduced textile fibers. In contrast, recent studies indicate that MD is a true somatic illness associated with tickborne infection, that the filaments are keratin and collagen in composition and that they result from proliferation and activation of keratinocytes and fibroblasts in the skin. Previously, spirochetes have been detected in the	Not included

	dermatological specimens from four MD patients, thus providing evidence of an infectious process. *METHODS & RESULTS:* Based on culture, histology, immunohistochemistry, electron microscopy and molecular testing, we present corroborating evidence of spirochetal infection in a larger group of 25 MD patients. Irrespective of Lyme serological reactivity, all patients in our study group demonstrated histological evidence of epithelial spirochetal infection. Strength of evidence based on other testing varied among patients. Spirochetes identified as Borrelia strains by polymerase chain reaction (PCR) and/or in-situ DNA hybridization were detected in 24/25 of our study patients. Skin cultures containing Borrelia spirochetes were obtained from four patients, thus demonstrating that the organisms present in dermatological specimens were viable. Spirochetes identified by PCR as Borrelia burgdorferi were cultured from blood in seven patients and from vaginal secretions in three patients, demonstrating systemic infection. Based on these observations, a clinical classification system for MD is proposed. *CONCLUSIONS:* Our study using multiple detection methods confirms that MD is a true somatic illness associated with Borrelia spirochetes that cause Lyme disease. Further studies are needed to determine the optimal treatment for this spirochete-associated dermopathy.	
Microbiology Reviews, "Biology of Borrelia species": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC373079/?page=1 Microbiol Rev. 1986 Dec; 50(4): 381–400.	Out of date range	Not included
Molecular and Cellular Probes, "Emerging borreliae - Expanding beyond Lyme borreliosis": https://www.ncbi.nlm.nih.gov/pubmed/27523487	Out of scope – Other overseas tick-borne diseases, including Relapsing fever, are not being included in the DSCATT Clinical Pathway. 2017 article Abstract: Lyme borreliosis (or Lyme disease) has become a virtual household term to the exclusion of other forgotten, emerging	Not included

	or re-emerging borreliae. We review current knowledge regarding these other borreliae, exploring their ecology, epidemiology and pathological potential, for example, for the newly described B. mayonii. These bacteria range from tick-borne, relapsing fever-inducing strains detected in some soft ticks, such as B. mvumii, to those from bat ticks resembling B. turicatae. Some of these emerging pathogens remain unnamed, such as the borrelial strains found in South African penguins and some African cattle ticks. Others, such as B. microti and unnamed Iranian strains, have not been recognised through a lack of discriminatory diagnostic methods. Technical improvements in phylogenetic methods have allowed the differentiation of B. merionesi from other borrelial species that co-circulate in the same region. Furthermore, we discuss members that challenge the existing dogma that Lyme disease-inducing strains are transmitted by hard ticks, whilst the relapsing fever-inducing spirochaetes are transmitted by soft ticks. Controversially, the genus has now been split with Lyme disease-associated members being transferred to Borreliella, whilst the relapsing fever species retain the Borrelia genus name. It took some 60 years for the correlation with clinical presentations now known as Lyme borreliosis to be attributed to their spirochaetal cause. Many of the borreliae discussed here are currently considered exotic curiosities, whilst others, such as B. miyamotoi, are emerging as significant causes of morbidity. To elucidate their role as potential pathogenic agents, we first need to recognise their presence through suitable diagnostic approaches.	
Morgellons: a novel dermatological perspective as the multisystem infective disease borreliosis https://f1000research.com/articles/2-118 Peter Mayne , John S English , Edward J Kilbane , Jennie M Burke , Marianne J 1 2 3 4 Middelveen , Raphael B Stricker 1: http://f1000r.es/116	Out of scope 2013 article - journal is open peer-review Morgellons disease (MD) is a term that has been used in the last decade to describe filaments that can be found in human epidermis. It is the subject of considerable debate within the medical profession and is often labeled as delusions of parasitosis or dermatitis artefacta. This view is challenged by recent published scientific data put forward between 2011-2013 identifying the filaments found in MD as keratin and collagen based and furthermore associated with spirochetal infection. The novel model of the dermopathy put forward by	Not included

	those authors is further described and, in particular, presented as a dermal manifestation of the multi-system disease complex borreliosis otherwise called Lyme disease. A differential diagnosis is drawn from a dermatological perspective. The requirements for a diagnosis of delusional disorder from a psychiatric perspective are clarified and the psychological or psychiatric co-morbidity that can be found with MD cases is presented. A concurrent case incidence is also included. Management of the multisytem disease complex is discussed both in general and from a dermatological perspective. Finally replacement of the term 'Morgellons' by 'borrelial dermatitis' is proposed within the profession.	
Neurotherapeutics, "Ketogenic Diets for Adult Neurological Disorders": https://www.ncbi.nlm.nih.gov/pubmed/30225789	Out of scope – Complementary medicine/practices. A+C has provided high-level guidance (including NHMRC) on the use of complementary and alternative therapies in Australia.	Not included
Pediatrics & Therapeutics, "From Research Subgroup to Clinical Syndrome: Modifying the PANDAS Criteria to Describe PANS (Pediatric Acute-on-set Neuropsychiatric Syndrome)": https://www.longdom.org/open-access/from-research-subgroup-to-clinical-syndrome-modifying-the-pandas-criteria-to-describe-pans-pediatric-acute-onset-neuropsychiatr.pdf	Out of scope	Not included
Peer J, "Severity of chronic Lyme disease compared to other chronic conditions: a quality of life survey": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3976119/	This is about 'Chronic' Lyme disease patients. Survey conducted by an advocacy organisation. Large sample size but bias in patient self-selection. Is not relevant to DSCATT or treatment of classical Lyme disease. Patient Selection and Characteristics: The sample for this analysis was gathered in early 2013 from individuals who participated in or visited Lyme disease patient-centered online forums in which the survey was posted or publicized. The survey was conducted by LymeDisease.org, a grassroots organization that promotes Lyme disease education and research, and written informed consent was obtained from each subject. Analysis of the survey data was exempted from review by the Carnegie Mellon University Institutional Review Board (IRB) because none of the data contained	Not included

