A patient perspective

Submission to the Senate Inquiry on the Growing Evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients

Lyme Disease Association of Australia
March 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
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Background

On 12 November 2015, the Senate referred the following matter to the Senate Community Affairs References Committee for inquiry and report:

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

The terms of reference are:

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

Introduction

The Lyme Disease Association of Australia (LDAA) is a registered charity comprised of a small number of volunteers committed to making changes to how Lyme-like illness is viewed, and how patients are treated in Australia.

The association undertakes activities in four key areas: information, support, education and awareness. The LDAA’s 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 fundraise to assist people living with Lyme disease and Lyme-like illness.

In response to the Senate Inquiry, the LDAA lodge a submission on behalf of patients suffering from a Lyme-like illness in Australia.

Our submission represents those patients who are too ill to tell their own stories and all those who are too small to have a voice. We write not only for those patients, but for their families and friends, the people who love them and watch them suffer every day with a disease that conventional medicine cannot name, diagnose, treat or explain. We represent the many Australians who have already lost their lives to this devastating illness. We represent the tragic few who have taken their own lives because they had lost all trust in the medical system that was supposed to support them; their hopes and dreams shattered by the hopelessness of their situation.
What’s in a name?
There is considerable contention around these two simple words ‘Lyme’ and ‘disease’. On their own they do not offend, used together they invoke very powerful, often emotive shifts in the demeanour, language and behaviours of others. Depending on your perspective, we either have it in Australia or we don’t - its binary.

It is impossible to find a precise and consistent definition of the term in Australia. It is used by the medical community to describe a very specific strain of a biological organism, or sometimes organisms; even they can’t decide. It is used by the rest of the world to describe a suite of symptoms and infections caused by a number of organisms.

If you listen to the medical and scientific community, its description is concise and easily delivered in a soundbite. It is one little bug that is manageable and marketable; it’s hard to get and easy to treat. There are widely available drugs to treat it at little cost to government. You can only get it from a tick, and only in certain locations, but certainly not in Australia. Doctors rarely learn about it in medical school as a foreign disease. This is the mainstream medical version of Lyme disease.

If you listen to those who actually live the experience, it has all the makings of a horror film. Lyme disease in this instance is code for a bombardment of sinister bugs and stealth infections that take over every single bodily system. It’s full of bad medicine, expensive and contentious treatment, and little contemporary science. It requires a pharmacy of drugs to control, and waits covertly to reappear when least expected. It sends you broke, and makes you dependant on a handful of super hero doctors. [1]

In the context of this submission, ‘Lyme disease’ is used interchangeably with the term ‘Lyme-like illness’.

We don’t know what people have. We do know that some people become seriously ill, sometimes after the bite of a tick, and that their symptoms closely resemble that of internationally defined Lyme disease.

Call it what you may, but don’t dismiss it.

[1] Adapted from Alison Childs: https://medium.com/@alisonchildiss/a-silent-epidemic-edbaf09269fe#4tf3phlxh
Executive summary

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 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.

The uncertainty for patients is compounded by the controversy that surrounds Lyme disease, especially in the United States of America (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; it is detrimental to patients.

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, reported throughout this submission, indicates the disease is non-discriminatory. It can affect anyone and 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 recently updated its surveillance figures by 900% estimating more than 300,000 new cases per year. Incidence rates from 39 other countries are reported; 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.

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. Australian authorities ignore this evidence. No investment into research on Lyme disease, its causative agent or its aetiology has occurred for twenty years. In that time there has been seven new Borrelia genospecies isolated internationally. Recent investments 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.

The recommended 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. They are said to be unaccredited, yet they participate in an international standards accreditation scheme that is mutually recognised.

A progressive and contemporary approach to this problem is urgently overdue. Recent developments in molecular technologies and next generation sequencing provide for new frontiers in discovery. There is acknowledgment that research is needed. The research priorities are established but the funding is not. Other emerging and infectious diseases establish important precedents for swift action, yet when it comes to ‘Lyme’ there is only bureaucratic inertia.

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.

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 preventable illness. The Australian community is undereducated about the risks associated with tick bites. Information and education about the prevention of tick-borne disease is urgently needed.

The Australian Government has a role in the management of the health of all Australians. It is obligated to prevent, treat and control epidemic disease. It must create conditions to assure all medical service and medical attention in the event of sickness. These obligations fall upon the state of Australia. The state cannot absolve itself of responsibility by leaving these matters to individual medical practitioners, any board or other body; and certainly not patients who currently bear the burden of proof.

As set out in this submission, it is obvious that the state of Australia is not meeting its obligations, certainly not to the extent required, in respect of Lyme-like illnesses, and those suffering from Lyme-like illnesses. It cannot be suggested that the state of Australia is progressively realising the right of those suffering from Lyme-like illnesses, to the highest attainable standard of physical and mental health. Australia has not taken the steps necessary for the prevention, treatment and control of the health outcomes for Australians who are suffering from a Lyme-like illness.

Australian patients are being misdiagnosed, mistreated and misunderstood by the medical community, allied health professionals and the Government. On behalf of all patients with Lyme-like illness, we implore the Committee to take a leadership position on this issue and make recommendations that prioritise immediate action.
Recommendations

We call upon the committee to recommend:

- the Council of Australian Governments (COAG) Health Council address a coordinated national response to Lyme-like disease as a matter of urgency
- a study of the prevalence and incidence of Lyme-like illness in Australia, including a clinical study of patients
- the National Health and Medical Research Council (NHMRC) provide funding to support the research set out by the Department of Health
- a legislative response be developed to ensure that Australian Lyme-patients receive the care they need in a safe and non-discriminatory health system
- the establishment of specialist, multi-disciplinary Lyme treatment clinics with services for patients
- expediting a solution to the diagnostic and testing issues outlined
- amendments to the diagnostic case definition to address the issues raised
- a broad education campaign be developed and rolled out, that includes:
  - Mandatory education for all health professionals concerning Lyme and tick-borne infection that includes diagnosis, signs, symptoms and types of treatment with requirements for continuing education as more research emerges;
  - Public dissemination for prevention and awareness;
  - Occupational education for outdoor workers; and
  - Prioritisation of funding and fellowships for researchers.
- the Government acknowledge the evidence of Lyme-like disease found in the overseas Lyme specialist laboratories that operate under the Mutual Recognition Arrangement (MRA). Advice to clinicians should be immediately updated to inform them about retrospectively accepting overseas testing results
- 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 the following:
  - research into the potential pathogens that Australian ticks carry;
  - an epidemiological study that examines the habitant 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; and
  - a tick borne disease research centre or Cooperative Research Centre (CRC).
Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients

Submission 528

A representation of the different types of Australian Patient Personas

**Illness following known tick bite**
Patients received a tick bite. They removed the tick themselves. They're unaware of the risk associated with tick bites. The bite didn't hurt. Following the bite they may have developed a rash or had a skin reaction. They've developed flu-like symptoms, a temperature, headaches and feel tired and unwell.

**Recent illness of unknown origin**
After camping, walking in the bush or a visit to a beach, these people have become unwell recently. They don't recall a bite of any kind, but they may have had an unexplained rash or some skin itchiness. They are sick with flu-like symptoms; they might have a sore neck and some pain in their joints.

**Long term illness of unknown origin**
These people have been sick for a few years. They used to be active and healthy. They can't remember an event that triggered their illness. They may have a vague memory of a tick or other bite. They've seen a few doctors who don't seem to have any explanation for the wide range of symptoms they have.

**Long term illness misdiagnosed**
These people have become gradually debilitated. They rely on others for their care. They've been through many medical tests. Their medical records are full of odd results and explanations. They have been diagnosed with other diseases. Their doctors don't know how to help them. They're depressed.

**Child of parent with Lyme-like illness**
These are children or babies infected with *Borrelia* before they are born. They may have had a rash and heart issues at birth. Some have poor muscle tone, it affects their development. They fail to thrive. Many have learning disabilities, fatigue and rashes. They suffer pain and don’t know why. They can’t express how they feel.

“I was an active and healthy man. I had a full time job and did lots of extra shifts. Until, at 45, I started to feel unusually tired. I couldn’t function. I had numbness and tingling in my arms and legs. After a few investigations with no sensible explanation, I was told I was crazy and my symptoms were all in my head.”

- Bob, 52

“When I’m sick I feel sad, bored and upset. I feel like I am on fire and something is going to go bang in my head. I don’t like it.”

- Sophie, 6

“I got a tick bite and felt really sick after it. I had a bull’s eye rash but didn’t understand its significance then. My health gradually deteriorated. I couldn’t walk unaided and couldn’t drive. I suffered in pain every day. I was severely depressed.”

- Lee, 58
(A) ToR the prevalence and geographic distribution of Lyme-like illness in Australia

Prevalence refers to the number of cases of the disease present in a population at any given time. It is impossible to talk about the prevalence of Lyme-like illness without a detailed discussion on epidemiology and surveillance.

In the absence of any government driven epidemiological study the LDAA has gathered evidence of the prevalence and geographic distribution of the disease. It is incredibly frustrating that the government continually proclaims there’s no Lyme in Australia while systematically ignoring all historical attempts to classify and count patients and fail to conduct any real investigation or surveillance on the issue.

Under this context the LDAA’s work must be counted as the evidence.

Our evidence shows:

- 352 cases of positive tests by Infectolab;
- 1,051 cases of diagnosed Lyme disease.

Given that Lyme disease can mirror many other diseases, is often misdiagnosed, and the large scale infection in many other countries, it makes absolute sense that we are looking at a large scale undiagnosed epidemic in Australia.

A 1. Disease surveillance

A hallmark practice in epidemiological studies is the aetiology (origin or causation) of disease, outbreak investigation and disease surveillance. Each of these aspects is typically used to inform prevalence calculations and underpin a public health response. In Australia, despite the thousands of people presenting with Lyme-like illness, we have no epidemiological study and no coordinated disease surveillance.

A.1.2 Historical case data is ignored

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 1: 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. A copy of the Queensland Health Letter is included in the Appendix 1-Figure 26 to this submission.

The book Bitten by the Bug, authored by Arthur C. Johnson reports from 1988 to 1994 there were 4,372 local (NSW) patients tested for Lyme disease, many were treated with antibiotics and returned to good health. Historical data on this study and its outcomes has not been located, but the LDAA remains interested in uncovering the source of this data.
As illustrated, in 1982, 1986, 1991 and 1994 researchers reported more cases; that’s a large number of cases given that *B. burgdorferi* is allegedly not present in Australia. Then in 1994, the Russell and Doggett Study (further discussed in ToR D) was published and effectively halted all research into and about tick-borne human pathogens for the next twenty years.

### A 1.3 Twenty years later – a contemporary view

In May 2013 the Commonwealth Department of Health (DoH), through its Communicable Diseases Network Australia (CDNA), 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\(^1\) 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.

Our review of the Department’s responses against the assessment criteria highlights several issues, for example:

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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’. If the current laboratory practices are mostly ineffective, yet the Department recommends monitoring them, why has the government not addressed the issue? The intent of this assertion is unclear and requires further explanation.

2. ‘To enhance understanding of the epidemiology and clinical course of the disease’ response asserting there is no evidence of local transmission is increasingly being proven to be incorrect. There are many historical studies that have been systematically dismissed, in favour of a single highly criticised study conducted more than 20 years ago.

3. ‘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”

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’.

The LDAA notes that the Department’s rationale for not providing surveillance of Lyme disease, given in May 2013, was insufficient.

A 1.4 International surveillance
As reported in our submission to the DoH’s Scoping Study (Attachment A accompanying this submission) more than two years ago, we conducted desk research and analysed international efforts in the surveillance of Lyme disease. We asserted then that Australia is many years behind similar jurisdictions in mounting a proper and effective public health response to monitoring and surveillance. Despite emerging evidence of countless pathogens contained in Australian ticks, we are still largely ignorant.

Australia has a different approach to disease surveillance to many other countries. Australia is the only Organisation for Economic Co-operation and Development country without a separate authority for national scientific leadership and coordination of communicable disease control and surveillance (Australia, Public Health Association of, April 2011). Instead, the monitoring of national health issues is managed by the considerably understaffed Office of Health Protection who manages their responsibility through six committees. Until recently these committees operated with little, if any, public transparency. It’s not hard to see how these overly bureaucratic processes contribute to the inertia when it comes to solving the complexities of Lyme disease or Lyme-like illness.

3 Refer to documents cited in Footnote 3
We maintain that a transparent surveillance system for Lyme-like illness should be a national public health priority. The evidence set out in this document indicates that it’s time for coordinated national action and we call upon the Committee to make this recommendation.

A 2. Prevalence
The LDAA has been collecting and compiling Australian data on the prevalence of Lyme-like illness since 2011 through detailed online surveys. To take part in our surveys the respondent must be diagnosed with a Lyme-like illness by a medical practitioner. 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. There are also likely to be many people who remain undiagnosed or worse; misdiagnosed.

We’ve previously reported our survey data in the *Lyme disease: Australian patient experience in 2012* report (Attachment B accompanying this submission). More recent data, collected in 2013/14, on the prevalence of Lyme-like illness and its impact on patients is reported throughout this document.

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

**FIGURE 2: DEMOGRAPHIC PROFILE OF AUSTRALIAN PATIENTS**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 18</td>
<td>32</td>
<td>55</td>
</tr>
<tr>
<td>19 – 35</td>
<td>60</td>
<td>177</td>
</tr>
<tr>
<td>36 – 45</td>
<td>48</td>
<td>217</td>
</tr>
<tr>
<td>46 – 55</td>
<td>82</td>
<td>177</td>
</tr>
<tr>
<td>56 and over</td>
<td>65</td>
<td>138</td>
</tr>
</tbody>
</table>

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.

Our data under-reports the growing incidence of Lyme-like illness in Australia; we believe these figures to be the tip of the iceberg when it comes to the real incidence of Lyme-like illness in Australia.
A 2.1 Geographical surveys
In addition to our detailed patient situation surveys, we make available a survey\(^5\) 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. We recently called for an update to this map and now plot 2,126 people.

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

For best effect, the map is interactive and allows a viewer to drill right 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/)

A 2.3 Alternate sources of data
In the absence of any official epidemiological study, we must rely on other data sources to gauge the incidence of Lyme-like illness in Australia. As such, we have presented each of these alternate data sources for further examination. We acknowledge that these data sources are not ideal. The data is only suggestive, not conclusive. Without an official epidemiological study, it is the best anyone has to go on.

