

The Senate

Community Affairs
References Committee

Growing evidence of an emerging tick-borne
disease that causes a Lyme-like illness for
many Australian patients

Interim report

May 2016

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44th Parliament

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Senator Zhenya Wang	Western Australia, PUP

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ABBREVIATIONS

ACIIDS	Australian Chronic Infectious and Inflammatory Disease Society
AHPPC	Australian Health Protection Principal Committee
AMA	Australian Medical Association
CACLD	Clinical Advisory Committee on Lyme Disease
CDNA	Communicable Diseases Network Australia
CMO	Chief Medical Officer
committee	Community Affairs References Committee
department	Department of Health
EM	Erythema Migrans
ESGBOR	European Society of Clinical Microbiology and Infectious Diseases Study Group for Lyme Borreliosis
IDSA	Infectious Disease Society of America
LDAA	Lyme Disease Association of Australia
ME/CFS	Myalgic Encephalomyelitis / Chronic Fatigue Syndrome
MRA	International Laboratory Accreditation Cooperation Mutual Recognition Arrangement
MSIDS	Multiple Systemic Infectious Disease Syndrome
NATA	National Association of Testing Authorities
NHMRC	National Health and Medical Research Council
NIAID	National Institute of Allergy and Infectious Diseases (US)
PCR	Polymerase Chain Reaction
RCPA	Royal College of Pathologists of Australasia
US	United States of America
US CDC	United States Centers for Disease Control and Prevention

LIST OF RECOMMENDATIONS

Recommendation 1

4.52 The committee recommends that the Community Affairs References Committee continue its inquiry into this matter in the 45th Parliament.

Recommendation 2

4.56 The committee recommends that the Department of Health further develop education and awareness strategies for:

- the public about the prevention of tick bites and seeking medical attention; and
- the medical profession about how to diagnose and treat classical Lyme disease acquired overseas and known tick-borne illnesses acquired in Australia.

Recommendation 3

4.58 The committee recommends that the Chief Medical Officer continue to consult with the medical and patient communities through mechanisms such as the Clinical Advisory Committee on Lyme Disease, and for the Department of Health to continue to facilitate meetings with medical and patient representatives.

Chapter 1

Introduction

My brother, Scott Chant, had a tick bite at a northern New South Wales property while doing some work there. He found out he had Lyme after seeing a Lyme-literate doctor. That was after probably 12 months of just not knowing. He gave up his fight on 8 February this year. I think every day about what led him to make that decision but, from reading these stories, it is obvious. Being so debilitated, he had to spend his days in bed or on his fold-out chair. It was not the life he envisaged or wanted to live.

I do blame the medical system in Australia. Yes, there were those who were doing their best to help, and I think of those people every day. Without them, he would not have lasted three years. But when the time came that we needed that next step of help, it was not there. Hospital admissions often ended with Scott being sent home and us, the family, being told it was all in his head and we should stop encouraging it. There were really rough nights. I do believe that, if those experiences had been different, Scott would be here right now speaking to you all and telling you his story.¹

1.1 During the course of this inquiry, the Senate Community Affairs References Committee (committee) has heard many personal accounts of Australians suffering from chronic debilitating symptoms who have struggled to access appropriate medical treatment. The committee is deeply concerned to hear that frustration and dismay with the lack of treatment options has contributed to some patients, like Mr Scott Chant, taking their own lives.

1.2 Patients, advocacy groups and medical authorities all recognise that patients are suffering, that their symptoms are real, and that they deserve access to medical treatment.

Terms of reference

1.3 On 12 November 2015, the Senate referred the following matter to the committee for inquiry and report by 20 June 2015: 'the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients'.

1.4 The terms of reference for this inquiry are:

- (a) the prevalence and geographic distribution of Lyme-like illness in Australia;
- (b) methods to reduce the stigma associated with Lyme-like illness for patients, doctors and researchers;
- (c) the process for diagnosis of patients with a Lyme-like illness, with a specific focus on the laboratory testing procedures and associated quality

1 Mr Matt Chant, *Committee Hansard*, Brisbane, 15 April 2016, p. 15.

assurance processes, including recognition of accredited international laboratory testing;

- (d) evidence of investments in contemporary research into Australian pathogens specifically acquired through the bite of a tick and including other potential vectors;
- (e) potential investment into research to discover unique local causative agents causing a growing number of Australians debilitating illness;
- (f) the signs and symptoms Australians with Lyme-like illness are enduring, and the treatment they receive from medical professionals; and
- (g) any other related matters.²

Conduct of inquiry

1.5 The committee invited submissions by 31 March 2015. As of 3 May 2016, the committee had accepted and published 1171 submissions. An overview of these submissions is provided below.

1.6 As of 3 May 2016, the committee had held three public hearings in Perth (14 April 2016), Brisbane (15 April 2016) and Canberra (20 April 2016).

1.7 The committee agreed to table an interim report for this inquiry on 4 May 2016. Due to the likelihood of the Federal election being called prior to the tabling date for the committee's final report, the committee agreed to table a summary of the evidence it has collected to date. It is the committee's intention that this inquiry will continue into the new parliament, and the committee table its final report later in 2016. The committee will continue to accept submissions to the inquiry following the tabling of this interim report.

Structure of interim report

1.8 This interim report provides a summary of the evidence heard by the committee as of 3 May 2016.

1.9 This interim report consists of four chapters:

- **Chapter 1** provides an outline of the key concepts and an overview of the submissions received to date;
- **Chapter 2** examines the experience of patients suffering chronic debilitating symptoms and the accessibility of treatment;
- **Chapter 3** examines how patients are diagnosed with Lyme-like illness and the available diagnostic testing procedures; and
- **Chapter 4** examines current and future opportunities for further research to assist patients suffering from chronic debilitating symptoms.

Key concepts

1.10 There is considerable debate in Australia and internationally about the terms 'Lyme disease' and 'Lyme-like illness'. The following section outlines the differing views on the following key terms used throughout this report:

- classical Lyme disease;
- chronic Lyme disease; and
- Lyme-like illness.

Classical Lyme disease

1.11 *Lyme borreliosis* (known as Lyme disease) is a tick-borne disease caused by various closely related species of *Borrelia* bacteria. Lyme disease is recognised as one of the most common tick-borne diseases in humans, and is found in parts of the United States of America (US), Europe and Asia. Lyme disease is named after the town of Lyme in Connecticut where it was first recognised in the early 1970s.³

1.12 One of the common species of *Borrelia* known to cause Lyme disease in the US is *Borrelia burgdorferi*. Other *Borrelia* species known to cause Lyme disease have been identified in parts of Europe and Northern Asia (such as *Borrelia afzelii* and *Borrelia garinii*).⁴ These related species of *Borrelia* are referred to as the *Borrelia burgdorferi* sensu lato complex (shortened in this report to '*Borrelia*').⁵

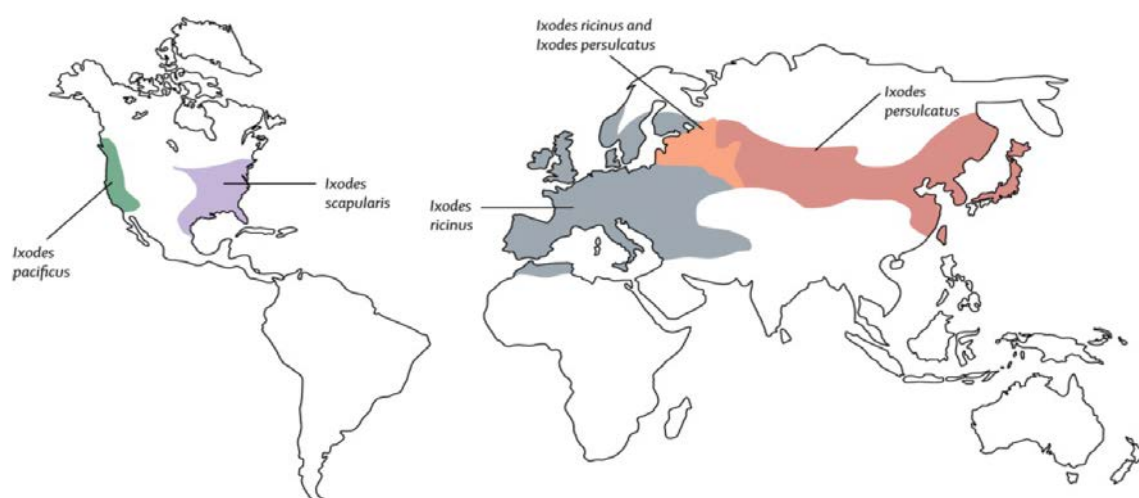
1.13 The most common vectors of the *Borrelia* bacteria known to cause Lyme disease are the *Ixodes* species of ticks. Figure 1.1 shows the global distribution of *Ixodes* ticks known to transmit *Borrelia* bacteria to humans. Lyme disease is considered to be endemic in areas where these vectors carrying *Borrelia* bacteria have been identified.

3 Department of Health, *Submission 495*, p. 2.

4 Professor John Mackenzie, *Scoping study to develop a research project(s) to investigate the presence or absence of Lyme disease in Australia*, 30 September 2013, p. 6, <http://www.health.gov.au/lyme-disease> (accessed 19 November 2015).

5 The committee notes that a number of other *Borrelia* species (not associated with Lyme disease) may cause a range of different diseases in humans and animals, such as *B. recurrentis*, *B. duttonii*, *B. hermsii* and *B. turicatae* (causes relapsing fever and transmitted to humans by lice and ticks in parts of Africa, Asia, southern Europe, North and South America); *B. theileri* (causes bovine borreliosis in cattle and transmitted by cattle ticks); *B. lonestari* (causes STARI – southern tick-associated rash illness – in the US); *B. miyamotoi* (found throughout Eurasia and the US and its role in human disease only recently demonstrated in Russia). See: Mackenzie, *Scoping study*, pp 12–13.

Figure 1.1 – Global distribution of the common vectors of *Borrelia* bacteria known to cause Lyme disease



Source: Professor John Mackenzie, *Scoping study to develop a research project(s) to investigate the presence or absence of Lyme disease in Australia*, 30 September 2013, p. 7.

1.14 Patients with classical Lyme disease commonly display the following key symptoms, depending on the stage of illness:

- **early disease:** erythema migrans (EM – a rash, sometimes in a bulls-eye shape) and an influenza-like illness;
- **early disseminated disease:** multiple EMs, meningitis (acute inflammation of the brain or spinal cord membrane), cranial nerve palsies and carditis (inflammation of the heart); or
- **late stage:** primarily arthritis.⁶

1.15 Lyme disease is regarded as an 'emerging disease', with increasing numbers of cases identified worldwide since the discovery of *B. burgdorferi* 1981 in the US. Estimates suggest there are over 65 000 cases in Europe and over 20 000 cases in the US annually. Professor John Mackenzie's 2013 scoping study on Lyme disease notes that these figures:

...may be a significant underestimate with many cases unreported, and compounded by the small number of countries in Europe to make Lyme disease notifiable, and the actual total may be closer to 255,000 cases annually.⁷

1.16 The US Centers for Disease Control and Prevention (CDC) reports that approximately 30 000 cases of Lyme disease are reported each year in the US but

⁶ Mackenzie, *Scoping study*, p. 5.

⁷ Mackenzie, *Scoping study*, p. 5.

notes that this number does not reflect every case of Lyme disease diagnosed.⁸ In 2013, the CDC suggested that as many as 300 000 people may be diagnosed with Lyme disease in the US each year.⁹

1.17 According to the Communicable Diseases Network Australia (CDNA), a standing committee of the Australian Health Protection Principal Committee (AHPPC), classical Lyme disease is a 'well-defined clinical entity', with a 'clear case definition' that can be confirmed by laboratory, clinical and epidemiological evidence.¹⁰

1.18 The Australian Department of Health's (department) guidelines for treating a confirmed case of classical Lyme disease acquired overseas in an endemic area, consistent with the Infectious Disease Society of America's (IDSA) guidelines,¹¹ recommend a short course of antibiotic treatment of two to four weeks.¹²

Chronic Lyme disease

1.19 Whereas 'classical' Lyme disease is clearly defined, there is considerable debate about the definition of what some practitioners refer to as 'chronic' Lyme disease. The committee recognises that this debate is not unique to Australia and is part of a global debate about 'chronic' Lyme disease.¹³

1.20 The controversy about 'chronic' Lyme disease centres on whether or not an ongoing, active *Borrelia* bacterial infection can result in chronic, debilitating symptoms. The debate is divided on two key questions:

- whether the symptoms described as 'chronic' Lyme disease are caused by an ongoing infection with *Borrelia* bacteria; or

8 US Centers for Disease Control and Prevention (CDC), 'How many people get Lyme disease?' <http://www.cdc.gov/lyme/stats/humancases.html> (accessed 9 December 2015).

9 US CDC, 'CDC provides estimate of Americans diagnosed with Lyme disease each year', 19 August 2013, <http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html> (accessed 21 April 2016).

10 CDNA, *Submission 531*, pp 1–2.

11 Infectious Disease Society of America, 'Lyme Disease', <http://www.idsociety.org/Lyme/> (accessed 8 December 2015). See: Gary Wormer et al, 'The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America', *Clinical Infectious Diseases*, vol. 43, no. 9, pp 1089–1134, <http://cid.oxfordjournals.org/content/43/9/1089.full> (accessed 8 December 2015).

12 Department of Health, 'An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis', August 2015, <http://www.health.gov.au/lyme-disease> (accessed 27 April 2016). See: *Submission 495*, Attachment K.

13 See for example: HM Feder et. al, 'A critical appraisal of "chronic Lyme disease"', *New England Journal of Medicine*, v. 357, 2007, pp 1422–1430, <http://www.nejm.org/doi/full/10.1056/NEJMra072023> (accessed 21 April 2016); Adriana Marques, 'Chronic Lyme Disease: An appraisal', *Infectious Disease Clinics of North America*, v. 22, n. 2, June 2008, pp 341–360, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2430045/> (accessed 21 April 2016).

- whether these symptoms are the result of a separate condition, or range of conditions, with a different underlying cause (such as residual damage from a previous infection).¹⁴

1.21 Patient advocacy groups and some medical practitioners in Australia and overseas argue that chronic Lyme disease is caused by an active ongoing infection with *Borrelia* bacteria, often with a number of other 'co-infections'.¹⁵ For example, the International Lyme and Associated Diseases Society (ILADS) argues that these chronic symptoms are a direct result of *Borrelia* infection and advocate for greater acceptance and recognition of 'chronic' Lyme disease in the US and internationally.¹⁶

1.22 In Australia, the Lyme Disease Association of Australia (LDAA), representing patients diagnosed with Lyme disease, states that most patients are suffering from 'chronic' stage symptoms of Lyme disease:

The later stage of Lyme disease is referred to as chronic or late stage and is usually marked by a progressive set of debilitating symptoms. Given the time it takes for Australian patients to reach a diagnosis for their Lyme-like illness ... this means that the majority of patients are in the chronic / late stage disease.¹⁷

1.23 Some Australian medical practitioners, such as those associated with the Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS), argue that if classical, or acute, Lyme disease is not treated, it can become chronic:

If the disease is left untreated patients often develop chronic Lyme-like Illness. Chronic Lyme-like Illness can cause a wide variety of symptoms, and in some cases profound disability.

The most common symptoms of chronic Lyme disease are fatigue, headache, muscle and joint pains and cognitive impairment ('brain fog') with poor memory and concentration.

Other symptoms of chronic Lyme-like Illness 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 (ringing in the ears).¹⁸

14 Department of Health, *Submission 495*, p. 2.

15 See: Lyme Disease Association of Australia (LDAA) *Submission 528*, Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS) *Submission 370*, Dr Richard Schloeffel *Submission 2*, and Dr Hugh Derham *Submission 453*.

16 International Lyme and Associated Diseases Society, 'About Us', <http://www.ilads.org/ilads/about-ilads.php> (accessed 8 December 2015).

17 LDAA, *Submission 528*, p. 57.

18 ACIIDS, *Submission 370*, p. [11].

1.24 These practitioners argue that treatment for 'chronic' Lyme disease is different to classical Lyme disease and recommend the use of long-term antibiotics and other treatments. These treatments are discussed in detail in **Chapter 2**.

1.25 In the US, the National Institute of Allergy and Infectious Diseases (NIAID) notes that most medical experts in the US do not support the use of the term 'chronic' Lyme disease as it may be used to describe a wide range of illnesses that are not related to infection with the *Borrelia* bacteria known to cause Lyme disease:

The term 'chronic Lyme disease' (CLD) has been used to describe people with different illnesses. While the term is sometimes used to describe illness in patients with Lyme disease, in many occasions it has been used to describe symptoms in people who have no evidence of a current or past infection with *B. burgdorferi*...Because of the confusion in how the term CLD is employed, experts in this field do not support its use...¹⁹

1.26 The US CDC suggests that 'chronic Lyme disease' is better defined as Post-Treatment Lyme Disease Syndrome (PTLDS). The CDC notes that there is significant controversy about the diagnosis and treatment of PTLDS:

The exact cause of PTLDS is not yet known. Most medical experts believe that the lingering symptoms are the result of residual damage to tissues and the immune system that occurred during the infection...In contrast, some health care providers tell patients that these symptoms reflect persistent infection with *Borrelia burgdorferi*.²⁰

1.27 Dr Gary Lum, Principal Medical Adviser in the Department of Health's Office of Health Protection, told the committee that Australian medical authorities, like their counterparts in the US, do not support the use of the term 'chronic' Lyme disease, and do not accept that the cause is an active, ongoing *Borrelia* infection:

The issue of chronic Lyme disease assumes that there is persistent, active infection. That is what is so contentious. The mainstream conventional position is that the sequelae that we see after an infection is post-infectious and not active infection ... So, in Australia, like in many other countries that we would be like-minded with in terms of medicine, the experts in microbiology and infectious disease will not readily accept that there is chronic Lyme disease or chronic persistent active infection. So, for that reason, and because of the association between what is happening in Australia with chronic Lyme disease, most of the medical profession expert in this field do not accept that it is Lyme disease.²¹

1.28 The committee received a number of submissions from Australian medical authorities that do not support the use of the term 'chronic' Lyme disease and do not agree that the chronic debilitating symptoms described by Australian patients are

19 National Institute of Allergy and Infectious Diseases, 'Chronic Lyme Disease', <http://www.niaid.nih.gov/topics/lymeDisease/Pages/chronic.aspx> (accessed 1 December 2015).

20 'Post-Treatment Lyme Disease Syndrome', US Centers for Disease Control and Prevention, <http://www.cdc.gov/lyme/postlds/index.html> (accessed 1 December 2015).

21 Dr Gary Lum, Department of Health, *Committee Hansard*, Canberra, 20 April 2016, p. 10.

caused by an ongoing infection of *Borrelia* bacteria.²² For example, NSW Health submitted that 'chronic' Lyme disease is used to describe a wide range of non-specific symptoms that may not be linked to infection with *Borrelia* bacteria:

The word 'chronic' has also been applied to Lyme disease in a wide variety of contexts and is sometimes used interchangeably with the preferred term 'late Lyme disease.' The chronic Lyme disease term is used by a small number of doctors (often described as 'Lyme-literate physicians') and patient advocacy groups to describe patients whom they believe have persistent *B. burgdorferi* infection, a condition they suggest requires long-term antibiotic treatment and/or a range of other treatments with little evidence of clinical benefit but with a significant risk of harm.

Although chronic Lyme disease can encompass post-Lyme disease syndrome in regions with endemic *B. burgdorferi* disease, it also includes a broad array of illnesses or symptom complexes for which there is no reproducible or convincing scientific evidence of any relationship to *B. burgdorferi* infection. Chronic Lyme disease is increasingly used as a diagnosis for patients with persistent pain, neurocognitive symptoms, fatigue, or all of these symptoms, with or without clinical or laboratory evidence of previous early or late Lyme disease.²³

Lyme-like illness

1.29 The committee heard that patient advocacy groups use the term 'Lyme-like illness' to describe the diagnosis by 'Lyme literate' practitioners of a range of infections that include *Borrelia* and co-infections such as *Babesia*, *Bartonella*, *Ehrlichia*, *Anaplasma* and *Mycoplasma pneumoniae*. For example, the terms 'Lyme disease', 'Lyme-like illness' or simply 'Lyme' are used interchangeably by the LDAA to describe this diagnosis.²⁴ Ms Rebecca Vary from the LDAA told the committee:

Lyme-like illness is caused by a constellation of different organisms: bugs, viruses and protozoans—a cocktail of pathogens that are making people sick ... What we can say is that, whatever you want to call it, there are commonalities in the symptoms experienced by patients. In many Australians sick for months, years and decades it is already chronic, it is debilitating, it is lifelong and it is sometimes deadly.²⁵

1.30 However, this definition of 'Lyme-like illness' (i.e. *Borreliosis* with a range of co-infections) is not recognised by Australian Commonwealth, state or territory

22 See: NSW Health, *Submission 457*; Australasian Society for Infectious Diseases Inc, *Submission 496*; Royal Australasian College of Physicians, *Submission 754*; Royal College of Pathologists Australasia, *Submission 532*.

23 NSW Health, *Submission 457*, p. 1.

24 Lyme Disease Association of Australia, *Submission 528*, p. 5.

25 Ms Rebecca Vary, *Committee Hansard*, Perth, 14 April 2016, p. 18.

governments, or Australian medical authorities.²⁶ The CDNA noted in its submission that the term may be used to describe a range of conditions:

The term 'Lyme-like illness' is used by some patients and health practitioners to describe constellations of symptoms, but what is included and what is not included within the spectrum of 'Lyme-like illness' has not been defined. Unlike most other diseases or conditions for which there are published, widely accepted definitions of the criteria required to be met in order to make a diagnosis of that disease or condition, the term 'Lyme-like illness' is applied to a variety of illnesses which may include an acute illness with headache, fever and fatigue which lasts weeks or months and a non-specific chronic illness with symptoms such as headache, myalgia, and arthralgia.²⁷

1.31 Evidence from submissions suggests that 'Lyme-like illness' may be used to describe a range of conditions, beyond those diagnosed by 'Lyme literate' practitioners, including:

- classical Lyme disease, caused by an acute infection caused by *Borrelia* bacteria transmitted to humans by ticks;
- 'chronic' Lyme disease and a range of 'co-infections' from bacteria;
- an infection of unknown cause transmitted by ticks or other vectors (such as mosquitoes or lice); or
- an illness of unknown cause and exhibiting a range of non-specific symptoms similar to chronic fatigue syndrome, fibromyalgia or multiple sclerosis.