	identifiable personal information. A total of 5,357 subjects responded to the survey, of which a final sample of 3,090 was examined. Acknowledgments: The authors thank Drs. Robert Bransfield, Joseph Burrascano, Chris Green, Nick Harris, Steven Harris, Dan Kinderlehrer and Betty Maloney for helpful discussion. We also thank Pam Weintraub and Kris Newby for their insight, and we are grateful to Pat Smith of the Lyme Disease Association, Diane Blanchard and Deb Siciliano of Lyme Research Alliance, Staci Grodin and David Roth of Tick-Borne Disease Alliance, and Barb Barsocchini, Dorothy Leland, and Phyllis Mervine of LymeDisease.org for continuing support. Lorraine Johnson,[1] Spencer Wilcox,[1] Jennifer Mankoff,[2] and Raphael B. Stricker[1,3] Academic Editor: Claus Wilke [1]LymeDisease.org, Chico, CA, USA [2]Human-Computer Interaction Institute, Carnegie Mellon University, Pittsburgh, PA, USA [3]International Lyme & Associated Diseases Society, Bethesda, MD, USA Corresponding author. Raphael B. Stricker: moc.demamsu@rekcirtsr Received 2014 Jan 17; Accepted 2014 Mar 5	
Persistent Borrelia Infection in Patients with Ongoing Symptoms of Lyme Disease: https://f1000research.com/articles/2-118 Marianne J. Middelveen, Eva Sapi, Jennie Burke, Katherine R. Filush, Agustin Franco, Melissa C. Fesler, and Raphael B. Stricker. Published online 2018 Apr 14.doi: 10.3390/healthcare6020033	Pilot study of 12 patients. Pilot study. Very small. 2018 article Abstract: We showed that patients with persistent Lyme disease symptoms may have ongoing spirochetal infection despite antibiotic treatment, similar to findings in non-human primates. The optimal treatment for persistent Borrelia infection remains to be determined. Abstract: *INTRODUCTION:* Lyme disease is a tickborne illness that generates controversy among medical providers and researchers. One of the key topics of debate is the existence of persistent infection with the Lyme spirochete, Borrelia burgdorferi, in patients who have been treated with recommended doses of antibiotics yet	Not included

	remain symptomatic. Persistent spirochetal infection despite antibiotic therapy has recently been demonstrated in non-human primates. We present evidence of persistent Borrelia infection despite antibiotic therapy in patients with ongoing Lyme disease symptoms. *METHODS:* In this pilot study, culture of body fluids and tissues was performed in a randomly selected group of 12 patients with persistent Lyme disease symptoms who had been treated or who were being treated with antibiotics. Cultures were also performed on a group of ten control subjects without Lyme disease. The cultures were subjected to corroborative microscopic, histopathological and molecular testing for *Borrelia* organisms in four independent laboratories in a blinded manner. *RESULTS:* Motile spirochetes identified histopathologically as *Borrelia* were detected in culture specimens, and these spirochetes were genetically identified as *Borreliaburgdorferi* by three distinct polymerase chain reaction (PCR)-based approaches. Spirochetes identified as *Borrelia burgdorferi* were cultured from the blood of seven subjects, from the genital secretions of ten subjects, and from a skin lesion of one subject. Cultures from control subjects without Lyme disease were negative for *Borrelia* using these methods. *CONCLUSIONS:* Using multiple corroborative detection methods, we showed that patients with persistent Lyme disease symptoms may have ongoing spirochetal infection despite antibiotic treatment, similar to findings in non-human primates. The optimal treatment for persistent *Borrelia* infection remains to be determined.	
PLoS One, "Molecular prevalence of Bartonella, Babesia, and hemotropic Mycoplasma species in dogs with hemangiosarcoma from across the United States": https://www.ncbi.nlm.nih.gov/pubmed/31923195	Out of scope – Animal study Other vector borne diseases are not being included in the DSCATT Clinical Pathway. 2020 article	Not included

PLoS One, "Tick surveillance for relapsing fever spirochete Borrelia miyamotoi in Hokkaido, Japan": https://www.ncbi.nlm.nih.gov/pubmed/25111141	Out of scope. Other overseas acquired tick-borne diseases are not being included in DSCATT Clinical Pathway. 2014 article Information about tick borne disease in Japan	Not included
S. W. J. M. a. R. B. S. Lorraine Johnson, "Severity of chronic Lyme disease compared to other chronic conditions: a quality of life survey," *Peer J,* vol. PeerJ2:e322;, no. DOI10.7717/peerj.322, 2014.	Out of scope. DoH is clear that chronic Lyme is a disputed diagnosis. Duplicate	Not included
The Medical Journal of Australia, "Estimating non-billable time in Australian general practice": https://www.mja.com.au/journal/2016/205/2/estimating-non-billable-time-australian-general-practice	Out of scope	Not included
The New England Journal of Medicine, "Seronegative Lyme disease": https://www.nejm.org/doi/full/10.1056/NEJM198812013192203	Outside of date range N Engl J Med 1988; 319:1441-1446 1988 article	Not included
Ticks Tick Bourne Dis, "Borrelia spirochetes in Russia: Genospecies differentiation by real-time PCR": https://www.ncbi.nlm.nih.gov/pubmed/25108777	Out of scope. There is already high-level information about the geographical distribution of Lyme disease in the DSCATT Clinical Pathway. Beyond scope. 2014 paper. Abstract: Spirochetes of the Borrelia burgdorferi sensu lato complex are the causative agent of Lyme borreliosis which is widespread in Russia. Nowadays, three clinically important B. burgdorferi s.l. genospecies, B. afzelii, B. garinii, B. bavariensis sp. nov., can be found in Russia, as well as B. miyamotoi, which belongs to the tick-borne relapsing fever group of spirochetes. Several techniques have been developed to differentiate Borrelia genospecies. However, most of them do not allow detection of all of these genospecies simultaneously. Also, no method based on the RT-PCR TaqMan approach has been proposed to differentiate the genetically closely related species B. bavariensis and B. garinii. In the present paper, we investigated two species of ticks, I. persulcatus and I. pavlovskyi (1343 and 92 adults, respectively). Two sets of primers and probes for RT-PCR, with uvrA, glpQ and nifS genes	Not included

	as targets, were designed to detect four Borrelia genospecies in positive samples. The average prevalence of Borrelia sp. was about 40%, with B. afzelii as the most prevalent genospecies. Mixed infections of B. bavariensis and B. garinii were found to be extremely rare. While B. bavariensis was predominant in I. persulcatus, I. pavlovskyi ticks were infected exclusively by B. garinii. The proposed technique proved to be efficient in selection of individual Borrelia species for further genetic analysis, in particular, for multilocus sequence typing. Also, it could be applied for the differentiation of Borrelia genospecies in clinical material.	