A 2.3.1 Number of patients undergoing treatment by ACIIDs\(^6\) 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.\(^7\)

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\(^6\) Australian Chronic Infectious and Inflammatory Disease Society is a group of doctors, primarily general practitioners, who specialize in the treatment of tick-borne diseases.

\(^7\) See Submission number: 370
**A 2.3.2 Online patient support forums and social media**

We have seen increasing numbers of participants in more than 12 Australian online patient forums whose combined memberships total over 1900 in January 2016.

Our own data also provides many insights. In March 2011, we launched an LDAA Facebook page. We commenced tracking our ‘followers’ in 2014. People who follow us have increased by over 400% in 2 years. In January we had 10,795 people following us.

We answer more than 280 emails per month, generally in supporting patients who are newly diagnosed with Lyme-like illness. This data clearly demonstrates that we are facing a very real problem that must be addressed quickly.

**A 2.3.3 Internet search engine analytics**

The use of internet search engines in epidemiological research can aid surveillance of disease. Using ‘Lyme disease’ and ‘Lyme’ as the search parameters in Google Trends using the ‘correlate’ function we show the steady increase in 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](image)

**A 2.3.4 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 300,000.8 A sobering 900% increase.

**A 2.4 Estimated number of Lyme-like illness cases in Australia**

If Australia were to increase the numbers of our current ‘self-reporters’ (1,051) by 900%, there would be 9,459 cases per year; that is the low end of the scale.

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If Australia were to use a similar prevalence rate to that reported in the USA, over the past 20 years there may be up to 426,542\(^\dagger\) 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).

It’s more than all of those diseases combined.

**Figure 5: Estimated cases per year - Lyme, breast cancer, HIV & MS\(^\dagger\)**

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lyme-like illness</td>
<td>6,117</td>
<td>16,539</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>145</td>
<td>15,600</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>976</td>
<td>105</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>250</td>
<td>750</td>
</tr>
</tbody>
</table>

**A 2.5 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 this submission and report statistics of the worldwide incidence of Lyme disease; see Appendix 2 Table 8: Incidence of Borreliosis in 39 countries. 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.\(^\dagger\)

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.

**A 2.6 Increases in tick populations: a warning**

Since 2003 we’ve been constantly warned about rising tick numbers due to global warming, weather patterns, overgrown gardens and the urban encroachment into traditionally bushed areas. Each of

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\(^\dagger\) Estimated 0.09% incidence per year x ABS Population statistics cumulated yearly since 1994


\(^\dagger\) Calculation: ABS 2015 population statistics (23,998,630) x 39 countries mean incidence rate (5.804%)
these elements contributes to a steady increase in tick numbers by enhancing the conditions and environment for survival.

A single female Ixodes tick lays between 2,000 and 6,000 eggs. In a two year life cycle this could equate to over 12,000 eggs. Many don’t survive if weather conditions are not favorable. Assuming only 10% (1,200) of eggs reach larvae stage and also reproduce, in just two years more than 7 million vectors are added to the population; from a single tick. This is occurring all over the world, not just Australia.

It’s no wonder the headline warnings are coming hard and fast.

A 2.7 Tick bite locations
With our Lyme disease count survey, we collect the locations where people report they acquired a tick bite that led to them becoming ill and plot the tick bite location. Our tick plot map shows the geographical spread of Lyme-like disease and the distribution of ticks that are making people ill. There are 910 bite locations plotted.

**Figure 6: Location of reported tick bites from patients with Lyme disease**

Again, for best effect, the map is interactive and allows a viewer to drill right down to postcode level data to gain a geographical understanding of the locations a tick bite has been reported. We recommend it is viewed online via: [http://www.lymedisease.org.au/stats/](http://www.lymedisease.org.au/stats/)

Our data shows that tick bites are increasing; since we commenced mapping in early 2014 we have increased the plot data by more than 143.97%. As a result more people are becoming aware of the link to tick bites and illness. In our surveys, 694 people (68%) tell us that they know of other people in their area who have been diagnosed with a Lyme-like illness.

A 3. Prevalence and geographic distribution conclusion
Added to these complications is geography; because of the lack of government foresight Australia is outside the reported endemic areas for Lyme disease and the long-term denial by Health Departments that Lyme disease exists here ensures doctors immediately conclude its impossibility.
Given emerging evidence of the increasing incidence of Lyme disease internationally, and the climatic and ecological ‘issues’ improving the lifecycle prospects of the tick vector and their hosts, it seems highly implausible that Australia would be the only continent on the globe without Lyme disease, or a Lyme-like illness.

International governments are starting to see Lyme disease as a serious threat to public health and Australia must follow suit and allocate resources to properly identify just how epidemic this disease is on our own shores. This should include a complete ecological and epidemiological study that is progressive and determined to get to the truth of the matter, and record the actual numbers of infected patients and the risk to public health.

Under the government evidenced based model a study of the prevalence and incidence of Lyme-like illness is Australia is well overdue. It is our hope that through the actions of this Senate Committee, the first official prevalence data is documented.
(B) ToR methods to reduce the stigma associated with Lyme-like illness for patients, doctors and researchers

The stigma that surrounds Lyme disease is multi-faceted but is broadly underpinned by the language used to define, discuss and deny. To assist the Committee, we set out five primary types of stigma associated with Lyme disease and methods to reduce them in this section.

B 1. Nomenclature associated stigma
As one of the leading bodies supporting patients with Lyme disease or Lyme-like illness we receive constant updates from Australians about how terribly they are treated by the medical profession if they mention that they suspect or have Lyme disease. Patient’s routinely report poor treatment by Australian GPs, infectious disease specialists and other hospital and specialist staff.

The term ‘Lyme’ is so stigmatised that many patients routinely advise others not to mention the disease at all when reporting their medical history. Some patient support organisations have specifically changed their name to omit the word ‘Lyme’ in order to disassociate with the negativity it invokes.

It is shamefully common to hear a patient’s account of a visit to a doctor or specialist that proceeds respectfully “until I mentioned the ‘L’ word”. We have countless reports of what comes next; it ranges from instant dismissiveness “you don’t have Lyme, we don’t have that here” to scientifically misinformed statements like “you don’t have to worry about that because you haven’t been cuddling any echidnas”. There are also cases that display an obvious lack of geographic knowledge after a patient reported they had recently travelled: “Boston is not an endemic area for Lyme disease”.

Simply, the word ‘Lyme’ carries with it a construct of dogma and controversy. Indeed, the title of this Senate Inquiry naming the disease in Australia as ‘Lyme-like illness’ instead of Lyme disease is yet another illustration of the nomenclature related stigma.

As part of an appearance before the House of Representatives Standing Committee on Health’s, Inquiry into Chronic Disease Prevention and Management in Primary Health Care, Dr Lum, Head of the Office of Health Protection in the DoH, told the committee that “it is clear that Australian ticks have lots of different bacteria inside them. There is no doubt about that at all.” Further “it is a bit of a mistake to focus too much on Borrelia. If people are getting sick from tick bites, it is quite possible, or at least plausible, that they are being infected by other bacteria, viruses or even protozoa. These ticks are full of micro-organisms. The focus on Borrelia I do not think is helpful in this discussion—or at least it is limiting”. 12 But this position is not echoed in the official documentation provided by the Department and does not reflect the findings of government funded research. Hence the debate continues to be limited by the focus on a single Borrelia strain.

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12 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.
Appropriately Ms Hall, a member of the committee asked ‘rather than there being a campaign saying that there is no Lyme disease in Australia, wouldn’t it be better to target research to find out why so many people are getting sick following a tick bite?’

B 1.2 Methods to address nomenclature related stigma

We’ve previously referenced the issue of nomenclature in our response to the DoH’s Scoping Study back in 2013. We raised the approach taken by the Brazilian government who avoided the term Lyme. They determined a nomenclature for their own Baggio-Yoshinari Syndrome (BYS) to describe the Brazilian version of a Lyme-like illness. They defined BYS as an “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”.

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.

In Australia, we have focused on the binomial nomenclature - *Borrelia burgdorferi* - to describe Lyme disease. Yet the description is being widely used as the catch all for a constellation of pathogens that are transmitted through tick bite to humans and are making them sick.

Australia should move away from the myopic focus on a single pathogen, *Borrelia burgdorferi*, because it doesn’t address the whole pathogen load that a patient receives when they are bitten by a tick. International expertise indicates that a single pathogen Lyme illness is rarely, if ever seen. USA experts report that scientific evidence indicates that a Lyme-like illness is caused by more than just one strain of pathogen.

**Figure 7: Borrelia Burgdorferi vs the constellation of pathogens found in Australian ticks**

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B 2. Stigma resulting from derogatory language

Derogatory words don’t just pop up in language; they are derived from the history, culture and worldview of the people who use them. They are fuelled when conflicts arise between people with opposing views, beliefs or morals. Often when people fail to use a logical argument to solve a conflict, they turn instead to an ignorant, destructive yet powerful strategy using insults, generalisations and detrimental stereotypes as their form of persuasion.14 This is what exactly we see in Australia in respect of Lyme disease. Sadly, there are many examples of this.

Derogatory words influence attitudes and serve to polarise the debate rather than solve the problem intelligently. It may seem clever or witty to call Lyme disease a ‘lemon’, a word which is not derogatory in itself, but its inferred meaning is. What does it imply to the ‘internationally recognised Australian scientists’15 in the field of entomology or infectious disease, who had gathered to hear a presentation, titled ‘Lyme Disease in Australia: The Real Deal, or just a Lemon?’16

It’s not surprising that a disease called ‘Lyme’ might attract lemon analogies. However, when an authority uses derogatory concepts such as lemon about Lyme disease, the reference is seen as acceptable. This was demonstrated by Senator Di Natale, also a medical doctor, who made a failed attempt at humour suggesting that lemons cure Lyme disease.17 The patient community was horrified that their suffering and the near impossible task of finding and affording a cure was the butt of a Federal Senator’s joke.

What outcomes do we expect when Dr Brad McKay, a media savvy doctor and television personality, writes a media article titled “The great Australian Lyme conspiracy?” 18 The portrayal of patients who believe they have Lyme disease as deluded or gullible is offensive. How are patients expected to behave when a majority of Australian doctors tell them ‘we don’t know what it is, but we know it’s not Lyme’? If they encounter a doctor who does believe them those doctors are portrayed as exploitive menaces to public health. The implications of ill-informed statements have an impact on fragile people who are often in life or death situations and are seeking medical help to return them to good health.

The stigma that surrounds Lyme disease acts as a vicious circle that damages the credibility of all involved. It is unclear why otherwise professional people, like Dr McKay, are motivated to act in a manner that further aggravates and undermines the seriousness of the issue. His article contains no scientific references to support his assertions and there are inaccuracies littered through his rhetoric. Because he is influential, irrespective of the actual facts, his derogatory language and inflammatory sentiment further contributes to the division and derision.

In May 2014 the LDAA sent a patient to the Lyme disease treatment roundtable; a gathering of medical professionals, scientists and treating doctors.19 The use of discriminatory and derogatory dialogue was particularly evident when many of the participants explained or justified their positions. These included references to patients, who unsatisfied with the lack of answers from local

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14 Concept originates from: http://www.hercampus.com/school/pitt/power-behind-derogatory-words-0
17 ABC TV Show “The Chaser’s Media Circus”, 19 November 2015
testing labs, were dismissed as ‘disillusioned’ because they sought answers to their growing health issues. They were told that Lyme is a ‘fashionable organism’. The summation, by one doctor, of the many case descriptions offered by the treating doctors in the room was referred to as ‘fluffy’. There were multiple assertions that Lyme was a ‘fashionable diagnosis’.

This widespread and seemingly acceptable use of derogatory terms to describe Lyme disease and patients within the medical community presents a barrier. When these terms are used and repeated they become the representative norm and so the stigma increases. Doctors themselves use these same derogatory terms to bully each other.

The roundtable meeting was summed up by the only psychiatrist in attendance who noted that the “entrenched belief systems characterised by a low tolerance of uncertainty, the obvious egos, body language, the dismissiveness, the lack of respect and eye rolling around the room is detrimental to patients”. It was a perfect illustration of how the derogatory language is used to negatively influence others.

That was two years ago. Now, according to Professor Chris Baggoley, Australia’s Chief Medical Officer (CMO) the real outcome is that “There are other doctors who, because of the controversy about this, just do not want to have anything to do with this group of patients”.20

Patients with Lyme disease and Lyme-like illness suffer terribly when they are the subject of jokes, and discriminatory innuendos, when their serious illness is trivialised by the people who are employed to help them. The impact of this derogatory and discriminatory stance is that some patients end up with real or perceived mental health issues.

Words are powerful tools and, whether intended or not, they have real and sometimes tragic impacts. Derogatory words diminish the trust a patient may have in the medical system that is intended to support them. Tragically some patients take their own lives when the words that are used to describe their situation reinforce the negativity and the hopelessness they already feel.

B 2.1 Methods to reduce the derogatory language that fuels the stigma

The LDAA have asked the DoH to change their language and take a more partisan position. We’ve suggested they use language like ‘DoH are seeking evidence of Lyme and Lyme-like disease in Australia’ as that can completely change the dynamic of the controversy.

The officials elected or employed to represent us must be impartial and should provide some guidance to others of what is unacceptable. This should include guidelines that focus on non-discriminatory and inclusive language, the ramifications of stereotyping patients, use of derogatory labels, and aversions to trivialisation and dismissiveness.

Only then we will be able to have a sensible, fair and progressive dialogue on solutions.

B 3. Treatment related stigma

The stigma attached to Lyme disease is often used to deny treatment, with patients being told ‘it is all in your head’, it is a ‘psychosomatic illness’, or ‘something else’ but definitely not Lyme. This

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20 See: Professor Chris Baggoley, Community Affairs Legislation Committee, Estimates, Committee Hansard, 10 February 2016, p. 128
effectively dismisses a patient and when they persist in pursuing treatment they are often referred for psychiatric care or, worse still, are treated for psychiatric issues.

The book *Bitten by the Bug* (Johnson), authored by a retired CSIRO veterinary researcher, tells the story of the most despicable mistreatment of a patient due to Lyme denial. The author’s wife Barbara, also a vet, underwent sixty (yes sixty) electroconvulsive therapy treatments due to her ‘depression’ because infectious disease specialists would not consider *Borreliosis*. Barbara died, yet Barbara could have been helped with the right treatment if someone had listened to her husband; a tick-borne researcher and vet.

