Lyme-like illness in Australia

A proposal for the National Health and Medical Research Council - Targeted Call for Research

Lyme Disease Association of Australia
September 16, 2016

“In the fullness of time, the mainstream handling of chronic Lyme disease will be viewed as one of the most shameful episodes in the history of medicine because elements of academic medicine, elements of government and virtually the entire insurance industry have colluded to deny a disease. This has resulted in needless suffering of many individuals who deteriorate and sometimes die for lack of timely application of treatment or denial of treatment beyond some arbitrary duration”.

Dr Kenneth B. Leigner
Table of Contents

Introduction .................................................................................................................................................. 2
About us .................................................................................................................................................... 2
What is Lyme disease or Lyme-like illness? .......................................................................................... 3
Australian Government priorities .............................................................................................................. 5
The knowledge gap .................................................................................................................................... 7
What is the current disease status? ........................................................................................................... 11
  Prevalence ................................................................................................................................................ 11
  Burden of disease on the individual and community ............................................................................ 15
  Costs to government ............................................................................................................................... 22
What is the current research effort in the disease area? ......................................................................... 23
  How much research is being done in the disease area? ....................................................................... 24
  Current NHMRC and other funding ....................................................................................................... 25
What is the current research capacity and capability in the discipline? .................................................... 26
  A metagenomic approach ....................................................................................................................... 26
  Are there new and/or novel treatments available? .................................................................................. 27
  When was the last breakthrough? ........................................................................................................ 27
Improving outcomes for individuals and community ............................................................................. 28
Reducing the burden of disease on the Australian health system ........................................................... 31
Contributing to the global research effort ............................................................................................... 33
**Introduction**

In November 2015, the Senate asked the Senate Community Affairs Reference Committee (the Committee) to inquire and report on ‘the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients.’

The Committee invited submissions and conducted 3 public hearings. Professor Anne Kelso, Chief Executive Officer of the National Health and Medical Research Council (NHMRC) gave evidence at the public hearing in Canberra on 20 April 2016. Professor Kelso outlined the Targeted Call for Research (TCR) concept and new online “mechanisms by which community and professional groups can assist NHMRC in identifying important under researched areas of unmet need.” Professor Kelso went on to suggest that the recommendations of the committee would “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.”

Over the past few years the Australian Government has conducted formal inquiries into Lyme disease. Each inquiry highlighted that there are significant gaps in our knowledge of Lyme disease, tick-borne infections and the associated impact on public health. Each inquiry has concluded that more research is needed. The research priorities have been firmly established and are perhaps one of the only things that patients and the scientific and medical communities all agree upon, but the funding for them has not.

The significant knowledge gap, made worse by the lack of funding for research impacts patients. Patients are caught in a catch 22. They are inexplicably burdened by the lack of scientific evidence that might explain their symptoms. The medical and scientific community cannot agree on a causative agent[s], appropriate, world class diagnostic tools and algorithms, or treatment protocols.

The prioritisation of funding to progress the recommended research is not only critical for patients, but is desperately needed to underpin a coordinated public health response for what appears to be an emerging epidemic. As such, the Lyme Disease Association of Australia (LDAA) proposes the NHMRC consider a Targeted Call for Research (TRC) on Lyme-like illness in Australia.

**Global research direction and collaboration**

Research into micro-organisms as a causal link to neuro-inflammatory diseases is an exciting area of focus. Australian research, investigating central nervous system diseases, the brain/biome axis, chronic diseases, rheumatoid arthritis and infectious diseases, are poised to take advantage of a significant shift in research. By introducing Lyme-like illness into the research priorities of the NHMRC, researchers will be open to more opportunities to collaborate, publish and become front line adapters of innovative approaches in scientific breakthroughs and diagnostic technologies focused on micro-organisms as a causal link to disease.

**About us**

The Lyme Disease Association of Australia (LDAA) is a registered charity. It's run by a small number of volunteers who work to change how ‘Lyme-like’ illness is viewed and how patients are treated. We

---

2 Professor Anne Kelso, *Committee Hansard*, Canberra, 20 April 2016, p. 4.
3 Communicable Disease Network Australia; Chief Medical Officers Clinical Advisory Committee on Lyme Disease; Scoping Study; Senate Inquiry.
represent patients and undertake activities in four key areas: information, support, education and awareness. Our mission is to:

- advocate for individuals and families living with Lyme-like illness;
- educate and seek support from governments, doctors and local communities;
- act as a conduit between international developments, treatments and other Lyme communities; and
- raise money to assist people living with Lyme disease and Lyme-like illness.

**What is Lyme disease or Lyme-like illness?**

The term ‘Lyme disease’ is the subject of wilful confusion and semantic debate here in Australia. In binomial nomenclature the organism that causes Lyme disease is a bacterium, in the form of a spirochaete of the genus *Borrelia*, species *burgdorferi*. Our medical and scientific community appropriately focus their discussion about Lyme disease on a single species - *B.burgdorferi*. Most recognise that Lyme disease in its ‘classic’ form results in a seriously debilitating illness. Yet there are many species of *Borrelia* that are known to cause disease in humans and there is much that we don’t know about other species.

Scientific literature dating back to 1959 firmly establishes that other species of *Borrelia* are present in Australia. Yet there is very little research that might inform us about the impact that other *Borrelia* species have on human health, or on the 60 year spread of an organism previously identified.

On the flipside of the medical and scientific community are patients who are suffering from some kind of debilitating illness following a tick bite. Patients use the term ‘Lyme disease’ to describe a constellation of symptoms and infections, generally acquired through the bite of a tick. In the absence of scientific inquiry, the most appropriate description that patients use for the phenomena occurring in Australia following a tick bite is ‘Lyme-like illness’. Many patients have empirical evidence supporting that the Lyme-like illness they encounter comprises of a range of diagnostically confirmed organisms as indicated in Figure 1.

**Figure 1: B.burgdorferi vs the constellation of pathogens found in Australian ticks**
The Committee’s own response to the term ‘Lyme disease’ acknowledges that focusing on a single species limits the scope of inquiry. The Committee adopts the term ‘Lyme-like illness’ in the absence of scientific proof of the condition.\(^4\)

**Australian Government priorities**

The Australian Government has prioritised a National Strategic Framework for Chronic Conditions (the Framework). Its first priority focuses on prevention of chronic illness. The Framework will support a range of health reform activities that consider how to best provide coordinated and multidisciplinary care to improve the prevention and management of chronic conditions in Australia.\(^5\)

While the spread of chronic conditions outlined in the Framework does not explicitly include Lyme-like illness, there is considerable speculation that many neuro-degenerative illnesses might be attributed to undiagnosed infectious processes, like Lyme-like illness. Certainly, evidence gathered through more than 4 years of patient data indicates that those with a Lyme-like illness in Australia are chronically ill. Many of these patients are children, and in line with the World Health Organisation (WHO) guidelines on governmental duty of care for children, they require priority access to health services.