3.3. Websites and other material assessed as not for inclusion

Websites	A+C assessment	A+C recommendation
ACCC on cartels (website): https://www.accc.gov.au/business/anti-competitive-behaviour/cartels	Out of scope	Not included
ACIIDS Guidelines: https://www.google.com/search?client=firefox-b-d&q=aciids+lyme&spell=1&sa=X&ved=0ahUKEwiHmvyJ5-DlAhWItI8KHb6pD2IQBQgsKAA&biw=2859&bih=1456	Incorrect link – cannot access	Not included
Antibodies Inaccuracy (See Armin Labs pdf) **How accurate are the tests for Lyme disease? Not nearly as accurate as HIV testing according to a recent analysis.** Modern medicine and clinical practice are now supported by a broad range of high technology tools that can assist with the diagnosis of disease. These range from high resolution X-ray and MRI systems, to blood and urine tests for many of the thousands of human diseases. It is generally assumed that these are accurate and clinicians frequently rely on the results to define treatment. Many of them are extremely accurate and deserve full confidence from clinicians. For example, HIV tests typically have sensitivities (the probability of disease given a positive test) greater than 99%, and specificity (the probability of not having the disease given a negative test) of greater than 99.5%. However high accuracy is not always the case and for Lyme disease the sensitivity of tests is poor as demonstrated in recently published papers. Lyme disease (Lyme borreliosis) is generally caused by the bite of a tick infected with one or more of many species of borrelia bacteria. Three recent papers with 25 authors detail the results from more than 70 independent studies of the sensitivity of Lyme disease test kits. These show that when commercial antibody test kits are used soon after an infected tick bite they typically identify 20% of cases, (80% of cases	Short document from Armin labs Not published in the peer-reviewed literature.	Not included

misdiagnosed) and with samples that were proven positive, only 59% were found to be positive (41% of cases misdiagnosed).
This is problematic since in the earliest stages of Lyme disease the symptoms are non-specific and include fatigue, and possibly joint and/or muscle pain. If not diagnosed and treated with antibiotics the borrelia bacteria disseminate to all regions of the body including the central nervous system and brain. The tests are more accurate at this later stage. However one analysis demonstrates that the test widely recommended by medical authorities where positive samples from an initial test are submitted to a second test (the so called two-tier test) misdiagnosed 74.9% of cases, a sensitivity of 25.1%.
In comparison to the methods used for HIV, Lyme disease testing can generate between 170 and 560 times as many false negative results. This degree of inaccuracy is probably unknown to the majority of clinicians and patients.
A negative test does not mean that Lyme disease is absent, and if not treated promptly can result in serious and long term illness.

References: 1. Leeflang M, Ang C, Berkhout J, Bijlmer H, Van Bortel W, Brandenburg H, et al. The diagnostic accuracy of serological tests for Lyme borreliosis : a systematic review and meta-analysis . BMC Infect Dis. BMC Infectious Diseases; 2016;16: 1–17.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4807538

2. Cook MJ, Puri BK. Commercial test kits for the detection of Lyme borreliosis: a meta-analysis of test accuracy. Int J Gen Med. 2016;9: 427–440.
http://www.ncbi.nlm.nih.gov/pubmed/25565881

3. Zeller H, Van Bortel W. A systematic literature review on the diagnosis accuracy of serological tests for Lyme borreliosis [Internet]. 2016 (Based on Leeflang et al).
http://ecdc.europa.eu/en/publications/Publications/lyme-borreliosis-diagnostic-accuracy-serological-tests-systematic-review.pdf

4. Cook MJ, Puri BK. Application of Bayesian decision-making to laboratory testing for Lyme disease and comparison with testing for HIV Application of Bayes to Lyme disease testing. Int J Gen Med. 2017;10: 113–123. https://www.dovepress.com/articles.php?article_id=32303		
ArminLabs, "Statement about Borrelia-Elispot" (See Armin Labs pdf)	Not published in the peer-reviewed literature.	Not included
Australian Curriculum, Assessment and Reporting Authority (ACARA): https://www.acara.edu.au/	Out of scope	Not included
Backlash to the 2019 IDSA guidelines. Organisations that have signed https://www.lymedisease.org/wp-content/uploads/2019/11/89-groups-in-12-countries.pdf	Not published in a peer-reviewed journal or Australian or international authority guidance or medical professional association guidelines.	Not included
Basic science (mostly) Lyme Borrelia references referring to chronic or persistent infection disease (See Armin Labs pdf)	Not published in the peer-reviewed literature.	Not included
Capital Health Network, *What is Stepped Care?*, https://www.chnact.org.au/what-is-stepped-care	Link not active	Not included
Centers for Disease Control and Prevention, "Lyme disease rashes and look-alikes" website: https://www.cdc.gov/lyme/signs_symptoms/rashes.html	Rashes associated with Lyme disease are covered in the DoH educational materials.	Not included
Department of Health, pp. 2, 5, "Stakeholder Engagement Framework"	Out of scope	Not included
"Dr Richard Schloeffel - Australian Lyme, a global view" (YouTube video): https://youtu.be/9dZYJHGTN24	Not published in a peer-reviewed journal.	Not included
s47F	A personal CV	Not included

s47F

	Not published in a peer-reviewed journal.	Not included
	A personal CV	Not included
IDSA Guidelines Deny Diagnosis https://www.lymedisease.org/guidelines-deny-lyme-diagnosis/	Not published in a peer-reviewed journal or Australian or international authority guidance or medical professional association guidelines.	Not included
In the United States, a federal lawsuit is in progress: *'Torrey, et al v. Infectious Diseases Society of America et al'*. In this case seven architects of the ISDA Guidelines (one now deceased) along with eight private health insurers are being prosecuted under the Racketeer Influenced and Corrupt Organisations (RICO) Act; The lawsuit essentially charges that the defendants have been working with the insurance companies to deny appropriate medical treatment to patients with Lyme disease, including through the development of the IDSA guidelines; and On 26 November, it was announced that one of the defendants, Kaiser Permanente, Inc had settled and mediation continues with the other parties: https://www.lymedisease.org/wp-content/uploads/2019/12/Torrey-et-al-Kaiser-settles.pdf	Out of scope	Not included
KMF's Multidisciplinary teams Model, A solution to some of the current DSCATT/TBD issues	This model is already published in the DoH DSCATT Patient Forum report 2018.	Not included
"Lyme Borreliosis – A short overview about symptoms, diagnostic tests and therapies" PowerPoint (See Armin Labs pdf)	Not published in the peer-reviewed literature. Power point presentation by Dr Armin Schwarzbach. Contains references, mostly early 2000s and earlier. A couple of references post 2008.	Not included
Lyme borreliosis in Australia – 1986	Outside of date range.	Not included