In response to an increase in hospital admissions reported by patients, our latest survey sought information on how many patients have had to visit a hospital to seek treatment for their Lyme related illness and whether they had encountered any difficulty obtaining treatment. As illustrated in Figure 8, 22.5% of patients reported they had attended a hospital and 15.5% of patients reported they had encountered a problem at least once, with nearly 10% of patients encountering a problem on multiple occasions.

As a result many patients, usually the most debilitated, deny themselves the serious medical attention they need because of the increasing stigma associated discrimination they have experienced. Patients repeatedly tell us they “avoid hospital like the plague and certainly don’t mention the L word”.

Patients receiving intravenous antibiotics (IV) via a peripherally inserted central catheter (PICC) or a Portacath attract significant attention especially in a hospital setting. Many patients report infectious disease specialists interfering with their established treatment regimens; “they threatened to take my mode of treatment away from me. I can't take oral antibiotics, so IV is my only chance of recovery. If I go to hospital, they will take my port out and I will die.”

**FIGURE 8: HOSPITAL RELATED TREATMENT DIFFICULTIES**

<table>
<thead>
<tr>
<th>Hospital related treatment difficulties</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you had to visit a hospital to seek treatment for your Lyme disease?</td>
<td>191</td>
</tr>
<tr>
<td>Have you had difficulty obtaining treatment at a hospital for Lyme disease?</td>
<td>132</td>
</tr>
</tbody>
</table>

Such is the discriminatory treatment that is occurring in hospitals for Lyme patients that Mr Johnson, the retired vet whose story is told in *Bitten by the Bug* was actually published under a pseudonym. In his own failing health, he has left his home town of 50 years or more because he is unconvinced that
he will receive fair and appropriate treatment in the same rural hospital that he traversed with his wife, Barbara.

Trusting one's provider is an essential component in health recovery; but for people living with Lyme disease the issue of trust is particularly important and compounded by the ignorant judgements made about the disease. Patients report feeling distrusted by health services and in turn place limited trust in those services. This often results in a worsening of a patient’s condition.

This stigma has direct impacts upon patients who take an average of 10.7 years to reach a diagnosis for their chronic and debilitating illness. Table 1 presents the number of patients who recalled a tick bite prior to becoming ill and the number of years it took them to receive a diagnosis of Lyme disease or a Lyme-like illness. In Australia, the current situation is that the majority of patients are in the chronic long term stage of illness before they are ever appropriately treated. As such the recommended 30 day course of antibiotics is rarely going to help them.

**Table 1: Length of time from bite to diagnosis**

<table>
<thead>
<tr>
<th>Number of years</th>
<th>Number of people n=308</th>
<th>Average 10.75 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
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<tr>
<td>31 or more</td>
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</tbody>
</table>

**B 4. Research associated stigma**

As a result of the DoH's Scoping Study, a consolidated list of research projects were suggested and published on their website. It is perhaps the ONLY point that all parties associated with Lyme, patients and the medical and scientific community in Australia, agree upon; that more research is needed. It remains unclear though how a researcher might actively pursue any of the projects without associated funding. The Committee might consider posing a question to the National Health and Medical Research Council (NHMRC), the body responsible for health and medical research funding, on what they are doing to support the CMO’s proposed research needs.

The LDAA receives inquiries from researchers interested in investigating Lyme or tick-borne topics and are seeking funding. We don’t have the serious funds required for research so we refer them to

the DoH website and then NHMRC for funding. We’ve learnt that many potential researchers will not pursue the perceived ‘barriers’ to funding with the application process required. We also have reports of instances where research students are warned off looking into tick-borne illness or Lyme disease because of the stigma. Recently an honours degree supervisor of a Central Queensland University student was warned off sponsoring the research because of the controversy.

The Sydney University Tick-Borne Disease Unit which is privately funded, and the Murdoch University studies are the only contemporary research being done on ticks and tick related disease in twenty years. The former is not funded, the latter only marginally. Each paper or presentation that has resulted from each of these investigations has recommended further research.

It would be interesting to examine why the only research being conducted is within the Pharmacology faculty, and the Veterinary faculty?

B 4.1 Methods to reduce research related stigma
It is not unprecedented for a disease to be prevalent in a community before it is fully understood by the authorities. For example, the Zika virus was attributed to birth defects prior to the first solid evidence from two research laboratories.\(^{22}\) In January 2016 four Latin American countries called for pregnancies to be delayed and the USA warned travellers about countries where cases had been registered.\(^{23}\) The CDC released interim guidelines for pregnant women, evaluation and testing in January 2016.\(^{24}\)

The DoH has issued interim recommendations for the assessment of pregnant women in spite of also stating that further studies are required to prove that Zika is the cause.\(^{25}\)

For more than two years the LDAA has been calling for an interim solution to help the patients suffering from a Lyme-like illness while we wait for more research. However, this has not been forth coming. If there was no stigma, would it be considered reasonable to make sick and dying patients wait for research before they are offered potentially lifesaving antibiotics?

The Lyme-like stigma is not just because the disease isn’t fully understood by the medical establishment. We must make a concerted effort to understand why the medical community does not want to investigate what is touted elsewhere as a serious worldwide health issue; is it stigma related?

B 5. Medico-legal related stigma
Of serious concern is the increasing level of complaints being directed at doctors who are treating patients with Lyme disease. Over the past three years there have been conditions placed on three doctors (Ladhams, Du Preez and Kemp) treating patients with Lyme disease by the Australian Health Practitioner Regulation Agency (AHPRA). The conditions are specific in response to Lyme disease and relate to the diagnosis, treatment and prescribing practices of the doctors concerned.

\(^{24}\) http://www.cdc.gov/mmwr/volumes/65/wr/mm6502e1.htm
Professor Chris Baggoley, the CMO, answered questions about the role of AHPRA during the Senate Estimates session in October 2015. Professor Baggoley stated:

"The issue of doctors being warned off is one that is particularly interesting, and it is one that I have spoken about with the chief executive of AHPRA, Martin Fletcher, on a number of occasions. I think that it is important. Just recently I discussed with him this issue of Lyme disease and I have discussed this with him over the years whether the medical board have a particular issue about Lyme disease or doctors who diagnose it. I think that it is very important that I make their viewpoint clear.

As he pointed out to me on Monday, the role of the Medical Board of Australia is to protect the public, and the board only imposes conditions on the practitioner's registration to keep the public safe. The Medical Board of Australia does not set clinical standards or adjudicate on the treatment of specific conditions. The board does not have a position on Lyme disease in Australia or any disease or treatment regime. The board expects medical practitioners to work within their level of competence, training and experience, and to comply with all relevant laws and with its code of conduct—good medical practice.

The conditions imposed on the registration of any individual medical practitioner are always specific to that practitioner. They do not reflect the board's view about any disease state or treatment regime. That has been a constant position. The board does not have a position on Lyme disease; it does not have a position on doctors who diagnose or treat Lyme disease.

In the following section we set out the specific conditions placed upon the three doctors. While we appreciate that AHPRA have an oversight role to protect the public, it is difficult to reconcile the statements made by Professor Baggoley with the actions of AHPRA through the conditions that have been placed on the practice of these doctors.

The conditions placed upon Dr Andrew Ladhams on 20 December 2013 illustrate the targeted nature of the concerns. An excerpt:

1. For the purposes of these conditions, Lyme Disease includes any illness caused by an organism known as Borrelia burgdorferi (including any strains of that organism, namely Borrelia garinii, Borrelia afzelii and Borrelia Burgdorferi (stricto sensu)).

2. The practitioner must not diagnose and/or treat Lyme disease without his having obtained a positive diagnosis of Lyme Disease from a laboratory accredited by the National Association of Testing Authorities (NATA) using Centres for Disease Control (CDC) criteria.

3. The practitioner must not treat any patient for Lyme disease with intravenous antibiotics without having referred the patient to an Infectious Diseases Specialist for the development of a written Medical Treatment Plan. Before referring any patient to an Infectious Diseases Specialist, the practitioner must first obtain the approval of the Medical Board of Australia to refer patients to that specialist for that purpose.26


26 For full conditions placed on Dr Ladhams see: http://www.ahpra.gov.au/Registration/Registers-of-Practitioners.aspx?q=ME0000954625&t=B3fwUu70YMF9Ct2Abv
Condition 1 is at odds with that espoused by the DoH who define Lyme disease as only *B. burgdorferi*; yet the Medical Board of Queensland, responsible for the conditions, have made their own interpretation of what constitutes Lyme disease.

Condition 2 also overreaches in its prescription of the diagnostic criteria required to declare a positive result. We question the validity of using the CDC criteria that is established for surveillance in an endemic country in the section C 1. *The historical context for diagnosis and the emergence of the two-tier test*.

Condition 3 is confounding. Internationally, intravenous (IV) antibiotics are the recommended treatment for people with serious cases of Lyme disease as set out in both the sets of guidelines discussed in the section F 2. *The treatment of patients with Lyme-like illness*. In Australia we have no treatment guidelines so doctors are left only with overseas recommendations on treatment. This condition is so limiting that this doctor cannot even refer an ill patient to a specialist without permission; it completely interferes with this doctor’s ability to perform his role.

The Committee might consider exploring in how many other diseases a general practitioner requires the permission of the state’s Medical Board for a patient to be referred to a specialist.

The conditions placed upon Dr Du Preez are also specific to the diagnosis and treatment of Lyme disease and Lyme-like illness. They require the doctor to refer any patient onto an infectious disease specialist or a specialist pathologist: An excerpt:

1. *The Registrant will not treat patients with a diagnosis, or suspected case, of Lyme disease, without prior consultation with, and direction by, a specialist microbiologist or specialist infectious diseases physician registered in Australia.*

2. *Should a patient present with a diagnosis, or suspected case, of Lyme Disease, the Registrant will refer the patient to a specialist microbiologist or specialist infectious diseases physician registered in Australia.*

More recently, Doctor Geoffrey Kemp has undergone conditional restrictions and was given until 23 March 2016 to secure a position in a group practice or he will have to retire from his practice of 50 years. The complaint made against Dr Kemp was in relation to a patient who had been diagnosed with MS. The conditions placed upon Dr Kemp are in relation to his prescribing practices: An excerpt:

2. *is to only prescribe medication in accordance with the Australian Therapeutic Guidelines.*
3. *is to comply with Good Medical Practice in accordance with the Medical Board of Australia’s Code of Conduct for Doctor’s in Australia (effective from 17 March 2014).*
4. *is not to use homeopathic medicine.*

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The conditions placed upon Dr Kemp are especially concerning as they relate to the type of medication that he can prescribe. According to the Australian Therapeutic Guidelines (ATG), no doctor is safe in prescribing the internationally recommended antibiotics covered under the Pharmaceutical Benefits Scheme AND operate within the ATG’s. For further discussion on this particular issue, see section F 2.2. The antibiotics used in the treatment of Lyme-like illness.

The small handful of doctors who are treating patients in Australia are being bullied and badgered from within their profession and also by AHPRA. It’s probable that any Australian doctor that chooses to treat Lyme-like disease will be investigated, given that they administer antibiotics for a longer period of time than the one month treatment protocol and operate outside the ATG’s. Further these doctors are not confident in referring patients onto an infectious disease specialist, given that Australian infectious disease specialists have a history of misdiagnosing, blatant discrimination, or outright withholding patient treatment.

This adds to the stigma surrounding the disease.

We’ve heard many anecdotal reports of Australian doctors who have stopped treating Lyme-like disease for fear of retribution. This reduces the number of doctors who are willing to take a risk and provide proper treatment and care for those who have tested positive for the disease. When Australian doctors feel intimidated by the surveillance and remove themselves from treating Lyme-like patients the problem is exacerbated for those doctors who remain committed.

On behalf of Lyme patients Senator John Madigan raised these issues with AHPRA and has ‘lashed out at the medical profession’s bullying of doctors treating patients with suspected Lyme disease’.30 In Senator Madigan’s words ‘this campaign of harassment and bullying is creating medical refugees out of thousands of sick Australians who now can’t obtain treatment or who must go overseas to do so’.

Due to the heavy handed medico-legal approach to these doctors, and the associated threats that permeate the medical profession, many doctors will not even consider a Lyme diagnosis in a patient who presents with typical signs and symptoms. We should not underestimate the impact that dogged fixation on Lyme disease and pursuance by AHPRA has on the doctors concerned. Reflecting on a similar situation in the USA Dr Kenneth Leigner, in his letter to Congressman Gibson notes that ‘even if a physician prevails in an encounter with a state medical board or exits with minimal sanctions, traversing this tortuous and often prolonged administrative process can be an emotionally and financially draining ordeal and distracts the physician from patient care.’31

So far there has been little fight back from patients who are too ill to traverse the complicated system of medico-legal complaint making in Australia. However, the LDAA cautions that it is not prudent for the medical community to assume that a lack of action will continue. Patients are sick, they are getting sicker and they are fed up. They are assembling for class action and will soon start pursuing serious complaints about the medical practitioners who fail to treat them.


It’s difficult to make recommendations on how to reduce the medico-legal stigma when the watchdog itself, AHPRA, is under serious scrutiny with many questions raised about their effectiveness. The Committee would be aware that a Senate Inquiry into the administration of health practitioner registration by the Australian Health Practitioner Regulation Agency (AHPRA) has also been established.

Crickey recently reviewed the effectiveness of AHPRA and published an infographic that illustrates statistical data about their performance. For simplicity it is replicated here.

**Figure 9: Overview of AHPRA’s performance across key functions**

There were forty-four actions against practitioners that resulted in limitations to their registration across the 14 boards that AHPRA administers. In the case of Lyme disease, we have documented the limitations to registration on three Lyme treating doctors above; using that figure there is a disproportionate amount of Lyme practitioners as compared to all practitioners (across 14 disciplines of medicine) that make up the forty-four with limitations placed on their registration. As such, it is difficult to defend that Lyme treating doctors are not being unduly targeted.

AHPRA must be properly scrutinised on the way it accepts and investigates complaints made against practitioners. Our desk research into their disciplinary processes raised serious concerns about how complaints are investigated and in the selection and appointment of the ‘performance and professional standards panels’ who are assigned as adjudicators. These panels consist of at least three members, selected from a list of people approved by the National Board i.e. the Medical Board of Australia. Our desk research indicates that one representative of the Medical Board of Australia occupies a position of influence in the Royal College of Pathologists of Australasia (RCPA); the body responsible for the position statement on Lyme disease asserting the ‘no lyme here position’.  