We also know that Lyme-like illness acquired through the bite of a tick is entirely preventable. Prevention is recognised as a key strategy in overcoming the burden of chronic disease. However, due to the low level of awareness in Australia about the potential for illness from a tick bite there are no prevention strategies in place. The stigma and controversy surrounding this illness presents a barrier to community awareness and the coordinated development of prevention strategies which can only be addressed through urgent and credible research.

The *House of Representatives Standing Committee on Health’s Inquiry into Chronic Disease Prevention and Management in Primary Health Care* has classified tick-borne and Lyme-like illness as a chronic disease within Australia.

The committee found that “evidence received demonstrated tick-borne or Lyme-like disease to be an example of a chronic illness which has significant, life-changing effects on its sufferers but which is commonly misunderstood in the medical community and relatively unknown in the broader community. People living with this condition express their frustration at the lack of medical understanding, which can result in misdiagnosis and delayed treatment. Evidence also reveals frustration people have at the controversy that surrounds the definition of tick-borne or Lyme-like disease, and whether true Lyme borreliosis is native to Australia.”\(^6\)

Further, the Australian Government’s Science and Research Priorities’ Health Capability statement has identified a future health challenge to be ‘improved prediction, identification, tracking, prevention and management of emerging local and regional health threats.’ LDAA’s surveys of prevalence (discussed further in the Current Disease Status section) reports patients suffering from tick-borne diseases are geographically spread around the nation including in regional areas. To that end, an understanding of tick-borne pathogens is of vital importance in achieving this capability.

It is the responsibility of the Australian Government to provide national leadership, policy advice, analysis, coordination and communication of health protection strategies and responses to emerging

---


and current disease threats to the Australian population. The National Health Security (NHS) Act provides for a system of public health surveillance, including the funding and monitoring of disease outbreaks and epidemics.

Recently, this has included a national response to the Zika virus. The scientific evidence around the Zika virus is similar to the gaps in knowledge we have with Lyme-like illness. Using Zika virus as the benchmark, there has been no causative agent identified, either scientifically or empirically. Yet, a public health response has been prioritised. Several millions of dollars have been allocated for research, with prevention and awareness education campaigns are underway. 

Furthermore, within our Human Rights obligations and its associated covenants, the state of Australia has undertaken, to the maximum of its available resources, to take steps to prevent, treat and control epidemic, endemic, occupational and other diseases. It has committed to create conditions which would assure to all medical service and medical attention in the event of sickness. The Australian Government has a role in the health protection of all Australians and has obligations in respect to emerging diseases. We consider that the emerging Lyme-like epidemic requires a targeted and urgent response and that patients, including our most vulnerable citizens, children, have a right to medical care irrespective of the causation of their illness.

---

The knowledge gap

In the past few years the government has held multiple inquiries into Lyme-like illness in Australia. Each of these inquiries highlights that there are significant gaps in our knowledge of Lyme-like and tick-borne illness in Australia. This section will examine each of those inquiries.

Clinical Advisory Committee on Lyme Disease (CACLD)

In 2013 the Chief Medical Officer (CMO) established a Clinical Advisory Committee on Lyme Disease (CACLD). The terms of reference were to provide advice to the CMO on:

1. the extent to which there is evidence of *Borrelia* spp causing illness in humans in Australia
2. the most appropriate laboratory diagnostic testing algorithms (best world practice) for persons who have suspected borreliosis in Australia
3. the most appropriate treatments for borreliosis in Australia
4. the most appropriate ways to disseminate information to health professionals and the general public on borreliosis/Lyme disease
5. the requirements for further research into borreliosis in Australia, and
6. the generation of appropriate new questions relevant to the terms of reference.9

While the CACLD concluded in 2014, its work contributed to a significant body of questions for which no one has answers. In 2013, the Committee commissioned a Scoping Study ‘To develop a research project(s) to investigate the presence or absence of Lyme disease in Australia’. The Study was published in September 2013 and highlighted the gaps in our knowledge of Lyme disease in Australia.10 Following a period of public consultation, the CACLD received 24 submissions including a highly detailed submission from the LDAA.11

The Department of Health published a response to the Scoping Study and recommended a series of research programmes be progressed as follows:

1. Retrospective investigation of chronic cases of Lyme borreliosis.
2. Clinical studies of patients presenting with symptoms suggestive of Lyme or Lyme disease-like syndrome.
3. Experimental programme to determine whether there is a *Borrelia* species in ticks in Australia causing Lyme disease-like syndrome, or whether another tick-borne pathogen is involved in human Lyme disease-like syndrome.
4. Do we have the best reagents for detecting novel *Borrelia* species, including *B. miyamotoi*, especially in clinical specimens?
   a. Conducting a formal review to elucidate the testing procedures currently used in public health laboratories to diagnose Lyme disease.
   b. Inviting relevant laboratories, both in Australian and overseas, to participate in a collaboration and comparison study to evaluate the current methodologies used. It may be possible to develop standard Australian diagnostic criteria as a result of this work.

---

10 Department of Health, Professor John McKenzie, *Scoping Study To develop a research project(s) to investigate the presence or absence of Lyme disease in Australia*, p.21
11 LDAA’s, *Scoping study Submission*, 2014
The Scoping Study also raised the need for additional research programs that would assist in determining whether there is a *Borrelia* spp causing illness in humans in Australia. These included:

5. Epidemiological research.
6. An examination of the parallels with other countries that have detected a novel *Borrelia*.

**Department of Health – CACLD & Lyme disease roundtable outcomes**

Following the Scoping Study, the Department held a Lyme Disease Roundtable meeting with a multidisciplinary range of medical practitioners. Outcomes of the roundtable discussion also highlighted potential research projects that would assist in clarifying the Australian Lyme disease-like syndrome.

A *Consolidated List of Research Projects* was published. It outlined 12 priority areas for research. These are reproduced as follows:

- Retrospective investigation of chronic cases of Lyme disease like syndrome.
- Clinical studies of patients presenting with symptoms suggestive of Lyme disease or Lyme disease-like syndrome.
- Experimental programme to determine whether there is a *Borrelia* species in ticks in Australia causing Lyme disease-like syndrome, or whether another tick-borne pathogen is involved in human Lyme disease-like syndrome.
- Do we have the best reagents for detecting novel *Borrelia* species, including *B. miyamotoi*, especially in clinical specimens?
  - A validation study on the methods currently used in Australian laboratories and if possible relevant international laboratories to diagnose borreliosis.
- Are Australian ticks competent to maintain and transmit *B. burgdorferi* s.l. genospecies, or other *Borrelia* species associated with relapsing fever?
- Epidemiological research
  - An initial epidemiological study into patients presenting with symptoms of a Lyme disease-like syndrome in Australia.
  - An epidemiological study on returned travellers from overseas endemic areas.
- Examine parallels with other countries that have detected a novel *Borrelia* species.
- Research into the incidence of neuroborreliosis cases using cerebrospinal fluid samples already collected from aseptic meningitis patients.
- A clinical randomised control trial (blinded) on the treatment of patients diagnosed with Lyme disease-like syndrome.
- The development of a register of patients with chronic neurological symptoms in partnership with neurologists and treating GPs to compare if treatment with antibiotics demonstrates any improvement in patient outcomes.
- The role of the host immunological response in the pathophysiology of infection caused by *Borrelia* species and the implications for diagnostic testing.
- Research into tick bite allergies and the prevention of tick bites in Australia.