1.32 The committee heard that 'Lyme-like illness' may be used to describe a range of different 'chronic debilitating illness that manifests as a constellation of chronic debilitating symptoms', not necessarily an acute or chronic infection of *Borrelia* bacteria and co-infections.²⁸ The Chief Medical Officer, Professor Chris Baggoley, told the Community Affairs Legislation Committee that there is unlikely to be a single cause for the range of conditions described by patients as 'Lyme-like illness':

There is no doubt there is quite a division and certainly a weight of opinion on the side of the infectious disease specialists and pathologists in this country who say there is not likely to be a unitary cause for their condition.²⁹

1.33 Similarly, the Australian Medical Association (AMA) submitted that it is not clear whether 'Lyme-like illness' is a single condition, or a range of conditions:

It is currently not clear if the 'Lyme-like illness' is one single condition or a collection of different illnesses that have overlapping clinical symptoms.

26 See: WA Department of Health, Submission 529; Victorian Department of Health and Human Services, *Submission 547*; NSW Health, *Submission 457*.

27 Communicable Diseases Network Australia, *Submission 531*, p. 1.

28 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, p. 5.

29 Professor Chris Baggoley, *Estimates Hansard*, 10 February 2016, p. 19.

This is a significant issue for treating practitioners as many patients present with symptoms that are similar to other chronic conditions.³⁰

Related and concurrent inquiries

Department of Health

1.34 In 2013, the Chief Medical Officer convened a Clinical Advisory Committee on Lyme Disease (CACLD) to provide advice on 'the evidence for Lyme disease in Australia, diagnostic testing, treatment and research requirements'.³¹ The CACLD met five times and held its final meeting on 15 July 2014. Although the CACLD formally ceased in 2014, it continues to consult with the department on research developments related to Lyme disease.³² In consultation with the CACLD, the department has undertaken a number of projects including:

- commissioning Professor John Mackenzie to complete a scoping study in 2013 to identify 'research needs for an investigation into whether a causative tick-borne microorganism (*Borrelia*) for Lyme disease exists in Australia';³³
- hosting the Lyme Disease Treatment Round Table Meeting on 27 May 2014 with members of the CACLD, general practitioners and other medical professionals to identify research projects;³⁴
- contracting the National Serology Reference Laboratory to undertake an evaluation of the serology assays currently used for the diagnosis of Lyme disease (currently in progress);
- developing the *Australian guideline on the diagnosis of overseas acquired Lyme disease/borreliosis* together with the Diagnostic Pathway Working Group, state and territory governments, the Public Health Laboratory Network and the Communicable Diseases Network Australia;³⁵ and

30 Australian Medical Association (AMA), *Submission 456*, p. 4.

31 For terms of reference, see: Department of Health, Clinical Advisory Committee on Lyme Disease (CACLD), <http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-cacld-lyme-disease.htm> (accessed 18 November 2015).

32 Professor Chris Baggoley AO, Chief Medical Officer, *Progress Report on Lyme Disease in Australia*, 31 July 2014, <http://www.health.gov.au/lyme-disease> (accessed 18 November 2015).

33 Professor John Mackenzie, *Scoping study to develop a research project(s) to investigate the presence or absence of Lyme disease in Australia*, 30 September 2013, p. 4, <http://www.health.gov.au/lyme-disease> (accessed 19 November 2015).

34 Department of Health, *Lyme Disease Treatment Round Table Meeting*, 27 May 2014, <http://www.health.gov.au/lyme-disease> (accessed 19 November 2015).

35 See: Department of Health, *An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis*, August 2015, <http://www.health.gov.au/lyme-disease> (accessed 7 January 2015).

- developing a revised tick bite education product together with the National Arbovirus and Malaria Advisory Committee and state and territory governments.³⁶

1.35 The department has previously advised the Community Affairs Legislation Committee during 2015-16 Supplementary Estimates that it is currently developing a 'national strategic framework for chronic diseases that will move away from a disease specific approach and address a broader range of chronic diseases'.³⁷

1.36 The committee notes that in March 2016, the Minister for Health, the Hon Sussan Ley MP announced the *Healthier Medicare* package to provide tailored care plans for patients with chronic diseases and complex conditions.³⁸ As part of the package, the department will trial the 'Health Care Homes' measure over two years to coordinate, manage and support care for approximately 65 000 patients with chronic diseases and complex conditions.³⁹

Department of Veterans' Affairs

1.37 In May 2015, the Repatriation Medical Authority (RMA) established an inquiry into whether Lyme disease could be related to eligible military service, including:

...whether there is information available about how Lyme disease may be suffered or contracted, or death from Lyme disease may occur, and the extent to which Lyme disease or death from Lyme disease may be war-caused, defence-caused, a service injury, a service disease or a service death.⁴⁰

1.38 The RMA presented its Statement of Principles concerning Lyme disease on 4 April 2016.⁴¹ The RMA found that 'that there is sound medical-scientific evidence that indicates that Lyme disease and death from Lyme disease can be related to

36 Professor Chris Baggoey AO, Chief Medical Officer, *Progress Report on Lyme Disease in Australia*, 20 August 2015, <http://www.health.gov.au/lyme-disease> (accessed 18 November 2015).

37 Department of Health, Response to question on notice SQ15-000771, Supplementary Estimates, 21 October 2015 (received 11 December 2015).

38 The *Healthier Medicare* package is a core part of the Australian Government's response to the recommendations of the Department of Health's Primary Health Care Advisory Group Report, *Better Outcomes for people with Chronic and Complex Health Conditions*, December 2015. See: <http://www.health.gov.au/internet/main/publishing.nsf/Content/primary-phcag-report> (accessed 22 April 2016).

39 Department of Health, 'A Healthier Medicare for chronically-ill patients', Joint Media Release, 31 March 2016, <https://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2016-ley021.htm> (accessed 22 April 2016).

40 Repatriation Medical Authority, Notice of Investigation: Section 196G of the *Veterans' Entitlements Act 1986*, 12 May 2015, <http://www.rma.gov.au/investigations/year/2015> (accessed 4 December 2015).

41 Repatriation Medical Authority, Lyme Disease, 4 April 2016, <http://www.rma.gov.au/sops/condition/lyme-disease> (accessed 21 April 2016).

particular kinds of service', where Lyme disease was acquired overseas in an endemic area.⁴²

Parliamentary inquiries

1.39 As part of its inquiry into chronic disease prevention and management in primary health care, the House of Representatives Standing Committee on Health held a public hearing on Lyme disease on 18 September 2015 in Sydney. The hearing included a roundtable discussion on the diagnosis, treatment and lived experience of Lyme-like illness with key stakeholders including Lyme disease support groups, medical practitioners and researchers. This inquiry is ongoing.⁴³ The committee notes the evidence provided to the House of Representatives Standing Committee on Health as part of this inquiry.

1.40 Notices of motion calling on the Government to support further research into Lyme disease have been raised in both the House of Representatives and Senate throughout 2015.⁴⁴

Overview of submissions

1.41 The committee has received over 1100 submissions to this inquiry to date. A small proportion of submissions were from medical practitioners, medical authorities and Commonwealth, state and territory governments.

1.42 The majority of submissions to the inquiry were from or on behalf of Australians who are suffering from chronic debilitating symptoms. In addition to submissions, the committee received over 250 short statements from the families and friends of patients expressing their support for the inquiry and urging changes to better assist patients to access appropriate treatment.

1.43 The majority of submissions from patients who are experiencing chronic debilitating symptoms came from NSW, Queensland, Victoria and Western Australia. Table 1.1 outlines the distribution by jurisdiction of 1017 submitters to this inquiry.⁴⁵

42 Explanatory Statement, Statement of Principles concerning Lyme disease (Reasonable Hypothesis) (no. 25 of 2016), 4 April 2016, <http://www.rma.gov.au/sops/condition/lyme-disease> (accessed 21 April 2016).

43 House of Representatives Standing Committee on Health, *Inquiry into Chronic Disease Prevention and Management in Primary Health Care*, http://www.aph.gov.au/Parliamentary_Business/Committees/House/Health/Chronic_Disease (accessed 7 December 2015).

44 See: Senator Claire Moore, *Senate Hansard*, No. 9–20 August 2015, p. 5885; Mr Ken Wyatt MP, *House of Representatives Hansard*, Federation Chamber, 20 August 2015, p. 9114; Ms Gai Brodtmann MP, *House of Representatives Hansard*, Federation Chamber, 17 August 2015, p. 8614; Ms Jill Hall MP, *House of Representatives Hansard*, Federation Chamber, 17 August 2015, pp 8586–8589; Mr Stephen Jones MP, *House of Representatives Hansard*, Federation Chamber, 17 August 2015, pp 8586–8587; Ms Jill Hall MP, *House of Representatives Hansard*, Federation Chamber, 28 May 2015, p. 5137; Mr John Murphy MP, *House of Representatives Hansard*, 15 May 2015, p. 3346.

Table 1.1 – Geographical distribution of submissions by jurisdiction at 30 April 2016

Jurisdiction	Number of submissions
NSW	344
Queensland	201
Victoria	200
Western Australia	193
Other (SA, ACT, NT, Tasmania)	71

1.44 A common theme throughout the submissions was of patients presenting to their local GP or medical practitioner with chronic and debilitating symptoms. In some cases they received a diagnosis for a range of non-specific conditions including chronic fatigue syndrome (CFS), fibromyalgia, Epstein-Barr virus or a mental health related condition such as depression. In other cases, they were referred on to multiple specialists and other practitioners who were not able to determine the cause of their illness. In some cases, submitters reported having visited over 20 or more medical practitioners and specialists to seek a diagnosis.⁴⁶

1.45 Submitters highlighted that the impact of these long-term, chronic debilitating symptoms are devastating. The committee heard countless accounts of how the lives of patients and their families have been adversely affected. Some submitters have been unable to work due to their illness or due to taking on carer responsibilities for an ill partner, relative or friend. The significant costs involved in managing a long-term illness have also pushed many submitters into significant financial hardship, often reliant on welfare payments or family members for support.⁴⁷

1.46 Submitters expressed significant frustrations that some medical practitioners were not able to diagnose or treat their symptoms. In cases where submitters did receive a diagnosis, they reported that the prescribed treatments were not effective and their condition continued to worsen. These submitters expressed feelings of being 'let down' by Australia's healthcare system.⁴⁸

45 This indicates those submitters who provided their postal address and whose submissions were accepted and published by 30 April 2016. This includes all submissions from each jurisdiction, including over 900 personal submissions, 28 submissions from organisations and a number of submissions from medical practitioners.

46 See, for example: *Submission 121*, *Submission 178*, *Submission 202*, and *Submission 614*.

47 See, for example: *Submission 1014*, *Submission 277*, *Submission 548*, *Submission 700*, *Submission 615*, *Submission 262*, and *Submission 184*.

48 See, for example: *Submission 606*, *Submission 164*, *Submission 324*, and *Submission 595*.

1.47 Submitters expressed particular concern that their descriptions of their symptoms have not been taken seriously by medical practitioners. Many submitters have been told that their symptoms were psychological, and that 'it's all in your head'. These submitters reported feeling humiliated and disrespected by individual medical practitioners, practices and hospitals and expressed significant anger and disappointment at the way they have been treated.⁴⁹

1.48 The committee is deeply concerned by evidence that suggests that this frustration at the lack of diagnosis and treatment has contributed to some Australians taking their own lives. At its public hearings in Perth and Brisbane, the committee heard from the families of individuals who had taken their own lives.⁵⁰ Mrs Meaghan Sullivan, whose brother Mr Scott Chant took his own life in early 2016, told the committee:

These people are being turned away, and they are sick. They are fighting for their lives, and they are having to find treatment on their own as well as battling each day just trying to get through. I do not blame him at all for doing what he did. I would do the same if I was in his shoes. Something needs to change because it is just going to keep happening.⁵¹

1.49 The committee is also particularly concerned by the impact of these symptoms on children. The committee received a number of submissions from parents on behalf of children suffering chronic debilitating symptoms, and from children themselves.⁵² Like adult patients, the committee heard that children experienced particular challenges in seeking a diagnosis and treatment. Ms Marie Huttley-Jackson, whose child suffers from chronic debilitating symptoms, noted in her submission that doctors blamed her parenting for the symptoms, rather than addressing the illness:

On discharge we were told her condition was the result of my bad parenting as I was letting her fake her symptoms. It is very difficult to understand why doctors would treat an unwell child so dismissively and with impunity.⁵³

1.50 Following their frustrations with some medical services, a large proportion of submitters reported seeking out 'Lyme literate' practitioners for assistance. Unlike other medical services, 'Lyme literate' practitioners diagnose the cause of these symptoms as 'Lyme disease' or 'Lyme-like illness'. Those submitters diagnosed with

49 Due to the large amount of criticism of medical practitioners made in submissions, the committee decided to redact the names of all practitioners, practices and hospitals from submissions.

50 At its hearings in Perth, the committee heard from Ms Michelle Nettle and Ms Carol Adams whose children had taken their own lives following a long battle with chronic debilitating symptoms. See: *Committee Hansard*, Perth, 14 April 2016, pp 47–49.

51 Mrs Meaghan Sullivan, *Committee Hansard*, Brisbane, 15 April 2016, p. 18.

52 To protect the privacy of children, the committee decided to redact the names of all children named in submissions. The committee also decided to accept any submission from children as unpublished correspondence.

53 Ms Marie Huttley-Jackson, *Submission 415*, p. 3.

Lyme-like illness by these practitioners expressed significant relief and hope at having finally received a diagnosis and options for treatment. One submitter noted:

What a relief to know that my symptoms had a name and I got my mind set on what to do next.⁵⁴

1.51 However, due to the controversy in Australia and overseas about 'Lyme disease' and 'Lyme-like illness' submitters reported that they experienced significant challenges in having their diagnosis recognised and accessing treatment. These challenges are examined in detail in **Chapter 2**.

Prevalence of Lyme-like illness

1.52 As Lyme-like illness is not clearly defined and not formally reported on, available statistics on its incidence across Australia are limited. The committee notes that there is no official data on the number of classical Lyme disease cases acquired overseas or Lyme-like illness acquired in Australia.⁵⁵

1.53 The committee heard that in 2013 the CDNA reviewed whether Lyme disease should be added to the National Notifiable Diseases List. The Joint Criteria Assessment Group, using the standard set of endorsed criteria developed by CDNA in 2008, concluded that:

... inclusion was not warranted as Lyme disease did not satisfy a majority of the endorsed criteria and there was no definitive evidence of Lyme disease being acquired in Australia.⁵⁶

1.54 Medical authorities state that without a clear and agreed definition, the prevalence of Lyme-like illness cannot be accurately estimated. For example, the Victorian Department of Health and Human Services submitted that:

It is not possible to describe the prevalence and geographic distribution of Lyme-like illness in Australia, as there is no agreed definition of 'Lyme-like illness'. A clear definition is required to diagnose a person with a particular condition, as is required for any medical condition irrespective of its cause. Without being able to definitively diagnose a person with a condition, it is not possible to count the number of people who have the condition, and therefore describe how frequent it is or where it occurs.⁵⁷

1.55 However, patient advocacy groups state that Lyme-like illness should be made a notifiable disease, and that the CDNA decision should be reviewed in light of

54 *Submission 519*, p. [1].

55 The committee heard that in Western Australia, relapsing fever (caused by a different species of *Borrelia*) was removed from the list of notifiable diseases in 2007 as no cases had been reported. The WA Department of Health advised that the removal of relapsing fever from the list of notifiable diseases was in accordance with the CDNA's guidelines and criteria for assessing whether an infectious disease should be notifiable. See WA Department of Health, Response to question on notice, received 22 April 2016.

56 CDNA, *Submission 531*, p. 7.

57 Victorian Department of Health and Human Services (DHHS), *Submission 547*, p. 1.

the increasing number of patients being diagnosed with the condition.⁵⁸ Ms Elaine Kelly for Sarcoidosis Lyme Australia told the committee that the decision by the CDNA was:

... based on a situation which is already changing and on rationale comments which are fundamentally flawed and frequently based on semantics and bureaucratic subjective opinions.⁵⁹

1.56 In its submission, the LDAA stated that based on data it had collected through online patient surveys, 1051 Australians have been diagnosed with Lyme-like illness since 2012. The LDAA estimates that these figures are the 'tip of the iceberg when it comes to the real incidence of Lyme-like illness in Australia'.⁶⁰ Ms Sharon Whiteman, President of the LDAA, told the committee that the LDAA estimates that:

... based on US figures, we expect there to be about 22 000 new cases of Lyme-like illness in Australia per year, and up to 450 000 cases from the past 22 years of stubborn and entrenched denial by our health officials.⁶¹

1.57 However, some state and territory governments challenged the notion that there is an 'epidemic' of Lyme-like illness in Australia. The Western Australian Department of Health noted in its submission that incidence of Lyme-like illness is probably overstated and reflects instead frustration with the Australian health system:

Lyme-like illness probably appears far more common than it actually is because one person with Lyme-like illness can write multiple letters to the Health Minister, their local Parliamentarian and other Parliamentarians. Their friends, families and peer support groups also write letters about the same person to multiple Parliamentarians. This probably reflects their frustration with the Australian health system, which they perceive as not meeting their needs and expectations, rather than an 'epidemic' of Lyme disease in Australia.⁶²

Definition of Lyme-like illness

1.58 Submitters to the inquiry highlighted that they are not concerned with finding an appropriate name for the debilitating symptoms that they suffer from; what they want is recognition of their illness and access to treatment. Ms Sharon Whiteman from the LDAA told the committee:

...to be honest, as patients we do not really care what it is called. That is not our area. We have progressed to 'Lyme-like' to try and embrace the Lyme

58 See, for example: Global Lyme and Invisible Illness Organisation / Lyme Australia Recognition and Awareness, *Submission 822*, p. 8.

59 Ms Elaine Kelly, *Committee Hansard*, Perth, 14 April 2016, p. 9.

60 According to these surveys, Lyme-like illness disproportionately affects women (73 per cent of respondents were female compared to 27 per cent male). See: LDAA, *Submission 528*, p. 13.

61 Ms Sharon Whiteman, *Committee Hansard*, Brisbane, 15 April 2016, p. 2.

62 WA Department of Health, *Submission 529*, p. 1.

deniers and the single-bug focus, because we are not trying to challenge what it is called; we would just like patients treated.⁶³

1.59 Similarly, Ms Rebecca Bool told the committee in Perth that patients want to be treated with respect by medical practitioners and offered treatment to get better:

We need to be treated with compassion. We need recognition. Ultimately, it does not matter what you name this awful disease; we need you to please help us. We need you to help us feel well. We want to feel well. We do not want to feel like a burden financially and physically on our families, friends and everyone around us in society.⁶⁴

Committee view

1.60 The committee is concerned by evidence from a large number of submitters experiencing a range of chronic debilitating symptoms. The committee recognises the effect of these symptoms on the lives of many Australians and their families.

1.61 The committee acknowledges that for many submitters it does not matter what the illness is called, or what it is caused by; their main concerns are recognising that people are ill and on securing treatment for patients.

1.62 The committee recognises that using the terms classical Lyme disease or chronic Lyme disease risks limiting the scope of the committee's inquiry. For the purposes of this inquiry, the committee prefers the use of the term 'Lyme-like illness' to describe the range of chronic debilitating symptoms experienced by submitters. The committee recognises that this is not a formal acknowledgement of 'Lyme-like illness' as a single entity, but as a broad descriptor for the possible condition or conditions that manifest in chronic debilitating symptoms.

63 Ms Sharon Whiteman, *Committee Hansard*, Brisbane, 15 April 2016, p. 5.

64 Ms Rebecca Bool, *Committee Hansard*, Perth, 14 April 2016, p. 26.

Chapter 2

Experience of patients and access to treatment

2.1 As outlined in Chapter 1, the committee has received over 1000 personal submissions from or on behalf of Australians suffering from chronic debilitating symptoms. The committee is deeply concerned by evidence that many submitters have experienced significant challenges in accessing appropriate healthcare to address their symptoms. In particular the committee is concerned by evidence that suggests submitters have been insulted and humiliated by some medical practitioners when seeking treatment.

2.2 This chapter examines the experience of submitters in accessing treatment, particularly those diagnosed with Lyme-like illness. It examines how the ongoing debate about whether Lyme disease is endemic to Australia contributes to the perceived stigma about diagnoses of Lyme-like illness and impacts on the ability of patients to access treatment. It also examines the treatments prescribed by Lyme-literate practitioners and allegations that these practitioners are unfairly targeted for disciplinary action by medical authorities.

Experience of sufferers of chronic debilitating symptoms

2.3 Submitters suffering chronic debilitating symptoms can be divided into four main groups:

- those who acquired and were diagnosed with classical Lyme disease in an endemic area overseas;
- those who acquired their illness overseas but weren't diagnosed;
- those who became ill following a tick or other insect bite in Australia; and
- those who have experienced a long-term chronic illness in Australia and may or may not have been bitten by a tick or other insect.