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32 See Footnote 50
B 5.1 Methods to reduce the medico-legal stigma

Many international jurisdictions are enacting legislative processes to protect their doctors from medical complaints. The Canadian government is developing a national framework to address Lyme disease and recently passed the Federal Framework on Lyme Disease Act (Bill C-442). The USA Congress passed the S.1503 - Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2015. Several states in the USA have also enacted legislation to provide a better situation for patients and to protect the medical professionals who treat them.

In the continued absence of a public health strategy that addresses the issues Lyme disease and Lyme-like illness in Australia the Committee should consider a recommendation that prioritises a legislative response.

B 3. Reducing the ignorance based stigma through education

In 2013 we responded to the DoH's Scoping Study. Our response included a Strategic Action Plan that listed all the activities to underpin a public policy response to this growing epidemic.

Despite claims to the contrary, there has been a serious lack of action. There is no comprehensive public policy response to the problem and no interim solution. When a Hendra, Ebola, or Zika virus response can be rolled out in a matter of weeks, it is inexcusable and totally inadequate that people with a Lyme-like illness are abandoned into a medical no man’s land and are left with a treatment burden that they are ill equipped to manage (see section F 3. The treatment patients received from medical professionals). The facts are that even acute Lyme disease acquired overseas is poorly recognised in Australia by doctors and we still have no official data to indicate the extent of the problem.

The current lack of official and factual information on Lyme-like illness is a concern. Our survey data shows that patients learn about Lyme disease and associated illness primarily from the media or our own website; not from any official government source.

**TABLE 2: HOW PEOPLE LEARN ABOUT LYME DISEASE**

<table>
<thead>
<tr>
<th>How did you learn about Lyme disease?</th>
<th>0</th>
<th>50</th>
<th>100</th>
<th>150</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>Social media / website</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Media article</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local Lyme disease event</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>World Wide Lyme Protest</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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While our survey data is limited to people who have been diagnosed with Lyme disease, our social media reach tells a different story. A single informative post from us can reach up to 160,000 people. Our social media page receives an average of six messages / visitor posts every day, mostly from persons seeking information and assistance to find a doctor or navigate pathology testing. Apart from the handful of volunteer run websites, there is little information out there and certainly no coordinated preventive information.

To help diffuse the stigma, we recommend the Committee consider calling for a broad education campaign that includes:

1. Mandatory education for all health professionals concerning Lyme and tick-borne infection that includes diagnosis, signs, symptoms and types of treatment with requirements for continuing education as more research emerges;
2. Public dissemination for prevention and awareness;
3. Occupational education for outdoor workers; and
4. Prioritisation of funding and fellowships for researchers.
(C) TOR 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

In Australia the process for diagnosis of patients with a Lyme-like illness has been clearly set out in the Australian Government guidelines on the diagnosis of overseas acquired Lyme disease/Borreliosis (the Guideline). The Guideline was published in 2015 after more than a year of deliberations. It outlines its purpose, describes the criteria needed to support a confirmed case of Lyme disease, and provides some treatment guidance. It underpins the decision making framework for doctors.

The Guideline acknowledges its own limitation, in that it specifically excludes locally acquired Lyme-like illness; in fact there is a whole paragraph that covers the disclaimer. In the absence of any official information about diagnostics for the patient who hasn’t travelled overseas but also has all the carefully described symptoms, doctors will refer to this Guideline and follow its recommendations set out in the flow chart (p.2 of the guideline document). It recommends that patients be ‘referred for testing for tick-borne infections in Australia (Lyme disease is not an Australian tick borne infection)’. To do otherwise might place the doctors who treat patients under scrutiny, or disciplinary action. As such, an examination of the Guideline is warranted.

C 1. An examination of the Australian guideline on the diagnosis of overseas Lyme disease / Borreliosis

The Guideline opening sentence states ‘While classical Lyme disease cannot be acquired in Australia, patients may present who have travelled through endemic areas’. Referring to our earlier discussion on nomenclature and influence, this immediately reinforces the conclusion there is no Lyme disease in Australia, despite emerging evidence to the contrary (see D 3. Murdoch University - Molecular toolkits to investigate zoonotic tick-borne pathogens). The Guideline requires epidemiological evidence AND clinical evidence AND definitive laboratory diagnostic evidence before a doctor can confirm a case of Lyme disease.

The Guideline was developed as part of the Diagnostic Pathway Working group under the CMO’s Clinical Advisory Committee on Lyme disease. The LDAA’s patient representative raised concerns about the Guideline that remain valid today. These are outlined below:

1. A case definition for Lyme disease acquired overseas in the USA and in Europe already exists. It is unclear why the DoH attempts to redefine overseas acquired Lyme disease that differs from the well-established case definitions in countries where Lyme is endemic and there is vastly more clinical and laboratory experience than exists here;

2. It ignores the pathognomonic rash that occurs in classic Lyme borreliosis;

3. The criteria used to deem a test positive when interpreting reactive bands on immunoblots is not standardised; the Guideline must define the criteria (see b). Lack of defined diagnostic criteria for immunoblot tests;

4. The requirement that an Immunoglobulin G (IgG) and Immunoglobulin M (IgM) response be detected in both an immunoassay and an immunoblot (the two tier process) does not recognise that Lyme disease causes immune dysfunction. Isotype switching from IgM to IgG does not occur in all patients (see c). Impact of immune dysregulation and diagnostic limitations;

5. In describing the clinical evidence disease stages, it is unclear why the DoH failed to include the clinical manifestations of ‘untreated Lyme disease’. The majority of Australian patients have long term infections that have not been properly diagnosed or treated, or in fact have been undertreated, resulting in a chronic status of infection. There already exists much controversy over the existence of ‘chronic’, or ‘post treatment’ Lyme disease. It has nothing to do with delayed symptomology. These patients have had symptoms all along that have been dismissed or misdiagnosed;

6. The suggestion that Lyme Neuro Borreliosis (LNB) must be proven with an additional layer of highly invasive, expensive and risky tests like lumbar puncture is dubious and places patients who are severely affected at much greater risk. The clinical neurological manifestations combined with the earlier required serological test should be sufficient for diagnosis; and

7. Epidemiological evidence. It is difficult to understand where an Australian clinician will locate information about the endemicity of Lyme disease when only a handful of organisations produce such data. Similarly, it is imprudent to expect that a clinician has either the time or research skills to determine epidemiological factors of Lyme disease when there is such categorical denial of its possible existence in Australia. Any clinician who did conduct their own research into the dispersal of tick vectors in Australia to determine what might be interpreted as epidemiologically relevant would no doubt arrive at the Sydney University Medical Entomology pages,36 and be informed that there is no such ‘Ixodes’ tick competent to transmit Borrelia in Australia and so their patient would again be misdiagnosed.

The concerns we raised in the working group remain valid and underpin further diagnostic and pathology testing points set out in this section of the Submission.

In summary there are several issues that are interrelated and require explanation; these are discussed in the following order:

a) Historical context for diagnosis and the emergence of two tier testing;

b) Lack of defined diagnostic criteria for immunoblot tests; and

c) Impact of immune dysregulation and diagnostic limitations.

a) The historical context for diagnosis and the emergence of the two-tier test

To understand the controversies that surround diagnosis of Lyme disease that specifically relate to diagnostic testing, it is important that the committee are made aware of the historical context and how the recommended two-tier testing method first came about.

This is best explained by Doctor Kenneth Leigner, an international expert on Lyme disease with more than 25 years of speciality in the area. In his 2012 letter to Congressman Gibson, he provides an outline of the statement he provided the New York State Assembly Committee on Health hearings on Lyme disease. Within his statement Dr Leigner notes the USA CDC has maintained that Lyme disease is necessarily a ‘clinical’ diagnosis, with support from the laboratory. However, for epidemiologic and surveillance purposes case and laboratory definitions were developed. The CDC made clear that failure to satisfy the epidemiologic case definition did not negate a clinical diagnosis of Lyme disease (p.4 of Leigner’s letter.).

To establish the surveillance criteria, the 2nd National Conference on Lyme Disease Testing, held in Dearborn, Michigan in 1994, set official laboratory criteria for diagnosis of Lyme disease for epidemiologic case surveillance purposes. A two-tiered methodology was recommended with a screening test (Lyme serology or Lyme E.L.I.S.A. [acronym for Enzyme Linked Immunosorbent Assay]) followed by IgM and IgG Lyme Western blot.

The ELISA screening test, required under Australian Guideline, is estimated to be only 50% sensitive, making the two-tier approach inappropriate. Both Coulter et al (2005) and Wojciechowska-Koszko (2011), support this notion. As such, 50% of patients will fail to progress to the more sensitive Western blot test and their disease will be dismissed.

If a patient tests positive in the ELISA, a Western blot follows. Under CDC criteria, a positive IgM Western blot result requires presence of 2 out of 3 particular bands and a positive IgG Western blot requires 5 out of 10 particular bands - see Table 3: CDC surveillance criteria - bands required for Western blot positive result, for outline of bands. The CDC excluded two important bands from their criteria at the Dearborn meeting; these were the 31 kiloDalton (kDa) band and the 34 kDa band.

Leigner’s testimony notes ‘One of these bands was the basis of a Lyme disease vaccine developed by SmithKline Beecham (the 31 kDa band). As it happened, the SmithKline Beecham vaccine, LymeRix, was withdrawn from the market. Perhaps it was thought it would be too confusing to include the 31 kDa band in the Western blot criteria when it was thought large numbers of persons might have been vaccinated’.

The conclusion drawn by Leigner, is that ‘omission of these two highly specific bands has needlessly diminished the sensitivity of the Lyme Western blot as a diagnostic tool since most labs do not test for or report antibodies to the 31 and 34 kiloDalton bands’ (p.5.)

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38 Ibid.
Leigner further notes that the ‘CDC never intended failure to satisfy the stringent case surveillance laboratory criteria to rule out a diagnosis of Lyme disease’. Yet the criteria established by CDC for ‘surveillance’ purposes has become the standard for determination of Lyme disease by insurance agencies and the general medical community in the US. The adoption of the CDC ‘surveillance’ criteria in the Guideline imports this problem to Australia. The utility of applying other countries epidemiological surveillance criteria in Australia, in the absence of the LymeRix vaccine (and therefore the disqualifying bands), is highly questionable.

The Committee might consider inquiring into the decision making that established this situation.

**b). Lack of defined diagnostic criteria for immunoblot tests**

The Australian Guideline states ‘A positive diagnosis can only be achieved with a reactive screening immunoassay and sufficient number of reactive bands in an IB’, yet fails to identify what a ‘sufficient number of reactive bands’ should comprise. The Guideline must make clear the precise diagnostic criteria to be applied in determining a positive or a negative result.

The LDAAs response to the DoH’s Scoping Study preceded the development of the guideline. Our response highlighted that two of the existing National Association of Testing Authorities (NATA) accredited laboratories commissioned to perform immunoblot tests for Lyme disease use different criteria to determine the outcome of the test. One lab uses CDC criteria set out in Table 3, the other lab uses the less stringent European criteria; this is indefensible. Without these clarifications it is anybody’s guess on what actually constitutes a positive result under the Guidelines. This is a gross

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*Table 3: CDC surveillance criteria - bands required for Western blot positive result*

<table>
<thead>
<tr>
<th>Bands</th>
<th>CDC surveillance criteria for Western blot</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IgM</td>
</tr>
<tr>
<td><strong>Required</strong></td>
<td></td>
</tr>
<tr>
<td>18kDa</td>
<td>2 of 3 bands</td>
</tr>
<tr>
<td>21kDa</td>
<td>Y</td>
</tr>
<tr>
<td>23-25KDa</td>
<td>Y</td>
</tr>
<tr>
<td>28kDa</td>
<td>Y</td>
</tr>
<tr>
<td>30kDa</td>
<td>Y</td>
</tr>
<tr>
<td>31kDa</td>
<td>excluded</td>
</tr>
<tr>
<td>34kDa</td>
<td>excluded</td>
</tr>
<tr>
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</tr>
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<td>41kDa</td>
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<tr>
<td>45kDa</td>
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<td>Y</td>
</tr>
<tr>
<td>83-93kDa</td>
<td>Y</td>
</tr>
</tbody>
</table>

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39Table developed from CDC, Notice to Readers Recommendations for Test Performance and Interpretation from the Second National Conference on Serologic Diagnosis of Lyme Disease [http://www.cdc.gov/mmwr/preview/mmwrhtml/00038469.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/00038469.htm)

40 Attachment A, p.28 – Figure 2: Comparison of test processes
oversight and requires urgent explanation as Australian patients are being denied proper diagnostic care and treatment on the basis of these inadequacies.

c). Impact of immune dysregulation and diagnostic limitations
A further complication arises in serological tests that rely on the patient mounting a proper immune response and producing antibodies that can be measured. If doctors are relying on the detection of an immune response and the development of antibodies, a large capacity for error arises given that a proper immune response does not occur in all patients.

Dr Leigner (in his letter to Congressman Gibson, 2012) suggests that the relevance of IgM reactivity has been arbitrarily dismissed in late stage disease. He further notes, the ‘Development of IgG antibodies is characteristic of old or healed infection for many illnesses which are rapidly vanquished by patients’ immune systems. A subset of patients with Lyme disease do show fully diagnostic IgG Western blots. However, another subset of patients, some of whom exhibit signs and symptoms of chronic Lyme disease demonstrate a preponderance of IgM reactivity, often with an expanded pattern of highly relevant bands. This implies long exposure of the immune system to the organism and ongoing antigen-presentation as would occur with a chronic persistent infection. Some authors have noted IgM reactivity late in active disease’.

For example, Table 4 shows a four-year history of repeated immunoblot tests, from the same lab for a single Australian patient. While the utility of applying the the CDC surveillance criteria is questionable in the Australian context, the results show how immune responses change over time and may prove to be the most unreliable test method for the determination, or otherwise, of Lyme disease.

**Table 4: Longitudinal patient results showing diversity of bands**

<table>
<thead>
<tr>
<th>Date</th>
<th>10/3/09</th>
<th>7/2/10</th>
<th>7/2/11</th>
<th>20/4/12</th>
<th>4/12/12</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>B. Burgdorferi</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18kDa</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>IgG</td>
<td>Y</td>
</tr>
<tr>
<td>21kDa</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>IgM</td>
<td>-</td>
</tr>
<tr>
<td>23-25kDa</td>
<td>Y</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>-</td>
</tr>
<tr>
<td>30kDa</td>
<td>-</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>31kDa (ex.)</td>
<td>Y</td>
<td>-</td>
<td>-</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>34kDa (ex.)</td>
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<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>39kDa</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>41kDa</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<td>83-93kDa</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

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

Doctor Mualla McManus, founder and Director of the Karl McManus Foundation, also reports the interpretation of indirect diagnostic test, like those performed under the two-tier process advocated in our guidelines, is complicated due to immune dysregulation (McManus & Cincotta, 2015). They provide insight into the process of how immune dysregulation occurs with *Borrelia* infection. In
Table 3 of their in press paper, *Effects of Borrelia on host immune system: Possible consequence from diagnostics*, each of the limitations of the indirect diagnostic tests is outlined.