While these projects were recommended, funding has not been provided or prioritised.

---

Communicable Disease Network Australia

In May 2013 the Commonwealth Department of Health (DoH), through its Communicable Diseases Network Australia (CDNA), inquired into Lyme disease and determined that surveillance for Lyme disease was unnecessary and that monitoring of laboratory diagnoses was more appropriate.

To better understand their decision making, the LDAA submitted a Freedom of Information (FOI) request seeking:

1. the criteria used to determine if a disease should be added to the National Notifiable Disease List (NNDL); and
2. the assessment of whether Lyme disease should become nationally notifiable in Australia.

The Department’s response, available from the FOI disclosure log\textsuperscript{13} provides an illogical conclusion; the department won’t collect any data until it knows how big the [unquantified] problem is. In the FOI document, the Department also addresses a number of standardised criteria that are used to assess whether a disease is added to the notifiable diseases list. We examined the CDNA’s response to the assessment criteria. Their responses highlighted several issues, for example:

1. ‘Changes in incidence and/or morbidity and mortality’ response asserts that ‘changes in laboratory practices would likely be the biggest influence on changes in occurrence in Australia’. This raises questions about the efficacy of current Medicare funded laboratory practices.
2. ‘International concern’ response is misleading. There is considerable international concern with the ten-fold increase in Lyme disease cases reported by the Centre for Disease Control and Prevention (CDC) in the United States of America (USA) and with increasing incidence in Europe, the United Kingdom (UK) and Asia. The World Health Organization (WHO) prioritised vector-borne disease, including Lyme disease, as their topic for World Health Day in 2014. WHO has called upon governments globally to renew momentum in the fight against vector-borne disease. They specifically request that ministries of health ‘improve surveillance and monitoring of vector-borne diseases’. The Director-General notes that “No one in the 21st century should die from the bite of a mosquito, a sand fly, a blackfly or a tick.”\textsuperscript{14}

The summary provided as part of the CDNA assessment for the need for national notification of Lyme disease also stated that the ‘position may be reassessed if new information about the causative agents of disease in people with Lyme disease-like syndromes in Australia and any known competent vector becomes available’.\textsuperscript{15}

The LDAA notes that the Department’s rationale for not providing surveillance of Lyme disease, given in May 2013, was insufficient. As such there is a gap in our knowledge about how many people are affected as no official data on the incidence or spread of Lyme disease or Lyme-like illness is available in Australia.

\textsuperscript{14} WHO: A global brief on vector-borne diseases - http://apps.who.int/iris/bitstream/10665/11008/1/WHO_DCO_WHD_2014.1_eng.pdf
\textsuperscript{15} http://www.health.gov.au/internet/main/publishing.nsf/Content/3E60F0EDD20B97D7CA257CA6000E3798/$File/Document%20%20Assessment%20of%20national%20notification%20of%20Lyme%20disease%20in%20Australia%20Final%20June%202013.PDF
Senate inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australia patient’s.

The Terms of Reference of the Senate Inquiry focused on addressing some of the knowledge gaps. These are reproduced here as:

(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 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.

According to the Interim report of the Committee, it accepted and published 1171 submissions. Including a submission from the LDAA.

Parliamentary inquiry

In 2015, 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 discussion on the diagnosis, treatment and lived experience of Lyme-like illness with patients, medical practitioners and researchers. This inquiry is ongoing.16

In addition, there have been several notices of motion calling on the Government to support further research into Lyme disease raised in both the House of Representatives and Senate throughout 2015.17

---


17 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.
What is the current disease status?

Prevalence

In the absence of any government associated data collection, the LDAA has been collecting and compiling Australian data on the prevalence of Lyme-like illness since 2011 through detailed online surveys. Our surveys are limited to people who have online access. We therefore miss a cohort of patients who are not online, are physically or cognitively unable to use a computer, or are too young to answer. With these limitations, there are likely many people who have a Lyme-like illness who our surveys do not reach.

We’ve previously reported our survey data in the *Lyme disease: Australian patient experience in 2012* report. More recent data, collected in 2013/14, on the prevalence of Lyme-like illness and its impact on patients is reported in our submission (#528) to the Senate Inquiry.

The demographic profile of Australian patients who have self-reported to the LDAA is shown in Figure 2.

**Figure 2: Demographic profile of Australian patients**

The gender split in Australia is 73% female to 27% male. Studies of the prevalence of Lyme disease in the USA indicate that there is a similar gender discrepancy with more females acquiring Lyme disease than males; our data also supports this oddity. To date there has been no study anywhere in the world that might explain the gender discrepancy.

Geographical surveys

In addition to our detailed patient surveys, we make available a survey that counts people who live in Australia and report they have been diagnosed with a Lyme-like illness by a medical practitioner.  

---


We periodically plot this data, by postcode, on a map of Australia. Our current plot from early 2016 includes 2,126 people.

**FIGURE 3: DISTRIBUTION OF PATIENTS WITH POSITIVE DIAGNOSIS OF LYME DISEASE**

The map is interactive and allows a viewer to drill down to postcode level data to gain a geographical understanding of where patients live. We recommend viewing it online via: [http://www.lymedisease.org.au/stats/](http://www.lymedisease.org.au/stats/) We also plot the geographical location where people report being bitten by a tick, the map can be viewed at the same URL.

**Alternate sources of data**

In the absence of any official epidemiological study, the LDAA rely on other data sources to gauge the incidence of Lyme-like illness in Australia. We acknowledge that these data sources are not ideal. The data is only suggestive, not conclusive. Without an official epidemiological study or by making Lyme-like illness a notifiable disease, we have gaps in our knowledge.

We present each of the alternate data sources in the following section.

**Number of patients undergoing treatment by ACIIDs doctors**

The very small group of doctors actively treating Lyme-like illness in Australia report their current case load to be in the order of 1,500 patients. Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS) doctors report that they have treated over 4,000 patients for Lyme-like illness.

**Online patient support forums and social media**

There are increasing numbers of participants in 12 Australian online patient forums whose combined memberships total over 1900 in January 2016.

---

20 Australian Chronic Infectious and Inflammatory Disease Society is a group of doctors, primarily general practitioners, who specialize in the treatment of tick-borne diseases.