2.4 The common experiences of patients in these groups are summarised below.

Illness acquired overseas

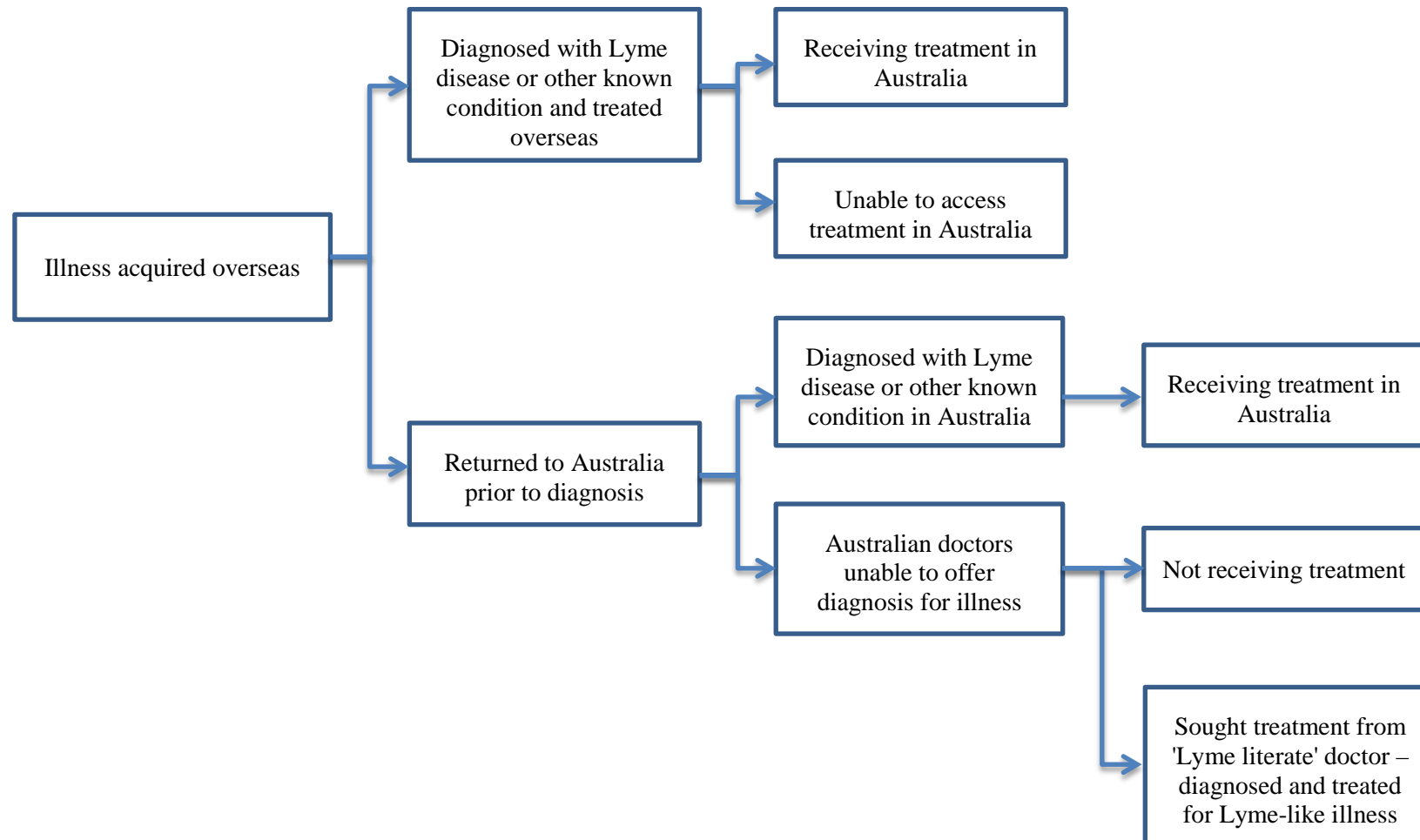
2.5 A small number of submitters explained that they acquired their illness overseas. In some cases, patients became ill following a tick bite in an area where classical Lyme disease is endemic.¹ In other cases, patients do not recall a tick bite, but became ill following another kind of bite (such as bed-bugs).² A number of submitters do not recall any kind of bite and their symptoms did not manifest until after returning to Australia.³ The common treatment pathways for these submitters are illustrated in Figure 2.1.

1 See: *Submission 42; Submission 298.*

2 See: *Submission 123; Submission 287.*

3 See: *Submission 405, Submission 586; Submission 834.*

Figure 2.1 – Patient treatment pathways –Illness acquired overseas



Illness acquired in Australia

2.6 The majority of submitters stated that they acquired their illness in Australia. In many cases submitters had no history of travel to an endemic area for classical Lyme disease.

Illness following tick bite

2.7 Some submitters state that they became ill immediately following a tick bite in Australia. Symptoms described by these submitters include a rash around the bite and a range of symptoms including fatigue, arthritis and chronic pain.⁴

2.8 In some cases, submitters were diagnosed with other known tick-borne infections, such as Q fever, Spotted Fever, Rickettsia, Queensland Tick Typhus or allergy to tick toxin, and received treatment.⁵

2.9 However, in most cases, the submitters state that medical practitioners were not able to identify or diagnose the illness, or offer any effective treatment.⁶

Long-term chronic illness

2.10 The largest group of submitters is those who have experienced a long-term chronic illness. In many cases, these submitters cannot recall being bitten by a tick. In cases where submitters can recall a tick bite, this may have predated the onset of their illness by a number of years.⁷

2.11 Figure 2.2 outlines the treatment pathways for these submitters.

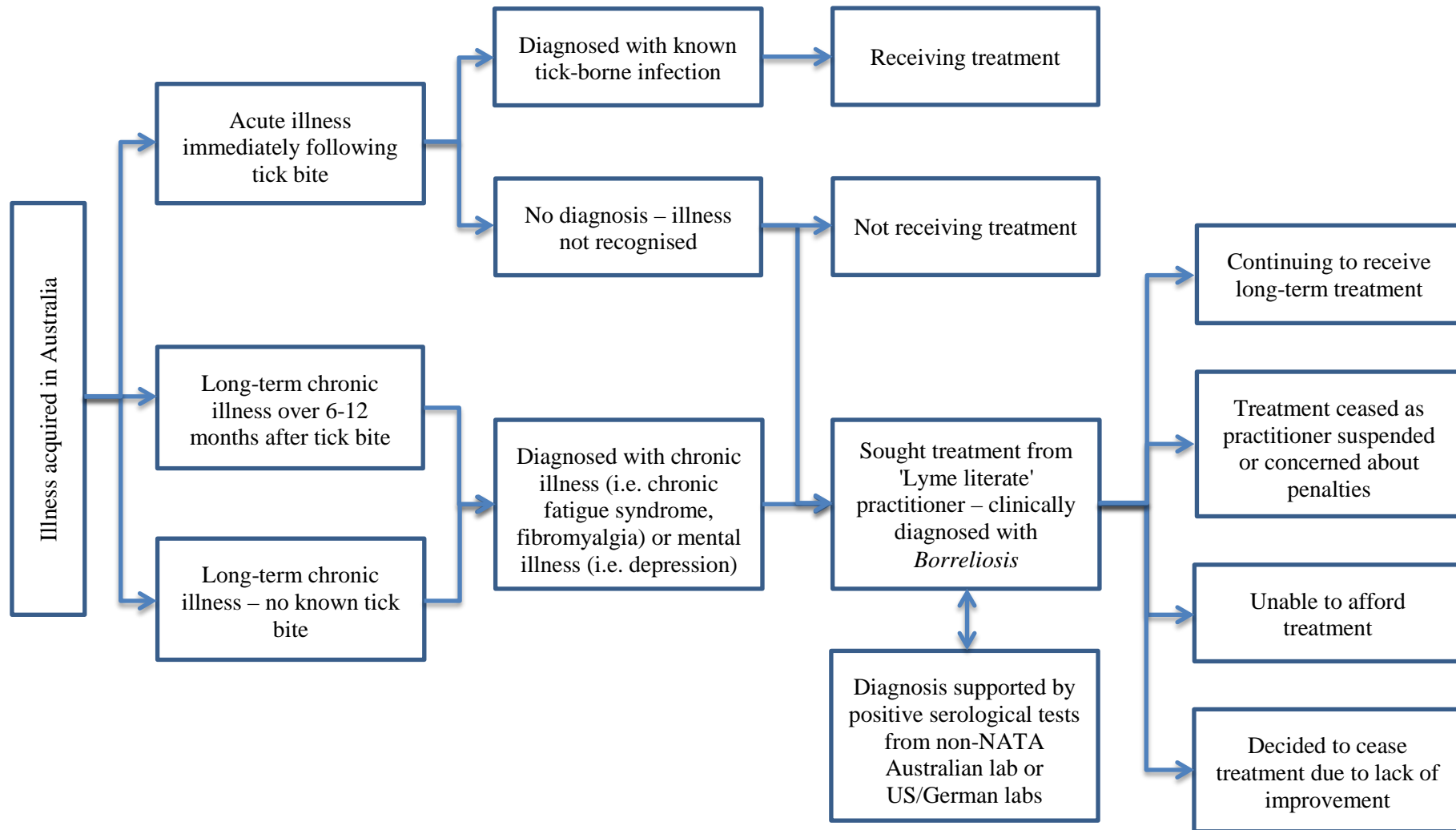
4 See, for example: *Submission 104; Submission 149; Submission 206; Submission 295; Submission 320.*

5 See, for example: *Submission 110; Submission 116; Submission 186.*

6 See, for example: *Submission 19; Mr Paul Fenwick, Submission 27; Ms Christine Linigen, Submission 70; Submission 72; Submission 104; Ms Natalie Young, Submission 140; Submission 142; Submission 143; Submission 149; Submission 163; Submission 169; Submission 198; Submission 206.*

7 See, for example: *Submission 114; Submission 170; Submission 178; Submission 196.*

Figure 2.2 – Patient treatment pathways from submissions – Illness acquired in Australia



Treatment for patients

2.12 The committee heard that patients diagnosed with chronic debilitating symptoms experience significant difficulties accessing diagnosis and treatment from Australian healthcare services.

Illness acquired overseas

2.13 Submitters who acquired their illness overseas expressed particular concern that Australian medical practitioners may not recognise or effectively diagnose overseas illnesses, such as classical Lyme disease.

2.14 The committee heard that as part of the Chief Medical Officer's Clinical Advisory Council on Lyme Disease, the department has been working with states and territories to raise awareness and assist with the diagnosis of classical Lyme disease through the development of the *Australian guideline on the diagnosis of overseas acquired Lyme disease/borreliosis*. Dr Gary Lum from the Department of Health (department) told the committee:

This guide was developed with the assistance of patient advocates as well as experts in immunology, microbiology and infectious diseases. The guideline was shared with Australian general practitioners, emergency physicians, other relevant specialists as well as the Australian Medical Association.⁸

2.15 However, evidence from some submitters with a history of travel to an area where classical Lyme disease is endemic suggested that some Australian doctors may not be aware of Lyme disease and the appropriate methods for diagnosis and treatment. For example, one submitter noted that he acquired Lyme disease in the United States (US) following a tick bite and was diagnosed and treated by US doctors. Upon returning to Australia, he continued to experience symptoms but struggled to get appropriate treatment:

For me the issue was not so much that the disease was active, it was that doctors were unable to understand the left over side effects that continue to deteriorate my general health and well-being ... I would love to see more education and awareness about Lymes disease here in Australia, particularly around managing the ongoing side-effects.⁹

2.16 Similarly, another submitter who was bitten by a tick in the US expressed frustration at not being treated for Lyme disease in Australia:

People say being diagnosed with cancer is very scary, but try being diagnosed with a potentially fatal disease when there is no help from the medical profession nor support from the Government.

8 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, pp 2–3.

9 Name withheld, *Submission 298*, p. 2.

Regardless if the Lyme bacteria is in Australia or not, I was bitten in the USA, so why shouldn't I be treated? People who contact Malaria or tuberculosis overseas can receive treatment in Australia.¹⁰

2.17 Dr Lum told the committee that despite efforts by the department to educate practitioners, there was a risk that people infected with classical Lyme disease overseas may not be appropriately treated in Australia:

We recognise that people infected overseas who return to Australia have a risk that their classical Lyme disease will not be recognised or appropriately treated, in spite of our regular advice to Australia's doctors to pay attention to this situation.¹¹

2.18 Dr Lum noted that the department was committed to education and awareness raising of classical Lyme disease, but acknowledged it could do more to communicate with the medical profession:

What the department has been trying to do is communicate with the medical profession. If, as part of the Senate inquiry and as part of the recommendation, we could possibly do more to communicate with the medical profession on this, we certainly would.¹²

Illness acquired in Australia

2.19 More commonly, submitters have acquired their illness in Australia, but have not been able to be readily diagnosed and treated by Australian medical practitioners.

2.20 As discussed in Chapter 1, many of these submitters have been diagnosed with Lyme disease or Lyme-like illness by 'Lyme literate' practitioners. However, due to the significant debate in Australia about the existence of Lyme disease, these submitters noted that they have experienced significant challenges in accessing treatment in Australia.

The Lyme disease debate in Australia

2.21 The existence of Lyme disease in Australia is highly controversial and has attracted significant media attention and public debate. This debate relates to two closely related questions:

- whether the causative agent for classical Lyme disease (either known *Borrelia* species such as *B. burgdorferi* or an as yet unidentified *Borrelia* species) is endemic to Australia (i.e. has been identified in Australia); and
- consistent with the international debate about 'chronic' Lyme disease, whether the chronic debilitating symptoms experienced by Australian patients are caused by an ongoing active infection of *Borrelia* and associated co-infections, or another as yet unidentified underlying cause or causes.

10 See: Name withheld, *Submission 519*, pp 2–3.

11 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, p. 2.

12 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, p. 13.

Is classical Lyme disease endemic to Australia?

2.22 The position of Australian Commonwealth, state and territory governments and medical authorities is that the causative agent for classical Lyme disease is not endemic to Australia.¹³ In their submissions to the inquiry, these authorities state that there is no evidence to suggest that *B. burgdorferi* or any other *Borrelia* species known to cause Lyme disease have been identified in Australian ticks or patients.¹⁴ In his 2014 progress report on Lyme disease in Australia, the Chief Medical Officer (CMO), Professor Chris Baggooley, stated that there is no evidence that the bacteria causing Lyme disease are endemic to Australia:

There is still no routine finding of *Borrelia* spp in ticks in Australia.

The conclusive finding of a bacterium that could cause Lyme disease-like syndrome in Australia has yet to be made. Such a finding would put beyond doubt the existence of Lyme disease, or a Lyme disease-like syndrome in Australia.¹⁵

2.23 Most submissions from medical authorities¹⁶ support the Royal College of Pathologists Australasia (RCPA) position paper on diagnostic testing for Lyme disease in Australia that states that:

Only a genuine case in a non-travelling Australian patient would confirm the disease as being present in Australia.¹⁷

2.24 The CMO has stated that other 'vectors and routes of transmission are postulated, but yet to be demonstrated'.¹⁸ In evidence to the committee, Dr Gary Lum noted that there may be a range of possible causes for Lyme-like illness:

In the context of evolving Australian research data, we need to consider that the cause may not be limited to a single bacterial species. Parasitic and viral causes, as well as environmental toxins, should also be considered for investigation, as well as other potential medical explanations.¹⁹

13 See, for example: Department of Health, *Submission 495*; Western Australian Department of Health, *Submission 529*; Victorian Department of Health and Human Services (DHHS), *Submission 547*; Royal College of Pathologists of Australasia, *Submission 532*.

14 *Submission 495*, p. 2.

15 Professor Chris Baggooley, Progress Report on Lyme Disease in Australia, 31 July 2014, <http://www.health.gov.au/lyme-disease> (accessed 3 May 2016).

16 See: Communicable Diseases Network Australia (CDNA), *Submission 531*; Royal Australasian College of Physicians, *Submission 754*; Australian Society for Microbiology, *Submission 781*; NSW Health, *Submission 457*; Victorian DHHS, *Submission 547*.

17 RCPA, *Position statement: Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand*, February 2014, <http://www.rcpa.edu.au/Library/College-Policies/Position-Statements/Diagnostic-Laboratory-testing-for-Borreliosis-Lyme> (accessed 7 December 2015).

18 Professor Chris Baggooley, Progress Report on Lyme Disease in Australia, 31 July 2014, <http://www.health.gov.au/lyme-disease> (accessed 3 May 2016).

19 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, p. 2.

2.25 The first Australian cases of a syndrome consistent with Lyme disease were reported in the Hunter Valley region of NSW in 1982. Further clinical cases were reported on the NSW south and central coast in 1986, and in Queensland between 1986 and 1989.²⁰ Since these cases, there have been a number of studies examining whether locally acquired Lyme disease exists in Australia. According to a recent paper summarising research into Lyme disease in Australia, these studies have found no conclusive evidence that indicates the presence of the causative agent for Lyme Disease—*Borrelia burgdorferi*—in Australia and 'the diagnoses of [Australian] Lyme Borreliosis ... have been primarily by clinical presentation and laboratory results of tentative reliability and the true cause of these illnesses remains unknown'.²¹

2.26 However, patient advocacy groups and some medical practitioners challenge this position and state that *Borrelia* bacteria known to cause Lyme disease are endemic to Australia. These groups argue that Lyme disease is a 'hidden epidemic' in Australia. They are concerned that there have been a number of cases reported in the media of Australians who have been diagnosed with Lyme disease acquired in Australia, but that these patients have been 'ignored' by the Australian health care system.²²

2.27 In its submission, the Lyme Disease Association of Australia (LDAA) suggests that evidence over the past fifty years that has demonstrated the existence of an endemic species of *Borrelia* known to cause Lyme disease in Australia has been 'systematically ignored' by medical authorities:

The presence of *Borrelia*, the causative agent of Lyme disease, was established in Australian fauna in 1959 and human cases of Lyme disease

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- 20 R.C. Russell et al, 'Lyme disease: a search for a causative agent in ticks in south-eastern Australia', *Epidemiology and Infections*, v. 122, n. 2, 1994, p. 376, <https://www.jstor.org/stable/3864539> (accessed 11 January 2015).
- 21 Paper provided to the committee by Professor John Mackenzie: Melissa Judith Chalada, John Stenos, Richard Stewart Bradbury, 'Is there a Lyme-like disease in Australia', *One Health*, 2016, Volume 2, pp 42–54, <http://www.sciencedirect.com/science/article/pii/S2352771416300039> (accessed 20 April 2016).
- 22 See, for example: 'The brutal bite of a hidden illness in Australia', *Sunday Times Magazine* (WA), 18 April 2016, <http://www.perthnow.com.au/news/western-australia/stm/the-brutal-bite-of-a-hidden-illness-in-australia--lyme-disease/news-story/7eff05d29199ba092742fd5ff9f23266> (accessed 29 April 2016); 'Lyme disease: Australians "being treated worse than a dog riddled with mange"', *ABC Online*, 12 January 2015, <http://www.abc.net.au/news/2016-01-11/lyme-disease-treatment-in-australia-criticised-by-john-madigan/7080708> (accessed 18 January 2015), 'Canberra family ticked off about lack of recognition of Lyme disease', *Canberra Times*, 24 December 2015, <http://www.canberratimes.com.au/act-news/canberra-family-ticked-off-about-lack-of-recognition-of-lyme-disease-20151217-glpoivr.html> (accessed 5 January 2015); 'Lyme disease from tick bite but the doctors say it doesn't exist', *Courier Mail*, 15 November 2015 (accessed 5 January 2015); 'Lyme disease: Federal MP calls for greater recognition of tick-borne illness affecting "thousands"', *ABC Online*, 22 August 2015, <http://www.abc.net.au/news/2015-08-20/federal-parliament-calls-for-lyme-disease-recognition/6710810> (accessed 5 January 2015).

have been reported since the early eighties. Australian authorities ignore this evidence.²³

2.28 These groups highlight recent studies by Dr Peter Mayne, a retired NSW medical practitioner, that suggest infection from *B. burgdorferi* has been acquired in Australia by one patient and can be transmitted by Australian ticks.²⁴ However, the Communicable Diseases Network Australia has highlighted that the absence of a published method to facilitate the replication of this finding undermines its significance.²⁵

2.29 Other groups, such as the Karl McManus Foundation, a charity that raises funding for tick-borne disease research at the University of Sydney, assert that the causative agent in Australia is not the same as classical Lyme disease overseas, but an indigenous, Australian species of *Borrelia*:

...we do not have *Borrelia burgdorferi*, or Lyme disease, in Australia. What we have is a unique *Borrelia* infection.²⁶

2.30 The diagnostic procedures for testing for *Borrelia* bacteria in Australia are examined in detail in **Chapter 3**.

Is an ongoing infection of Borrelia bacteria responsible for chronic debilitating symptoms in Australian patients?

2.31 As noted in Chapter 1, the committee has heard that Australian governments and medical authorities do not agree that the chronic debilitating symptoms described by Australian patients are caused by an ongoing *Borrelia* infection. These authorities assert that there is no evidence that the *Borrelia* bacteria that cause Lyme disease are endemic to Australia and suggest that there may be another as yet unidentified underlying cause or causes.²⁷

2.32 For example, Professor Stephen Graves from the RCPA told the committee that there is 'clearly something in Australian ticks, or some species of Australian ticks, that is making some Australians sick',²⁸ but it is unlikely to be caused by *Borrelia*:

23 Lyme Disease Association of Australia (LDAA), *Submission 528*, p. 6.

24 See: Peter Mayne, 'Emerging incidence of Lyme borreliosis, babesiosis, bartonellosis, and granulocytic ehrlichiosis in Australia', *International Journal of General Medicine*, v. 4, 2011, pp 850–851, https://www.dovepress.com/articles.php?article_id=19731 (accessed 7 January 2015); Peter Mayne et al, 'Evidence for Ixodes holocyclus (Acarina: Ixodidae) as a Vector for Human Lyme Borreliosis Infection in Australia', *Journal of Insect Science*, v. 14, 2014, p. 3, <http://jinsectscience.oxfordjournals.org/content/14/1/271> (accessed 7 January 2015).

25 Communicable Diseases Network Australia (CDNA), *Submission 531*, pp 5–6.

26 Dr Mualla McManus, *Committee Hansard*, Brisbane, 15 April 2016, p. 28.

27 See, for example: Australian Medical Association (AMA), *Submission 456*; Australian Society for Microbiology, *Submission 781*; Australian Rickettsial Reference Laboratory Foundation, *Submission 459*; CDNA, *Submission 531*.