Lyme disease: A counter argument to the Australian Government's denial. K. Smith LARA (pdf provided)	Self-publication on LARA website. Not published in a peer-reviewed journal.	Not included
Lyme Disease/Borreliosis. A overview of Lyme and direction for further research required in Australia. Karen Smith. (LARA) (pdf provided)	Self-publication on LARA website. Not published in a peer-reviewed journal.	Not included
Medicine: Science or Art? https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3190445/	Out of scope	Not included
National Health and Medical Research Council (NHMRC) Guidelines for Guidelines (website): https://www.nhmrc.gov.au/guidelinesforguidelines/review/public-consultation	Out of scope	Not included
PhD Thesis by Michelle Wills in 1995 '*Lyme Borreliosis, an Australian Perspective*': https://pdfs.semanticscholar.org/47b1/4806da6ee45838beea98c1bbb1b46013a030.pdf	Outside of date range. The findings of this thesis were discussed in the review by Chalada et al. (2016), which is included in the literature review.	Not included
RACGP, General Practice Health of the Nation 2018 (annual report) https://www.racgp.org.au/download/Documents/Publications/Health-of-the-Nation-2018-Report.pdf	Out of scope	Not included
Seronegativity in Lyme borreliosis and Other Spirochetal Infections (See Armin Labs pdf)	Outside of date range Scientific articles in a presentation (dated 16 September 2003). The most recent article in the document was published in 2002.	Not included
Spoon theory (Wikipedia page): https://en.wikipedia.org/wiki/Spoon_theory	A theory used for chronic illness, invisible illness, ego depletion. It does not appear to be a validated tool.	Not included
The Ad Hoc committee recommendations against the IDSA guidelines https://www.lymedisease.org/wp-	Not published in a peer-reviewed journal or Australian or international authority guidance or medical professional association guidelines.	Not included

content/uploads/2019/08/Ad-Hoc-Patient-Physician-Coalition-Comments.pdf		
The Spoon Theory: https://www.scarymommy.com/wp-content/uploads/2017/12/spoon-theory-feature.jpg	A theory used for chronic illness, invisible illness, ego depletion. It does not appear to be a validated tool.	Not included
TIARA "Allergic Conditions caused by Tick Bites" pamphlet	Out of scope	Not included
TIARA prevention and management pamphlet	Out of scope	Not included
Tick Induced Allergies Research & Awareness (TIARA) website: https://www.tiara.org.au/	Out of scope	Not included
Treat Lyme, "Lyme Disease Treatments" website: https://www.treatlyme.net/	Not published in a peer-reviewed journal/international authority guidance /professional medical association guideline.	Not included
U.S. Government Printing Office, "Health Insurance Coverage in the United States: 2018" Current Population Reports: https://www.chn.org/wp-content/uploads/2019/09/2018-Health-Insurance-Coverage.pdf	Out of scope	Not included

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Progress Report - DSCATT Clinical Pathway – 13 Nov 20

Client: s22 Department of Health
Date of Report: 13 November 2020
Drafted by: s47F

Introduction	This report provides an update on the work undertaken between 7 August and 13 November 2020
Main activities <u>this</u> period	s22 **Final Clinical Pathway** • Incoroporated 2nd round of feedback from the department • Provided final Clinical Pathway to the department on Friday 16 October 2020 for AHPPC approval • All work complete **Literature Review** • Update draft Literature Review following 3rd round of feedback from the department • Revised draft Literature Review to include additional, relevant sources and information • Provided 2nd draft of the Literature Review to the department for review and feedback on Thursday 22 October 2020

s22

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Budget Estimates 2020 - 2021
Outcome: 5 - Regulation, Safety and Protection

PDR Number: SQ20-000635

Question Subject: literature review and research for the Clinical Guidelines

Type of Question: Written

Senator: Rachel Siewert

Question:
• In relation to the literature review for the Clinical Guidelines, what evidence and research did the Department of Health and its consultants or contractors rely upon, specifically providing the full list of actual citations relied upon.

Answer:
The Debilitating Symptom Complexes Attributed to Ticks (DSCATT) clinical pathway was published on the Department's website in November 2020, and includes a full reference list.
www1.health.gov.au/internet/main/publishing.nsf/Content/4594AB5B9B2A90D4CA257BF0001A8D43/$File/Clinical-Pathway.pdf

The comprehensive literature review will be published on the Department's website in late 2020.

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Budget Estimates 2020 - 2021
Outcome: 5 - Regulation, Safety and Protection

PDR Number: SQ20-000638

Question Subject: Exclusion and inclusion of evidence and research for the Clinical Guidelines

Type of Question: Written

Senator: Rachel Siewert

Question:
• What framework and methodology was used to establish the exclusion and inclusion of evidence and research for the Clinical Guidelines (both draft and final draft)?

Answer:
A detailed description of the methodology used to develop the Debilitating Symptom Complexes Attributed to Ticks (DSCATT) clinical pathway will be published as part of the literature review. The literature review is due to be published on the Department's website in late 2020.

The information and evidence collected through the literature review, along with the feedback received during the consultation phase, informed the development of the clinical pathway.

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Budget Estimates 2020 - 2021
Outcome: 5 - Regulation, Safety and Protection

PDR Number: SQ20-000642

Question Subject: Tick-borne illness groups

Type of Question: Written

Senator: Rachel Siewert

Question:
• Throughout the consultation process, a number of tick-borne illness groups raised the fact that additional groups had not been considered or excluded including those explicitly listed within the relevant tender documents but no contact was made with them. Some of these groups then wrote submissions and these were apparently not accepted. Is this correct? If so can you explain why these groups were not included? Can you explain why their submissions were excluded once they had been identified and the Department of Health and/or Allen + Clarke were informed?

Answer:
The DSCATT clinical pathway Approach to Market (ATM) documentation included a list of patient group organisations that at a minimum would be included in the stakeholder consultation process. The minimum list provided was:

- Lyme Disease Association Australia (LDAA)
- Karl McManus Foundation (KMF)
- Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS)
- Multiple Systemic Infectious Disease Syndrome (MSIDS)
- Tick-borne Illness Community Network Australia (TICNA)
- Sarcoidosis Lyme Australia (SLA)
- Lyme Australia and Friends Group
- Lyme Australia Recognition and Awareness (LARA)
- Global Lyme and Invisible Illness Organisation (GLIIO)
- ME/CFS and Lyme Association of WA Inc.
- Chrysalis CFS/ME and Lyme Support
- The Kojonup Lyme Supporters Association Inc.
- Relevant ME/CFS, emerging biotoxins, or other similar disease patient groups.

These patient groups were invited to participate in the DSCATT clinical pathway consultation process. A total of 40 patient groups were invited to participate in this process.

The consultation period was undertaken from 13 November 2019 to 24 January 2020. Stakeholder feedback received during the consultation period was used to inform the finalisation of the pathway. Feedback that was received outside of the consultation period, that was out of scope, or that was not supported by the current scientific evidence base, was not incorporated into the final clinical pathway.

ALLEN+CLARKE

DSCATT Literature Review (Working draft) Summary of Feedback and A+C comments and proposed approach

Please see the Department's comments below in red for the suggested/proposed approach.