21 See Submission number: 370
Our own data from the LDAA Facebook page indicates we had 10,795 people following us in January, this represents a 400% increase in 2 years. We answer more than 280 emails per month, generally in supporting patients who are newly diagnosed with Lyme-like illness. This data clearly demonstrates the increasing interest in and awareness of Lyme disease and Lyme-like illness. It also highlights there is a lack of educational material, advice and support for people when they encounter a tick bite.

Internet search engine analytics
Using ‘Lyme disease’ and ‘Lyme’ as the search parameters in the Google Trends ‘correlate’ function, Figure 4 shows the steady increase in Australian web searches. There is no doubt that increased media on the topic drives internet traffic, however it also drives awareness and saves lives.

**Figure 4: Google search terms - Lyme Disease Australia**

![Google search terms - Lyme Disease Australia](image)

Incidence of Lyme disease in the USA
Australia’s incidence of tick-borne illness must be placed in the context of the international Lyme epidemic. In 2013 the CDC revised its annual estimate of Lyme disease cases in the USA from 30,000 to 300,000.\(^2\) A sobering 900% increase.

Submissions to the Inquiry on the Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients
The Senate Inquiries interim report notes ‘the committee received over 1000 personal submissions from or on behalf of Australians suffering from chronic debilitating symptoms.’

*Estimated number of Lyme-like illness cases in Australia*
If Australia were to increase the number of our ‘self-reporters’ (1,051) by 900%, there would be 9,459 cases per year; we anticipate that is the low end of the scale. If Australia were to use the same

\(^2\) [http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html](http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html)
prevalence rate to that reported in the USA, over the past 20 years there may be up to 426,542\textsuperscript{23} Australians with Lyme disease; that’s 1.78\% of the population. In 2015, that equates to 22,656 cases annually. This is almost 7,000 more cases than breast cancer and twenty times more than reported cases of HIV/AIDS and multiple sclerosis (MS) as shown in Figure 5.

It’s more than all of those diseases combined.

**FIGURE 5: ESTIMATED CASES PER YEAR - LYME, BREAST CANCER, HIV & MS\textsuperscript{24}**

<table>
<thead>
<tr>
<th></th>
<th>Australia: Estimated cases per year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>male</td>
</tr>
<tr>
<td>Lyme-like illness</td>
<td>6,117</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>145</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>976</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>250</td>
</tr>
</tbody>
</table>

**Incidence of Lyme disease in other countries**

Many other countries report an increasing incidence in the rate of Lyme disease-like illnesses. We examined all current literature as part of our desk research in the preparation of our submission to the Senate Inquiry and reported statistics on the worldwide incidence of Lyme disease.\textsuperscript{25} Overall, in the 39 countries examined, there is a mean incidence of 5.804\%. If we were to apply this figure to Australia to calculate a potential incidence rate, there would be an estimated 1.3 million people with a Lyme-like illness.\textsuperscript{26}

While we appreciate the argument that Australia has a different climate and different species of ticks to many other countries, it is highly probable that our incidence rates would reflect at least those countries with similar climates. Put simply, until there is a coordinated monitoring and surveillance program and official statistics are collected there is no data to contest; this is a significant knowledge gap and it is affecting thousands of people who are denied appropriate medical care for their illness.

---

\textsuperscript{23} Estimated 0.09\% incidence pa x ABS Population statistics cumulated yearly since 1994


\textsuperscript{25} See: LDAA, Senate Inquiry Submission #528, Appendix Error! Reference source not found.

\textsuperscript{26} Calculation: ABS 2015 population statistics (23,998,630) x 39 countries mean incidence rate (5.804\%)
Burden of disease on the individual and community

Disability Adjusted Life Years
Data on the impact of Lyme disease worldwide is scarce.

Burden of disease studies, expressed in disability adjusted life years (DALY’s) are, to our knowledge, limited to a single study funded by the Health Department in the Netherlands and conducted a year ago. The study concluded that the total burden for Lyme disease in the Netherlands was 10.55 DALYs average. Researchers noted that Lyme Borreliosis ‘causes a substantial disease burden with the vast majority of this burden caused by Lyme-related persisting symptoms’. They further conclude that Lyme-related persisting symptoms had a somewhat higher disease burden than Crohn’s disease and moderate Parkinson’s disease, and somewhat lower than moderate multiple sclerosis and a moderate episode of a major depression.

Health related Quality of Life indicators
A 2015 article by Johnson examined the Severity of chronic Lyme disease compared to other chronic conditions: a quality of life survey in the USA. This study used the CDC’s health-related quality of life (HRQoL) indicators to determine the burden of disease, identify health needs, and direct public health policy. It established that ‘patients with chronic Lyme disease reported significantly lower health quality status, more bad mental and physical health days, a significant symptom disease burden, and greater activity limitations. They also reported impairment in their ability to work, increased utilization of healthcare services, and greater out of pocket medical costs’.

The USA study concluded that people with Lyme disease have a significantly impaired HRQoL. It also noted that earlier diagnosis and innovative treatment approaches might reduce the heavy burden of illness, and economic costs faced by Lyme patients.

The situation in Australia presents a grimmer picture.
No one has studied the DALY nor the HRQoL for Australian patients. In addition to the burden of disease placed on patients through their symptoms, Australian patients report strong psychological impacts due to the stigma and denial of the existence of Lyme disease in Australia.

Quality of Life impacts
We examine quality of life indicators as part of our detailed patient surveys. Our data shows that Lyme disease and Lyme-like illness has many personal impacts. Patients face significant decline in their quality of life, they have deficits in their ability to function, including serious impacts on their mobility, and many become dependent on their family and friends creating even more burden. Figure 6 shows these impacts.

28 See: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3976119/
Quality of life impacts do not occur in isolation of families and friends. If the Lyme affected patient was the primary bread winner there are consequential impacts for the whole family. Patients report the slow progression in their loss of dignity that is caused by their gradual isolation from their jobs, their schooling and their social circles. Lyme-like illness impacts their work life and their ability to maintain employment or schooling as shown in Figure 7.

The burden of treatment for Australian patients is extremely disproportionate to other diseases. This is compounded by the controversy and stigma that surround Lyme disease in Australia. Patients report that their illness has profound effects on their psychological wellbeing as shown in Figure 8.
Tragically, of the 43.87% of patients (354 out 807 patients) who report having suicidal thoughts, 7 have taken their own lives in the past three years.

The impacts upon children
In most Lyme disease surveys around the world, children are significantly under-represented. The same is true in Australia. Within the Australian patient community there are many families with multiple children infected with a Lyme-like illness. The impacts upon those families are particularly devastating when the parents, themselves suffering from Lyme like illness, must also attend to the care and wellbeing of their very ill children. In many of these families, parents and other siblings often go without proper care or treatment so they are able to afford treatment for the child who is sickest at that moment.