28 Professor Stephen Graves, *Committee Hansard*, Brisbane, 15 April 2016, p. 45.

I actually do not think what we are talking about is the *Borrelia* infection. It is not classic Lyme disease. It is not a *Borrelia* infection, although I am keeping an open mind on that possibility—but I do not think it is. What is it?²⁹

2.33 Dr Margaret Hardy, a research fellow at the University of Queensland's Institute for Molecular Bioscience, told the committee that due to Australia's geographic isolation, unique species of ticks and host animals, it is unlikely that a *Borrelia* species similar to the *Borrelia* bacteria found in North America and Europe would also be found in Australia:

America and Europe are much more geographically close as well, so it would make sense that if you had two co-evolving types of *Borrelia* you would see them across that close geographic range rather than coming all the way up from there, missing Africa and Asia entirely, and popping up over in Australia.³⁰

2.34 Whereas Australian medical authorities suggest that the cause of the chronic debilitating symptoms described by patients is not yet known, patient advocacy groups assert that the cause is infection with *Borrelia*, together with a range of other bacterial co-infections.³¹ These groups highlight that chronic *Borrelia* infection is just one of many co-infections that are transmitted to humans by ticks and responsible for causing chronic debilitating illness. For example, the LDAA submitted:

Emerging international research shows that Lyme disease is rarely ever found in isolation of other pathogens; our research supports that ... Typically these are referred to as co-infections, but they are individual and sometimes life threatening infections in their own right. As well as *Borrelia*, an infection from each of those pathogens increases the complexity in the type of symptoms patients actually endure.³²

Tick-borne illnesses in Australia

2.35 The committee heard that due to the debate about Lyme disease, some medical practitioners have limited awareness of other possible tick-borne illnesses. A number of submitters reported that on presenting to their GP with tick bites they were not offered any specific treatments and were told that there are no tick borne illnesses in Australia. For example, Ms Linda Ebdon told the committee in Perth about her consultation with her GP:

I was covered in tick bites. He said to me: 'You have an allergy. Go home and take some Phenergan.' I said to him, 'Is it possible that it is something from the ticks?' He said, 'No, we do not have tick bite diseases in Australia.'

29 Professor Stephen Graves, *Committee Hansard*, Brisbane, 15 April 2016, p. 46.

30 Dr Margaret Hardy, *Committee Hansard*, Brisbane, 15 April 2016, p. 39.

31 LDAA, *Submission 528*, pp 57–58.

32 *Submission 528*, p. 58.

So I never learnt to protect myself. I thought being bitten by ticks was just part and parcel of living in the hills.³³

2.36 Ms Natalie Young, a National Parks Officer in NSW, noted in her submission that she experienced over 300 tick bites over the course of her career. As a result she suffered a range of debilitating symptoms including headaches, fever, migratory pains and anxiety. Ms Young noted:

Doctor after doctor refused to acknowledge my large number of tick bites as a causation of my illness even though I had had over 300 tick bites at work over seven years. Local GP's were at a loss to explain my illness. After I saw approximately ten local GP's, the referral process started to specialists of varying fields. GP's were considering diagnoses of Chronic Fatigue Syndrome, Tennis Elbow, Lupus, post-viral infections to Barmah and Ross River Fever but as my disease severity worsened, they ruled these out.³⁴

2.37 Whereas the committee acknowledges that there is significant debate about whether or not *Borrelia* bacteria known to cause Lyme disease are endemic to Australia, evidence to the committee suggests that both patient advocacy groups and some medical authorities agree that there are likely to be other pathogens in Australian ticks making people sick. Professor Peter Collignon told the committee:

Ticks can cause lots of diseases, not only in Australia but overseas. I think there are probably lots of organisms in ticks—bacteria and even viruses—that we do not know of yet, so I think we have to keep an open mind about what diseases may be transmitted by ticks and what therapy is available or should be used for them.³⁵

2.38 According to the department, there are 70 species of hard and soft ticks in Australia, of which 16 species of hard ticks have been reported to bite humans. The Paralysis Tick (*Ixodes holocyclus*) is understood to be responsible for 95 per cent of tick bites in Eastern Australia.³⁶ In Western Australia, a completely different species of tick, the ornate kangaroo tick (*Amblyomma triguttatum*), is responsible for most tick bites in humans.³⁷

2.39 Ticks are hosts and vectors of a number of parasites, bacteria and viruses. The main organisms that may be transmitted by ticks and associated with disease known in Australia are outlined below:

- **Anaplasma** – causes disease in cattle (bovine anaplasmosis, or 'bovine tick fever') and dogs (canine anaplasmosis);

33 Ms Linda Ebdon, *Committee Hansard*, Perth, 14 April 2016, p. 24.

34 Ms Natalie Young, *Submission 140*, p. 4.

35 Professor Peter Collignon, *Committee Hansard*, Perth, 14 April 2016, p. 31.

36 Department of Health, Preventing and treating tick bites, October 2015, <http://www.health.gov.au/lyme-disease> (accessed 20 November 2015).

37 Professor Stephen Graves, *Committee Hansard*, Brisbane, 15 April 2016, p. 45.

- **Babesia** – a significant cause of disease in cattle (Bovine babesiosis) and dogs (Canine babesiosis);³⁸
- **Bartonella** – causes disease in domestic and wild animals including cats and kangaroos – uncertain whether it can cause human disease;
- **Ehrlichia** – causes disease in dogs worldwide but has not been recognised in Australia;
- **Francisella** – relatively rare and no evidence to suggest pathogenic for humans;
- **Rickettsia** – causes several diseases in humans including Queensland tick typhus (*Rickettsia australis*), Flinders Island spotted fever (*Rickettsia honei*), variation of spotted fever (*R. marmionii*) and Q fever (*Coxiella burnetii* – rarely tick-borne).³⁹

2.40 The incidence of these tick-borne illnesses and their effects on humans are not clearly known. A number of groups, including the RCPA, suggest that further research needs to be undertaken into these other tick-borne diseases and their impacts on humans. Professor Stephen Graves told the committee:

Let us say it is bacteria, for argument's sake. Which one is it? Or is it more than one? We cannot tell because we do not have the assays to detect those bacteria or the antibodies produced in response to those bacteria in the patients, because those assays have not been developed. That research has not been done, and that is because the money has not been made available to do it. Sorry to come back to money, but that is really what it takes ... Someone has to look at *Babesia* and other protozoa that might be responsible, and somebody has to look at viruses. In other parts of the world, there are many viruses that are tick transmitted and cause very nasty diseases. And we do not have one in Australia? Well, I cannot believe that. I cannot believe that, senators. There have to be some viral tick-transmitted infections in Australia; it is just that we do not know what they are.⁴⁰

2.41 Both patient advocacy groups and medical authorities highlighted that more research is needed into a range of key areas including identifying possible pathogens in ticks and other vectors and clinical studies of patients. These opportunities for research are examined in detail in **Chapter 4**.

2.42 A number of submitters and witnesses highlighted the need for better education and awareness about preventing tick bites to avoid any potential illnesses. Professor Peter Collignon told the committee:

38 The first reported case of human babesiosis acquired in Australia was published in 2012. See: Sanjaya Senanayake et al, 'First report of human babesiosis in Australia', *Medical Journal of Australia*, v. 196, 2012, pp 350–352. See: Professor Peter Collignon, *Submission 458*, Attachment B.

39 Mackenzie, *Scoping study*, pp 17–19.

40 Professor Stephen Graves, *Committee Hansard*, Brisbane, 15 April 2016, p. 46.

We should avoid people being bitten by ticks. Ticks are bad for lots of reasons, the same as mosquitos are really bad for people with, in Australia, Ross River virus, Barmah Forest virus and a lot of things. So the two insects that I think we should avoid being bitten by are ticks and mosquitoes. I think we need to have a program to say what to do and, particularly, how you remove a tick without causing more damage by squirting more toxins or whatever into the person. So, yes, I think we need a tick education program.⁴¹

2.43 The department noted in its submission that it is committed to education and awareness raising about the prevention of tick bites and has produced a publicly available information sheet on tick bites:⁴²

In an effort to prevent tick-borne bites [sic] and raise awareness of tick bite first aid, we collaborated with the National Arbovirus and Malaria Advisory Committee as well as with states and territories on a tick bite prevention document for public distribution. It is hoped in future we will incorporate emerging research into tick bite associated mammalian meat allergy and newer techniques for tick removal. The department is committed to such education and awareness raising.⁴³

Committee view

2.44 The committee acknowledges that there is a debate about whether or not Lyme disease is endemic to Australia. The committee notes the position of the Chief Medical Officer that Lyme disease is not endemic to Australia as the species of *Borrelia* bacteria responsible for causing the disease have not been identified in Australia. The committee also notes evidence from Dr Gary Lum that acknowledges that there may be another causative agent or agents for the chronic debilitating illness described by patients.

2.45 The committee acknowledges that there may be illnesses transmitted by ticks and potentially other vectors that warrant further research. The committee notes that this issue needs further inquiry.

2.46 The committee recognises that more could be done to educate the public and medical professionals about the risk of tick bites and tick-related illnesses in Australia, as well as classical Lyme disease acquired overseas.

41 Professor Peter Collignon, *Committee Hansard*, Perth, 14 April 2016, pp 34–35.

42 See: *Submission 495*, Attachment I. In his 2015 progress report on the Clinical Advisory Committee on Lyme Disease (CACLD), sent to the President of the Australian Medical Association and presidents of relevant medical colleges, the Chief Medical Officer advised that this prevention document was being prepared and would be available from the department's website. See: *Submission 495*, Attachment J.

43 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, pp 2–3.

Treatment for patients diagnosed with Lyme-like illness

2.47 Patient advocacy groups argue that because Lyme disease is not recognised as being endemic to Australia, patients seeking treatment experience significant challenges accessing treatment.⁴⁴ These difficulties include:

- denial that someone is ill and denial of care;
- stigma and humiliation associated with Lyme-like illness from some medical services;
- accessibility and costs of treatments prescribed by 'Lyme literate practitioners'; and
- limitations placed on 'Lyme literate' practitioners by medical authorities.

Stigma and Lyme-like illness

2.48 Submitters expressed concern that because Lyme-like illness is not recognised in Australia, patients experience significant stigma when seeking treatment from some medical practitioners. These submitters note that medical practitioners dismiss Lyme disease as a possible diagnosis, arguing that Australia is not an endemic area and therefore Lyme disease does not exist here.⁴⁵

2.49 The committee notes that a large proportion of submitters to the inquiry requested to have their submissions marked as either name withheld or confidential to avoid any possible negative repercussions from their family, friends, employers and medical practitioners.

2.50 One submitter described the treatment her 29 year old daughter had received from medical professionals when she presented with Lyme-like illness:

The worst part of having this illness is the treatment and discrimination that she has received by the majority of the medical profession. She always had to justify why she was there and try to get them to understand that she has pain, but after [a] brief discussion she would be told that there is nothing medically wrong with her and her illness doesn't exist and that stress is causing it all.⁴⁶

2.51 Similarly, Ms Emily O'Sullivan, writing on behalf of her sister Amy, who has been suffering chronic debilitating symptoms for 10 years and has been diagnosed with Lyme-like illness, submitted that:

The Australian medical community not only fails to recognise the disease but seem to have a proactive aversion to accepting Lyme Disease as a possible diagnosis. This has left Amy in an unnerving cycle of denied care. If she claimed to have Lyme Disease in GP clinics and ... hospitals (even

44 See, for example: LDAA, *Submission 528*; Lyme Australia Recognition and Awareness; and Global Lyme and Invisible Illness Organisation Inc, *Submission 822*; ME/CFS and Lyme Association of WA, *Submission 802*.

45 See, for example: *Submission 1085*; *Submission 571*; *Submission 948*; *Submission 164*.

46 Name Withheld, *Submission 82*, p. [1].

with positive blood tests), she was deemed 'crazy or looking for drugs' and didn't receive care because 'Lyme Disease doesn't exist in Australia'.⁴⁷

2.52 The committee heard from a number of organisations representing patients that indicated that patients are not treated with respect and care by some medical practitioners. The LDAA noted in its submission that it receives:

... constant updates from Australians about how terribly they are treated by the medical profession if they mention that they suspect or have Lyme disease. Patient's [sic] routinely report poor treatment by Australian GPs, infectious disease specialists and other hospital and specialist staff.⁴⁸

2.53 The LDAA notes that the name 'Lyme disease' has attracted such a stigma that 'many patients routinely advise others not to mention the disease at all when reporting their medical history'.⁴⁹

2.54 The committee is particularly concerned by evidence that suggests some patients are humiliated or insulted by medical practitioners for seeking tests or treatments for Lyme-like illness.⁵⁰ The Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS), representing 'Lyme literate' practitioners, indicated that many patients have been traumatised by some medical practitioners:

Discrimination against patients suffering from this illness, and the doctors who treat them, is rife. Many patients have been traumatised by their experience with medical specialists and in hospital emergency departments; they have been subject to derision and verbal abuse.⁵¹

2.55 For example, one submitter described how their neurologist ridiculed them when they brought up Lyme disease:

[My neurologist] spent a whole appointment ridiculing me and asking me why I 'thought I had Lyme'. Repeating 'Lyme Disease is not in Australia' [and] 'It can't be Lyme Disease, we don't have Lyme in Australia' [and] 'Show me proof it's here' [...]

I mentioned the paper that had just been realised [sic] from Curtin [sic] University. This was found to have *Borrelia* on our native Fauna.

'That's on animals' he says.

So I leave another appointment in tears, frustrated and going nowhere.⁵²

2.56 One submitter, the father of a child with Lyme-like illness, said that over three years of seeking treatment for his daughter the family faced a series of refusals to treat and abuse by medical practitioners. During an appointment with one neurologist, the

47 Ms Emily O'Sullivan, *Submission 15*, p. [2].

48 Lyme Disease Association of Australia, *Submission 528*, p. 19.

49 Lyme Disease Association of Australia, *Submission 528*, p. 19.

50 See: *Submission 12*; *Submission 447*.

51 ACIIDS, *Submission 370*, p. 5.

52 Name Withheld, *Submission 296*, p. [3].

family was subjected to a 'highly abusive, emotional and irrational' outburst that included accusing the child of feigning the symptoms and 'personal insults and attacks on the character' of the child and their parents that 'deeply traumatised' the family.⁵³

2.57 'Lyme literate' practitioners, such as Dr Richard Schloeffel, suggest that the treatment of patients with Lyme-like illness by some medical practitioners amounts to malpractice:

I cannot talk for other doctors and their thought processes, but I would like to say to every doctor in Australia, 'Wake up to yourselves. Start listening that we've got a real illness. Let's have a proper conversation. Let's do the proper science. Let's fund it ... But we have to put money into it, we have to have a proper conversation and the denialism has to stop, because that is actually malpractice. It is actually negligence on the part of the medical profession.'⁵⁴

2.58 Some medical authorities do not accept that there is any particular stigma associated with Lyme disease or Lyme-like illness. For example, the Australian Rickettsial Reference Laboratory submitted:

We do not accept that there is any more stigma associated with "Lyme-like illness" than there is to many other medical conditions from which many Australian patients already also suffer. Stigma, where it exists, can be broken down by community education over time.

"Stigma" may be in the mind of the beholder. Some patients may perceive that they are being stigmatised, but are probably not. Their doctor is simply trying to obtain a diagnosis of their condition and trying to treat the patient with the best of intentions and based on the current state of medical knowledge. There are many patients who have an illness that has not been currently diagnosed and for which there may be no recognised treatment. Patients with "Lyme-like illness" are not the only patients in this unfortunate position.⁵⁵

2.59 Medical authorities noted that just because there is no evidence that Lyme disease is endemic to Australia, it does not mean that doctors don't care about the welfare of patients. Professor Samuel Zagarella told the committee:

When doctors say that Lyme disease does not exist in Australia I think that a lot of people misinterpret that as being non-caring. The question is whether these people are suffering from Lyme disease [or] a different disease. We believe that at the moment there is no evidence to say that they are suffering from Lyme disease caused by ticks, and caused by *Borrelia burgdorferi* specifically. These people may be suffering from other conditions. There are a lot of non-specific symptoms that these people suffer from, such as arthritis, arthralgia, weakness, lethargy, pain and

53 Mr Carl Jackson, *Submission 416*, pp [3-4].

54 Dr Richard Schloeffel, *Committee Hansard*, Brisbane, 15 April 2016, p. 24.

55 *Submission 459*, p. 2.

depression. They certainly have some issues, but there is no evidence that Lyme disease as such exists in Australia.⁵⁶

Measures to reduce stigma

2.60 Some witnesses suggested that the stigma experienced by patients could be reduced by avoiding use of the names 'Lyme disease' or 'Lyme-like illness'. As noted in Chapter 1, submitters reported that they do not care what their illness is called; they just want to be able to access treatment.

2.61 One alternative name suggested by Dr Lance Sanders is Hunter Valley disease (HVD), in reference to the first documented case of a Lyme-like illness reported in the Hunter Valley in the 1980s. Dr Sanders noted that this broad term does not assume that the cause or causes for the symptoms have been identified.⁵⁷

2.62 In the United Kingdom, the name 'chronic arthropod-borne neuropathy' is suggested by Dr Matthew Dryden to describe the range of symptoms experienced by patients similar to those in Australia.⁵⁸

2.63 Other possible names for the condition are advocated for by 'Lyme literate' practitioners who argue that the symptoms are caused by *Borreliosis* and a range of co-infections, such as US physician Dr Richard Horowitz.⁵⁹ The name Multiple Systemic Infectious Disease Syndrome (MSIDS) is already used by some patient advocacy groups in Western Australia in an attempt to move away from the association with Lyme disease.⁶⁰

2.64 Dr Lum told the committee that the department would support moving away from the 'Lyme' label to better describe the 'chronic debilitating illness that manifests as a constellation of chronic debilitating symptoms' described by submitters:

We are well aware from the patient community and from various members of the medical profession that moving right away from the notion of Lyme disease and Lyme-disease-like illness is probably a very good move.

The problem that we have in Australia in terms of how we work with patients, advocacy groups and the medical profession is that this is not unique to Australia. The issue of a chronic Lyme disease is very contentious and very controversial to the extent that we would like to steer away from that. That is why in the work that we have been doing we have

56 Professor Samuel Zagarella, *Committee Hansard*, Perth, 14 April 2016, p. 31.

57 Dr Lance Sanders, *Submission 452*, p. 4.

58 Dr Gary Lum, Department of Health, *Committee Hansard*, 20 April 2016, p. 5. See: Matthew Dryden *et al*, 'Lyme borreliosis in southern United Kingdom and a case for a new syndrome, chronic arthropod-borne neuropathy', *Epidemiology and Infection*, v. 143, n. 3, February 2015, pp 561–572, <http://dx.doi.org/10.1017/S0950268814001071> (accessed 23 April 2016).

59 Dr Richard Horowitz uses the name Multiple Systemic Infectious Disease Syndrome to represent 'sixteen potential overlapping medical problems contributing to persistent symptoms in the Lyme patient'. Dr Horowitz reports to have seen over 12,000 chronically ill patients from around the world, including Australia. See: Dr Richard Horowitz, *Submission 936*, pp 1–2.

60 See: Ms Kate Daniels, *Committee Hansard*, Perth, 15 April 2016, p. 13.

tried to distinguish it by describing a chronic debilitating illness that manifests as a constellation of chronic debilitating symptoms. That is a mouthful and I would not propose that as a name. What I am trying to suggest though is that getting away from that name is probably a very good move.⁶¹

2.65 Another measure to reduce stigma recommended by patients and advocacy groups is formal recognition by Australian medical authorities of Lyme-like illness.⁶² At its Brisbane hearing, the committee was presented with a 'Time to Recognise Lyme' clock by Ms Karen Smith and Mr Matt Chant.⁶³ Mr Chant told the committee:

The time to recognise Lyme clock is a call to action to show that acknowledgement and treatment can help restore hope and health, that the denial of Lyme and other vector borne diseases in Australia is causing devastation and the loss of years of people's lives, and, in far too many instances, their death.⁶⁴

2.66 However, as noted in Chapter 1, Australian medical authorities do not recognise Lyme-like illness as a defined condition, noting that it may be used to describe a 'constellation of debilitating symptoms'.⁶⁵

Committee view

2.67 The committee is concerned by the treatment of patients diagnosed with Lyme-like illness by some medical practitioners.

2.68 The committee notes that there are issues that need further inquiry, such as:

- ways to improve education and awareness about Lyme disease acquired overseas;
- ways to improve Australia's health care system to better meet the needs of Australians with chronic illness; and
- possible pathways for identifying an appropriate name and definition for Lyme-like illness.

Accessibility and cost of treatment

2.69 A large number of patients diagnosed with Lyme-like illness expressed concerns about the accessibility and high cost of treatments prescribed by 'Lyme literate' practitioners. 'Lyme literate' practitioners often prescribe a course of treatment

61 Dr Gary Lum, Department of Health, *Committee Hansard*, 20 April 2016, p. 5.

62 See: *Submission 91*; *Submission 396*; *Submission 550*; LDAA, *Submission 528*; Global Lyme & Invisible Illness Organisation / Lyme Australia Recognition & Awareness, *Submission 822*.

63 See: Global Lyme and Invisible Illness Organisation / Lyme Australia Recognition and Awareness, *Submission 822*, p. 27.

64 Mr Matt Chant, *Committee Hansard*, Brisbane, 15 April 2016, p. 14.

65 See: Australian Medical Association, *Submission 456*, p. 4.

that may include antibiotics and other natural remedies that are not supported by Medicare or the pharmaceutical benefits scheme (PBS).⁶⁶

2.70 The committee heard that the cost of consulting 'Lyme literate' practitioners is very expensive, with practitioners allegedly charging between \$300 and \$900 for consultations.⁶⁷ Diagnostic tests used by 'Lyme literate' practitioners also involve significant expense (for example, \$800 for tests in Australia and \$2 000 for tests from overseas laboratories).⁶⁸

2.71 The treatments prescribed by 'Lyme literate' practitioners are also very expensive, often costing hundreds of dollars per week. In one case, a submitter claims to have spent over \$100,000 on treatment since diagnosis.⁶⁹ As a result of the high costs, a number of submitters, particularly those receiving welfare or pension payments, note that they have not been able to afford the prescribed treatments.⁷⁰ For example, one submitter noted:

One drug for one of the coinfections alone costs over \$1000 per month (and commonly needs to be taken for several months) but \$6.10 if on the PBS. This is just one example and most prescription treatments needed for Lyme and coinfections are unsubsidized on the PBS so it is obvious that it quickly becomes extremely costly to try to gain effective treatment for this illness. The financial burden is enormous and I don't know what I'll do when I run out of money.⁷¹

2.72 In some cases, submitters highlighted that some treatments prescribed by 'Lyme literate' doctors are not available in Australia. For example, submitters have been referred to a clinic in Germany (Klinik St Georg in Bad Aibling) to undertake 'hyperthermia treatment', where the body is heated to kill off bacteria. This treatment is not available in Australia and costs approximately \$30 000 per course.⁷² Other

66 See, for example: *Submission 136*; *Submission 203*.

67 See, for example: *Submission 101*.

68 See, for example: *Submission 67*; *Submission 119*; *Submission 123*; *Submission 156*.

69 See: Ms Christine Linigen, *Submission 70*. Other submitters have spent between \$20,000 and \$50,000 on treatment. See: *Submission 85*, *Submission 105*; *Submission 121*; *Submission 253*; *Submission 259*.