GENERAL COMMENTS			
DOH comments	A+ C comment	Our suggested/proposed approach	DoH Decision/Comments
Overall, the literature review needs to be consistent in regards to terminology about Lyme disease, other infectious diseases and DSCATT. The review needs to carefully differentiate between diagnosed classical Lyme disease and other diseases.	We agree that there is a wide range of terminology used in the literature. We highlight this in section 1.5 Interdependencies, where we also raised the issue/disagreement about chronic Lyme disease and the Australian Government's position on chronic Lyme disease. Most of the Australian literature (which we have included irrespective of quality but quality appraised) refers to Australian Lyme-like cases and Lyme-like illness. This is the case in the high quality review by Chalada et al. and these terms are used heavily in the Senate Inquiry. We didn't change the terms used by authors in the Working Draft. We also noted in the working draft that the patient advocacy groups, especially LDAA use several terms and use these interchangeably, leading to confusion.	For clarity and consistency, we can change the terms used in papers and the Senate Report to DSCATT, with a statement up front saying we have done that. Happy to discuss.	Agreed, the Literature Review needs to clarify that multiple terms are grouped under DSCATT and define the term.
It is important that terms are not used that are incorrect - for example, don't refer to 'chronic lyme borreliosis' as a condition,	Regarding the use of the term chronic Lyme borreliosis, this was the exact term used by Chalada et al. so we retained it.	We can make it clear that chronic Lyme borreliosis was the term used by Chalada	As per our original comments, please refer to medically defined conditions only.

GENERAL COMMENTS			
and don't use the term 'illness' when referring to DSCATT.	Chalada et al. wrote "*Since diffuse arthralgia, cognitive difficulties and fatigue are common in chronic Lyme borreliosis, it is possible for fibromyalgia to be mistaken for Lyme borreliosis and vice versa [147,148]*" We wrote: - It is possible for fibromyalgia to be mistaken for Lyme Borreliosis and vice versa as diffuse arthralgia, cognitive difficulties and fatigue are common in chronic Lyme Borreliosis.	et al, not us. Happy to discuss the best way forward to avoid confusion.	
More rigour about the hierarchy of evidence would be valuable – for example, statements and self-reported information from the senate enquiry must still meet the same criteria for inclusion as all other evidence.	We have done the quality review of papers but this hasn't been articulated in the working draft of literature review yet. The Senate Inquiry reports were provided as key documents which were to be used to inform the development of the Clinical Pathway (irrespective of their quality). As grey literature the reports will be assessed using AACODS. However, within those reports all of the evidence presented to the Inquiry about symptoms and co-morbidities was by patients and was self-reported or was anecdotal evidence from Lyme literate doctors.	We will assess the Senate Inquiry reports using AACODS as stated in the ToR, however, within those reports as much of the evidence presented to the Inquiry was by patients and was self-reported. It would be really helpful to discuss the inclusion/exclusion of information from the Senate Inquiry/DSCATT Forum reports given that these documents are key documents. Also how we respectfully acknowledge the self-reported and anecdotal evidence provided by patients and patient advocacy groups to the Senate Inquiry (where it is the only information available, while also acknowledging the level of evidence	Senate Inquiry documents should be used to *inform* the work (as stated in the ToR). The methodology of the review needs to clearly articulate a hierarchy of sources, for example the WHO>> Australian Government guidelines>> published peer-reviewed reports in reputable journals. Any grey literature should be explored for reference to black literature (e.g. published peer-reviewed references) and only the black literature cited.

GENERAL COMMENTS			
	Regarding what is included from the Senate Inquiry we understood from the workshop conversation that no quotes or specific references attributed to submitters, irrespective of whether they were experts/expert bodies or by patient advocacy groups were to be included; rather any issues raised were to be as dot points.	does not reach the level of quality to inform an evidence based pathway). We can either only have dot points on issues raised at the Senate Inquiry with no specific submissions attributed to those dot points OR If submissions are to be acknowledged, and if there is a reference cited in the submission to support the statement in the submission we can note the reference that was cited. If there was no reference cited we can note that too.	For an example of a comprehensive methodology description, please refer to pages 30-31 of the NHMRC Systemic review of the human health effects of wind farms (2015).
Each section should be linked to how that impacts the design of the clinical pathway.	Noted.	This was not in the ToR but we can include a statement(s) about this.	Agreed.
Be really careful with statements that attribute cause and effect. For example - Pg 3, Lit review report, second last paragraph "*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 diseases*".	That statement is included in the Literature search draft report and is taken directly from the agreed ToR. We included the systematic reviews that underpin the NICE guidelines on non-specific symptoms of Lyme disease and on-going symptoms of Lyme disease because they were symptoms reported by ACIIDS to be similar to DSCATT. But	We need to agree the best way to articulate this given it is in the finalised ToR.	The text from the ToR is: "*..particularly where these have been used in the development of clinical guidelines internationally and are* ***relevant*** *to the development of a clinical pathway..*" These guidelines need only be used if they are relevant to DSCATT and associated

GENERAL COMMENTS			
▪ Just because a person may have similar non-specific symptoms, it may not be appropriate to apply Lyme disease treatment evidence. Non-specific symptoms may be indicative of many different diseases.	we agree DSCATT is not Lyme disease so even though the symptoms are similar this could cause confusion.		symptoms. If they are not relevant they should not be included.
Don't focus on treatment for Lyme disease or any of its complications, as this is already covered in *An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis* and other international guidelines.	We mentioned in the working draft of the literature review we had included the Lyme disease treatment guidelines because Lyme-literate doctors and ACIIDS state they use Lyme disease guidelines to treat patients with Lyme-like illness (based on their view and in the ACIIDS submission that the symptoms are very similar to European Lyme disease). We included the NICE treatment guidelines for Lyme disease to demonstrate the latest guidance (NICE 2018) on Lyme disease does not support long term antibiotic therapy, or multiple courses of antibiotics for people with on going symptoms of Lyme disease (symptoms which are similar to those reported by patients who identify as having DSCATT). However, we realise that this could be confusing as DSCATT is not classical Lyme disease, and DSCATT is	We can remove all of the treatment guideline reviews. However, if we remove all of the international treatment guidance on Lyme disease the PICO questions will also go to. We included PICO questions in the ToR because we knew that the NICE guidelines had specifically done PICO questions on antibiotic treatment and we intended to report these in our literature review. OR We will note that guidelines X, Y and Z do not support long term antibiotic therapy. Happy to discuss. Preferred approach.	Do not need to include details of the guidelines. State the guideline, its point of view, and then include a reference. Detailed information can be found in the guideline documents.