Our data reports there are 87 people under the age of 18 who have a Lyme-like illness. More than 80% of them have taken extended time off school, or do not even attend school because of their inability to maintain the energy or stamina required. Some can’t attend school because they are wracked with daily seizures. The trauma of the seizure and the associated isolation a seizure brings makes it impossible. Other children are home schooled by parents who can keep them safer in their home environments while still meeting their child’s educational and medical needs.

In a few cases some parents with seriously ill children have been labelled by the medical system with Munchausen by proxy; they are accused of fabricating the illness in their children. For these families the situation is untenable.

Economic and financial burden of treatment
The earlier graphs show the impact of the disease on the income of families, with more than 10% of patients having to sell their homes and 64.5% reporting they had spent all their savings and financial resources. There is a considerable financial burden upon patients, which in turn impacts upon their ability to access and afford health care and ongoing treatment. Many of these costs might have been avoided if patients were tested appropriately, diagnosed promptly and treated accordingly for Lyme disease, before it became chronic.
The expense of treatment for patients is unaffordable. Each component of the treatment costs for Lyme disease is outlined below:

- **Accessing health care** – the majority of patients have to travel more than 100km to see a medical practitioner
  - Some practitioners consult with patients over Skype, however these costs are not reimbursed by Medicare and for many are unaffordable.
- **Diagnostic investigations** – for many patients this is at least a blood test and usually performed both in Australian and in overseas laboratories; the average cost of a suite of overseas blood testing is around $1000
  - Many patients also have magnetic resonance imaging, SPECT scans, ultrasounds and other investigative procedures to support empirical evidence of their illness.
- **Therapeutic regimens** – the standard treatment for Lyme disease and Lyme-like illness at the acute stage is Doxycycline for 30 days, the average cost is around $100. Many Australians are not in an acute stage, but are in the long term and chronic stage of illness where costs skyrocket:
  - PICC lines and Portacaths cost around $2000 to insert;
  - IV antibiotics cost some patients up to $2000 per month;
  - Supplements and supporting therapeutic regimens can cost up to $600 per month; and
  - Supportive therapies, like lymphatic drainage massage, physiotherapy and pain management add more cost.
- **Mobility aids** – 15% of patients report they are reliant on mobility aids, this generally means wheelchairs at an average cost of around $500, or carers (28%) who will have their own financial burden.

At the Inquiry into Chronic Health, referenced earlier, Dr Richard Schloeffel told the Committee that there ‘is enormous cost in the investigation’. Local Lyme treating doctors lack confidence in the pathology tests for Lyme disease carried out by the government reference laboratories in Australia. So they ask patients to be tested either through Australian Biologics, a private laboratory or in overseas laboratories. A primary laboratory for testing is IGeneX in the USA.

The LDAA fulfils test kits for IGeneX in Australia. Using our fulfilment data and assuming that 80% of the test kits we have fulfilled have been used; we can calculate a personal and non-rebatable cost to Australian patients of over $2.4 million. Add to that the 718 Elispot and 672 *Borrelia* blot tests performed at Infectolab in Germany, and you have another $260,000 spent on investigations alone.29

Regarding the number of doctor visits, Dr Scholeffel also reports that patients ‘spend a huge amount of money seeing naturopaths, seeing other doctors, having lots of tests and doing all sorts of things and then they come to me. I am regarded as probably the doctor of last resort if you have a chronic fatiguing illness. It costs a little bit to see me, but fortunately there is a thing called the Medicare safety net. Most of the time, by the time I have seen the patients they have already reached that because they have seen 20 or 30 other specialists or doctors before they get to me.’

---

29 Calculations: IGeneX 2465 x $1000 ($2,465,000) Infectolab 718 x $215 + 672 X $158 ($260,546)
Our data supports this statement, with nearly half the patients reporting they had seen more than seven doctors prior to diagnosis. Each doctor visit costs at a minimum $75; for those seeing seven doctors that is a cost of $525, without consideration of whether a visit included fees for a specialist.

In respect to the therapeutic treatment, Dr Schoeffel also reported that the cost of treatment burdens the patient as ‘a lot of these medications are off-label. Therefore, they have to pay for them. They are not covered. As a doctor, you cannot write a script and put it under health cover, because they are not designated illnesses’. As an example, 43% of patients with Babesia require a common drug called Wellvone it costs $1,467 per 28-day supply. It is not rebated because we are not supposed to have that disease here either. Other common treatments for Babesia include Malarone, in which a 30-day supply is $600. Malarone is approved for treating Malaria but not Babesia a Malaria like illness.

An example of the type of medications used to treat Lyme-like illness in a 3 year-old is illustrated in Figure 9; the average cost of this treatment per month is almost $600 for just one child, in a family where all four members are affected.

**Figure 9: Therapeutic treatment example for a child**

![Image of various medications]

Dr Schoeffel asserts that the average cost per patient per year are between $50,000 - $60,000. There would be very few Australians who could afford that type of expense yearly, even if they did have an income.

Our data paints a very grim picture of the overall financial impact on patients. 47% of patients report receiving sickness or disability benefits and 35% had to access their insurance or superannuation.
**Figure 10: Economic burden of illness on patient income** illustrates the issue.
Alarmingly, we have a growing situation in Australia where many seriously ill people are forced to travel overseas to obtain the treatment they need. Many Australians travel to clinics in Germany, where two specialist multidisciplinary clinics have been established to support and treat Lyme patients.

The Klinik St George in Germany monitors where its patients come from. In a recent visit a patient provided us with a photo of their plots. We count over 130 pins from Australian patients.
Importantly, many patients go to Germany to seek hyperthermia treatment that is not available in Australia for patients with Lyme disease. The average cost of this treatment is around $30,000 AUD.

Of particular concern to the LDAA is the Australian Government’s abolishment of out of pocket medical expenses as part of the yearly taxation assessment which is in full effect as of this tax year. This is detrimental to Lyme patients who are in the chronic illness category. Without significant immediate effort and attention by the Government, patients will continue to be unfairly burdened with the price of their care without any hope of reimbursement. Patients will be placed in the risky situation of either stopping their care or treating intermittently to remain functioning enough to earn an income.

**Costs to government**

On the opposite side of the patient costs are the costs to government for Lyme disease and Lyme-like illness. From the 1,051 patients that we know about, we calculate a cost of more than $7.5 million in support for those who are on sickness or disability benefit, and those that have spent a night in a hospital due to Lyme related illness.

A full and transparent review of the cost of Lyme and Lyme-like illness, including the cost burden on the medical system due to failure to treat is needed. The review should include a calculation of the burden of disease for Australians and assess the DALY’s for Australians with long term Lyme-like illness and their consequential disability.
What is the current research effort in the disease area?

Historically, there have been multiple reports of *Borrelia* infection in the Australian population dating back to the early eighties. The timeline of *Borrelia* discovery in Australia illustrates the discovery of *Borrelia* organisms and shows that there are historical references to case reports of Australians with Lyme disease; see Figure 12.