For patients, the outcomes of these limitations are very real. Consider the reality of what is occurring here from the perspective of the patient.

... a 5 year old has been bitten by a tick and develops a round red raised rash, with concentric rings (a typical Erythema migrans (EM)). Her parents visit their local doctor who recommends testing. The parents do not consent to EM biopsy due to its invasiveness, preferring a simple blood test. Their doctor orders serology. An ELISA is positive but the immunoblot fails to provide any positive bands. The child is not diagnosed with Lyme disease and remains untreated while the infection disseminates through her body resulting in late stage Lyme as her health deteriorates.

C 2. Pathology testing in Australia produces discordant results
The DoH acknowledges that there are discordant issues with Australia pathology tests. However these results are consistently relied upon to justify the non-Lyme stance.

The Australian laboratories accredited to test for *Borrelia*, test for only three strains. No laboratory in Australia tests for strains more likely to be found in this region, for example *B. miyamotoi*. The DoH advises that ‘commercial in vitro assays for *B.miyamotoi* are not widely available’, but assures us that ‘pathologists will communicate with overseas experts if they deem it necessary’. A full listing of all *Borrelia*, as known today, is included at Table 9: Listing of known *Borrelia* species in the Appendix of this document. It highlights the inadequate situation we have when we rely upon pathology tests that have known limitations which are further limited by the narrow selection of strains we can actually detect.

Compounding the issues of limited strains in NATA accredited testing, the test kits used in Australian government laboratories are not standardised. Each laboratory uses commercially-produced Lyme test kits whose accuracy and reproducibility of results are acknowledged by the DoH to be generally poor (Mackenzie, 2013). The LDAA raised this issue in our Response to the Scoping Study more than two years ago. Alarmingly the product data accompanying the commercial test kits cautions that the ‘negative results should not be used to exclude Lyme disease’ and that ‘the diagnosis of Lyme disease must include careful clinical evaluation and should not be based upon the detection of antibodies to *B. afzelii/garinii/burgdorferi* alone; a negative interpretation does not exclude the possibility of infection with *B. afzelii/garinii/burgdorferi*.

In July 2014 the DoH committed to look into the ‘discordant results’ from Australian laboratories and...
have recently funded the National Serology Reference Laboratory (NRL) to compare the different serology assays used in Australia (see further discussion in D 5, Research recommendations). More than one year later the DoH reports the NRL project is just commencing and ‘results will be published in a peer reviewed medical journal’.\(^{47}\) 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.

Until further research determines the causative agent for Lyme-like illness is Australia, the European guidelines should be applied simply because they cover both the US and European strains of *Borrelia*. Through application of the European guidelines, whereby two or three bands denote a positive (depending on which bands are shown), it would be evident that up to eight times more patients would have tested positive on the immunoblot testing performed at Westmead laboratory.\(^{48}\)

Drawing from the Westmead data, between 1994 and 2012, it was calculated that this would represent between 300 and 690 patients who may have tested positive by applying the more relevant European guidelines. In a 2012 paper, Westmead acknowledges that over 900 samples might have been classified positive, but quote 71 (or 4% of total specimens) are reported as positive because of the ‘required five or more specific IgG bands’.\(^{49}\) This does not take into account false negatives as a result of Westmead testing not considering *B. garinii*.

On a single lab’s testing figures there are likely to be hundreds, if not thousands, of patients whose serum has been subjected to inadequate testing procedures. This is especially in regard to tests with low sensitivity and using outdated solutions or employing inaccurate commercial test kits. To highlight further diagnostic hurdles, any positive results are then subject to further degradation because they are measured against stringent surveillance criteria designed for another country.

There is currently no Quality Assurance Program in place to address these testing issues.\(^{50}\)

**C 2.1 Indirect test methods are unreliable in patients whose immune system is compromised**

We have already established that there is an issue with immune dysregulation. Yet the Australian Guideline mandates the two-step method be used which relies on a functioning immune response. Not all patients mount an appropriate immune response to a *Borreliosis* infection, requiring and applying an antibody test to such individuals is unlikely to be effective. Lack of an antibody response should not be unilaterally interpreted as an absence of the disease.

It should be noted that these tests are all Medicare funded and therefore could provide a reliable data source. However, without government input it is unknown how many of these kinds of tests are run, how much they cost, and whether there is any reporting or monitoring of these tests and their result in any health department in the country.

During the Chronic Disease Inquiry,\(^{51}\) committee member Jones asked about the testing that picked up *Borrelia* relapsing fever in the Murdoch University Study in 2015. Dr Stephen Graves, pathologist

\(^{47}\) Ibid. SQ15-000759, Supplementary Budget Estimates, 21 October 2015  
\(^{50}\) The Royal College of Pathologists of Australasia, Position Statement on Diagnostic Laboratory Testing for Borreliosis Lyme
and spokesperson on Lyme disease for the Royal College of Pathologists Australasia (RCPA), stated ‘We are using a grosser test that picks up the ones that we know are human pathogens’; omitting that these labs only look for 3 of a possible 55 strains of the Borrelia pathogen. We’ve already established that the chance of obtaining a positive result from current Medicare funded Australian laboratory tests is no better than coin toss odds.

Although they are yet to report their findings, a Sydney University researcher presented preliminary results at the Tick Borne Disease Conference in 2014. Shirvington (2014) reports 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; Wojciechowska-Koszko (2011) reports that only 55% of diagnosed patients returned a positive ELISA, 100% returned a positive Western blot.

During the Lyme disease Treatment Roundtable a representative from the Sonic Health Group, the main provider of the first screening test in the two-tier method, advised the roundtable of their testing numbers and results. At that time (May 2014) they reported they had performed 11,400 ELISA tests in the previous 5 years. Of those 279 of were POSITIVE, that’s a rate of 2.4%. Following the two-tier test process, 18 tests were Western blot positive. It should be noted here that 11,400 tests being requested by doctors who have some clinical evidence of Lyme-like illness is further evidence of the potential scale of the problem.

According to Australian patients who participate in our surveys, they are being diagnosed with Lyme disease on a combination of diagnostic tests and clinical symptoms; Figure 10 provides the data.

**Figure 10: Method of diagnosis in Australian patients**

<table>
<thead>
<tr>
<th>How were you diagnosed with Lyme disease?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood test, Clinical symptoms</td>
</tr>
<tr>
<td>Blood test</td>
</tr>
<tr>
<td>Clinical symptoms</td>
</tr>
<tr>
<td>Blood test, Bulls eye rash, Clinical symptoms</td>
</tr>
<tr>
<td>Bulls eye rash, Clinical symptoms</td>
</tr>
<tr>
<td>Bulls eye rash</td>
</tr>
</tbody>
</table>

Number of people n=696

---

Committee member Jones, House of Representatives Standing Committee on Health, Inquiry into Chronic Disease Prevention and Management in Primary Health Care, 18 September 2015.
C 2.2. Direct diagnostic test methods are a more reliable approach for patients

One Australian laboratory, Australian Biologics, uses a more direct test method. They isolate organisms via Polymerase Chain Reaction (PCR). This means that they locate the DNA of the organism instead of relying upon an often absent antibody. This specialist laboratory consistently identifies *Borrelia* in Australian patients. They also find *Borrelia* in animals and ticks. When they isolate sufficient amounts of the organism, they pass it to the Australian Genome Research Facility (AGRF) for sequencing. AGRF is a NATA-accredited lab, which consistently sequences organisms related to known strains of *B. burgdorferi*. This suggests that an indigenous strain of *Borrelia* may be present in Australia.

These findings are routinely dismissed because the original isolating lab is not NATA-accredited. The result is that the red tape issue of obtaining accreditation under the NATA system is elusive and until it is obtained, all results originating from this lab and the AGRF sequencing on them will be conveniently disregarded, further supporting the ‘no Lyme here’ position.

Despite the elusive NATA accreditation, Australian Biologics voluntarily participates in an internationally benchmarked and externally monitored quality assurance program; Quality Control for Molecular Diagnostics (QCMD). It is the largest independent external quality assessment organisation in the world and is used extensively by governments globally; but not ours. Australian Biologics submit their Borreliosis PCR to the QCMD process and report a 95% sensitivity and 100% specificity rate as validated QCMD. No NATA lab in Australia can provide this level of independent validation for their *Borrelia* testing services.

Australian Biologics began their NATA accreditation process about two years ago; it was rejected in November 2015 after long and extensive delays on the part of the accrediting body. The lab has since appealed the rejection and is progressing. The overly bureaucratic accreditation process has meant that these labs results will not be considered ‘adequate’ evidence that Lyme exists in Australia. This laboratory has over 350 positive test results with 31 patients who have never travelled overseas; the results are not accepted by the mainstream Australian medical fraternity. By CDC standards, Australia would be known as a Lyme endemic country on the basis of these results.

Until NATA accreditation is obtained, all results originating for this laboratory and the AGRF sequencing on them will be disregarded. The Committee might consider asking whether, upon NATA accreditation of Australian Biologics, the government retrospectively accept all positive tests?

C 2.3. Type of tests that return a positive result for Australian patients

Through our surveys, patients report the type of tests that form the basis of their positive diagnostic result.

Figure 11 show that ELISA tests, the first type of test in the two-tier process are one of the least reliable tests. It should be noted that at the time of the survey Elispot tests were relatively new and were not widely used. The utility of the Elispot test is being proven by InfectoLab in Germany, whose aggregated results are covered in the following section.
More recently patients have reported that they are now returning positive test results from the Australian Rickettsial Reference Laboratory (ARRL) in Geelong. From the LDAA’s participation in the CACLD, we were updated in July last year on the ongoing development of new testing at ARRL. However, those tests revolved around the newly discovered Neoehrlichia, with assays developed from the findings of the Murdoch Study (discussed in the section D 3. Murdoch University - Molecular toolkits to investigate zoonotic tick-borne pathogens).

Doctors are also confirming that tests carried out at ARRL are returning positive results for Borrelia testing where previously they hadn’t. The LDAA has been unable to confirm the number of tests, the test type and the positive results emerging from the ARRL, and ask that the Committee pursue the questions included at the end of this section.

C 3. The use of overseas laboratories in testing for Lyme disease in Australian patients

Australian laboratories who are accredited by NATA produce results which are acknowledged to be ‘discordant’. As a result, Australian doctors who treat Lyme-like disease regularly use overseas specialist laboratories. These laboratories routinely find Borrelia and other coinfections in Australian patients. However, the DoH presumed to justify not accepting the evidence of positive blood tests as overseas laboratory accreditations were not recognised in Australia.

The cost to a patient to test in an overseas laboratory runs into the hundreds of dollars if not thousands, depending on their level of illness. Due to the existing controversy and limitations of the local testing processes, patients are forced to endure the burden of cost and stress in sending their blood overseas.

Many patients have received positive test results from overseas laboratories and have been successfully treated on the basis of those results. However, it is normally an expensive and long road to a diagnosis as patients are first referred through the Australian recommended two-tier testing process. This invariably results in a false negative test result and for an untrained doctor, with little
knowledge of the testing conundrum; it often results in a consequential denial of a diagnosis, treatment and the abhorrent degeneration to a state of chronic disease for the patient.

If specialist overseas laboratories are effectively isolating the pathogens, it is essential that international coordination of testing is made a priority. An objective and credible identification of laboratories that are effective in isolating both locally and internationally acquired Lyme-like pathogens is required as a matter of urgency. Ideally tests undertaken in these laboratories would be covered by Medicare which also requires the laboratories have NATA accreditation.

Our aggregated survey data (2012 – 2014) shows that 57% of laboratory tests Australian patients pay for are conducted in overseas laboratories; see Table 5: Testing laboratories used by Australians. Of the tests reported in Australia, 66% of them are done through Australian Biologics; a non NATA accredited lab which means tests are personally funded by the patient.

**Table 5: Testing laboratories used by Australians**

<table>
<thead>
<tr>
<th>In which Laboratory have you tested positive to Lyme disease through a blood or other specimen test?</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Australian Laboratory</strong></td>
<td></td>
</tr>
<tr>
<td>Australian Biologics, Sydney</td>
<td>260</td>
</tr>
<tr>
<td>Australian Rickettsial Reference Laboratory, Geelong</td>
<td>30</td>
</tr>
<tr>
<td>Local collection centre</td>
<td>71</td>
</tr>
<tr>
<td>PalLMS, Sydney</td>
<td>20</td>
</tr>
<tr>
<td>University of Newcastle</td>
<td>3</td>
</tr>
<tr>
<td>Westmead Hospital, Sydney</td>
<td>6</td>
</tr>
<tr>
<td><strong>Overseas Laboratory</strong></td>
<td></td>
</tr>
<tr>
<td>IGeneX, Palo Alto, USA</td>
<td>396</td>
</tr>
<tr>
<td>InfectoLab, Germany</td>
<td>114</td>
</tr>
<tr>
<td>Blank / unsure</td>
<td>129</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1029</td>
</tr>
</tbody>
</table>

**C 3.1. Infectolab - Germany**

In late 2015 we asked Infectolab Germany, to provide some insight into the number of Australians being tested in their laboratory. Infectolab provided depersonalised data on 800 samples from Australian patients. In analysing that data we found:

- Nearly half (49%) of 718 *Borrelia* Elispot tests; 351 tests were positive or borderline for *Borrelia*;
- Of the 672 *Borrelia* Blot tests, 35% were positive or borderline for *Borrelia*; 235 Australians.

In addition to the *Borrelia* testing, 116 patients were positive for *Chlamydia*; 63 were positive *Ehrlichia*; 13 were positive for *Rickettsia*; 27 were positive for *Bartonella*; and 7 were positive for *Babesia*.

**C 3.2. IGeneX, United States**

To minimize shipping delays the LDAA stocks IGeneX test kits for Australian patients. As patients request test kits through IGeneX, we are advised to ship the kit to the patient in preparation for
testing. From the time we commenced this in 2012, we have shipped over 3,080 test kits to Australian patients or their doctors. As IGeneX do not keep data on test results by country, we do not know the number of those kits that have been used, however it should be recognised that people don’t generally go to the expense of requesting kits they have little intention of using.