70 See, for example: *Submission 177*; *Submission 197*; *Submission 201*; *Submission 353*.

71 *Submission 241*, p. 9.

72 See, for example: *Submission 111*; *Submission 125*; *Submission 150*; *Submission 172*; *Submission 187*.

submitters were referred to other similarly expensive treatments in the US or elsewhere overseas (such as ozone therapy in Indonesia).⁷³

2.73 As a result of these high costs, a number of submitters have highlighted that they were experiencing significant financial hardship. Many submitters reported having sold or mortgaged their homes, borrowed money from family and friends or moved in with their parents or carers in order to afford treatments.⁷⁴

2.74 Submitters have also highlighted that because Lyme-like illness is not formally recognised, they have experienced difficulties in accessing social welfare payments, income protection insurance and/or early access to superannuation to pay for treatment and expressed concern and frustration that they did not qualify for these payments and services.⁷⁵

2.75 The department noted that to address the costs of treatments prescribed by 'Lyme literate' practitioners, it would welcome an application for a review of treatments to determine whether they could be included in the PBS:

...given the desire by patients and advocates for subsidised pharmaceutical agents, the department would welcome a submission by the advocacy groups to the Pharmaceutical Benefits Advisory Committee for a review of the evidence.⁷⁶

Appropriateness of treatments

2.76 The committee also heard concerns from medical authorities about some of the treatments offered by 'Lyme literate' practitioners, such as side-effects from antibiotics, infections from intravenous catheters (such as PICC lines) and potential toxins from unregulated medications.⁷⁷ These authorities argue that these treatments are not evidence based and risk causing harm to patients.⁷⁸

2.77 For example, one infectious disease specialist submitted:

I have been referred patients with Lyme disease, or such patients have been referred to my colleagues. Sometime they already have another diagnosis

73 See, for example: *Submission 125*; *Submission 129*; *Submission 140*; *Submission 150*. Evidence from submitters indicates that the outcomes of these overseas treatments differ widely. One submitter received hypothermia treatment along with other treatments at the German clinic and experienced a significant improvement in their health, which included increased energy, improved balance and improved cognitive ability. Another submitter who also received treatment at the clinic expressed only a limited improvement in their condition. See: *Submission 24* and *Submission 38*.

74 See, for example: *Submission 447*; *Submission 615*; *Submission 1045*; *Submission 1094*; *Submission 152*.

75 See, for example: *Submission 127*; *Submission 198*; *Submission 304*; *Submission 333*.

76 Department of Health, *Submission 495*, p. 3.

77 Royal Australasian College of Physicians, *Submission 754*, p. 2.

78 See, for example: NSW Health, *Submission 457*, p. 4; Royal Australasian College of Physicians, *Submission 754*, p. 2; Victorian Department of Health and Human Services, *Submission 547*, p. 5; Australasian Society for Infectious Diseases, *Submission 496*, p. [3].

such as Motor Neurone Disease (MND). Then they are offered a different diagnosis in a non-accredited lab, usually overseas. The lab is usually not accredited in the overseas country and charges much more for tests than mainstream labs ...

The patients are often given multiple diagnoses, none of which are seen in Australia such as Babesiosis. In addition the treatment is not standard, even were the diagnosis to be correct and invariably is for much longer than in the IDSA (Infectious Diseases Society of America) guidelines. In other words, even were the diagnosis to be correct the treatment is not standard, and almost always has greater risks of side effects than conventional treatment ...

The circumstances are not universal but there is a cluster of patients diagnosed outside of medicine in unaccredited [sic] laboratories and given unorthodox treatment to the potentially severe detriment of their medical and physical health as well as bearing a great financial and psychological burden.⁷⁹

2.78 In particular, the committee heard concerns about the use of long-term antibiotics to address symptoms ascribed to Lyme-like illness. The Communicable Diseases Network Australia, supported by state and territory health departments, noted that:

There is no evidence to support the use of combination antibiotics, immunoglobulin, hyperbaric oxygen, specific nutritional supplements, or prolonged courses of antibiotics for the management of Lyme disease.⁸⁰

2.79 Associate Professor Samuel Zagarella from the Australasian College of Dermatologists provided the committee with a recent study of a randomised trial of long-term antibiotic therapy for symptoms attributed to Lyme disease in Europe which concluded:

In patients with persistent symptoms attributed to Lyme disease, longer-term antibiotic treatment did not have additional beneficial effects on health-related quality of life beyond those with shorter-term treatment.⁸¹

2.80 The RCPA further noted that the consequences of long-term antibiotic use can have negative effects for both the individual and the broader community:

Unproven long term broad spectrum antibiotic treatment is not only potentially harmful to the individual patient due to side-effects up to and including death, it is harmful to the patient and the Australian community in general because it promotes the proliferation of multi-drug resistant organisms. This resistance renders all anti-biotics ineffective against

79 Name withheld, *Submission 462*, p. 1.

80 WA Department of Health, *Submission 529*, p. 5.

81 Professor Samuel Zagarella, Response to question on notice, received 14 April 2016. See: Anneleen Berende et al, 'Randomized Trial of Longer-Term Therapy for Symptoms Attributed to Lyme Disease', *New England Journal of Medicine*, v. 374, n. 13, 31 March 2016, p. 1209.

common (non-Lyme Disease) infections and is a genuine crisis in modern healthcare.⁸²

2.81 However, 'Lyme literate' practitioners told the committee that the use of long-term antibiotics was evidence based and in many cases assisted patients to get better. Dr Richard Schloeffel, a Lyme literate practitioner in Sydney, told the committee:

We have treated 4 000 patients in five years. We are currently treating only 1 500 patients. Of the other 2 500 patients we have treated, most are better. They are getting better because they are having an appropriate diagnosis and appropriate treatment, sometimes with long-term antibiotics—oral in the main. But because we have so many sick patients we are doing a lot of intravenous therapies as well, including intravenous antibiotics for long periods of time, which is leading to a positive outcome, but under the same rigor that any intensive therapy would require, and we are doctors who are extremely qualified to do this work.⁸³

Committee view

2.82 The committee notes that the following issues need further inquiry:

- treatments prescribed for patients with Lyme-like illness, including costs, efficacy and evidence base; and
- the potential for a review of treatments by an expert panel.

Limitations on 'Lyme literate' practitioners

2.83 Submitters expressed particular concern that 'Lyme literate' practitioners experience stigma from medical authorities. In some cases, practitioners have ceased providing treatment due to sanctions by or fear of sanctions by medical authorities such as the Australian Health Practitioner Regulation Agency (AHPRA). These submitters argue strongly that 'Lyme literate' practitioners should not be prohibited from treating for Lyme-like illness.⁸⁴

2.84 The committee notes that a number of practitioners who made submissions to the inquiry requested that their name be withheld due to fear of disciplinary action by AHPRA.⁸⁵ Mr John Curnow, whose wife suffered from Lyme-like illness, noted in his submission: 'The few doctors that do try to treat [this] Lyme like illness are ostracised and called charlatans by their colleagues'.⁸⁶

2.85 The LDAA also addressed this issue, noting that:

82 RCPA, *Submission 532*, p. 10.

83 Dr Richard Schloeffel, *Committee Hansard*, Brisbane, 15 April 2016, p. 20.

84 See: Mr Greg Watts, *Submission 9*; *Submission 12*; *Submission 77*; Mr Chris Willis, *Submission 127*; *Submission 136*; *Submission 165*.

85 To address these concerns, the committee decided to redact the names of all doctors named in submissions, including Lyme literate practitioners.

86 Mr John Curnow, *Submission 351*, p. 1.

Of serious concern is the increasing level of complaints being directed at doctors who are treating patients with Lyme disease. Over the past three years there have been conditions placed on three doctors (Ladhams, Du Preez and Kemp) treating patients with Lyme disease by the Australian Health Practitioner Regulation Agency (AHPRA). The conditions are specific in response to Lyme disease and relate to the diagnosis, treatment and prescribing practices of the doctors concerned.⁸⁷

2.86 According to the LDAA:

The small handful of doctors who are treating patients in Australia are being bullied and badgered from within their profession and also by AHPRA. It's probable that any Australian doctor that chooses to treat Lyme-like disease will be investigated, given that they administer antibiotics for a longer period of time than the one month treatment protocol and operate outside the ATG's [Australian Therapeutic Guidelines].⁸⁸

2.87 One doctor who made a submission to this inquiry noted that the effect of such investigations was to constrain those doctors in their ability to treat patients:

To my knowledge there are 7 medical practitioners who have been 'targeted' for investigation and / or disciplinary measures. This makes those of us willing to treat this condition fearful of such treatment.⁸⁹

2.88 As a result of limitations placed on their practitioners by AHPRA, some submitters noted that they were no longer able to get treatment. For example, one submitter noted:

In 2013 I came under the care of a Lyme-literate doctor and began receiving antibiotic treatment via a Portacath. I started to notice changes quickly and then improvements within months...

In late 2013 my Lyme literate doctor faced disciplinary action and was [told] he could no longer treat patients with Lyme disease. This left me without a Lyme-literate doctor, or any doctor at all and with no access to assistance with my Portacath for IV treatment. My husband rang many medical centres in our local Redlands area and no one would help me.

As a result my health rapidly declined and I was dealing with a Portacath that clotted and had no medical practitioner to assist with flushing it. Thankfully my husband learned how to manage my Portacath with videos that he found on YouTube.⁹⁰

2.89 In response to this perception, representatives from AHPRA and the Medical Board of Australia (MBA) told the committee at its Brisbane hearing that AHPRA

87 LDAA, *Submission 528*, p. 25.

88 LDAA, *Submission 528*, p. 28.

89 Dr Adam Nuttall, *Submission 601*, p. 2.

90 Name withheld, *Submission 23*, p. [1]. See also: *Submission 109*.

does not target Lyme-literate practitioners and only responds on the basis of complaints:

... we recognise that there is a perception by some patients that we have targeted medical practitioners who diagnose, treat or have a relationship with Lyme-like illness. I would like to put it quite clearly on the record that this is not true. In all the Lyme-related cases that we are or have been involved with, the board has always acted—not in isolation or on its own behalf—in response to a complaint.⁹¹

2.90 The Australian Medical Association (AMA) submitted that investigations are initiated on the basis of specific complaints about the individual practitioner:

The very small number of doctors who come before the MBA often have a history of complaints made about them from the public and the profession. The conditions imposed on the registration of any individual medical practitioner are always specific to that practitioner. They do not reflect the Board's view about any disease state or treatment regime. The AMA continues to support the role of AHPRA and the MBA in this respect.⁹²

2.91 Representatives from AHPRA and the MBA further stressed that in most cases regarding Lyme literate practitioners, they have decided not to act. In the small minority of cases where AHPRA does act, this is in response to the professional conduct of the practitioners in question:

I would like to point out that in the majority of notifications that have been in some way related with Lyme disease or Lyme in some way, the board has decided not to act—not to act, to protect the public. The matters have simply been investigated and then closed. It is in the small number of cases where there is a greater risk, we perceive, to the public that the board has taken a regulatory action to protect the public. It is on the public record that we have received notifications about practitioners who have diagnosed and treated Lyme disease. I would like to point out that it is not because of the diagnosis that they are there before us, but because of their professional conduct in the management of these patients. It is for these patients that we have taken regulatory action.⁹³

2.92 The MBA and AHPRA told the committee that in 2013-14 and 2014-15, of complaints received relating to the treatment of Lyme-like symptoms:

- 9.3 per cent were made by medical practitioners (as mandatory notifications under the Health Practitioner Regulation National Law); and
- 90.7 per cent were made by members of the public.⁹⁴

2.93 The MBA and AHPRA listed some of the concerns related to Lyme disease or Lyme-like illness which have led to an investigation of a medical practitioner:

91 Associate Professor Stephen Bradshaw, AHPRA, *Committee Hansard*, 15 April 2016, p. 62.

92 AMA, *Submission 456*, p. 5.

93 Associate Professor Stephen Bradshaw, AHPRA, *Committee Hansard*, 15 April 2016, p. 62.

94 MBA and AHPRA, Response to question on notice, received 26 April 2016.

- the use of unconventional diagnostic techniques (e.g. kinesiology) to diagnose Lyme-like disease;
- the reliance on non-accredited laboratories to diagnose Lyme-like disease;
- the potential for financial exploitation of patients, both through the use of overseas non-accredited laboratories and in charging high fees for services;
- not referring patients with complex diagnoses to specialists, where this would have been appropriate;
- not managing other co-existing medical conditions once Lyme-like disease was diagnosed;
- diagnosis of a large proportion of a medical practitioner's patients with Lyme-like disease without considering or excluding other conditions. There is a concern that patients may be deprived of the opportunity to have more appropriate treatment for another condition because the alternative condition is not considered once Lyme-like illness has been diagnosed. Treating Lyme-like illness with long-term antibiotic treatment, in the absence of an identified infection, is of concern. This management is at odds with advice from public health authorities regarding the dangers of antibiotic resistance. We understand that some practitioners are prescribing and administering antibiotics for years (whereas the treatment of Lyme disease is for weeks); and
- treatment for Lyme-like disease resulting in complications and interacting or interfering with other treatments. Examples include, use of large lines (e.g. PICC lines) to administer long-term antibiotics, which can result in infections and thrombosis, and antibiotics interacting with other necessary treatments.⁹⁵

2.94 The committee heard that AHPRA and the MBA have not considered ways to communicate decisions about 'Lyme literate' practitioners to other practitioners and the patient community. At the suggestion of the committee that this be considered, Associate Professor Stephen Bradshaw from AHPRA told the committee:

To be honest with you, we have not considered what you have just suggested. We may consider that after. I re-emphasise to you that we are not a disease-focused organisation—be it Lyme disease, cancer or whatever. We are looking for good medical practice. It is disappointing that there is this perception out there that we are targeting particular groups; I re-emphasise and will keep re-emphasising that we certainly are not. At the end of the day, the number of practitioners that have regulatory action taken against them on this topic is extremely small. There are huge other areas of practice that have a lot more practitioners before us than practitioners looking after patients with Lyme disease.⁹⁶

95 Medical Board of Australia and Australian Health Practitioner Regulation Agency, *Submission 533*, p. 3.

96 Associate Professor Stephen Bradshaw, AHPRA, *Committee Hansard*, 15 April 2016, p. 66.

Chapter 3

Diagnostic testing for Lyme-like illness

3.1 As noted in Chapter 1, patients diagnosed with Lyme-like illness often have their clinical diagnoses confirmed by laboratory tests conducted in overseas laboratories or non-accredited laboratories in Australia. These conflicting diagnoses cause concern and frustration to sufferers of chronic debilitating symptoms.

3.2 This chapter examines the diagnostic process by which patients come to be diagnosed with Lyme-like illness. It explores the discordant results for Lyme disease testing between accredited laboratories in Australia and laboratories overseas and non-accredited laboratories in Australia.

Diagnostic testing for Lyme disease

3.3 In 2015, the Department of Health (department) released Australian guidelines on the diagnosis of overseas acquired Lyme disease. The department emphasised that these guidelines are for the diagnosis of classical Lyme disease only, and do not apply to Lyme-like illness acquired in Australia.¹

3.4 The diagnostic protocols in the department's guidelines are consistent with the 2014 position statement prepared by the Royal College of Pathologists of Australasia (RCPA), *Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand*.² Submissions to the inquiry from medical authorities and state and territory governments supported the RCPA's position statement and highlighted that the diagnostic protocol it outlines should be followed for diagnosing Lyme disease or any similar syndromes.³

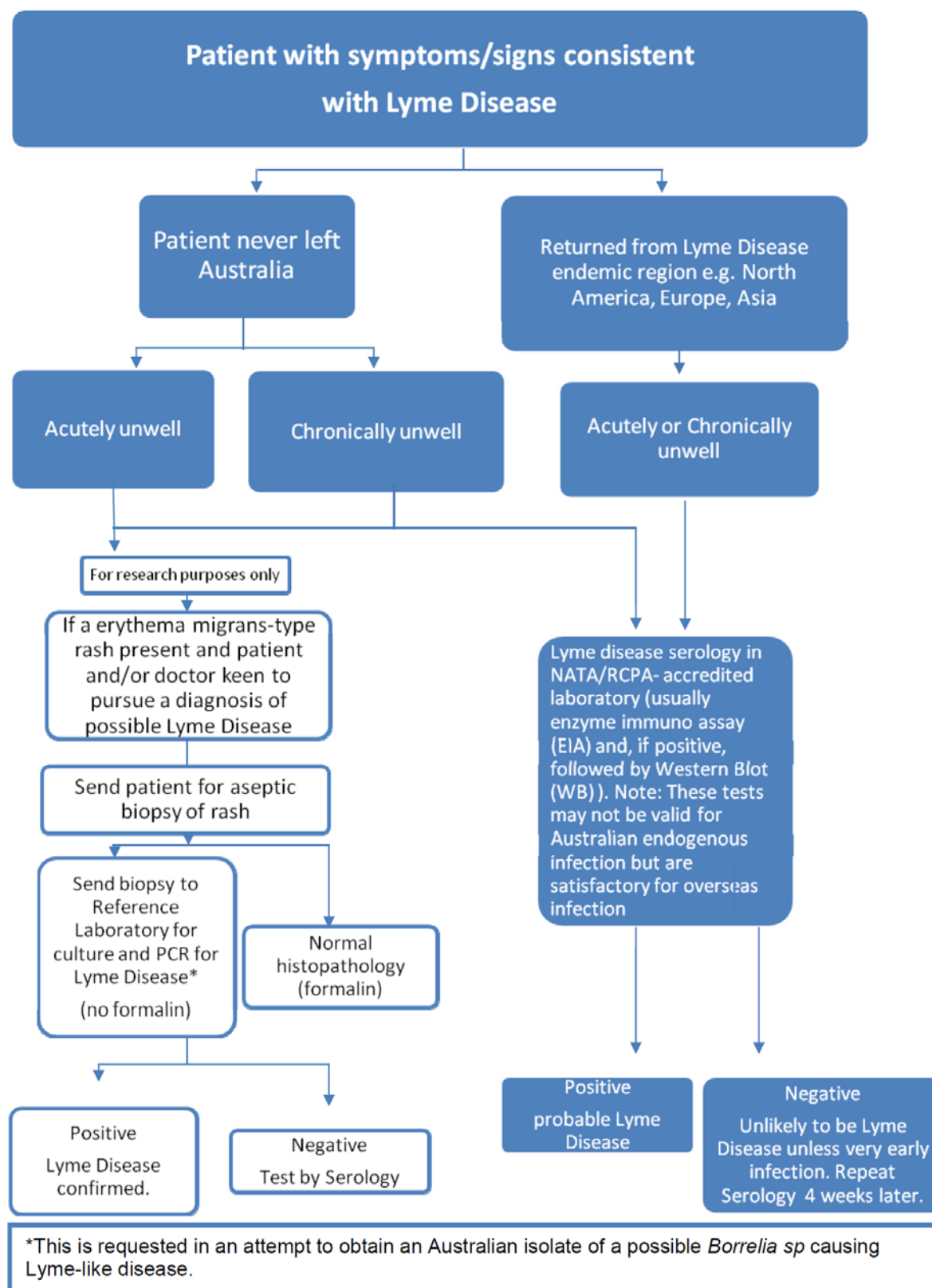
3.5 Figure 3.1 outlines the proposed protocol for diagnosing cases of suspected Lyme disease in Australia recommended by the RCPA's 2014 position statement on the treatment of Lyme disease and related syndromes.

1 Department of Health, *An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis*, August 2015, <http://www.health.gov.au/lyme-disease> (accessed 1 December 2015).

2 Royal College of Pathologists Australasia (RCPA), *Position statement: Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand*, February 2014, <http://www.rcpa.edu.au/Library/College-Policies/Position-Statements/Diagnostic-Laboratory-testing-for-Borreliosis-Lyme> (accessed 7 December 2015).

3 See, for example: Royal Australia College of Physicians, *Submission 754*; Australian Society for Microbiology, *Submission 781*; WA Department of Health, *Submission 529*; NSW Health, *Submission 457*; Victorian Department of Health and Human Services, *Submission 547*.

Figure 3.1 – Recommended protocol for laboratory testing of patients with suspected Lyme disease in Australia



Source: Royal College of Pathologists of Australasia, *Submission 532*, p. 8.