**Figure 12: Illustration of the Timeline of Borrelia Discovery in Australia**

One historical record from the Queensland Health Department in 1990 highlights that Lyme disease is becoming ‘more common in Australia’ with 30% of people having tested positive out of just 488; that’s 146 people positive in Queensland in 1990.

As illustrated, in 1982, 1986, 1991 and 1994 researchers reported more cases. Then in 1994, the Russell and Doggett Study was published and effectively halted all research into and about tick-borne human pathogens for the next twenty years. Investment into this area of research is well overdue.
How much research is being done in the disease area?

Terms of Reference (d) of the Senate Inquiry, noted earlier, sought submissions on ‘evidence of investments in contemporary research into Australian pathogens specifically acquired through the bite of a tick and including other potential vectors’. As such the LDAA committed several hours of desk research to identify the contemporary research being undertaken, most focused on identifying a causative agent for Lyme disease or on ticks rather than people who are ill.

We found that most of the current research is being conducted out of Murdoch University, Western Australia, in the School of Veterinary and Biomedical Sciences, under the auspices of Associate Professor Peter Irwin. Each of these studies is outlined in the LDAA Submission (#528).

In 2014 Murdoch University was awarded an ARC Linkage grant to further their tick research program. The ARC grant value is $295K and is supported through an industry linkage project with Bayer Australia Ltd - Bayer Healthcare, who contributed additional research funds to bring the total value of the research to $650K over 3 years. It is unclear what the commercial or intellectual property arrangements are for the outcomes of this study.

The outcomes of this research have been reported in two separate papers. The first paper reported the results of testing 196 ticks. It found evidence of pathogens that may be making Australian patients with Lyme-like symptoms sick. They identified a Borrelia relapsing fever group, Bartonella henselae and a new type of Neoehrlichia bacterium, Anaplasma and Rickettsia in the Australian paralysis tick. This provides the scientific evidence that Lyme-like pathogens, in this case a Borrelia, is present in at least 1 Australian tick.

In a second report, A/Prof Irwin’s team found multiple bacteria in Australian biting ticks. Several new/novel bacteria were found. The research notes that ‘determining whether these newly discovered organisms cause disease in humans or animals like closely related bacteria do abroad, is of public health importance and requires further investigation’.

Additional research is being done at Sydney University Tick-Borne Disease Unit which is privately funded. Although they are yet to report their findings, a Sydney University researcher presented preliminary results at the Tick Borne Disease Conference in 2014 which indicated that they were looking at the efficacy of the two tier pathology testing process used to diagnose Lyme disease. Shirvington reported that of the 96 patients whose blood he analysed using the two-tier test process only 3.16% returned a positive ELISA result. Of those, 93 patients would be excluded from the second tier test and told they don’t have Lyme disease. These findings are echoed by other researchers who report that only 55% of diagnosed patients returned a positive ELISA, 100% returned a positive Western blot. This raises significant questions about the reliability of the testing processes used in Australia, yet there is little research investigating the issue.

30 Gofton, A. et al (2015), Inhibition of the endosymbiont “Candidatus Midichloria mitochondrii” during 16S rRNA gene profiling reveals potential pathogens in ixodes ticks from Australia, Parasites & Vectors, 8, 1
The Interim report of the Senate Inquiry dedicates their Chapter (4) to research issues. They summarise a number of other studies associated with tick-borne infection currently underway. These are:

- Marie Bashir Institute: metagenomic studies aiming to identify and characterise a common microbial agent or agents in ticks and patients;\(^{33}\)
- 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;\(^{34}\) 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.\(^{35}\)

The Committee recognised the need for further research across a range of areas to better assist patients and their families. They also noted there were opportunities for further research into lyme-like illness and other tick-borne illness. Given the knowledge gaps we have in this area and the lack of contemporary or adequate research, and the repeated recommendations for more research, it is imperative that a Targeted Research Call (TRC) be seriously considered.

**Current NHMRC and other funding**

In her appearance before the Senate Inquiry committee, Professor Anne Kelso told the Committee:

> ‘In preparation for this inquiry, we have searched our electronic grants database to see whether we have received any applications or awarded any grants on Lyme disease or Lyme-like illness.

We found that, between 1997 and 2015, 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.’\(^{36}\)

---

\(^{33}\) Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, p. 2.

\(^{34}\) Professor Edward Holmes, *Submission 546*, pp 1–2

\(^{35}\) Professor Stephen Graves, *Committee Hansard*, Brisbane, 15 April 2016, p. 47.

\(^{36}\) Professor Anne Kelso, *Committee Hansard*, Canberra, 20 April 2016, p. 4.
What is the current research capacity and capability in the discipline?

A metagenomic approach

In 2011, Professor Edward Holmes was awarded a “Fellowship to develop a major computer resource, a ‘virtual laboratory’, to enable researchers across Australia to analyse the genome sequences of emerging pathogens. Professor Holmes is analysing the patterns, rates and factors that influence the spread of viruses in Australia to “create a unique knowledge base of the landscape, demographic, behavioural and socioeconomic features in Australia that are likely to have a major impact on disease transmission. This is to be named the ‘Australian Disease Database’, and will be the first such resource generated anywhere in the world.”

Through his NMHRC funded research, Professor Holmes is applying this approach in investigating Lyme-like illness. In his submission (#546) to the Senate Inquiry he asserts that it is possible “Lyme-like disease encompasses a diversity of clinical syndromes caused by a diversity of microbes. The most powerful way to reveal the microbial cause(s) of Lyme-like disease is through metagenomics”.

Conducting a detailed study on the entire genomic sequence in patients with a Lyme-like illness, and local tick populations, would enable researchers to reveal all possible microbial candidates. These can then be followed up in subsequent studies.

Professor Holmes has proven this approach and has already discovered a novel tick virus from ticks found in Northern Sydney suburbs, known for its high incidence of mammalian meat allergy following tick bite. He has collaborated with the Chinese Center for Disease Control and Prevention to apply the technique to tick populations in China. They have discovered 37 novel viruses. Professor Holmes now plans to employ the same metagenomic techniques to human samples.

Similarly, the research of Murdoch University established that there are other pathogens that are transmitted through the bite of a tick that might be addressed through a metagenomic approach.

Dr Lum, of the Health Department told the Inquiry into Chronic Disease Prevention and Management in Primary Health Care ‘…there are other bacteria in these ticks. Certainly, in some of the work we have just recently done, we found that a lot of the paralysis ticks, which are perhaps the most common biters of people here in the eastern states, are full of a bacterium called Neoehrlichia, and it is closely related to a known pathogen overseas, so that might be a candidate pathogen here’. As yet little has been done for patients that may be infected with that pathogen.

A/Prof Irwin also told the same hearing that a metagenomic approach was needed - ‘being able to analyse and search for a large number of different bacteria at the same time using a molecular technique—closing the circle between work that we do in the ticks and the diagnostic work done in people, is perhaps the way to go’.