It is incumbent on the government to establish the number of tests that are occurring outside of Australia as part of an epidemiological study.

C 4. The pathology accreditation process in Australia appears conflicted

The guidelines state that ‘testing should be performed in a laboratory which has Lyme disease testing in its scope of accreditation, and which is compliant with AS ISO 15189 Medical laboratories with particular requirements for quality and competence.’ The Australian Government and medical authorities routinely disregard pathology results that are not accredited by the National Association of Testing Authorities (NATA).

NATA are responsible for the accreditation of laboratories and pathology tests. They operate under a Memorandum of Understanding (MoU) with the RCPA. In 2014 the RCPA made a public statement denouncing the possibility of Lyme disease in Australia.\(^52\)

In their statement, the RCPA asserts that ‘No confidence can be attached to the results of such invalidated tests’ referring to laboratory test results from non-NATA/RCPA accredited laboratories in Australia and overseas. Despite the fact that many of the international laboratories are certified to international standards, as the pre-eminent pathology organisation, their view permeates the entire medical industry that routinely dismiss patients with positive international test results.

Currently, NATA is the only endorsed Australian assessment body for pathology accreditation.\(^53\) The LDAA highlighted the inconsistency and extreme bias in the RCPA’s stance on Lyme disease in our Response to the RCPA position statement on Lyme disease included in Attachment C. When the RCPA has been the agency most actively and widely promoting the position ‘there is no Lyme here’, this stance places NATA in a significant conflict of interest when called upon to exercise the impartiality and scientific objectivity required of their role in accrediting laboratories, particularly in relation to a laboratory which consistently isolates organisms that are species of *Borrelia*.

The LDAA asserts the current pathology regulation process appears conflicted when it comes to Lyme disease and Lyme-like illness.

C 5. International coordination of laboratory accreditation

In January 2016, new international pathology accreditation arrangements were enacted;\(^54\) this challenges the status quo for ‘Australia only’ testing. For some time NATA was not resourced to do international medical laboratory accreditation which prevented overseas laboratories from applying for NATA accreditation. However, in a significant development NATA applied for membership of the International Laboratory Accreditation Cooperation (ILAC) MRA in 2015 and in January 2016 it was finalised. This means that overseas laboratories meeting ISO standards for both their laboratory and medical testing are able to be recognised and accredited by NATA.

For example, Infectolab (Germany) regularly finds *Borrelia* in Australian patients. They are accredited by the German conformity assessment bodies DAkkS in accordance with ISO 15189. Australia has also adopted the medical testing standard ISO 15189. As DAkkS are a signatory to the ILAC MRA, NATA can now legitimately recognise the results from Infectolab.

We recommend the Committee call upon the government to acknowledge the evidence of Lyme-like disease found in the overseas Lyme specialist laboratories that operate under the MRA. Advice to clinicians should be immediately updated to inform them about retrospectively accepting overseas testing results.

### C 6. Other diagnostic tests that could aid in the detection of Lyme disease

With the limitations of indirect diagnostic methods, there are other diagnostic tests that may aid in the development of empirical evidence to support a diagnosis of Lyme disease.

#### C. 6.1. Single-photon emission computed tomography (SPECT) scans

A study undertaken in 1994 revealed that MRI results of late-stage Lyme sufferers were generally found to be normal; however, Single-photon emission computed tomography (SPECT) scans returned hypo perfusion in cerebral white matter in these patients (Fallon et al, 1994). This study was later supported by additional research noting that 51.4% of suspected Lyme patients had significant perfusion abnormalities (Fallon et al, 1997). These abnormalities were found primarily in the frontal and temporal lobes of 75% of the patients with researchers concluding that ‘these scans can be used to provide objective evidence in support of the clinical diagnosis’ (Donta et al, 2012).

A reported 75% of Lyme patients were found to return abnormal SPECT results. These abnormal results were found to be consistent whether a suspected Lyme patient had previously returned seropositive or seronegative results under CDC criteria (Donta et al, 2012).

These findings suggest that SPECT scans should be considered as a diagnostic tool for Lyme disease. More importantly, with the debate currently surrounding the accuracy of serology testing in Australia, SPECT scans would be beneficial in supporting a current clinical diagnosis. However, it follows that if SPECT scans were adopted doctors and radiologists would need to be appropriately informed and educated regarding SPECT investigations appropriate to Lyme disease. In line with the above findings, SPECT scans can also be used to monitor improvements. Consideration should also be given to initial diagnostic use, if a patient is already undergoing antibiotic treatment.

### C 7. Unanswered questions regarding pathology testing in Australia

Following the February 2016 DoH Senate Estimates hearing, Senator John Madigan submitted a series of Questions on Notice (QoN) seeking clarification around a number of pathology and testing issues. The questions are reproduced with the permission of Senator Madigan with answers expected to be published on 4 April:

1. Does the Communicable Disease Network Australia monitor Lyme disease testing and pathology outcomes? If not, who does?
2. How many people have been tested for Lyme disease (*B. burgdorferi, B. afzelii, B. garinii*) using ELISA tests that were Medicare funded, by year, since 2000?
3. How many of the number of Medicare funded ELISA tests were:

55 Personal correspondence with Senator Madigan’s office.
a) positive and referred for Western blot testing;
b) positive and not referred for Western blot testing;
c) false positive;
d) negative; and
e) equivocal.

4. If a Medicare funded ELISA test is reported as equivocal, what is the procedural action taken?

5. Which NATA accredited laboratories in Australia are testing for Lyme disease – including \textit{B. burgdorferi, B. afzelii, B. garinii} – by Western blot as part of Medicare funded services?

6. How many people were tested for Lyme disease using a Western blot? What were the results of the Medicare funded Western blot tests?

7. Individually, how much do an ELISA and a Western blot test cost:
   a) for the laboratory;
   b) for the patient; and
   c) what is the Medicare funded component?

8. Why do laboratories who provide Medicare funded Western blot tests, not report the full Western blot result by band?

9. Does the Australian Government have guidelines for the determination of a positive result on a Western blot test? If so, please state it.

10. How many and which bands are considered on a Western blot test for a positive diagnosis to be made? Who established that criteria?

11. Please state the type and manufacturer of all test kits used by the laboratories providing Medicare funded ELISA and Western blot tests for Lyme disease in Australia.

12. In October (Ref No: SQ15-000759), you reported that “The National Serology Reference Laboratory (NRL) has been contracted to evaluate laboratory tests used in the serological diagnosis of Lyme disease.” And that “the NRL project is commencing. Specimens are being collected. The results will be published in a peer reviewed medical journal.” It is inappropriate for outcomes of tax payer funded contracts to be delayed for publication in research journals, especially when the outcomes are of a public health interest. Patients cannot wait for an academic journal to go through its peer review process before they receive appropriate testing.
   a. Is the evaluation completed? If not, when will it be completed?
   b. Please list all the laboratories that were included in the NRL study?
   c. What is the outcome of the evaluation? If you cannot yet provide the outcome, when will it be made publicly available?

13. In October (Ref No: SQ15-000761) I asked about the different strains of \textit{Borrelia} being tested in Australia. You stated “Australian pathologists will routinely communicate with overseas experts in reference centres, e.g. the Centers for Disease Control and Prevention in the United States and arrange for testing if deemed necessary.”
   a. To date what, if any, other \textit{Borrelia} strains have made it into the Australian testing regimen?
   b. If there are none, when will emerging strains be added to the Australian testing regimen?

14. In the QoN (Ref No: SQ15-000762) the Department advises the interpretation of the results from overseas laboratories “are often at odds with the standardised criteria that are established by large agencies, like the Centers for Disease Control and Prevention (CDC), in the United States, as well as that overseas laboratory tests used in other centres in Europe for communicable
diseases. The criteria that are used need to be stringent, because they are criteria used not only for surveillance but also they assist with diagnosis.”

a. What are the interpretive criteria [state the number and specific bands] for a positive result on a Western blot test in Australia?

b. Which of these bands are used in Australia for surveillance?

c. How is surveillance conducted and by whom?

C 8. Diagnostic processes require urgent review

As demonstrated, there are numerous issues that surround the current diagnostic processes for Lyme disease and Lyme-like illness in Australia. In summary, our government:

1. Has endorsed the two-tier test method which was designed to support a surveillance system established for another country;
2. Focuses on testing for strains of organisms that are not typically found in the Asia-Pacific region and refuses to test for more than three strains;
3. Fails to define proper diagnostic criteria that can be consistently applied;
4. Dismisses the issue of immune dysregulation and expect all patients’ immune systems to respond identically;
5. Fails to address the limitations in the indirect testing processes it recommends;
6. Acknowledges there is a problem with discordant test results but fails to expedite a solution;
7. Allows opinion pieces from the bodies who purport to educate pathologists (i.e. the RCPA) to influence the debate without evidence or accountability;
8. Allows the denigration of overseas testing laboratories on opinion not evidence;
9. Fails to recognise there are serious problems with the integrity of Australia's accreditation and regulation authorities (e.g. RCPA, NATA);
10. Is slow to demonstrate any leadership on the international coordination of laboratory accreditation.

The handful of Australian doctors who treat the patients affected with Lyme disease rely on international laboratories that are recognised as world leaders in testing for the multiple pathogens that comprise Lyme disease.
(D) ToR evidence of investments in contemporary research into Australian pathogens specifically acquired through the bite of a tick and including other potential vectors

Contemporary research into Australian pathogens is primarily focused on a number of studies originating in Murdoch University, Western Australia in the School of Veterinary and Biomedical Sciences, under the auspices of Associate Professor Peter Irwin.

To date A/Prof Irwin has conducted several studies on tick-borne pathogens with findings that are relevant to this Committee. Each of these studies is discussed in this section.

D 1. Murdoch University - Investigations into Babesiosis

In 2012 the first reported case of an Australian with Babesia was published (Senanyake et al, 2010). A/Prof Irwin of Murdoch University participated in that discovery and confirmed the Babesia organism. Irwin shared further insights into that study in the May 2014 Lyme Disease Treatment Roundtable. He noted that there is no known vector for Babesia microti in Australia, and questioned how Babesia microti could turn up in a man that hasn’t travelled outside of Australia? The research conducted by Murdoch indicated that the Babesia microti found in this case was genetically isolated to the Babesia microti on Nantucket Island. Without epidemiological research this is unable to be explained.

Following the discovery of the first case of human babesiosis (Babesia microti) in an Australian man (Senanyake et al, 2012), A/Prof Irwin’s team embarked on a study into Babesiosis. Babesiosis is a tick-transmitted blood parasite infection of animals and is a common pathogen transmitted during the bite of a tick. Normally, in nature, Babesia parasites infect a wide range of domesticated animals (such as cattle and dogs) and wildlife such as small mammals like rodents. These creatures are infected when they are bitten by a tick carrying Babesia parasites, and the life cycle is completed when another tick takes a blood meal from an infected mammal. According to A/Prof Irwin, ‘Babesia parasites are very host-specific and are well adapted to their preferred mammals and ticks. However, humans can become infected by a Babesia parasite after tick bite, and when this occurs it is known as ‘human babesiosis’.

Patients who had tested positive for Babesiosis in overseas laboratories were invited via their medical practitioner to participate in the study by providing a blood sample for testing. A positive result confirmed Babesia infection; a negative result suggested that the patient was not infected with Babesia, but did not completely eliminate the possibility that they could have very low numbers of parasites in their body.

Patients who participated in this study received the outcomes of their test results in 2013; however there are no published papers from this study so the findings and conclusions are unknown.

The LDAA is unaware of the funding or investment arrangements for this study.

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56 Extract from patient consent forms for the Babesia study.
D 2. Murdoch University - Investigations into Lyme Borreliosis, Bartonellosis and Rickettsiosis

The Murdoch team, again led by A/Prof Irwin, conducted a second study into Lyme Borreliosis, Bartonellosis and Rickettsiosis. In this study patients who had been diagnosed with Lyme disease by their medical professional AND who had a close association with a dog or dogs, were invited to participate.

The intent of the study was to investigate the transmission of Lyme and other related pathogens in people who also had dogs, as people’s dogs are also often infected by the same organism. According to the patient consent form, this is because dogs, being ‘closer to the ground’ and having ready access to the undergrowth, are even more likely than their owners to be exposed to the vector ticks. Dogs are often regarded in these regions as ‘sentinels’ of infection; in other words, the dogs can act as an early warning of potential infection in humans in the area.

The study examined whether the dogs in the life of patients had been exposed to Borrelia and/or other pathogens that can also cause illness in people, such as Bartonella bacteria or Rickettsia (another bacterium-like micro-organism). Participating patients provided information about themselves and their dog(s) and provided blood samples from their dog(s). Patients also provided blood or tissue samples of their own.

The study used the Idexx Snap 4Dx test for the dog blood samples and initial results of the blood tests on the dog(s) were provided to owners. It provided information on whether a patient’s dog had been exposed to three bacterial organisms (Borrelia, Ehrlichia and Anaplasma) and whether the dog had heartworm.

Although the results of that study are in the process of being reported, A/Prof Irwin provided insights to the study during the May 2014 Lyme Disease Treatment Roundtable. He reported that no dog was positive for Borrelia via the Idexx Snap 4Dx test, or Western Blot (using 3 or more bands), however a considerable number of dogs (up to 40%) reacted with the whole Borrelia lysate. A/Prof Irwin hypothesised that this is a cross reactive antigen but they are yet to determine the cause of the cross reaction.

The LDAA is unaware of the funding or investment arrangements for this study.

D 3. Murdoch University - Molecular toolkits to investigate zoonotic tick-borne pathogens

In 2014 Murdoch University in Western Australia were awarded an Australian Research Council (ARC) Linkage grant to further their tick research program under the leadership of A/Prof Peter Irwin. The grant enabled the development of ‘a new molecular toolkit to investigate zoonotic tick-borne pathogens in Australia’. The research used molecular diagnostic techniques to address unanswered questions about potential tick-transmitted diseases of humans and companion animals in Australia. The study was intended to identify ‘hot-spots’ for tick-borne pathogens and identify areas of potential risk for humans.

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 (Gofton et al, 2015). 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 an Australian tick.