Diagnosis of overseas acquired classical Lyme disease

3.6 According to the guidelines for the diagnosis of overseas acquired Lyme disease prepared by the department, a confirmed case of Lyme disease requires laboratory definitive evidence (culture, DNA or serological assays), clinical evidence and epidemiological evidence. The guidelines highlight the importance of epidemiological evidence in determining whether a patient has Lyme disease:

Epidemiological context is important. Determining a travel history and tick exposure prone activities are essential. The likelihood of Lyme disease increases as the probability of a tick bite increases in a geographically endemic area (particularly wooded, brushy, or grassy habitats).⁴

3.7 Laboratory definitive evidence for Lyme disease can be collected through culture, DNA or serological assays. The 'gold standard' for specificity of *Borrelia* infection is culture of spirochaetes from patient specimens. Molecular detection of *Borrelia* bacteria using a Polymerase Chain Reaction (PCR) test in patient specimens may also be used. However, these tests are not regarded as reliable as the bacteria are difficult to detect and appropriate samples are difficult to obtain.⁵

3.8 The more common way for diagnosing Lyme disease is through testing for antibodies to *Borrelia* bacteria through serological assays. The United States (US) Centers for Disease Control and Prevention (CDC) notes that serological test results need to be interpreted according to strict criteria, including whether Lyme disease is endemic to a particular area and whether the patient exhibits clinical symptoms.⁶

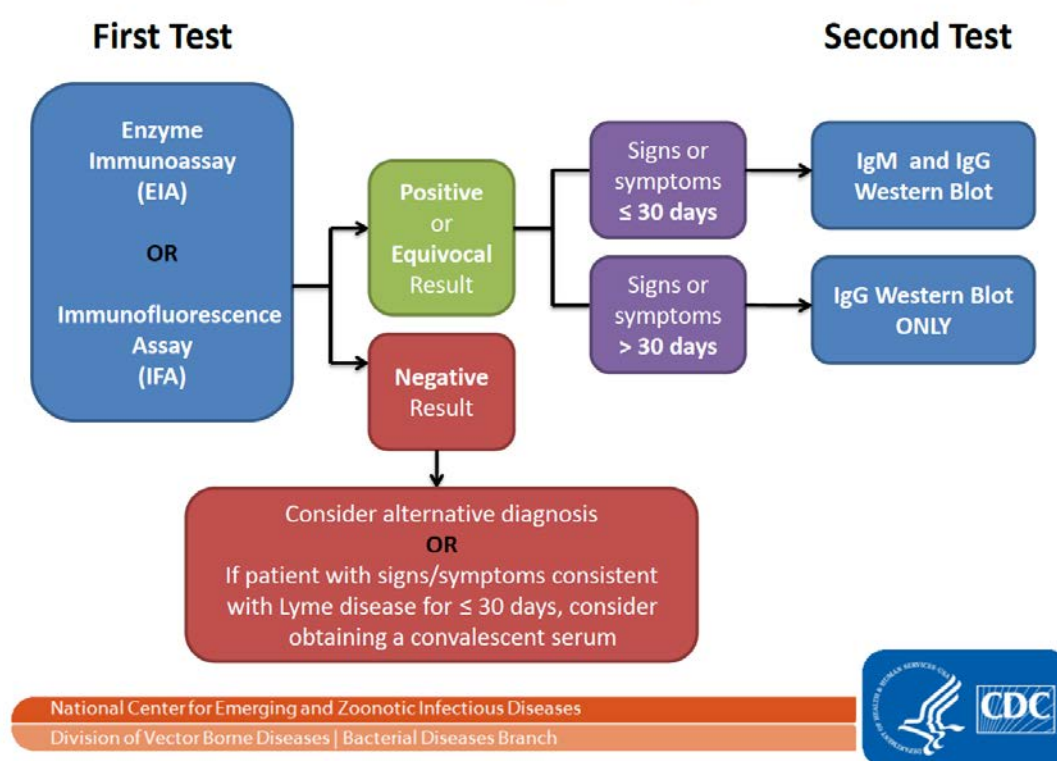
3.9 Most serological diagnostic protocols in the US and Europe use a two tier system. The first stage is most commonly an enzyme-linked immunosorbent assay (ELISA), followed by a Western blot. Western blots are interpreted using standardised criteria. These criteria differ between the US and Europe depending on the different genospecies of *B. burgdorferi* in different regions. The RCPA's position statement recommends the use of the two-tiered system and highlights that Western blot tests 'must be interpreted with caution, especially in the absence of an Australian *Borrelia* sp'.⁷ Figure 3.2 outlines the two-tiered testing process recommended by the US CDC.

4 Department of Health, *An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis*, August 2015, <http://www.health.gov.au/lyme-disease> (accessed 1 December 2015).

5 Professor John Mackenzie, *Scoping study to develop a research project(s) to investigate the presence or absence of Lyme disease in Australia*, 30 September 2013, p. 15.

6 Barbara Johnson, 'Laboratory diagnostic testing for *Borrelia burgdorferi* infection', in *Lyme Disease: An Evidence Based Approach*, John Halperin (ed.), CABI International, 2011, p. 73, http://www.cdc.gov/lyme/resources/Halperin_2012_Chap4_JohnsonB.pdf (accessed 9 December 2015).

7 RCPA, *Position statement: Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand*, February 2014, p. 4.

Figure 3.2 – Two-tiered testing for Lyme disease

Source: US CDC, http://www.cdc.gov/lyme/healthcare/clinician_twotier.html (accessed 8 December 2015).

3.10 Australian laboratories are accredited for medical testing by the National Association of Testing Authorities Australia (NATA) in conjunction with the RCPA.⁸ According to the department, NATA accredited laboratories can readily test for Lyme disease acquired overseas where patients have travelled to an endemic area. Dr Gary Lum told the Community Affairs Legislation Committee:

If a patient who is from Maine, Connecticut or another area in the north-east of the United States or from the Black Forest of Germany, who has been bitten by a tick and then travels to visit Australia and sees a general practitioner and has a blood test, we get a positive diagnosis. The same is true for Australians travelling to those areas and coming back with a rash and feeling unwell. Lyme disease is considered because they were in an endemic area, and a diagnosis is readily made in an Australian accredited medical testing laboratory.⁹

3.11 The Public Health Laboratory Network (PHLN) submitted that the interpretation of serology tests depend on three key factors:

8 National Association of Testing Authorities (NATA), 'Types of Accreditation', <http://www.nata.com.au/nata/accreditation-info/types-of-accreditation> (accessed 8 December 2015).

9 Dr Gary Lum, Principal Medical Adviser, *Estimates Hansard*, 21 October 2015, p. 14.

- the sensitivity of the test (the percentage of people with the disease who will have a positive test);
- the specificity of the test (the percentage of people without the disease who will have a negative test); and
- the pre-test likelihood of the person having the disease, based on the prevalence of the disease in the population being tested.¹⁰

3.12 As classical Lyme disease is considered to have a low prevalence in Australia, locally acquired cases are considered likely to return negative results for *Borrelia*. The PHLN notes that positive results for locally acquired Lyme disease are likely to be 'false positives' and are not uncommon in patients suffering other conditions:

... a positive result is more likely to be a false-positive if the test is performed on a person with a low pre-test likelihood of having the condition, such as testing for Lyme disease in Australia. There are two factors at play here – the first is that when less stringent interpretative criteria are used ... the results will be skewed to more patients with the disease. The other factor is that the assays were developed for classical Lyme disease, so for patients in a low prevalence population with nonspecific symptoms, the predictive value is low and reactive results are more likely to reflect absence of disease while nonreactive results likely reflect true absence of disease. False positive results for Lyme disease are not uncommon in patients suffering from other conditions.¹¹

Diagnostic testing for Lyme-like illness

3.13 The diagnostic protocol for testing for classical Lyme disease acquired overseas outlined above is widely accepted by Australian medical authorities. However, due to the debate about the cause or causes of Lyme-like illness, the diagnostic protocol for Lyme-like illness is more disputed.

3.14 The RCPA position paper states that for patients presenting with 'syndromes resembling Lyme disease' with no history of travel to an endemic area:

... although [i]t is not entirely possible to rule in or rule out locally acquired Borreliosis on the basis of a series of negative results, it is important that patients are not diagnosed erroneously as having Lyme Disease, when they may well have some other, potentially treatable, conditions: examples include chronic pain syndromes including fibromyalgia; complex neurodegenerative disorders such as motor neurone disease; or psychiatric illness such as major depression with somatisation.¹²

3.15 As noted in Chapter 1, 'Lyme literate' practitioners assert that Lyme-like illness is caused by an ongoing *Borrelia* bacterial infection, together with other co-infections. Most other medical authorities assert that the *Borrelia* responsible for

10 Public Health Laboratory Network (PHLN), *Submission 319*, p. 1.

11 PHLN, *Submission 319*, p. 2.

12 RCPA, *Position statement: Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand*, February 2014, pp 2–3.

causing Lyme disease is not endemic to Australia and suggest that there may be multiple causes of Lyme-like illness that are yet to be identified.

3.16 Many submitters who have acquired their illness in Australia stated that when their blood samples have been sent to an accredited Australian laboratory to test for *Borrelia* bacteria, the results have come back negative.¹³

3.17 However, when these same submitters consulted a 'Lyme literate' practitioner, they have recommended sending their blood samples to either a non-accredited laboratory in Australia or laboratories in the US or Germany. As these tests are not covered under the Australian Medicare system, the costs for patients are significant (for example, \$800 for tests in Australia and \$2 000 for tests from overseas laboratories).¹⁴

3.18 Tests results from these laboratories have returned a positive result for *Borrelia*, often with a number of co-infections such as *Bartonella* and *Babesia*. These results have been used by 'Lyme literate' practitioners to confirm their clinical diagnosis. Dr Hugh Derham, a 'Lyme literate' practitioner in Western Australia, told the committee:

Almost all of my patients have a clinical diagnosis of Lyme disease and reasonable to excellent laboratory evidence as well, and at least half of them have some laboratory evidence from an accredited laboratory, either accredited by or recognised by NATA. I do not have hundreds of patients who believe they have Lyme disease; their belief is founded on good evidence.¹⁵

3.19 Evidence from submissions suggests that the differences between laboratory results can cause significant confusion and frustration for patients. Submitters expressed their deep concern that results from overseas laboratories are disregarded by Australian medical authorities, particularly infectious disease specialists:

Patients who attempt IDS [infectious disease specialist] consults are turned away with negative test results even though they may have gone to huge expense to be tested in accredited laboratories overseas and carry positive test results with them, they are still disregarded by the IDS.¹⁶

3.20 The issue of discordant results between accredited laboratories in Australia and non-accredited Australian and overseas laboratories needs further inquiry.

Accreditation of Australian laboratories

3.21 The committee heard that one non-accredited Australian laboratory, Australian Biologics, is used by a number of 'Lyme literate' practitioners to test for

13 See, for example: Ms Michelle Wood, *Submission 129*; *Submission 282*; *Submission 307*; *Submission 508*.

14 See, for example: *Submission 67*; *Submission 119*; *Submission 123*; *Submission 156*; *Submission 303*; *Submission 403*; *Submission 616*; *Submission 853*.

15 Dr Hugh Derham, *Committee Hansard*, Perth, 14 April 2016, p. 41.

16 *Submission 101*, p. 2.

Lyme-like illness. In her evidence to the committee, the Director of Australian Biologics, Ms Jennie Burke stated that through their testing process, Australian Biologics has identified evidence of *Borrelia* in Australian paralysis ticks.¹⁷

3.22 Unlike other Australian accredited laboratories, Australian Biologics uses Polymerase Chain Reaction (PCR) assays to test for the presence of *Borrelia* DNA in human samples. Australian Biologics also uses different serological tests for *Borrelia* imported from Germany (the Mikrogen *recom*Line and AID EliSpot Lymphocyte Transformation Test). In their submission, Australian Biologics asserts that the serological tests used by other Australian laboratories are not effective for patients with a chronic infection of *Borrelia* and that PCR and the German serological tests are more effective.¹⁸ A large number of submitters who have been diagnosed with Lyme-like illness have noted that they have had positive tests for *Borrelia* from Australian Biologics.¹⁹

3.23 A number of submissions have expressed concerns about the reliability of the tests provided by Australian Biologics. For example, one infectious disease specialist suggested that the false positive rate for the tests used by laboratories such as Australian Biologics 'appears to be extremely high'.²⁰

3.24 Australian medical authorities noted that results from laboratories that are not accredited by NATA and the RCPA, such as Australian Biologics, should be interpreted with caution. The RCPA submitted:

If a laboratory is not NATA/RCPA accredited this means that the laboratory may not have testing protocols and quality assurance processes in place that would be considered satisfactory compared to the standards. Such laboratories may be more likely to obtain an incorrect result for a particular laboratory investigation.²¹

3.25 However, Ms Burke expressed concerns about the process by which laboratories are accredited by NATA. Australian Biologics applied for accreditation in 2014 for its PCR testing. Ms Burke stated that NATA does not acknowledge the accuracy of their testing protocols for *Borrelia* or their quality assurance programs, and that it breached its charter in assessing their accreditation application by disclosing confidential intellectual property information to a rival laboratory.²²

17 Ms Jennie Burke, *Committee Hansard*, Brisbane, 15 April 2016, p. 56.

18 *Submission 545*, pp 1–2.

19 See, for example: *Submission 103*; *Submission 104*; *Submission 112*; *Submission 122*.

20 See: *Submission 362*.

21 RCPA, *Submission 532*, p. 9.

22 At its hearing in Brisbane, Ms Burke alleged that the CEO of NATA told her during a meeting that "We do not believe that you are detecting *Borrelia*". See: Ms Jennie Burke, *Committee Hansard*, Brisbane, 15 April 2016, p. 57.

3.26 In evidence to the committee, representatives from NATA highlighted that in the accreditation process for innovative laboratory processes, such as PCR testing for *Borrelia*, the threshold for evidence is higher than for usual accreditation:

For new and innovative methods for which the availability of appropriate validation is limited or where standard methods have been modified or, indeed, used outside their design parameters, the threshold of evidence for acceptance naturally becomes higher. The soundness of evidence provided is judged by relevant experts and professional bodies, not by employees of NATA. NATA must seek the best advice from expert sources, peers of the laboratory, before it commits to a precedent that will impact on the health and safety of the Australian population.²³

Recognition of overseas laboratories

3.27 The committee heard arguments from 'Lyme literate' practitioners that the tests for *Borrelia* conducted by accredited Australian laboratories are not appropriate, and the criteria by which they are interpreted are inadequate. These practitioners assert that the two-tier process recommended by the RCPA and the US CDC does not adequately detect *Borrelia* and other co-infections acquired in Australia.²⁴

3.28 For example, Dr Peter Dobie from the Australian Chronic Infectious and Inflammatory Disease Society told the committee that the ELISA test – the first tier in the two tier process – is not sensitive enough to detect Lyme-like illness and should be 'abandoned':

...most Australian pathology laboratories are doing the wrong blood test for Lyme disease. This is one reason why Lyme disease and Lyme-like illness are underdiagnosed in Australia. Most laboratories are using a test called the ELISA test. This test is not sensitive enough to detect most cases of this illness ... Pathology laboratories should be doing western blot and PCR as the frontline tests for Lyme disease, not the ELISA test.²⁵

3.29 These practitioners insist that overseas laboratories (specifically IGeneX in California and Arminlabs or Infectolab in Germany) are better placed to accurately test for *Borrelia*. Dr Dobie told the committee that the main reason that 'Lyme-literate' practitioners use overseas laboratories is that these laboratories will do the Western blot test if requested, whereas Australian laboratories will only do so if the ELISA test is positive:

One of the reasons that doctors are using these overseas laboratories is that these laboratories will do the western blot on request. Doctors treating this illness are not interested in the result of the ELISA test. If Australian

23 Mr John Mitchell, *Committee Hansard*, Canberra, 20 April 2016, p. 19.

24 See: Dr Hugh Derham and Dr Adam Nuttall, *Committee Hansard*, Perth, 14 April 2016, pp 40–46; Dr Peter Dobie and Dr Richard Schloeffel, *Committee Hansard*, Brisbane, 15 April 2016, pp 19–27.

25 Dr Peter Dobie, *Committee Hansard*, Brisbane, 15 April 2016, p. 19.

laboratories would do the western blot on request, there would be less need for us to use overseas laboratories.²⁶

3.30 The committee also heard that the US CDC criteria used to interpret serological tests in accredited Australian laboratories focus too narrowly on *Borrelia burgdorferi*. Dr Mualla McManus told the committee that the CDC criteria are not appropriate for identifying other possible Australian species of *Borrelia*:

The government only thinks of Lyme disease, and follows the CDC criteria ... We have *Borrelia burgdorferi*, and a subset of that is Lyme disease. We have relapsing fever, and it has over 20 genospecies already. We have reptilian borrelia, but the infection has not yet been found in humans. So if we concentrate on Lyme disease we are missing out on 80 per cent of other borrelia infections, and that is really dangerous. We are being short-sighted ... We could have a unique class of borrelia.²⁷

3.31 Some submitters suggested that results from overseas laboratories should be interpreted with caution, as each test has its own sensitivity and specificity based on the composition of the causative agent. According to these submitters, in the absence of a known causative agent in Australia, a positive test result is likely to indicate a false positive due to cross reactions from other bacteria.²⁸ The RCPA submitted:

If caused by a tick-born microbe, the causative microbe has not yet been identified and thus its antigenic make-up is unknown. Without knowing its antigenic make-up, it is impossible to design a proper serological test with measurable sensitivity and specificity. Cross-reactivity between patient antibodies and *Borrelia* antigens from overseas *Borrelia* used in vitro in Australian diagnostic assays are hard to predict.

There are many species of spirochetes (including *Borrelia spp.*) present in the normal human gastrointestinal tract (including the oral cavity) and some of these may potentially cause cross-reacting antibodies to be produced by the patient.²⁹

3.32 Some submitters also suggested that tests conducted in non-NATA accredited laboratories in Australia and laboratories overseas may produce different results to accredited Australian laboratories because they may not interpret their results

26 Dr Peter Dobie, *Committee Hansard*, Brisbane, 15 April 2016, p. 19.

27 Dr Mualla McManus, *Committee Hansard*, Brisbane, 15 April 2016, p. 29.

28 Mackenzie, *Scoping study*, p. 15.

29 RCPA, *Submission 532*, p. 7.

according to the criteria set by the US CDC and the European Society of Clinical Microbiology and Infectious Diseases.³⁰ Dr Lum told the committee:

... when these tests are performed overseas, and also in some specialist laboratories in Australia, the interpretive criteria are different. What I mean by that is that they place less serological stringency on the test interpretation, so it makes it easier to diagnose a reactive [positive] result.³¹

3.33 The RCPA cautioned that it is difficult to assess the accuracy of results from serological tests conducted in overseas laboratories that are not accredited to Australian standards:

Overseas laboratories are by definition, not accredited to Australian standards so their use by Australian doctors and patients is on the basis of unknown quality of testing. While some may be excellent laboratories, accredited to international and their own country's standards and producing accurate and precise results, others may not be so. Australian authorities are not in a position to regulate or monitor these overseas laboratories and it is very difficult for Australian clinicians and patients sending specimens overseas to assess what veracity to place on the results and reports that they receive.³²

3.34 The RCPA also warned that the overseas laboratories favoured by 'Lyme literate' practitioners are not used by 'mainstream' practitioners in their own countries and are likely to return false positive results. Professor Stephen Graves from the RCPA told the committee:

The laboratories in Germany and the United States that you are talking about, and that we are talking about now, are a minority. They are an exception. The mainstream doctors in those countries do not use those laboratories. They do not use them because they give them the wrong result. They give them false positive results. So it is not just us. The doctors in those countries say, 'Don't send your stuff to such and such a laboratory; you can't trust the result.' People here who are not getting results from mainstream laboratories are sending them to very off-the-mainstream types of laboratories in other countries. They are not the mainstream laboratories that are doing the routine testing all the time.³³

3.35 'Lyme literate' practitioners suggested that NATA, the body responsible for accrediting Australian laboratories, should recognise the overseas accreditation of

30 See: Dr Gary Lum, *Estimates Hansard*, 21 October 2015, p. 12; RCPA, *Position Statement*, February 2014. Dr Lum has previously told the Community Affairs Legislation Committee that 'when serologically less stringent interpretive criteria are employed along with poor predictive value associated with testing a low prevalence population with nonspecific symptoms, reactive serological results should be viewed cautiously'. See: Community Affairs Legislation Committee, *Additional Estimates 2015-16*, Response to question on notice SQ16-000221, received 4 April 2016.

31 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, p. 6.

