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]

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[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]

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[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 known[9]);
- 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:

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[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]

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[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/2010/11/20140129LDAAScopingStudyResponse.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:

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[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:

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[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

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[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

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[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

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[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.

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[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
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> (c) the creation and distribution of standard-ized [sic] educational materials related to Lyme disease, for use by any public health care provider within

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[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]

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[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.

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[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