---

37 NHMRC Media release: $24 Million for Six of the Best Researchers in Australia, 5 March 2011.
38 Professor Edward Holmes, Submission number 546 to Senate Inquiry on “Growing evidence of an emerging tick-borne disease that causes yme-like illness for many Australian patients”.
39 Dr Gary Lum in House of Representatives Standing Committee on Health, Inquiry into Chronic Disease Prevention and Management in Primary Health Care, 18 September 2015.
40 Ibid.
The LDAA recommend the NHMRC seek 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. This could be achieved by prioritising:

- additional research into the potential pathogens that Australian ticks carry;
- an epidemiological study that examines the habitat of vectors and hosts and how they come to be in contact with humans;
- immediate development of diagnostic tests that recognise the pathogens being discovered;
- a tick borne disease research centre or CRC; and
- a research cohort comprising cross and multi-disciplinary teams investigating neuro inflammatory disease linked to micro organisms

**Are there new and/or novel treatments available?**

A group of Australian scientists has established a neuro-inflammation disease working group, acting as a bridge between diagnosis and clinical trial. If the findings of this working group yield a breakthrough in our understanding of neuro-inflammatory disease, this working group could potentially form an innovative working arm of GBM AGILE led by Australian researchers and a cohort of International experts. GBM AGILE is a global adaptive learning system and clinical trial platform in brain cancer exploring biomarker matches to effective therapeutics repurposed for use in brain cancer, saving time and cost for patients to access effective treatments.

**When was the last breakthrough?**

As noted earlier, A/Prof Irwin’s research being carried out at Murdoch University, referenced on page 22, provides the latest Australian breakthroughs for pathogens found in Australian ticks. It does not provide causal links to disease in humans, this remains a knowledge gap.

Additionally the Department of Health are awaiting the findings of the 2014 research they commissioned through the National Serology Reference Laboratory (NRL) into ‘discordant results’ obtained from Australian laboratories. The NRL intended to compare the different serology assays used in Australia. Nearly two years later we are still awaiting the ‘results to be published in a peer reviewed medical journal’.41 We assert that the delays are inadequate given the gravity of the situation for the doctors who need reliable tests, and for patients whose lives depend on them.

41 Ibid. SQ15-000759, Supplementary Budget Estimates, 21 October 2015
Improving outcomes for individuals and community

A TRC would help to:

1. **address existing uncertainty around Lyme-like illness**
   The situation for Australian patients is dire. For four years the LDAA has been working to highlight the plight of more than a thousand people per year who have been diagnosed with an illness that resembles Lyme disease. Many patients arrive at a diagnosis following years of unexplained illness and debilitating symptoms that have impacted their lives in ways that are incomprehensible to most people. For many the day of diagnosis is bittersweet. They are relieved to have a name for the illness that has plagued their lives, but they are also anxious because no one actually understands their illness and doctors are ill equipped to treat it. There is little assurance that their illness can be brought under control; there are so many unanswered questions. This is the uncertainty that patients with a Lyme-like illness in Australia face.

2. **‘de-stigmatise’ Lyme-like illness and end controversy**
   The uncertainty for patients is compounded by the controversy that surrounds Lyme disease, especially in the USA. The controversy emerges with the diagnosis of a disease that can mimic many others. It continues with the nomenclature used to describe the illness. The diagnostic processes are widely debated. There are two opposing views on the length and type of treatment. There is research that can support either side of the argument. Australia is not immune to this controversy.

   The controversy creates stigma. The stigma is broadly underpinned by the language used to define, discuss and deny the illness. Much of the language is derogatory. Patients are told that Lyme is a ‘fashionable organism’ and they are ‘disillusioned’ because they seek answers to their increasingly debilitating health problems. Some doctors refuse to have anything to do with patients who have Lyme disease because of the stigma. Rather than solving a problem intelligently, the use of derogatory language in association with Lyme disease influences others and further polarises the debate. Most of the stigma evolves from ignorance and is detrimental to patients.

3. **quantify the size of the Lyme-like problem in Australia.**
   There is no official data that may help to quantify the size of the ‘Lyme’ problem in Australia. There has been no epidemiological study or surveillance mechanism established. The only evidence of the prevalence and geographic distribution of the disease is collected by the LDAA. Our data indicates the disease is non-discriminatory. It can affect anyone. It occurs in all states of Australia. Our data suggests that we are looking at a large scale undiagnosed epidemic. Internationally, the incidence of Lyme-like illness is on the rise. The USA updated its surveillance figures by 900% estimating more than 300,000 new cases per year. Incidence rates from 39 other countries are high, and it seems highly implausible that Australia is the only continent without this disease. A study of the prevalence and incidence of Lyme-like illness is well overdue.

4. **accelerate research to isolate the causative agent(s) for Lyme-like illness in Australia**
   The presence of *Borrelia*, the causative agent of Lyme disease, was established in Australian fauna in 1959 and human cases of Lyme disease have been reported since the early eighties. No investment into research on Lyme-like disease, its causative agent, or its aetiology has occurred for twenty years. In that time there has been seven new *Borrelia* genospecies isolated internationally. A single
recent investment into research that isolated organisms in ticks show that Australian ticks are full of pathogens; many of them are known to cause disease. Yet, there has been no investment in, or priority placed upon, the clinical study of patients. This is contrary to the research and treatment conducted by veterinarians of animals presenting with a Lyme-like illness.

5. address the current issues that surround diagnostic testing and ideally detect Lyme-like illness before it becomes chronic

The recommended Australian diagnostic protocols, processes and tests are flawed. The pathology tests recommended are not standardised across laboratories. The criteria used to determine a positive test result is not defined. Some patients’ immune systems don’t function; they have trouble producing the antibodies needed for a positive test. Australian laboratories produce conflicting test results. Patients routinely send their blood overseas for testing in specialist laboratories. Overseas laboratories and the results they produce are routinely dismissed. More training and innovative diagnostics including polymerase chain reaction testing can be introduced to Australian pathology labs.

6. establish Australia as a world leader in the fight against Lyme-like illness

A progressive and contemporary approach to the issues of lyme-like illness is urgently overdue. Recent developments in molecular technologies and next generation sequencing provide for new frontiers in discovery. We have the demonstrated expertise in Australia to harness world leading technology and put it to use in solving the Lyme conundrum. There is acknowledgment that research is needed. The research priorities are well established, but the funding is not. Other emerging and infectious diseases for example Zika Virus, establishes important precedents for swift action, yet when it comes to ‘Lyme’ there is bureaucratic inertia.