A significant discovery is that the *Borrelia* is hidden inside other organisms which make them very hard to detect using the current testing processes. This may provide an explanation for the ineffectiveness of current serological testing and sequencing. This breakthrough has the potential to halt the plethora of false negative pathology tests both in Australia and worldwide. According to Murdoch University the research provides new information about the bacteria associated with the Australian paralysis tick (*Ixodes holocyclus*) and their potential to cause disease in people.

In a second report, A/Prof Irwin’s team found multiple bacteria in Australian biting ticks (Gofton et al, 2015). 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’. Perhaps another reason Lyme-like disease is difficult to detect is because the pathogen is new and no one is actually looking for them.

**D 4. Historical evidence of Borrelia in Australia is systematically ignored**

The Murdoch University research findings add further evidence to the research published over the last fifty years demonstrating incidences of *Borrelia* in Australia. All of which has been ignored by the governments of the time in favour of a single research piece conducted by Russell & Doggett also in 1994. 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. A copy of the Queensland Health letter is included in the Appendix 1-Figure 26 to this submission.

The book *Bitten by the Bug* (Johnson), reports from 1988 to 1994 there were 4,372 local (NSW) patients tested for Lyme disease, many were treated with antibiotics and returned to good health. Historical data on this study and its outcomes has not been located, but the LDAA remains interested in uncovering the source of this data.

**D 4.1. The Russell and Doggett Study of 1994**

This study has been previously criticised by the LDAA and others for its dismissal of ‘spirochete like objects’ (SLOs) as ‘aberrant artefacts’. With the dismissal of these SLOs, no further research was conducted into what other pathogens might be found in Australian ticks. This single study has led to more than twenty years of denial of the existence of *Borrelia*, a ‘spirochete’. The LDAA have previously argued it is negligent to have concluded a tax payer funded research project without recommending that further investigation is required. Had further investigations been conducted into those SLOs we might have uncovered more pathogens with the potential to cause human disease.
It is interesting to note that the first report of the Murdoch University Study (3), outlined earlier reports 'Detection of *Leptospira inadai* during this study may explain the observation over twenty years ago of spirochaete-like objects (SLOs) identified by dark field microscopy of various tick species including I. holocyclus (Russell et al, 1994). It further highlighted that the SLOs shown in Figs. 1 and 2 from Russell et al. bear a strong resemblance to various *Leptospira* spp., including *L. inadai*. Further work isolating and imaging *L. inadai* from *I. holocyclus* is required to confirm this possibility'. The Murdoch researchers also note that the high prevalence of *L.inadai* in Australian paralysis ticks warrants further investigation.

According to the CDC, leptospirosis, caused by *Leptospira* can ‘cause a wide range of symptoms, some of which may be mistaken for other diseases.’

That means that this pathogen (*L.inadai*) which can cause life-threatening disease may have been transmitted to humans by Australian ticks for the last 20 years without any knowledge by doctors or the Australian public. Furthermore, the bacteria has been isolated in Australian ticks and reported in June 2015, and there has been no acknowledgment from the DoH and no action to highlight it as a public health concern. This is grossly negligent and irresponsible.

D 4.2 Other Australian studies

- Mackerras (1959) reported the isolation of *Borrelia* from Australian fauna including kangaroos, wallabies and bandicoots.
- McCrossin (1986) reported on ‘Lyme disease on the NSW South Coast’ in a letter to the Medical Journal of Australia.
- Rothwell et al. (1989) also reported on ‘Suspected Lyme disease in a cow’ in the Australian Veterinary Journal.
- Carley & Pope (1962) identified an Australian strain of *Borrelia* they named *B. queenslandica* isolated from wild rats.
- Wills & Barry (1991) assert more than a dozen Australians on the northern beaches of Sydney and in the Hunter Valley have acquired Lyme disease, as reported in a letter to the Medical Journal of Australia. In addition, it found 70 out of 167 Australian ticks were culture positive for *Borrelia*-like spirochetes.
- Hudson et al. (1994) reported on Lyme in the article ‘Does Lyme Borreliosis Exist in Australia?’ in the Journal of Spirochaetel and Tick-Borne Diseases. They proposed existence of an Indigenous form of Lyme disease based on data collected since 1991 and described the clinical presentations of *erythema migrans* (bullseye) rash, arthritis.
- Mayne (2011) reported on the ‘Emerging Incidence of Lyme Borreliosis, Babesiosis, Bartonellosis and Granulocytic Ehrlichiosis in Australia’.
- Mayne (2012) also provided evidence of *B.burgdorferi* genotypes in Australia obtained from erythema migrans tissue.
- Mayne (2015) reported in the International Journal of General Medicine that 54% of 500 Australian patients tested positive for Lyme disease.

57http://www.cdc.gov/leptospirosis/
D 5. Research recommendations

To date there have been several recommendations for the conduct of research into the pathogens that might be making Australians sick. The first of these originate in the outcomes of the DoH’s Scoping Study (Mackenzie, 2013). It recommended the following research:

- ‘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;
- Are Australian ticks competent to maintain and transmit *B. burgdorferi* s.l. genospecies, or other *Borrelia* species associated with relapsing fever?
- Does Australia have the best reagents 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’.

A further set of research needs were identified in the 2014 Lyme Disease Treatment Roundtable. These are summarised as:

- ‘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 GPs to compare if treatment with antibiotics demonstrates any improvement in patient outcomes’.

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**D 6. Other vectors**

Our surveys ask participants who recall a bite if they know what bit them. About 30% of patients don’t recall a bite, but of those who do they report that tick bite is most common.

**FIGURE 12: OTHER VECTORS**

![Graph showing the distribution of bites from different vectors](image)

**D 7. Options for contemporary research into Australian Pathogens**

Through the research of Murdoch University it is established that there are other pathogens that are transmitted through the bite of a tick. 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 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’.60

The LDAA recommend the Committee 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 for the following:

- research into the potential pathogens that Australian ticks carry;

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59 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.

60 Ibid.
• an epidemiological study that examines the habitant 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; and
• a tick borne disease research centre or CRC.
(E)ToR potential investment into research to discover unique local causative agents causing a growing number of Australian’s debilitating illness

As outlined in the previous section there has been little research on the causative agents that might cause disease in humans over the past twenty years. We have established the timeline of research, their findings, and the systematic rejection of those findings.

There have been repeated calls from both patients and the medical community for the clinical study of patients. The Brazilian government progressed in this way and was able to side step the derogatory stigma of Lyme disease by studying patients and disassociating the name of their syndrome from such.

In the Lyme Treatment Roundtable, Dr Rachel Welch stated that ‘We didn’t know what was going on at the beginning of the HIV epidemic and we don’t know what is going on here’, and called for clinical studies. In fact, it was a key point of the discussions (see D 5. Research recommendations in previous section). Now, nearly two years later we await the prioritisation of those studies.

Investment is what is required to progress research in this area, without it we will remain stuck in denial and more people will become ill and more patients will die. The DoH has published a whole page of information that defers the issue of research funding for Lyme disease and Lyme-like illness to the body within its Portfolio that is responsible - the National Health and Medical Research Council (NHMRC). It is very careful to note that the ‘Department of Health is not a research funding agency’ but fails to acknowledge its collective responsibility to deliver better health outcomes for all Australians.

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.

E 1. Investments into multiple sclerosis research total $2.75 million

As illustrated in Figure 5: Estimated cases per year - Lyme, Breast Cancer, HIV & MS the estimated number of cases for Lyme disease in Australia outstrip those of MS by twenty times. Since 2012, more than $2.75 million has been invested in research into MS. In the first announcement, the then Minister for Health Tanya Plibersek, announced $1.75 million would be directed to researchers at Monash University in Melbourne. According to the NHMRC, the grant is the ‘Australian component of international spending on the research in collaboration with USA funding body, the California Institute for Regenerative Medicine. The combined value of this international collaboration is more than $6 million.’ In 2013 the Health Minister announced another commitment to MS research.

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with a $1 million dollar grant to Multiple Sclerosis Research Australia (MSRA). The grant underpins collaborative research that in part focuses on methods to slow the progression of MS.63

E 2. International research to discover unique local causative agents
Earlier this year a new *Borrelia* species, *B.mayonii* was discovered by researchers at the Mayo Clinic in the USA (Pritt et al, 2016). Instead of testing ticks, the researchers tested over 100,000 diagnostic specimens from patients over 10 years. In the last two years of the study they detected six specimens with atypical PCR results. The six patients presented with varying symptoms that included fever, rash, neurological inclusion and knee pain and swelling; these symptoms differ from those of classical Lyme disease. They used multigene sequencing to identify the spirochete as a novel *B.burgdorferi* sensu lato genospecies, and then verified that the same genospecies could be detected in ticks collected at the probable patient exposure site.

E 3. Research to cover epidemiology of disease through the study of patients
The LDAA has maintained that studying patients will provide the most expedient pathway to a solution. A systematic review of the blood samples from existing patients with Lyme-like illness could be an important tool in identifying the etiological agent in Australia, as in the *B.mayonii* example discussed.

There are also other options for consideration.

In the USA a study being run by the Lyme Disease Organisation plans to use patient data registries to provide insights.64 They will be using data collected from thousands of Lyme sufferers across the USA. According to Johnson, President of the organisation, ‘the only way we are going to increase our understanding of chronic Lyme disease and be able to answer the important questions that directly impact patients’ lives is through big data projects like MyLymeData’.

Indeed there are already such data bases available that not only support patients but provide valuable symptom related research data as well. An example of this can be seen with the [www.patientslikeme.com](http://www.patientslikeme.com) website. Launched in 2005 it connects patients, improves outcomes and enables research. An example of the utility of the Patients Like Me site is included in Table 10: Patients Like Me website.

E 4. Recommendations to prioritise investments into research into unique causative agents in Australia
As noted earlier, all stakeholders associated with the Lyme-like illness in Australia are in support of progressing research. Professor Stocks, representative of the Royal Australian College of General Practitioners, summed this up well in his testimony to the Inquiry into Chronic Disease: “We recognise that in Australia there is a Lyme-like illness with no consistent causative organism, very little epidemiology, unstructured treatment and poor evidence about outcomes of current management. There is a great need for further research into what can be a very disabling condition for patients’.

64 https://www.lymedisease.org/johnson-tells-aaas-big-data-may-solve-lyme/
At the *Lyme disease Treatment Roundtable* Dr Matthew Dryden, Director of the NHS National Lyme Disease Referral clinic in the UK, acknowledged that ‘patients are undoubtedly unwell; and we need more research to support them as we haven’t got anything in conventional medicine that supports these patients’. He concluded that there is a ‘gulf between patients and the medical practice, we need to bridge the gap because patients have a definite problem that we are not addressing in conventional medicine, and we need to find a solution’. Dr Dryden highlighted the following needs:

1. More research with new technology, looking for unknown pathogens;
2. To look more closely at chronic illness, post infectious symptoms, immune dysfunction;
3. To find a therapeutic way of blocking the responses; and
4. To spend some money in sharing samples across the world for diagnostic reliability.

The LDAA concurs with these recommendations and note that through an epidemiological study of patients we might address the following questions:

1. Is the disease model different than other parts of the world?
2. Do we have enough in patient survey data to do journey maps and provide a deep image of the typical clinical picture of Lyme in Australia?
3. Are there clusters?
4. Investigation into other models of disease- local agent and vertical transmission?
5. Possible LDAA campaign to alert medical researchers to the Inquiry and subsequent opportunity to apply for research funding.
(F) ToR the signs and symptoms Australians with Lyme-like illness are enduring, and the treatment they receive from medical professionals

The situation for Lyme and Lyme-like disease patients in Australia is dire. Indeed it has worsened since our initial patient report in 2012 (at Attachment B). It is broadly accepted that people are unwell after the bite from a tick.

The stories of discrimination and stigma associated issues have been outlined in the response to ToR B, but there are many more that are unheard and unspoken because patients are too sick to tell their stories or too small to have a voice. The hundreds of submissions already lodged under this Inquiry tell of the heartbreaking issues that are faced by many patients. They also provide a highly detailed symptom overview of Lyme-like illness in Australian patients within the context of their lives. We look forward to the epidemiological data that should emerge from the submissions of patients who have taken the time to make a submission.

F 1. Signs and symptoms
There are many research papers and sources of data that provide detailed symptoms of Lyme disease; these are also outlined in our web pages.65 Typically Lyme disease is characterised in stages, with an early acute stage that follows a tick or other bite, before the bacteria has disseminated through a patient’s body. The later stage of Lyme disease is referred to as chronic or late stage and is usually marked by a progressive set of debilitating symptoms. Given the time it takes for Australian patients to reach a diagnosis for their Lyme-like illness (10.75 years – see Table 1: Length of time from bite to diagnosis) this means that the majority of patients are in the chronic / late stage disease.

It is of little value to the Committee to repeat the contextual details of the signs and symptoms already reported in the hundreds of submissions made by patients. Instead, we present the aggregated data of the surveys we have conducted that explore the symptoms of Australian patients. The data is an aggregation of all our surveys from 2012 – 2014.

In presenting a range of statements for ranking, respondents were able to provide a profile of the symptoms associated with Lyme-like illness. Figure 13 highlights the responses of 1,051 patients.

**FIGURE 13: COMMON SYMPTOMS OF AUSTRALIAN PATIENTS**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>When I first got sick I had flu like symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>When I first got sick I had a bulls eye rash</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Doctor(s) told me my symptoms were not related</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Doctor told me I had Chronic Fatigue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The initial treatment I received was more than 30...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My rash was documented with photos</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My rash was diagnosed as ringworm / spider bite</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I received treatment for a tick related rash</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Number of responses n= 1051

F 1.1. The complexity of symptoms with multiple pathogen infections

Emerging international research shows that Lyme disease is rarely ever found in isolation of other pathogens; our research supports that. In our earlier discussion on nomenclature we presented the image of a tick with the multiple organisms it might harbour. We discussed the limitations of the term Lyme disease and made note that it is being widely used as the catch all for a constellation of pathogens transmitted from ticks to humans. Typically these are referred to as co-infections, but they are individual and sometimes life threatening infections in their own right. As well as *Borrelia*, an infection from each of those pathogens increases the complexity in the type of symptoms patients actually endure.

The majority of patients report that, as well as their Lyme disease diagnosis, they have also been diagnosed with a number of co-infections. Only 20% of patients (183) report being infected solely with *Borrelia*; see Figure 14: Common co-infections reported.
FIGURE 14: COMMON CO-INFECTIONS REPORTED

![Bar chart showing common co-infections reported](chart_image)

It is well reported that multiple infections with more than one pathogen causes more severe and prolonged symptoms. To demonstrate the complexity of symptoms and organs involved Table 10 extracted from an article published by Berghoff in the Open Neurology Journal (2012) is included in Figure 15.⁶⁶

FIGURE 15: MANIFESTATION OF CHRONIC LYME DISEASE AND OTHER CO-INFECTIONS

Table 10.