GENERAL COMMENTS			
	associated with symptoms and symptom complexes. The major concern about long term antibiotic treatment prescribing and AMR was raised in the Senate Report and by papers such as Collignon et al. So we thought including the latest guidance on antibiotic prescribing for Lyme disease made sense and addressed the concerns about prescribing practices of Lyme literate doctors made by medical professional bodies to the Senate Inquiry and in published papers. We also included the other international treatment guidelines to show similarity in guidance, except for the ILADS and German Borreliosis Society guidelines that ACIIDS uses – which are in contrast to IDSA (2006) guidelines that the Australian Government uses. Regarding the discussion at the workshop about complementary treatments, it was raised that we could look to include the evidence base on treatments such as herbs and supplements if it were given to us by patients during the consultation.	We use the advice provided by DOH on other treatment modalities as already included in the literature review. OR If DoH want the evidence on complementary therapies reviewed, this will need to be considered as a new scope in the literature review. Happy to discuss. Use advice provided by DoH and already included in the literature review. Anything else is out of	

GENERAL COMMENTS			
	We had previously agreed with DOH that we would not review the complementary therapies and have included the advice provided by DoH that DOH had given previously to patients.	scope of the project. Please include a statement in the literature review indicating that this is beyond the scope of this project.	

SPECIFIC COMMENTS REGARDING CHAPTER 4			
DOH comments	A+C comment	Our suggested/ proposed approach	DoH decision/comments
The questions should be structured much more like a literature review, with a question and then the evidence against that question, with it being very clear what the quality of that evidence is. Alternatively, turn the evidence and grading into recommendations for the pathway. For example "*there are many different conditions that may cause chronic non-specific symptoms. It is recommended that a full history, examination and targeted tests be undertaken as a first step. If no cause is found, referral to a relevant specialist is recommended.*"	We agreed the research questions with DOH. The question "What information is available on diseases and disorders Australian patients experiencing DSCATT have been diagnosed with and what are the most likely differential diagnoses" can be answered in two ways. For the first part of the question we have answered the question by including lists/graphs of diseases and disorders as reported in submissions to the Senate Inquiry. We recognise these are self-reported and therefore of low reliability. However, this is the information available.	We can certainly reorganise the information in the chapter and have more discrete headings, and as above include the grading of evidence which we have not included in the working draft. Happy to discuss which approach works best to inform the Clinical Pathway.	Perhaps state there is no published epidemiological or clinical evidence to answer the question, and then include that there is only relevant self-reported and anecdotal information available.

SPECIFIC COMMENTS REGARDING CHAPTER 4			
	Alternatively, the question could be answered from the perspective that there is no published epidemiological or clinical evidence to answer this question. The only information available comes from the Senate Inquiry, and submissions to the Senate Inquiry, all of which is self-reported and anecdotal and of low reliability and we therefore have not included any of information. If we take this approach we will have no list of diseases/disorders to be considered when patients with debilitating symptoms present to the GP.		
4.1 – This information is from sources that are self-reported and in some cases not supported by evidence that meets the literature review criteria. For the purpose of the clinical pathway, the identification of a list of other tick borne pathogens has a place, however these can be found in the existing clinical pathway.	We have answered the question by including lists of self-reported diseases and disorders as reported in submissions to the Senate Inquiry. We recognise these are self-reported and therefore of low reliability. However, this is the information available. The Senate Inquiry reports are key documents that had to be included in the literature review irrespective of the quality.	As above, we are happy to discuss the best way forward regarding the level of evidence and what is included.	As above.
4.2 – This could be a long list of other conditions that have been diagnosed in	Do you mean including a list of conditions (e.g MNS, MS) that people	Happy to discuss	Please provide some text to describe how co-morbidities may

SPECIFIC COMMENTS REGARDING CHAPTER 4			
people with these symptoms. Perhaps include a statement about how symptoms of these conditions may have significant overlap, and that a good history and examination with judicious testing can help diagnose which of these may be causing the symptoms. - *The major problem here is the fundamental difference in opinion between some DSCATT sufferers and their medical professional.*	(not DSCATT patients) have been diagnosed as having based on similar symptomology to DSCATT? For example, the MAYO Clinic provides a range of conditions commonly associated with ongoing fatigue. See https://www.mayoclinic.org/symptoms/fatigue/basics/causes/sym-20050894ue		affect symptoms, no need to list the actual conditions.
4.2.3 – Rather than refer to experts' evidence at the inquiry, wherever possible use of the papers used to reach the opinions presented by these experts would give stronger evidence. This would also better support the criteria outlined in the literature review ToR.	We refer our question above about the decision that needs to be made about what is included from the Senate Inquiry and the level of detail- dot points of issues with no attribution, or if attribution is given whether there is evidence to support the statement.		As above.
4.2.4 – There are currently 4 different lists of Australian tick pathogens in this chapter. We suggest that this be tidied up to either: o match each disease with the evidence available; or o batch them into categories, matched with the appropriate evidence. For example, "*proven to be in Australia*", "*could be transmitted if introduced*	We agree there is a lot of detail and some overlap in this working draft.	We will make this more succinct and divide into headings DoH suggests.	Agreed.

SPECIFIC COMMENTS REGARDING CHAPTER 4			
but no cases yet seen", and "*zoonosis of unknown potential*".			
4.2.5 – Suggest this be removed as it does not appear to be relevant to the clinical pathway and may cause confusion.	We included this information because we understood that while symptoms of DSCATT may be attributed to ticks, the cause is yet unknown and, as mentioned in the Senate Inquiry reports there may be other causes for the symptoms in some patients that need to be investigated in a Clinical Pathway, e.g, parasitic and viral causes and environmental toxins.	We can remove this section if DOH considers it is confusing. Happy to discuss if it fits better elsewhere, or not at all.	Please remove.
4.2.6 – This is why the "check for other tick borne diseases" is an important inclusion in the current plan for the diagnostic pathway. The known infections that can have a chronic manifestation from this section would more readily fit in the differential diagnosis section of this chapter.		We can move this and make it more clear and succinct.	Agreed.
4.2.7 – As above. This information is about longer lasting or chronic infections and would more readily fit into a differential diagnosis section.		We can move this.	Agreed.
4.2.8 – It is unclear how this should be used. As an alternative, another table could be used instead. For example, Table 30 in	This section includes the information reported by ACIIDS doctors and patients on conditions that have or should be	It will be easier to address this once we have a clear way forward about inclusion of Senate Inquiry evidence.	See above.

SPECIFIC COMMENTS REGARDING CHAPTER 4			
this chapter, with alternative diagnoses matched to supporting evidence.	considered in patients with symptoms that have led to a diagnosis of Lyme-like illness DSCATT. We acknowledge this is all anecdotal and no evidence has been provided to support the anecdotal evidence. Again this is a discussion about how much is included from the /Senate Inquiry and the DSCATT Forum reports.		