32 RCPA, *Submission 532*, p. 9.

33 Professor Stephen Graves, *Committee Hansard*, Brisbane, 15 April 2016, p. 51.

these specific laboratories overseas, through such measures as the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (MRA).³⁴ Some advocacy groups also suggested that NATA should acknowledge that the overseas laboratories in question are accredited to the international standards for medical testing (ISO 15189) and should therefore recognise results from these laboratories. For example, Ms Rebecca Vary from the Lyme Disease Association of Australia (LDAA) suggested to the committee that NATA should recognise results from a German laboratory, Infectolab:

Infectolab were accredited with ISO 15189, and they have been accredited to that standard for quite a while. What happened in January was that NATA became a member of that accreditation as well, so NATA now has the right to recognise the other labs in ISO 15189, so it can therefore recognise the Infectolab results.³⁵

3.36 In evidence to the committee, representatives from NATA confirmed it had achieved international recognition for medical testing (ISO 15189) in January 2016 under the MRA. However, NATA emphasised that the effect of MRA recognition is of equivalence of overseas testing methods; it does not expect or require laboratories or medical authorities in Australia to recognise another country's specific requirements or context:

Our role under the MRA is to promote recognition of equivalence. It is the end user, however, who is actually the individual making the final decision on the recognition.³⁶

Limits on diagnostic testing under Medicare

3.37 The committee also heard that under the current Medicare Benefits Schedule, laboratories are only able to test for what the referring doctor requests. The Australian Rickettsial Reference Laboratory suggested that these limits mean that when a patient sample is referred for a Lyme disease test, laboratories are not be able to test for other known pathogens:

Diagnostic tests on patient specimens are generally bulk-billed and the income from this [85% of the Medical Benefit Schedule recommended fee] only covers the cost of undertaking the test requested by the referring doctor. Thus if the doctor asks for investigations for Lyme Disease, the laboratory is unable to also test for other potentially tick-transmitted diseases, despite the possibility that the patient may have acquired one of these, eg a rickettsial infection, which the referring doctor did not include on his/her list of differential diagnoses.³⁷

3.38 Professor Stephen Graves from the RCPA and also Director of the Australian Rickettsial Reference Laboratory, suggested that the Medicare rules around laboratory

34 See: Dr Peter Dobie, *Committee Hansard*, Brisbane, 15 April 2016, p. 20.

35 Ms Rebecca Vary, *Committee Hansard*, Perth, 14 April 2016, p. 19.

36 Mr John Mitchell, *Committee Hansard*, Canberra, 20 April 2016, p. 19.

37 Australian Rickettsial Reference Laboratory, *Submission 459*, p. 4.

testing should be changed to allow laboratories to explore other possible diagnoses when a test is referred for Lyme disease:

...what I am proposing ... is somehow make it possible for diagnostic laboratories—the sort of laboratory that is part of the Public Health Laboratory Network, like my laboratory, the Australian Rickettsial Reference Laboratory. If we get a serum specimen in from a patient who has query Lyme disease—endemic Australian Lyme disease—we can currently only test for Lyme disease. That is all I am allowed to do. If I do any other testing, it is basically called overservicing and, as a pathologist, I can get into big trouble over it. So I just have to do what is requested. So I do the Lyme disease testing. It is negative—end of story. But if I could also test for Coxiella, Rickettsia, Anaplasma, Ehrlichia, Neoehrlichia—although we do not have an assay for that yet—Bartonella or Babesia, that would make a big difference. We could possibly find out what is affecting these people. But not only cannot we do it; we are not allowed to do it.³⁸

3.39 The department confirmed that there are 'coning' rules in place that only allow laboratories to seek remuneration for up to three tests under the current Medicare rules:

...under the current way that pathology testing is remunerated, that there not be any sense of overservicing, but if there is a legitimate request then there will not be overservicing. The important thing to remember, though, is that the pathology profession is subject to various rules under the Medicare Benefits Schedule and, when referrals are made by general practitioners, there are rules in place which make it difficult compared to when, say, another specialist medical practitioner makes a referral, such that the ability to make a claim on those tests is different. That needs to be understood. For example, if a general practitioner requests more than three tests, there is a coning rule in place, and the pathology practice will only receive remuneration for the most expensive three tests, rather than all of the tests.³⁹

Measures to address discordant results

3.40 To address the discordant results between overseas laboratories and accredited laboratories in Australia, Professor John Mackenzie, author of the 2013 scoping study, suggested that the department coordinate a quality assurance/quality control (QA/QC) assessment of overseas testing procedures:

... the use of an international panel of specimens should be used for QA/QC is an essential step, and any putative positives should then be investigated fully in collaboration with the laboratory which has made the positive claim, and in parallel and together with an accredited public health reference laboratory to substantiate the claim ... The DOH [Department of Health] should indeed urgently liaise with overseas laboratories which claim to find positive results to ensure they participate in a QA/QC

38 Professor Stephen Graves, *Committee Hansard*, Brisbane, 15 April 2016, p. 48.

39 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, p. 8.

assessment, and to ensure this is carried out properly, an international accredited and unaligned laboratory such as the UK Institute for Biological Standards and Control should be engaged to oversee the conduct and interpretation of the QA/QC results.⁴⁰

3.41 The committee heard that the department is currently investigating the different approaches to the laboratory diagnosis of Lyme disease worldwide. The department has contracted the National Serology Reference Laboratory⁴¹ to:

... evaluate the serological assays used to diagnose Lyme disease in specialist laboratories in Australia and overseas as well as accredited pathology laboratories in Australia. The specimens being tested are from individuals in Australia and overseas both with and without symptoms. The results will be used to examine the performance characteristics of these laboratory tests and hopefully resolve the conundrum of discordant results in laboratories in Australia and overseas.⁴²

3.42 The committee notes that the department has previously advised the Senate Community Affairs Legislation Committee that ten laboratories have been approached and invited to participate in this evaluation, which is due to report in early 2017.⁴³

3.43 The department suggested that it would welcome a review of current laboratory testing processes and treatments by the Medicare Services Advisory Committee and the Pharmaceutical Benefits Advisory Committee. The department submitted:

Both committees are in the best position to review the current data for the available diagnosis and treatment. Should the committees advise that supportive evidence of effectiveness and cost-effectiveness does exist, steps can be taken to update the Medicare Benefits Schedule and the Pharmaceutical Benefits Schedule.⁴⁴

40 Professor John Mackenzie, Response to Question on Notice, received 21 April 2016.

41 The National Serology Reference Laboratory (NRL) is a not-for-profit scientific organisation that was established in 1985 as part of the Australian Government's HIV/AIDS Strategy, to evaluate HIV tests and adjudicate on the interpretation of HIV test results. The NRL's overall goal is 'to support laboratories, in Australia and internationally, that perform testing for the diagnosis and management of human infectious disease'. See: <http://www.nrl.gov.au/About+Us> (accessed 26 April 2016).

42 *Submission 495*, p. 3. The department advised that a progress report on the status of this project is due on 31 July 2016, with the final report due on 31 January 2017.

43 The ten laboratories approached and invited to participate include: Australian Red Cross Blood Service; the Australian Rickettsial Reference Laboratory; the Institute for Clinical Pathology and Medical Research; Sullivan Nicolaides Pathology; Australian Biologics; Pacific Laboratory Medicine Service; iGeneX (USA); Infectolab (Germany); Arminlab (Germany); and Rare and Imported Pathogens Laboratory. See: Community Affairs Legislation Committee, *Additional Estimates 2015-16*, Response to question on notice SQ16-000219, received 4 April 2016.

44 *Submission 495*, p. 3.

Committee view

3.44 The committee is aware that discordant laboratory results between accredited laboratories in Australia and non-accredited Australian and overseas laboratories cause confusion and frustration for patients.

3.45 The committee supports the department's work with the National Serology Reference Laboratory to conduct an evidence-based assessment of laboratory testing in Australia and overseas, with a focus on tests for Lyme-like illness.

3.46 The committee notes that the following issues need further inquiry:

- progress of the National Serology Reference Laboratory's assessment of Australian and overseas laboratory testing for Lyme-like illness;
- the process of laboratory recognition and accreditation to assist patients in understanding why there are discordant results; and
- options for changing the Medicare rules to allow accredited Australian laboratories to explore possible alternate pathogens.

Chapter 4

Next steps for further investigation

4.1 Most submitters to the inquiry agreed that more research is needed to both identify the cause of Lyme-like illness, and to improve diagnostic and treatment options for sufferers.

4.2 This chapter examines current research projects underway to investigate tick-borne illnesses in Australia, and opportunities for further research identified by governments, medical authorities and patient advocacy groups. The committee recognises that these issues are not unique to Australia, and further investigation of overseas responses to Lyme-like illness is warranted.

Opportunities for research

4.3 The committee notes that the Australian Government, through the Department of Health (department), has recently undertaken a number of projects to address Lyme disease in Australia, including establishing the Clinical Advisory Committee on Lyme Disease (CACLD).¹ The Chief Medical Officer, Professor Chris Baggoley, told the Community Affairs Legislation Committee at 2015-16 Supplementary Estimates that the department is 'particularly concerned about the plight of people who suffer from a disease which has been diagnosed as Lyme disease, because many of them have very difficult and miserable lives'.²

4.4 In 2013, the department commissioned a scoping study into Lyme disease in Australia that identified 11 key research questions for further investigation, and recommended the following major research programs:

- an experimental program to determine whether there is a *Borrelia* species in ticks in Australia causing Lyme-like disease, or whether another tick-borne pathogen is involved in human Lyme-like disease;
- whether Australian ticks can transmit *B.burgdorferi*, or other *Borrelia* species associated with relapsing fever;
- whether Australia has the best diagnostic tests for detecting novel *Borrelia* species, including *B. miyamotoi*, especially in clinical specimens;
- clinical studies of patients presenting with symptoms suggestive of Lyme or Lyme-like disease; and
- retrospective investigation of chronic cases of *Lyme borreliosis*.³

1 See: Department of Health, *Submission 495*.

2 Professor Chris Baggoley, Chief Medical Officer, *Estimates Hansard*, 21 October 2015, p. 15.

3 Professor John Mackenzie, *Scoping study to develop a research project(s) to investigate the presence or absence of Lyme disease in Australia*, 30 September 2013, pp 22–26, <http://www.health.gov.au/lyme-disease> (accessed 19 November 2015).

4.5 Of these programs, the scoping study highlighted that:

...the single most important issue to be addressed is whether *Borrelia* strains exist in Australia which can cause Lyme disease, or whether other pathogenic organisms are responsible...⁴

4.6 On 27 May 2014, the department hosted the Lyme Disease Treatment Round Table Meeting. Participants included members of the CACLD, general practitioners and other medical professionals. The round table suggested the following possible research activities, which were considered by the CACLD at its final meeting on 15 July 2014:

- a validation study on the methods currently used in Australian laboratories and if possible relevant international laboratories to diagnose borreliosis;
- an initial epidemiological study into patients presenting with symptoms of *Borrelia* infection acquired in Australia;
- an epidemiological study on returned travellers from endemic areas;
- research into the incidence of neuroborreliosis cases using CSF [cerebrospinal fluids] samples already collected from aseptic meningitis patients;
- a clinical randomised control trial (blinded) on the treatment of patients diagnosed with chronic Lyme disease; and
- the development of a register of patients with chronic neurological symptoms in partnership with neurologists and treating general practitioners (GPs) to compare if treatment with antibiotics demonstrates any improvement in patient outcomes.⁵

4.7 Many submitters agreed that research into chronic debilitating symptoms must be broader than seeking to identify *Borellia* bacteria as the symptoms may reflect a number of interactions between multiple pathogens causing a number of chronic illnesses. For example, the Communicable Diseases Network Australia (CDNA) noted:

Given the constellation of symptoms it is likely that there are multiple different diseases with different causes within the widely inclusive term 'Lyme-like illness'. The search for a causative agent for 'Lyme-like illness' should not assume or be narrowed to 'a unique local causative agent.' It is possible the causative agent(s) or clinical determinants are multiple and may not be unique to Australia. As 'Lyme-like illness' may not be caused by an infectious agent, investigation should not be limited to infectious agents. It is likely that there are multiple underlying causes for the constellations of symptoms experienced by these patients, many of which are not infectious, such as hormonal, metabolic, neuromuscular and psychological disorders.⁶

4 Mackenzie, *Scoping study*, p. 23.

5 Department of Health, *Lyme Disease Treatment Round Table Meeting*, 27 May 2014, <http://www.health.gov.au/lyme-disease> (accessed 19 November 2015).

6 Communicable Diseases Network Australia (CDNA), *Submission 531*, p. 5.

4.8 The department agreed with this assessment in its submission:

...we can say with greater confidence that past and recent research in Australian ticks makes finding a classical Lyme disease causing *Borrelia sp* unlikely. However, the groundswell of interest from patients, their families and some members of the medical profession in the hundreds of Australians presenting with a constellation of chronic debilitating symptoms associated with tick bites cannot be ignored and must be explored.⁷

Patient treatment priorities

4.9 In addition to the research priorities identified by the department, which focus on identifying the possible causative agent or agents for chronic debilitating symptoms, patient advocacy groups support research into the symptoms being experienced by patients. Ms Elaine Kelly, from Sarcoidosis Lyme Australia, told the committee:

... epidemiological and clinical studies are required as a matter of urgency to be inclusive of patients' symptomatology and general pathology. Current research is focusing on the causative agents and the disease, but an epidemiological study would focus on the patients and the illness.⁸

4.10 Following advice from the CACLD, the department sought public comment on its 2013 scoping study. In addition to the five research programs recommended by the scoping study, submitters to the department identified the following areas of focus:

- epidemiological research of patients who have been diagnosed with a Lyme-like illness, including geographical location, detailed symptoms and test results;
- comparisons with other countries that have detected a different causative agent, such as Brazil (recent research into Baggio-Yoshinari Syndrome, a Lyme-like illness in Brazil has identified that the disease is transmitted by ticks, but the causative agent is not yet known⁹);
- treatment options or guidelines for Lyme disease or Lyme-like illness; and
- patient focussed strategic approach to the 'Lyme problem' in Australia.¹⁰

4.11 The committee notes the Lyme Disease Association of Australia's (LDAA) 2014 submission to the department's response to the scoping study included a Patient-focussed Action Plan. This action plan included four key objectives:

7 *Submission 495*, p. 4.

8 Ms Elaine Kelly, *Committee Hansard*, Perth, 14 April 2016, p. 10.

9 Natalino Hajime Yoshinari et al, 'Brazilian Lyme-like disease or Baggio-Yoshinari Syndrome: exotic and emerging Brazilian tick-borne zoonosis', *Revista da Associação Médica Brasileira*, vol. 56, no. 3, 2010, http://www.scielo.br/scielo.php?pid=S0104-42302010000300025&script=sci_arttext&tlng=en (accessed 4 January 2015).

10 Department of Health, *Response to Professor John Mackenzie's Scoping Study*, August 2014, p. [7], <http://www.health.gov.au/lyme-disease> (accessed 19 November 2015).

- ensure patients can readily access affordable and reliable diagnosis and 'best practice' laboratory testing by 2016;
- ensure patients with Lyme-like illness are able to access appropriate and affordable treatment by 2016;
- reduce the risk of an epidemic of late stage Lyme-like illness by ensuring the Australian public is aware of the potential risks of exposure to possible transmission(s) and by improving access to early intervention treatment protocols throughout Australia by 2016; and
- ensure an end to discrimination by raising public awareness of Lyme-like illness by 2016.¹¹

4.12 The LDAA expressed particular concern that the work done by the department to date has been largely a 'bureaucratic process' and has not directly assisted patients. Ms Sharon Whiteman, President of the LDAA, told the committee:

In the past few years, the Australian government has done several things to try and support the Lyme community, however, it has largely been a bureaucratic process that has gone nowhere. It commenced with a clinical advisory committee, which abandoned after five meetings with no tangible progress. The advisory committee provided advice to the Chief Medical Officer, who sought advice from the Communicable Diseases Network, who needed more advice from the Joint Criteria Assessment Group, who provided even more advice. That advice resulted in more advice for the chief medical officers in each of the states and territories, who provided more advice to clinicians. Those are the frontline doctors who rely on contemporary and evidence based advice. That advice currently states that Lyme disease is not in Australia. At the core of all this advice stating that Lyme disease is not in Australia is: 'because it cannot be found in an Australian tick'.¹²

4.13 In its submission to this inquiry, the LDAA recommended a number of key research projects including:

- a study of the prevalence and incidence of Lyme-like illness in Australia, including a clinical study of patients; and
- a progressive and contemporary approach to research that harnesses next generation sequencing and new molecular techniques to better understand the pathogens that reside in Australian ticks and how they can infect humans.¹³

11 See: Lyme Disease Association of Australia (LDAA), *Lyme Disease in Australia: Patient submission to the Australian Government Department of Health's 'Scoping Study to develop a research project(s) to investigate the presence or absence of Lyme disease in Australia'*, January 2014, http://www.lymedisease.org.au/wp-content/uploads/2010/11/20140129LDAA_ScopingStudyResponse.pdf (accessed 12 April 2016).

12 Ms Sharon Whiteman, *Committee Hansard*, Brisbane, 15 April 2016, p. 3.

13 LDAA, *Submission 528*, p. 8.

Alternative methods of transmission

4.14 In particular, the LDAA recommended further research into alternative methods of transmission of Lyme-like illness besides tick bites, including through blood transfusions, in-utero or sexually transmitted. The LDAA highlighted that 10 per cent of respondents to its patient survey suggested that they did not acquire their illness from a tick bite and suggested that these methods warrant further research.¹⁴

4.15 Some submitters expressed particular concern that Lyme disease may be transmitted via blood transfusions. Ms Vicki White told the committee at its hearing in Perth that she acquired her illness following a blood transfusion:

... I hope to say to the medical experts that were here this morning but have not stayed to listen, 'Would you take a blood transfusion from one of us?' I doubt they would. But that is exactly what happened to me. My symptoms began after receiving blood transfusions.¹⁵

4.16 Dr Hugh Derham, a 'Lyme literate' practitioner from Western Australia, told the committee that there is some evidence to suggest transmission from Lyme disease is possible from mother to foetus and between sexual partners, but has not been demonstrated to be transmitted via blood transfusions:

The evidence is that *Borrelia* can be passed from mother to foetus and between sexual partners. It has been shown that it survives in blood transfusion products, but nobody has ever shown that it has been given to somebody via blood transfusion.¹⁶

4.17 Dr Donna Mak from the Western Australian Department of Health told the committee that there was limited evidence to support alternative methods of transmission of Lyme disease:

The scientific evidence so far shows that there is no evidence of transmission from mother to child through the placenta, or through blood transfusions. It is a tick-borne disease. We are aware that there are many doctors who say that it can be acquired through these alternative ways, but after looking at the scientific publications we do not actually believe that that is the case. We cannot find any evidence to support that.¹⁷

4.18 In its submission to the inquiry, the Red Cross Blood Service noted that while evidence that Lyme disease can be transmitted by blood transfusions has yet to be confirmed, it has a series of safeguards in place to minimise the risk of protecting its blood supply from possible infectious agents:

14 LDAA, *Submission 528*, pp 81–82. In response to questions on notice, the LDAA provided the committee with a number of published articles suggesting alternative methods of transmission of bacterial infections. See: LDAA, *Response to Questions on Notice*, received 27 April 2016.

15 Ms Vicki White, *Committee Hansard*, Perth, 14 April 2016, p. 30.

16 Dr Hugh Derham, *Committee Hansard*, Perth, 14 April 2016, p. 43.

17 Dr Donna Mak, *Committee Hansard*, Perth, 14 April 2016, p. 2.

While transfusion-transmitted Lyme disease or the transfusion-transmission of a Lyme-like illness has not been confirmed to date, the Blood Service remains vigilant in maintaining the safety of the blood supply. In the absence of a specific licensed screening test for the causative agent of Lyme disease and the absence of an identifiable causative agent in Lyme-like illness, the strict donor questionnaire and selection guidelines that the Blood Service has in place effectively minimises the risk from infectious agents to as low as reasonably achievable.¹⁸

Funding for research

4.19 A number of submitters and witnesses highlighted the need for increased funding for the projects identified by the department and those advocated for by patient support groups.

4.20 The LDAA, like many patient advocacy groups, expressed concern about the current lack of specific funding for research into Lyme-like illness:

While we are fatigued by the political arguments of fiscal constraints and lack of research funds, the reality is that no one is listening, and no one is helping patients with Lyme-like illness. Continuing to seek ideas on how these issues could be solved without any intention of prioritising the funding required to solve them is reprehensible. Funding has been prioritised for research into diseases with fewer incidences that are of equivalent impact to Lyme-like illness.¹⁹

4.21 The department noted in its submission that it is not a research funding agency and that researchers could access funds from other means:

...the Department of Health is not a research funding agency. The majority of Australian Government health and medical research funding is administered by the National Health and Medical Research Council (NHMRC). The Australian Research Council (ARC) has funded some Special Research Initiatives in the health and medical areas however the ARC does not generally fund medical research. Researchers may also seek other avenues for funding including the higher education sector, business sector or the private non-profit sector.²⁰

4.22 Some patients expressed concern that the department was not being proactive enough in supporting and encouraging research, and that patients who are sick now need support. Ms Elaine Kelly told the committee:

18 The Red Cross Blood Service noted that it implements a combination of methods to ensure the safety of the blood supply, including a framework to effectively manage the risk from emerging, re-emerging and emerged infectious diseases; the donor questionnaire screening tool to identify potentially unwell individuals; guidelines for the selection of blood donors to determine the eligibility of individuals to donate blood; and recall of donations from donors who subsequently become unwell. See: Red Cross Blood Service, *Submission 992*, p. 5.

19 LDAA, *Submission 528*, p. 7.

20 *Submission 495*, p. 4.

The statement that the Department of Health is not a funding body, which we continually hear, is a roadblock, an excuse. Lack of funding translates into lack of recognition of urgency, lack of commitment to the many Australians who are ill. Ticks did not go knocking on the door of the Department of Health; patients did ... Let us be done with the official complacency. Patients do not have the time to wait a decade until research on ticks and other vectors is complete. It is time to remember the sick humans.²¹

4.23 The committee heard that there are currently few research projects into Lyme-like illness and other tick-borne illness funded by the Australian Government. Professor Anne Kelso, Chief Executive Officer of the National Health and Medical Research Council (NHMRC) told the committee that between 1997 and 2015 few projects into Lyme disease had been funded:

NHMRC received 13 applications investigating diseases related to Lyme disease and one directly investigating Lyme disease. The one application directly investigating Lyme disease was submitted in 1999 and was not successful in winning funding. Of the 13 other applications, only one was successful. This was a postgraduate scholarship for the period 1999 to 2001 for work on a bacterium, *Bartonella henselae*, which is carried by ticks as well as some other insects and is often observed in patients with Lyme disease. But this project was not directly on Lyme disease.²²

4.24 Professor Kelso highlighted that the NHMRC has initiated a new process for 'targeted calls for research' that could be utilised for funding research into chronic debilitating symptoms:

We recognise the need to consider the priorities not only of government but also of the wider community, so in addition to working with Australian governments we will shortly offer a web portal through which community and professional groups may submit topics for consideration for targeted funding. These will be evaluated and prioritised by a committee made up of consumers, health system and service experts, clinicians, Aboriginal and Torres Strait Islander health experts and experienced researchers. Recommendations of this committee will assist NHMRC in rolling out a series of targeted calls for research to address significant government and community health needs which are not already being supported through our other funding schemes.²³

4.25 Professor Kelso told the committee that the NHMRC would 'welcome high-quality research proposals on Lyme-like illness to our investigator-initiated research funding schemes'. Professor Kelso also noted that:

NHMRC would welcome applications that address the many questions that currently surround Lyme-like illness in Australia, and shortly we will also

21 Ms Elaine Kelly, *Committee Hansard*, Perth, 14 April 2016, p. 9.

22 Professor Anne Kelso, *Committee Hansard*, Canberra, 20 April 2016, p. 4.

23 Professor Anne Kelso, *Committee Hansard*, Canberra, 20 April 2016, p. 4.

offer a mechanism by which community and professional groups can assist NHMRC in identifying important under researched areas of unmet need.²⁴

4.26 The committee heard that the 'Targeted Calls for Research' scheme currently being developed would be open soon, and that the NHMRC is currently establishing a committee made up of a broad range of people to consider and prioritise the submissions put forward. Professor Kelso indicated that the NHMRC is also investigating ways to 'bring in and leverage' extra funding for areas that are not currently being adequately researched, such as Lyme disease:

From that point of view, Lyme disease fits that type of field of something where it is under researched—there is clearly a gap, an unmet need—and it might be a suitable priority area.²⁵

Current research projects

4.27 The committee heard that current research into tick-borne illnesses in Australia focusses on identifying a possible causative agent. A number of submitters and witnesses highlighted two major projects by Murdoch University and the University of Sydney Tick Borne Diseases Unit. These projects are summarised below.