7. reduce the burden of illness for patients

Patients are sick, they suffer with more than one infection, it is not just Lyme disease it is much more. They experience debilitating symptoms. The burden of illness, measured by quality of life impacts is substantial. The burden of treatment is unmanageable for many. Patients face a loss of employment; they suffer financial hardship and marriage breakdowns. They are isolated; they suffer discrimination, lose their dignity and become depressed. Children lose their childhood. Some are bound by daily seizures that prevent their schooling, they have no social contact and their lives are defined by treatment events. Some young people live in the aged care system unable to care for themselves independently. All patients suffer the effects of stigma; some tragically take their own lives.

8. educate the medical profession in the diagnosis and treatment of Lyme-like illness and an awareness and prevention campaign would stem the flow of new patients

The Australian medical community is undereducated on Lyme disease. They are reliant on official information that is inadequate and outdated. They need better support, contemporary research, clear guidelines and sensible dialogue. Lyme disease is a 100% preventable illness. The Australian community is undereducated about the risks associated with tick bites. Information and education about the prevention, treatment and triage of tick-borne disease is urgently needed.
9. awareness and communications

Provide credible evidence to inform Government agencies, schools, outdoor workplace, the general public and media on risks, liability, forecasts and prevention strategies

Lyme disease, acquired through the bite of a tick, is a 100% preventable illness. Yet the Australian public is undereducated about the incidence, risks and treatment options associated with tick bites. Those that are aware, are reliant on information sourced from the internet or word of mouth. Many more are turned away by trusted sources that provide incomplete information and further confuse those seeking help. Information and education about the prevention, triage and treatment of tick-borne disease is urgently needed.

There is an unmet duty of care for organisations responsible for children and outdoor workforces in their care to provide adequate guidelines on awareness and prevention. They need better data, contemporary research, clear guidelines, an understanding of legal and workplace health and safety requirements and workplace policies. The media need to report responsibly on the incidence of Lyme-like illness in Australia, needing access to data, contemporary research, spokespeople, key messages and reference sites to use as placeholders when reporting on Lyme-like illness.
Reducing the burden of disease on the Australian health system

As detailed in the LDAA Senate Inquiry Submission (#528), there is considerable stigma associated with all aspects of the Lyme disease discussion in Australia. The stigma associated with Lyme like illness in Australia is detrimental to patients. Doctors are concerned about diagnosing it; pathology tests are discordant; there is little education or awareness about treatment and there are a growing number of patients who are seriously unwell, many are abandoned by the medical system and some take their own lives.

The Senate Inquiry Committee noted they are “concerned by the treatment of patients diagnosed with Lyme-like illness. They note 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.”

Would it improve prediction, and/or identification, and/or tracking, and/or prevention, and/or management within the disease area?

An epidemiological study has long been on the priority list for research. Depending on the design of the epidemiological research, it would help to identify clusters of disease, geographical areas where risks are high and would provide the first official data on the incidence and prevalence.

Is there a need for a community engagement plan to be requested of applicants for this TCR? If not, why is this not required?

A community engagement plan would be required for epidemiological research. A credible plan to establish a suitable sample of patients is essential to ensure a reliable research outcome. A comprehensive study should involve not just the patient community, but also those who have been undiagnosed or misdiagnosed and remain chronically unwell. A community engagement plan would facilitate the capture of data from a representative sample.

How would it be translated into changes in policy?

A targeted research call has potential to attract significant research interest around qualitative and quantitative research that is desperately needed as the evidence base to inform policy in this area.

The LDAA recently scoped a research plan proposing independent analysis of the typical paths of sufferers, along with describing the extremes of experiences (ranging from those where a quick diagnosis and/or effective treatment is obtained, through to those where diagnosis and treatment are protracted). It would look at the consequences of the experience to the participants’ health, both in the progression of their disease and their perceptions of its effect on their mental health.

We’d like to know:

---

42 Community Affairs References Committee, Interim report on the Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients, May 2016. p 36.
• primarily, a patients experience from the time they first observed symptoms, through all contact with the medical system including diagnosis until the current time, and
• secondly, to help identify the barriers and enablers to obtaining a diagnosis of Lyme disease and finding opportunities to improve sufferers’ health.

The outcomes of this kind of research could be used to inform the development of policy recommendations by explaining the consequences of current health policies around Lyme disease. Used in company with data collected under the Senate Inquiry, it might also provide the first paper based epidemiological study of its kind in Australia.

**How would it reduce healthcare expenditure, and/or give greater value for given expenditure?**

Apart from the costs collected through the LDAA surveys, there is no data on broader healthcare expenditure because we do not monitor the illness, it’s not currently notifiable, and the health payment systems do not itemise for Lyme related symptoms.

We do know that following a tick bite, there is often an acute and sometimes allergic reaction. If a patient is provided with a $28 course of Doxycycline as a prophylactic then the risk of any pathogen they have been infected with progressing into an untreated and undiagnosed illness is severely diminished. Instead, the general lack of awareness in the medical community about tick bites means that many patients will go untreated and then become progressively ill until their illness is considered chronic. It’s a simple equation, a $28 course of antibiotics vs a lifetime of chronic care.
Contributing to the global research effort

The Department of Industry Innovation and Science has identified that Australia has a strong record in health and medical research, particularly in relation to emergent epidemics and novel pathogens. Australia is well recognised as a global hub of excellence in influenza research. This places Australia in a good position to add to the international reputation by contributing to the research being undertaken around the world on Lyme disease.

Numerous bodies and governments are undertaking Lyme disease research:

Global Research Groups
Global Lyme Alliance, formed by the merger of Lyme Research Alliance (LRA) and Tick-Borne Disease Alliance (TBDA), is a leading private non-profit organization in the United States dedicated to finding a cure and accurate test for Lyme disease as well as educating physicians and the public about the dangers of Lyme. Today GLA has gained national prominence for its commitment to changing the course of Lyme disease by funding ground-breaking research, while expanding education programs for the general public and physicians.

One of the key goals is to serve as an information resource for current medical research and findings with respect to Lyme disease.

UK Lyme Research
The National Health System in the UK is currently undertaking numerous research project related to Lyme disease. In May 2013 a UK Lyme borreliosis epidemiology report was published.

World Health Organisation (WHO) list of Clinical trials relating to Lyme disease
WHO register of Clinical trials relating to Lyme disease contains a list of 44 projects from around the world including Norway, USA, Germany and France. Many nations are undertaking research into Lyme disease as can be found in the register. Australia’s high calibre contribution to the body of knowledge would be significant.

ILADS Annual Conference
One mechanism to contribute to the global research effort would be to have Lyme disease research published in Australia presented at the annual International Lyme and Associated Disease conference.

Global Tourism
Tourists bitten while visiting Australia who return unwell to their home country will need guidance on diagnosis and treatment. Australian research into diagnosis and treatment of locally acquired Lyme disease would contribute to the care and wellbeing of such patients.

45 http://www.nhs.uk/Conditions/Lyme-disease/Pages/clinical-trial.aspx?pn=2
46 http://www.ilads.org/lyme_programs/ilads-conferences.php