SPECIFIC COMMENTS REGARDING CHAPTER 5			
DOH comments	A+C comment	Our suggested/proposed approach	DoH decision/comments
Is the NRL report listed in the initial table of evidence?	Noted.	It will definitely be included.	Noted.
It needs to be clear when comments and evidence are applicable to acute, classical Lyme disease (e.g. the NICE guidelines), and when people are using the tests in situations for which it wasn't designed (e.g. years or decades after symptoms began).	Noted. We included all of the NICE guidelines including the findings of their PICO questions in the chapter on treatment modalities and the evidence for those modalities. Do you see some of the guidelines and evidence-based reviews including PICO questions fitting more appropriately in this section?	Happy to discuss the best approach for inclusion.	Noted. Can discuss in teleconference.

The Hon Greg Hunt MP
Minister for Health
Minister Assisting the Prime Minister for the Public Service and Cabinet

s22

s47F

s47F

Dear

I refer to your letter of 23 January 2020 concerning the development of an evidence-based clinical pathway and multidisciplinary care model for patients suffering from Debilitating Symptom Complexes Attributed to Ticks (DSCATT) and s22

s22 I apologise for the delay in responding.

s22

These projects are intended to benefit multiple stakeholders and will provide much needed guidance for health professionals and the public. Overall feedback on these projects has been largely positive, particularly among health professional groups. The Australian Government will continue to work closely with the project consultants to ensure that the final clinical pathway and education materials are evidence-based and reflect best practice.

Parliament House Canberra ACT 2600 Telephone: (02) 6277 7220

s22

s22

Feedback provided by your organisations within this timeframe will be taken into consideration when finalising the clinical pathway

s22

Thank you for writing on this matter.

Yours sincerely

Greg Hunt

s22

Darren Chester

Federal Member for Gippsland

April 24, 2020

The Hon Greg Hunt, MP
Minister for Health
Parliament House
CANBERRA ACT 2600

Dear Minister

I wish to make supporting representations s47F
s47F Sale regarding the draft clinical pathway for Debilitating Symptom Complexes Attributed to Ticks (DSCATT).

Please find enclosed self explanatory correspondence received from s47F which I believe has been forwarded to you directly.

I would be grateful to receive your comments on the matters raised so that I can respond to my constituent.

s22

Yours sincerely

DARREN CHESTER
The Nationals

All correspondence to: PO Box 486 Sale Victoria 3853 Telephone: 1300 131 785
Email: darren.chester.mp@aph.gov.au Website: www.darrenchester.com

s47F

The Hon. Greg Hunt, MP
Minister for Health
PO Box 6022
House of Representatives
Parliament House
Canberra ACT 2600

29th January 2020

Dear Minister,

RE: Draft Clinical Pathway for Debilitating Symptom Complexes Attributed to Ticks (DSCATT)

In our capacity as representatives of the patient community, we write seeking your intervention by way of moratorium to suspend the development of the DSCATT Clinical Pathway until such time as all applicable stakeholders have been consulted and a risk assessment of the pathway has been undertaken.

We request that the draft DSCATT Clinical Pathway (a) be revised in line with stakeholder feedback and assessment outcomes and; (b) be reissued to all stakeholders for further comment before proceeding to final publication.

s22

s22

Risk Assessment

The literature review has not been provided and the stakeholder body is unsure if it has been undertaken. The literature review reduces risk by establishing the patient pathway requirements in context of the known science and existing care delivery. The draft pathway is blatantly unscientific, ignoring large bodies of published research as evidenced by a selective and limited bibliography.

The clinical pathway is dependent on diagnostic testing being ordered by infectious disease specialists and advice from microbiologists. This precludes general practitioners and other specialists from ordering testing, diagnosing or prescribing treatment. In the absence of scientific assessment, the clinical pathway lists many presently utilised modalities of treatment as 'not recommended', including combined antimicrobials, vitamins and nutritional management. It specifies use of NATA/RCPA laboratories for diagnosis, this excludes many laboratories presently utilised. These restrictions in the clinical pathway model present an increased risk to the health of Australians with associated legal exposure to the healthcare system that must be assessed in consideration of (but not limited to) those points listed in Attachment 1.

s22

The patient stakeholder community unanimously rejects the draft clinical pathway. Key pathway requirements of consultation and scientific review have been so poorly executed as to warrant investigation into contractual processes.

In absence of appropriate stakeholder consultation, scientific review and risk assessment, the draft DSCATT Clinical Pathway is unfit for purpose and worsens the situation surrounding tick borne infection in Australia.

s22

s47F

s22

The Hon Greg Hunt MP
Minister for Health
Minister Assisting the Prime Minister for the Public Service and Cabinet

s22

The Hon Darren Chester MP
Minister for Defence Personnel
Minister for Veterans' Affairs
Member for Gippsland
PO Box 486
SALE VIC 3853

28 MAY 2020

Dear Minister Darren

I refer to your letter of 24 April 2020 s47F concerning the Debilitating Symptom Complexes Attributed to Ticks (DSCATT) clinical pathway project.

s47F

s22

In terms of the development process, the clinical pathway project has been undertaken on behalf of my Department by an external consultant, and been informed by two key components: a literature review; and stakeholder consultation. Stakeholder consultation included a Think Tank forum held in May 2019, and consultation on the draft clinical pathway, which took place from 13 November 2019 to 24 January 2020. Through these approaches, medical and health professionals, patient groups, and relevant state and territory governments have been engaged. Feedback provided within these consultation approaches is being considered while finalising the clinical pathway. I appreciate that there is significant stakeholder interest in this project, and my Department will soon be reaching out to stakeholder groups to provide an update on the development process of the clinical pathway project.

s47F also seeks an understanding of how the clinical pathway project fits into the broader health system. The clinical pathway project is a critical piece of work that is intended to benefit multiple stakeholders. It will support clinicians' decision-making on differential diagnosis and referral pathways for patients presenting with debilitating symptom complexes.

Parliament House Canberra ACT 2600 Telephone: (02) 6277 7220

It is intended that patients will benefit by receiving a comprehensive assessment of their symptoms, ensuring that patients with complex clinical presentations are appropriately diagnosed and managed.

s22

Thank you for bringing s47F concerns to my attention and I hope this information is of assistance.

Yours sincerely

Greg Hunt

Encl (1)

Australian Government
Department of Health

s47F s22

Dear s47F

Thank you for your correspondence of 29 January 2020 to the Minister for Health, the Hon Greg Hunt MP, s22
regarding the Debilitating Symptom Complexes Attributed to Ticks (DSCATT) clinical pathway project. The Minister has asked me to reply.

s22

The clinical pathway project is a critical piece of work underpinned by a literature review of the current evidence. The project is intended to benefit multiple stakeholders by supporting clinicians' decision-making on differential diagnosis and providing patients with a comprehensive assessment of their symptoms. The Department will continue to work closely with the project consultants to ensure that the final clinical pathway is evidence-based and reflects best practice.