4.28 The committee also heard that the following research into tick-borne illnesses is currently being undertaken:

- Marie Bashir Institute: metagenomic studies aiming to identify and characterise a common microbial agent or agents in ticks and patients;²⁶
- Professor Edward Holmes, University of Sydney: metagenomic studies in human specimens and local tick populations, which have identified a range of bacteria and a novel tick virus;²⁷ and
- Professor Stephen Graves, Australian Rickettsial Reference Laboratory: DNA analysis of 350 ticks from around Australia that has identified the presence of *Rickettsia* and *Coxiella* bacteria.²⁸

Murdoch University

4.29 Professor Peter Irwin, a veterinarian and expert in vector-borne diseases, and Professor Una Ryan, a molecular biologist with expertise in infectious pathogens, are currently collaborating on a research project at Murdoch University into vector-borne infectious organisms. The project is funded by the Australian Research Council (ARC) and industry partners Bayer Australia and Bayer AG (Germany).²⁹ Professor

24 Professor Anne Kelso, *Committee Hansard*, Canberra, 20 April 2016, p. 4.

25 Professor Anne Kelso, *Committee Hansard*, Canberra, 20 April 2016, p. 15.

26 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, p. 2.

27 Professor Edward Holmes, *Submission 546*, pp 1–2.

28 Professor Stephen Graves, *Committee Hansard*, Brisbane, 15 April 2016, p. 47.

29 Murdoch University, *Submission 497*, p. 1.

Ryan told the committee that funding for this project is due to run out at the end of 2016.³⁰

4.30 The Murdoch University team submitted that to date their research has not provided 'evidence for the presence in Australia of any known tick-borne pathogens (except *Rickettsia*)', including the causative agent for Lyme disease, *B. burgdorferi*, but has confirmed that the 'Australian ticks we have studied so far (*I. holocyclus* and *A. triguttatum*) are full of different types of bacteria'.³¹

4.31 Professor Ryan told the committee that the research into Australian ticks has identified a number of micro-organisms, including two new species of *Neoehrlichia*, and a novel *Borrelia* species in echidnas that is not related to the *Borrelia* species that causes Lyme disease.³² In their submission, the Murdoch University team submitted that discovery of new organisms is only 'part of the story' and more research is needed into the causal relationship between the organisms and disease, noting that if relationships do exist they are 'likely to be multifactorial and complex'.³³ Professor Irwin told the House of Representatives Standing Committee on Health that further study would be required into whether these organisms may cause disease:

I think we need to confirm this by more testing, and we would need to find it in many more ticks, I think, before we could say that it is a plausible cause of disease.³⁴

4.32 Professor Ryan told the committee that the 'next step' in this research is to examine humans who have been bitten by ticks:

We continue to search for and describe the types and species of bacteria, protozoa and viruses in Australian ticks as this is an essential scientific foundation for the current debate. The next logical step for our research is to screen the blood of and perform biopsies on Australian humans who have been bitten by ticks in Australia and have presented with and without Lyme-like illness. This will require careful epidemiological studies and case selection in collaboration with medical infectious disease specialists, but clearly further research is required.³⁵

4.33 In its submission, the department welcomed the research by the Murdoch University team, noting that the discovery of new microorganisms, while important, should not be overstated and requires further investigation:

The clinical significance of this finding is still to be determined and should not be overstated. The department will remain engaged with Professor

30 Professor Una Ryan, *Committee Hansard*, Perth, 14 April 2016, p. 58.

31 Murdoch University, *Submission 497*, p. 4.

32 Professor Una Ryan, *Committee Hansard*, Perth, 14 April 2016, p. 55.

33 Murdoch University, *Submission 497*, p. 5.

34 Professor Peter Irwin, House of Representatives Standing Committee on Health, *Committee Hansard*, 18 September 2015, p. 5.

35 Professor Una Ryan, *Committee Hansard*, Perth, 14 April 2016, p. 55.

Irwin to consider the implications of this research for human health in Australia ... Prof. Baggoley [Chief Medical Officer] had an opportunity to speak with Professor Irwin, who emphasised that it is not yet appropriate to link the bacteria he found in the ticks to them causing disease in humans. Nothing can be assumed without further research ... Determining whether these newly discovered organisms cause disease in humans and animals, like closely related bacteria do overseas, is of public health importance and requires further investigation.³⁶

University of Sydney – Tick Borne Diseases Unit

4.34 The committee heard that another key source of research into tick-borne illnesses is being undertaken by the Tick Borne Diseases Unit at the University of Sydney, funded by the Karl McManus Foundation.³⁷ The Tick Borne Diseases Unit does not receive any government funding and is funded entirely through donations and fundraising by the Karl McManus Foundation, the only charity in Australia funding research into tick-borne diseases. The Karl McManus Foundation noted that research outcomes are 'delayed due to lack of funding'.³⁸

4.35 Dr Mualla McManus, founder of the Karl McManus Foundation, told the committee that part of their work includes hosting an annual tick-borne disease conference. Dr McManus noted that the aim of these conferences is to bring all the key parties in Australia and overseas together to discuss how to address tick-borne diseases:

We want to hear everyone's opinion, and the only way a problem can be resolved is if people talk to each other. If they do not talk you will just continue going on in the same silence, and nothing will be solved.

There is a common ground—everyone agrees that there is something in our ticks that is making people ill in Australia ... Yet we do not have the knowledge in the medical fraternity to address these people and treat them. A lot of them get misdiagnosed, and that is not right.³⁹

International approaches

4.36 The committee also heard that further investigation into international responses to Lyme disease, tick-borne illnesses and chronic debilitating symptoms is warranted.

36 *Submission 495*, p. 4.

37 The Karl McManus Foundation was founded in memory of Mr Karl McManus who passed away from complications of tick-borne illnesses in 2010. The aim of the Karl McManus Foundation is to 'raise awareness of tick borne diseases, erode barriers to diagnosis and treatment by encouraging education and funding research in Australia'. See: Karl McManus Foundation, *Submission 530*, p. 1. The Chief Medical Officer, Professor Chris Baggoley, noted in his 2014 circular on Lyme disease that the department continues to monitor research by Dr Ann Mitrovic at Sydney University. See: *Submission 495*, Attachment H.

38 Karl McManus Foundation, *Submission 530*, p. 3.

39 Dr Mualla McManus, *Committee Hansard*, Brisbane, 15 April 2016, p. 32.

International responses to Lyme disease

4.37 The committee notes that in countries where Lyme disease is considered endemic, health authorities have taken significant steps to improve the public awareness, diagnosis and treatment of Lyme disease.

4.38 In the United States (US), the US Centers for Disease Control and Prevention (CDC) provides information and educational material on the diagnosis and treatment of Lyme disease.⁴⁰ The National Institute of Allergy and Infectious Diseases supports research into Lyme disease to identify more effective diagnosis and treatment options.⁴¹

4.39 In Europe, the European Society of Clinical Microbiology and Infectious Diseases Study Group for Lyme Borreliosis (ESGBOR) supports research into the diagnosis and treatment of Lyme disease. Established in 2010, the ESGBOR aims to 'review diagnostic and treatment guidelines for LB [*Lyme borreliosis*], facilitate research, organise thematic meetings and maintain the website as an information resource for health professionals'.⁴²

4.40 In Canada, the federal government has undertaken to develop a national framework for addressing Lyme Disease. In December 2014, the Canadian Parliament passed the Federal Framework on Lyme Disease Act (Bill C-442).⁴³ The committee notes that under the Act, within 12 months of commencement the Minister of Health must convene a conference with provincial and territorial ministers and stakeholders for the purposes of developing a comprehensive federal framework that includes:

- (a) the establishment of a national medical surveillance program to use data collected by the Agency [Public Health Agency of Canada] to properly track incidence rates and the associated economic costs of Lyme disease;
- (b) the establishment of guidelines regarding the prevention, identification, treatment and management of Lyme disease, and the sharing of best practices throughout Canada; and
- (c) the creation and distribution of standard-ized [sic] educational materials related to Lyme disease, for use by any public health care provider within

40 US Centers for Disease Control and Prevention (CDC), Lyme Disease, <http://www.cdc.gov/lyme/> (accessed 4 January 2015).

41 US National Institute of Allergy and Infectious Diseases, Lyme Disease, <https://www.niaid.nih.gov/topics/lymedisease/Pages/LymeDisease.aspx> (accessed 4 January).

42 ESCMID Study Group for Lyme Borreliosis, https://www.escmid.org/research_projects/study_groups/lyme_borreliosis/ (accessed 4 January 2015).

43 Parliament of Canada, Bill C-442, An Act respecting a Federal Framework on Lyme Disease, <http://www.parl.gc.ca/LegisInfo/BillDetails.aspx?Language=e&Mode=1&billId=6253923> (accessed 16 December 2015).

Canada, designed to increase national awareness about the disease and enhance its prevention, identification, treatment and management.⁴⁴

4.41 Mr Stephen Le Page, from the ME/CFS and Lyme Association of WA Inc, told the committee that some research bodies in Canada, such as the Nightingale Research Foundation of Canada,⁴⁵ offer a different approach to assessing patients presenting with Lyme-like illness:

A good model to follow is the Nightingale Research Foundation of Canada, run by expert diagnostician and author, Dr Byron Hyde. He typically spends between Can\$5 000 and Can\$8 000 thoroughly investigating each patient, funded by the Canadian healthcare system. His advanced investigation and testing methods reveal pathologies which would likely have gone undetected. Once pathologies have been identified, many can be treated, and this is often enough to bring patients back from the brink of disability, enabling them to function again and to return to the workforce as contributing members of society no longer needing financial support from the government but instead earning an income and paying income tax. This has a far better outcome for the government, with the Can\$8 000 investment per patient seeming trivial. This also has a far better outcome for the patient than leaving them in a state of chronic illness, dependent on a pension in order to survive.⁴⁶

4.42 The committee heard that a new approach to addressing Lyme disease is being implemented in Scotland, acknowledging that the causative agent in Scotland may be different to the causative agent elsewhere.⁴⁷ Dr Margaret Hardy told the committee:

The Scottish Highlands have an incredible prevalence of Lyme disease; something like 2 000 to 3 000 cases are diagnosed every year. It is not what I will call the American *Borrelia*. It is not the American Lyme disease. It is a different species. They realised that their testing was coming back positive for *Borrelia*, so it was showing that there was something there, but it was irregular. So they have gone back and done their own clinical development. They have their own laboratory assays as well as their own clinical diagnostics.⁴⁸

44 Statutes of Canada 2014, Chapter 37, Federal Framework on Lyme Disease Act 2014, <http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6836507&File=4> (accessed 16 December 2015). In 2015, the Public Health Agency of Canada undertook a public consultation process and arranged a conference on the development of the Federal Framework on Lyme Disease. See: Public Health Agency of Canada, Consultation on the Federal Framework on Lyme Disease, http://www.phac-aspc.gc.ca/about_apropos/engagement-participation/lyme-consultation-eng.php (accessed 4 January 2015).

45 Nightingale Research Foundation, <http://www.nightingale.ca/> (accessed 26 April 2016).

46 Mr Stephen Le Page, *Committee Hansard*, Perth, 14 April 2016, p. 17.

47 See: 'Tackling a "ticking" timebomb', NHS Highland, 13 May 2015, <http://www.nhshighland.scot.nhs.uk/News/Pages/Tqacklinga'ticking'timbbomb.aspx> (accessed 26 April 2016).

48 Dr Margaret Hardy, *Committee Hansard*, Brisbane, 15 April 2016, p. 34.

4.43 The committee also heard that a new approach to addressing tick-borne illnesses has been taken in Brazil where a similar Lyme-like illness has been identified, but the causative agent is yet to be identified.⁴⁹ To avoid the controversy about Lyme disease, Dr McManus told the committee that authorities in Brazil refer to the illness as 'Baggio-Yoshinari syndrome', to indicate a different causative agent.⁵⁰ In their submission, the LDAA suggested that the Australian Government consider the approach taken by authorities in Brazil:

In Brazil they studied patients and found that epidemiological, clinical and laboratorial features in the country were very different from those exhibited by North American and Eurasian Lyme disease patients. Like Australia, they were not able to consistently and reliably isolate *B.burgdorferi* (the causative agent of classical Lyme disease); their serology also showed little positivity to *B.burgdorferi* and provided discordant results between labs – as is the case here. It is difficult to understand why our government has not prioritised a journey to Brazil to see how they approached a resolution to the identical problem we face.⁵¹

Committee view

4.44 The committee acknowledges the research currently being undertaken into tick-borne illnesses, particularly by Professor Irwin and Professor Ryan at Murdoch University, and the projects and conferences funded by the Karl McManus Foundation. The committee acknowledges that determining the causative agent or agents for chronic and debilitating symptoms is only part of the story and that research is needed across a range of areas, including a clinical assessment of patients.

4.45 The committee acknowledges the work done by the department through the CACLD and the scoping study to identify areas for research. The committee supports ongoing efforts by the Chief Medical Officer and department to engage with the medical and patient communities in relation to this issue.

4.46 The committee is aware that funding for this area of research is limited and dependent on researchers being successful in applying for a limited pool of funds. The committee notes that the new NHMRC targeted research funding process provides a possible option for securing funding into chronic debilitating symptoms; however, the committee notes that this is reliant on successful submissions from community and/or professional groups.

49 Baggio-Yoshinari Syndrome is defined as: 'exotic and emerging Brazilian infectious disease, transmitted by ticks not belonging to the *Ixodes ricinus* complex, caused by latent spirochetes with atypical morphology, which originates [Lyme disease]-like symptoms, except for occurrence of relapsing episodes and auto-immune disorders'. See: Natalino Hajime Yoshinari et al, 'Brazilian Lyme-like disease or Baggio-Yoshinari Syndrome: exotic and emerging Brazilian tick-borne zoonosis', *Revista da Associação Médica Brasileira*, vol. 56, no. 3, 2010, http://www.scielo.br/scielo.php?pid=S0104-42302010000300025&script=sci_arttext&tlng=en (accessed 4 January 2015).

50 Dr Mualla McManus, *Committee Hansard*, Brisbane, 15 April 2016, p. 32.

51 LDAA, *Submission 528*, p. 20.

4.47 The committee notes that further inquiry is needed into other opportunities for research funding and international approaches to addressing Lyme-like illness in countries such as Canada, Scotland and Brazil.

Conclusion

4.48 The committee recognises that there are a large number of Australians suffering chronic debilitating symptoms and illnesses.

4.49 The committee recognises that there is a significant debate about the cause of these symptoms and recognises the need for further research across a range of areas to better assist patients and their families.

4.50 The committee notes the challenges some patients have faced in accessing affordable and appropriate medical treatment. The committee also notes the treatment of patients by some medical practitioners and emphasises that all patients deserve to be treated with dignity and respect when seeking medical care.

4.51 The committee notes that its inquiry to date has identified a range of issues that warrant further investigation in the next parliament. The committee recognises that the committee's inquiry is not yet complete, and further investigation into a range of areas is required before the committee is in a position to make any detailed recommendations, including:

- the treatment of patients with chronic debilitating symptoms by the medical profession;
- the cost and efficacy of treatments for patients diagnosed with Lyme-like illness;
- discordant laboratory results for Lyme-like illness between accredited laboratories in Australia and non-accredited Australian laboratories and international laboratories;
- opportunities for further research into Lyme-like illness and other tick-borne illnesses; and
- international comparisons of the public health response to Lyme-like illness from other countries.

Recommendation 1

4.52 The committee recommends that the Community Affairs References Committee continue its inquiry into this matter in the 45th Parliament.

4.53 The committee notes that Dr Gary Lum has indicated that the department would be open to doing more to improve communication with the Australian medical profession about classical Lyme disease and how to diagnose and treat it appropriately in Australia.

4.54 The committee notes that patients, patient advocacy groups and medical professionals support improving awareness and education among the public about the prevention of tick bites and when to seek medical attention. The committee also notes support for improving awareness and education among the medical profession about

diagnosis and treatment of known tick-borne illnesses in Australia to better assist patients.

4.55 The committee notes the work done by the department to date and supports improving education and awareness in Australia about how to prevent tick bites, the treatment of classical Lyme disease acquired overseas, and the diagnosis of known tick-borne illnesses in Australia.

Recommendation 2

4.56 The committee recommends that the Department of Health further develop education and awareness strategies for:

- **the public about the prevention of tick bites and seeking medical attention; and**
- **the medical profession about how to diagnose and treat classical Lyme disease acquired overseas and known tick-borne illnesses acquired in Australia.**

4.57 The committee recognises the work undertaken by the Chief Medical Officer to identify future research projects and engage with the medical and patient communities about Lyme disease and Lyme-like illness. The committee supports the Chief Medical Officer in continuing to engage with these communities through mechanisms such as the Clinical Advisory Committee on Lyme Disease (CACLD). The committee supports ongoing meetings facilitated by the department, such as the CACLD, to continue to raise awareness about ongoing research into Lyme disease and other tick-borne and vector-borne illnesses, as well as diagnostic and treatment options for patients presenting with tick-borne related illnesses.

Recommendation 3

4.58 The committee recommends that the Chief Medical Officer continue to consult with the medical and patient communities through mechanisms such as the Clinical Advisory Committee on Lyme Disease, and for the Department of Health to continue to facilitate meetings with medical and patient representatives.

Senator Rachel Siewert

Chair

Additional Comments—Senator John Madigan and Senator Zhenya Wang

1.1 The Department of Health must initiate an Australia-wide health sector education program to communicate to doctors, nurses, hospital staff and other health professionals the ongoing discrimination and vilification of those suffering symptoms of Lyme disease; that such responses by health professionals are unethical, unprofessional and counter to the credo of 'do no harm'.

1.2 The Department of Health must initiate a program of independent, properly funded prioritised research to look into the incidence of Lyme disease and Lyme-like illness in Australia.

1.3 The Department of Health must initiate an immediate public health education response to alert all Australians about the dangers of ticks, symptoms of Lyme disease and Lyme-like illness, and appropriate responses in the way it has done for other infections, such as Zika virus. There must be an immediate public awareness program for health professionals and the public about correct tick removal. We take this opportunity to refer to media reports of four major advertising campaigns under the Abbott and Turnbull governments to at least \$84.5 million. Public advocacy expenditure is not an unusual request in this case. We refer to testimony given to the committee by Professor Peter Collignon who said:

We should avoid people being bitten by ticks ... I think we need a tick education program.¹

1.4 The chief medical officer of every state and territory plus that of the Commonwealth must come together as a matter of urgency – along with patient representatives – to show leadership and devise a co-ordinated response.

1.5 Rules governing Medicare must be expanded to enable pathologists to undertake a suite of testing to respond appropriate to tick-borne illnesses.

1.6 We take this opportunity to highlight Dr Richard Schloeffel's evidence to the committee comparing the status of Lyme disease in Australia today with the onset of HIV. Dr Schloeffel is medical director of Pymble Grove Health Centre. He is also an adviser to the tick-borne diseases unit at Sydney University and he has been treating Lyme-like illness for 20 years. Additionally Dr Schloeffel is chairperson, Australian Chronic Infectious and Inflammatory Disease Society.

1.7 Dr Schloeffel stated:

In 1983 I was a GP in Bellingen; I was only very young. I had a few patients and they were gay men who were going to the bathhouses in San Francisco. They developed illnesses that I had never heard of before—

1 Professor Peter Collignon, *Committee Hansard*, Perth, 14 April 2016, p. 34.

strange pneumonia, strange gut infections—and they became immunosuppressed and they died.

So I took an interest in this. Then by the late 80s we were starting see a lot of these people, generally gay men, and we had the bowling ball and the Grim Reaper. We found a virus that caused an infection that lowered the immune response, and when the immune response was low enough people got opportunistic infections.

We had a whole army of scientists working this out, finding the virus and developing medications to prevent the virus from replicating, so we actually stopped the epidemic. There was an intellectual process, but it did not happen until children and women who got blood transfusions, and kids who had haemophilia from the blood, started to get sick and die. They went, 'Oh my God! We have to do something'.

Before it was only gay men, so it did not matter. There was the same sort of thought process among the medical profession, that some people are better than others and there was no emergency. Then it became very urgent and it was extremely urgent. I buried probably 100 of my male patients who had this disease before we had a treatment. Now, I was a GP treating their co-infections trying to work out how to help their immunity.

I was an integrated doctor, even then. Then I went to Byron Bay and worked up there. They were all coming up there to die and I did palliative care. I saw all this, and it was all too late for them. There were a lot of patients that we were able to treat in the early 90s who went on to AZT and the associated medication. They are still alive and still well, just on medication to suppress the virus. Now that is one germ, one entity.

The thing is that this illness is a multisystem infection with multiple organisms. Where people get it from is vague. It is sexually transmitted, it comes from blood transfusions, its congenital and it comes from vectors. The array of symptoms is enormous, which makes it different to AIDS, but the problem is the same. If you deny the illness is there but you have all these people sick, then what is wrong with them? If you say to them, 'Yes, you are sick. There's nothing you can do,' or, 'You're just putting it on,' that is not real medicine. That is denialism.²

1.8 Dr Schloeffel also spoke about the arrogance and miasma of much of Australia's medical orthodoxy on this issue.

1.9 He told the committee:

I cannot talk for other doctors and their thought processes, but I would like to say to every doctor in Australia, 'Wake up to yourselves. Start listening that we've got a real illness. Let's have a proper conversation. Let's do the proper science. Let's fund it.' We have tens of thousands of people with Lyme-like illness and co-infections, some of whom are dying, and they do not get a cent. Where is the research money for these infections? We have to put money into it, we have to have a proper conversation and the

2 Dr Richard Schloeffel, *Committee Hansard*, Brisbane, 15 April 2016, pp 23–24.

denialism has to stop, because that is actually malpractice. It is actually negligence on the part of the medical profession.³

1.10 The time for a co-ordinated response by our health authorities is now. The lives of thousands of Australians are at stake.

Senator John Madigan

Senator Zhenya Wang

3 Dr Richard Schloeffel, *Committee Hansard*, Brisbane, 15 April 2016, p. 24.