Key stakeholders have been consulted throughout the development of the clinical pathway, including many of the medical professionals identified in your correspondence. Additionally, all state and territory governments were given the opportunity to provide feedback. As you are aware, consultation closed on 24 January 2020; feedback provided by stakeholders within this timeframe will be taken into consideration when finalising the clinical pathway. The Department is also committed to continuing to engage with patient group representatives, s22 when finalising the pathway.

s22

GPO Box 9848 Canberra ACT 2601
Telephone: (02) 6289 1555

Thank you for writing on this matter.

Yours sincerely
s22

A/g Assistant Secretary
Health Protection Policy Branch
23 April 2020

The Hon. Greg Hunt, MP
Minister for Health
PO Box 6022
House of Representatives
Parliament House
Canberra ACT 2600

24th January 2020

Dear Minister,

RE: DSCATT Clinical Pathway Project

In our capacity as representatives of the patient community, we write seeking your urgent intervention by way of moratorium to suspend the development of the DSCATT Clinical Pathway until such time as all applicable stakeholders are consulted and afforded feedback and risk/impact assessment of the document has been undertaken. We request that the draft DSCATT Clinical pathway be revised in line with stakeholder feedback and assessment outcomes and be reissued to all stakeholders for further comment before proceeding to final publication.

s22

s22

The clinical pathway is dependent on diagnostic testing being ordered by Infectious Disease Specialists/ Microbiologists, excluding General Practitioners from ordering testing, diagnosing or treating the patients. It lists many presently utilised modalities of treatment as 'not recommended' (eg antimicrobials, vitamins and nutritional managements) in absence of comprehensive scientific assessment. In doing so, patient access to medical care, choice and control and the autonomy and clinical independence of Australian practitioners, specialists and healthcare professionals is significantly impacted. Organisations representing general practitioners, specialists, integrative practitioners and natural medicine providers were omitted from consultation by the Contractor.

s22

(b) In specifying NATA/RACP laboratories for diagnosis, validity against existing international reciprocity agreements governing test acceptance (ILAC) and TGA processes accrediting testing used by Australian laboratories for detection of infection were omitted. The clinical pathway directs testing to select laboratories, with significant impacts on other business and requires assessment against The Competition and Consumer Act 2010 (anti-competitive behaviour).

s22

(d) In specifying select laboratories for testing of individuals infected after suspected tick bite, the microorganisms able to be tested are limited. Within each microorganism able to be tested, the results are further limited by the species and strain variations detectable within

the context of the limited test types the laboratory employs to detect the microorganism. This poses a great deal of risk to the patient, treating medical community and public health.

The literature review reduces risk by establishing the patient and medical requirements in context of the science and care delivery models in place. The literature review has not been provided and the stakeholder body is unsure if it has been undertaken. The document is unscientific ignoring a large body of published research relating to treatment and persistence of infections and fails to include many infections. Despite a lack of supporting evidence and a body of evidence to the contrary, the guideline was founded around the assumption of absence of Lyme disease borrelia in Australian other than from overseas acquired, which was deemed to be very rare. From the top down, the document is unsuitable. It ignored relapsing fever borrelia and did not address infection by congenital and sexual transmission, presence in the blood supply, in imported livestock and semen.

The clinical pathway has been rejected in its entity by the patient community. It is far from best practice, unfit for purpose and scientifically unsound. We hope that you will suspend the process and initiate actions that necessitate proper scientific processes are undertaken in line with appropriate stakeholder consultation and risk/impact assessments.

Yours sincerely,

s47F

s22

From: s47F
Sent: Friday, 27 September 2019 4:27 PM
To: s22
Cc: s22 s47F
s47F

Subject: Draft DSCATT Clinical Pathway for consultation - updated version

Hi s22 and s22

We have reordered the body of the document as you suggested and have incorporated DoH comments and recommendations. The flow of the document now follows the diagram better.
We have also included relevant evidence from the 2019 IDSA/AAN/ACR draft guidelines. There is also specific evidence about treatment modalities not recommended for Lyme disease.
We have kept the evidence base in the document as we feel for the consultation it is better to have the evidence underpinning the Clinical Pathway available for stakeholders to see. It will be easier for us to discuss and defend the evidence-based Clinical Pathway.

We look forward to discussing the revised document once you have had a chance to review it.

Kind regards
s47F

w www.allenandclarke.co.nz

a PO Box 10730, Wellington 6143
Level 2, The Woolstore, 262 Thorndon Quay, Pipitea,
Wellington 6130
New Zealand

From: s47F
To: s22
Cc: s22 s47F
Subject: RE: Revised DSCATT Clinical Pathway [SEC=OFFICIAL]
Date: Wednesday, 16 September 2020 4:43:28 PM
Attachments: image006.png
image009.jpg
image004.png
image005.png
DSCATT Clinical Pathway - 16 September 2020.docx
DSCATT Clinical Pathway - 16 September 2020.pdf
DSCATT Clinical Pathway - Tracking document, 16 September 2020.pdf

Dear s22

Thank you again for the Department's most helpful feedback on the revised version of the DSCATT Draft Clinical Pathway. As Paul indicated in his email we have been working on finalising the Clinical Pathway and completing our internal QA. We are pleased to provide the Department with the final version of the DSCATT Clinical Pathway.

In this finalisation process we have addressed the Department's comments and incorporated the Department's feedback, including bringing recommended changes through the document for consistency where they pertained to more than one section.

We have added more information, as requested, about mental health support for patients with MUS or for patients who are identified as experiencing symptoms associated with DSCATT. We have also amended some of the text around DSCATT to reinforce that DSCATT cannot be a diagnosis. We have also added in the findings of the paper by Nigrovic et al. (2019) that Jess kindly posted to us. This paper, about a prospective study in the US, added to the existing information about many people diagnosed with Lyme disease not recalling a tick bite.

We have done a comprehensive review of the document and identified a few additional changes that were needed to ensure consistency in the Clinical Pathway document. This has included changes to the algorithm where the term 'specialist microbiologist' is now used consistently in all relevant boxes in differential diagnosis and initial management. We made a couple of minor changes to the headings throughout the Clinical Pathway to keep consistency. These minor changes were mainly to sections titled 'Patients presenting with persistent debilitating symptoms'.

In addition to our comprehensive internal QA process, s47F our Guidelines Technical Expert has completed a technical peer review. Through our QA and polishing, the footnotes and references have been all reviewed and tidied up where required. We have a new look cover page as well.

We attach three documents: a Word document and a PDF document of the DSCATT Clinical Pathway, and a PDF document of the tracking (compare and contrast).

As always, we are more than happy to discuss any aspect of the DSCATT Clinical Pathway.

Warm regards

s47F

s22