<table>
<thead>
<tr>
<th>Disease</th>
<th>Symptomatology</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GenS</td>
</tr>
<tr>
<td>Lyme disease</td>
<td>-</td>
</tr>
<tr>
<td>Bartonellosis</td>
<td>-</td>
</tr>
<tr>
<td>T. endercolitica</td>
<td>(t)</td>
</tr>
<tr>
<td>M. pneumoniae</td>
<td>(t)</td>
</tr>
<tr>
<td>C. pneumoniae</td>
<td>-</td>
</tr>
<tr>
<td>C. trachomatis</td>
<td>-</td>
</tr>
<tr>
<td>C. jejuni</td>
<td>-</td>
</tr>
</tbody>
</table>

Y. enterolitica = Yersinia enterocolitica; M. pneumoniae = Mycoplasma pneumoniae; C. pneumoniae = Chlamydophila pneumoniae; C. trachomatis = Chlamydia trachomatis; C. jejuni = Campylobacter jejuni; GenS = general symptoms (fatigue, head aches, lassitude); MuSh = musculoskeletal symptoms (arthritis, arthralgias, myalgias); NS = symptoms of the nervous system (CNS, polyneuropathy, radiculopathy); Skin = skin lesions (erythema migrans, ACA in cases of Lyme disease e.g. infected skin injury); LA = lymphadenopathy; Heart = heart disease (myocarditis, cardiomypathy, pericarditis); Eye = eye disease (uveitis, conjunctivitis, optic neuritis); GI = gastrointestinal complaints; uG = urogenital symptoms; rA = reactive arthritis; GBS = Guillain-Baré syndrome; t = positive; (t) = presumption based on general symptoms in cases of yersiniosis and Mycoplasma pneumoniae infection; + = probably chronic infectious, hypothetical autoimmune origin (mimicry).

It is not unusual to see a significant range of co-infections reported in a single person. The results in Table 6 show a total of nine infections on top of Borrelia for this patient whose occupation meant they were exposed to ticks on a daily basis. In repeated testing over a four-year period you can only imagine the impact that these infections had on this patient’s immune system.

**TABLE 6: PATIENT DATA - CO-INFECTION TESTING**

<table>
<thead>
<tr>
<th>Testing Date</th>
<th>Date</th>
<th>10/3/09</th>
<th>22/4/09</th>
<th>17/9/09</th>
<th>9/7/10</th>
<th>7/2/10</th>
<th>9/12/11</th>
<th>21/4/12</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Anaplasma</em></td>
<td>1:40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Babesia duncani</em></td>
<td>1:20</td>
<td></td>
<td></td>
<td>1:40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Babesia microti</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1:160</td>
</tr>
<tr>
<td><em>Mycoplasma pn</em></td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Chlymadia pn.</em></td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Coxsackie virus</em></td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Barmah Forest V.</em></td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Rickettsia spotted fever</em></td>
<td>1:160</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Rickettsia typhus fever</em></td>
<td>1:160</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Bartonella henselae</em></td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Brucellosis</em></td>
<td>IgM Pos</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In addition to the co-infections of Lyme disease outlined in Figure 14, patients were asked if they had been diagnosed with any commonly reported conditions that are often associated with chronic Lyme disease. As Lyme disease affects most bodily systems it has the potential to mimic other illnesses, e.g. multiple sclerosis (MS), or contribute to some conditions e.g. Hashimoto’s Thyroiditis. It can also cause other symptoms like chronic fatigue. Commonly reported illnesses are outlined in Figure 16.

**FIGURE 16: OTHER CONDITIONS LYME PATIENTS ARE DIAGNOSED WITH**

There is considerable speculation that some patients with other degenerative diseases like Alzheimer’s, Amyotrophic Lateral Sclerosis (ALS), Motor Neurone Disease, Parkinson’s disease and
MS could be misdiagnosed. In fact, Dr Klinghardt, a specialist Lyme physician in the USA, tells us in *Under our Skin*, a documentary on Lyme disease, that he has ‘never had a patient with Alzheimer’s, ALS, Parkinson’s OR MS who tested negative for Borrelia’.

**F 2. The treatment of patients with Lyme-like illness**

Internationally, the process and guidelines for the treatment of Lyme disease is set out by two opposing organisations, the Infectious Disease Society of America (IDSA) and the International Lyme and Associated Disease Society (ILADS). Each organisation produces its own guideline. Usually infectious disease specialists adopt the IDSA guideline while doctors with experience in the diagnosis and treatment of Lyme disease prefer the more evidenced based ILADS guideline.

A comparison of the ILADS and IDSA treatment recommendations by clinical situation are published as supplemental material to the ILADS guidelines. The contention between the treatment guidelines recommended by the two organisations primarily relates to the length of time for prescribing antibiotics, and the existence of post treatment Lyme disease syndrome. Our Commonwealth DoH recommends IDSA guidelines in the Australian Guideline on the diagnosis of overseas acquired Lyme disease discussed earlier.

Until recently the IDSA guidelines were espoused to be the gold standard for Lyme disease treatment but they have recently been removed from the National Guidelines Clearing House as they do not meet the standards for evidentiary based medical guidelines. The IDSA guideline has been widely criticised and became the subject of an antitrust investigation instigated by then Attorney General of Connecticut, Richard Blumenthal.

According to the Connecticut Attorney General’s office, the antitrust investigation uncovered serious flaws in the IDSA process for writing the guidelines. It found shortcomings in the panel established to write the guidelines noting that several panellists had conflicts of interest. It found there was serious close minded thinking when the selection of scientists and physicians with divergent views was blocked. Needless to say the guidelines now have been removed yet the DoH Guideline does not reflect this change.

In the absence of any evidence base in Australia, doctors rely upon the international guidelines when they make decisions about their patients. This includes the type of antibiotics they use, the dose and duration of the prescription.

**F 2.1. Referrals to infectious disease specialists**

The Department’s 29 May 2015 online response to Lyme disease stated ‘in terms of access to treatment, GPs in Australia are able to refer their patients to specialist clinics at public hospitals. For example, in a case of suspected Lyme-like illness, an appropriate referral could be to the infectious diseases clinic at the local hospital. Outpatient appointments at public hospitals are free-of-charge to the individual. In Australia, infectious diseases physicians are the appropriate specialists to

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67 See Under our Skin documentary available from: [http://www.underourskin.com/#home-underourskin](http://www.underourskin.com/#home-underourskin)


69 [https://www.lymedisease.org/idsa-guidelines-removed-ngc/](https://www.lymedisease.org/idsa-guidelines-removed-ngc/)

support patients with questions and concerns about Lyme disease.\textsuperscript{71}

The reality of the situation is that infectious disease specialists are reticent to diagnose Australian patients with Lyme-like illness. This is well illustrated in the submissions made to the inquiry from infectious disease specialists. For those that are open minded and do investigate, they will be unlikely to find Lyme-like pathogens in patients because they rely upon the previously established problems with the two-tier method of testing. Further there are no treatment guidelines for locally acquired Lyme-like disease, and chronic Lyme disease is not recognised. This means that effective treatment is unavailable for many Australia patients from within the hospital system. Specifically, long-term antibiotics are an issue in Australia. But it is recognised by leading Lyme disease experts as the treatment needed to return the patient to health.

\section*{F 2.2. The antibiotics used in the treatment of Lyme-like illness}

As noted earlier, some doctors in Australia are having specific limitations placed upon their registration for prescribing antibiotics to treat patients with Lyme-like illness. In \textit{B 5. Medico-legal related stigma}, we established that these restrictions included the use of IV antibiotics and one doctor was ‘to only prescribe medication in accordance with the Australian Therapeutic Guidelines’.

It’s important that the Committee understand the actual ramifications of those conditions and what it means in practice. For example, the recommendations on the type of antimicrobial treatment from the now removed IDSA guideline that our government recommends is shown in Table 7: \textit{IDSA recommended treatment}.\textsuperscript{72}

The most common antibiotic used in first line defence for Lyme disease is Doxycycline; for children it is Amoxicillin. Depending on the severity of symptoms, other antibiotics like Cefuroxime and Ceftriaxone are sometimes used and IV is recommended.


TABLE 7: IDSA RECOMMENDED TREATMENT

Recommended antimicrobial regimens for treatment of patients with Lyme disease.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage for adults</th>
<th>Dosage for children</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred oral regimens</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>500 mg 3 times per day(^a)</td>
<td>50 mg/kg per day in 3 divided doses (maximum, 500 mg per dose)(^d)</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>100 mg twice per day(^b)</td>
<td>Not recommended for children aged ≤6 years</td>
</tr>
<tr>
<td>Cefuroxime axial</td>
<td>500 mg twice per day</td>
<td>For children aged ≥6 years, 4 mg/kg per day in 2 divided doses (maximum, 100 mg per dose)</td>
</tr>
<tr>
<td>Alternative oral regimens</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selected macrolides(^c)</td>
<td>For recommended dosing regimens, see footnote (c) in table 3</td>
<td>For recommended dosing regimens, see footnote (c) in table 3</td>
</tr>
<tr>
<td>Preferred parenteral regimen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>2 g intravenously once per day</td>
<td>50-75 mg/kg intravenously per day in a single dose (maximum, 2 g)</td>
</tr>
<tr>
<td>Alternative parenteral regimens</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cefotaxime</td>
<td>2 g intravenously every 8 h(^d)</td>
<td>150-200 mg/kg per day intravenously in 3-4 divided doses (maximum, 8 g per day)</td>
</tr>
<tr>
<td>Penicillin G</td>
<td>18-24 million U per day intravenously, divided every 4 h(^c)</td>
<td>200,000-400,000 U/kg per day divided every 4 h (not to exceed 18-24 million U per day)</td>
</tr>
</tbody>
</table>

\(^a\) Although a higher dosage given twice per day might be equally as effective, in view of the absence of data on efficacy, twice-daily administration is not recommended.
\(^b\) Tetracycline is specifically contraindicated in pregnant or lactating women and in children ≤1 year of age.
\(^c\) Because of the lower effective maxima, doxycycline may be preferred in women of child-bearing age for whom serum levels of the macrolides are limited.
\(^d\) Doxycycline should be used for patients with normal renal function.


Clinical Infectious Diseases

A desktop review of the online Australian Therapeutic Guidelines (ATG) (eTG Complete for Practitioners) highlights that none of these antimicrobials are approved for use in Australia for Lyme disease (Borrelia), despite their recommended use internationally. A further desktop review of the Australian Therapeutic Register of Therapeutic Goods (ARTG) the authority that establishes which drug may be used for which disease, sets out the specific indications in which drugs may be prescribed. For Doxycycline, the online public ARTG summary states:

Specific indications:

Infections caused by the following organisms: Mycoplasma pneumoniae (primary atypical pneumonia); Rickettsiae (Queensland tick typhus, epidemic typhus fever, Q fever, murine epidemic typhus fever, Australia-Pacific endemic scrub typhus); Chlamydia psittaci (psitticosis); Chlamydia trachomatis (lymphogranuloma venereum, trachoma, inclusion conjunctivitis). (Doxycycline is indicated in the treatment of trachoma, although the infectious agent is not always eliminated.) Ureaplasma urealyticum (nonbacterial urethritis). Inclusion conjunctivitis may be treated with oral doxycycline alone, or in combination with topical agents.

Borrelia (relapsing fever), Ehrlichia, Anaplasma, Mycoplasma, Chlamydia, Treponema pallidum (syphilis), Treponema pertenue (yaws), Neisseria gonorrhoeae (see Dosage and Administration). Doxycycline is not the drug of choice in the treatment of any type of staphylococcal infection or infections due to Streptococcus pneumoniae, Haemophilus influenzae, Streptococcus pyogenes. Streptococcus faecalis or any type of enterococcal bacteria because many strains of these organisms may have been shown to be resistant to doxycycline.

Doxycycline should not be used in these infections unless the organism has been shown to be sensitive. For upper respiratory infections due to group A beta-haemolytic streptococci (including pharyngitis of rheumatic fever), penicillin is the usual drug of choice. In acute intestinal amoebiasis, doxycycline may be useful adjunct to amoebicides. In severe acute, doxycycline may be useful adjunctive therapy. Doxycycline is indicated, in adults and children older than 10 years, as chemoprophylaxis for malaria caused by Plasmodium falciparum and, in combination with other antimalarial agents, against malaria caused by Plasmodium vivax. Doxycycline is only able to suppress malaria caused by P. vivax. As there are relatively few locations where P. vivax does not co-exist to some extent with P. falciparum, it is recommended that doxycycline should be used routinely with other agents, for example, chloroquine.

According to our combined health departments we don’t have ‘relapsing fever’ in Australia, although the novel species discovered at Murdoch University by A/Professor Irwin’s research team, is of the relapsing fever family.
A second common antibiotic used for the treatment of Lyme disease, as recommended by the CDC and the IDSA is Cefuroxime, known as Zinnat commercially. Yet the TGA makes no reference to its utility in vector borne disease at all.

A third common, and recommended antibiotic used in the treatment of more severe cases of Lyme disease, and generally taken as in IV, is Ceftriaxone. The TGA recommendation for this antibiotic states:

Dr Geoffrey Kemp, a Victorian doctor has just been effectively stopped from treating his very ill patient base, leaving them without adequate treatment. To prescribe any antibiotic at all to treat his patient he is in contravention of the highly inadequate and outdated ATG.

The current situation is that anyone presenting with a tick bite and with symptoms are meant to be referred to an infectious disease physician, who might order some pathology tests which are highly questionable in the Australian context. On the rare chance that a patient receives a positive test their doctor cannot be prescribe ANY of the recommended antibiotics and remain within the ATG, unless they prescribe with a private script, which has significant financial impact for the patient.

For about a hundred dollars, a 30-day course of Doxycycline can significantly alter the course of future debilitating disease if provided early. It should be noted that this is the same drug prescribed to people who are travelling as a preventive for Malaria. But any doctor prescribing it for suspected Lyme disease is likely to be operating in contravention of the ATG and will need to prescribe it on a private script. Meanwhile patients can and do become increasingly debilitated, they lose their jobs, their families their livelihood and end up costing the health system a lot more than a hundred dollars.

**F 2.3. Doctors treating Lyme-like disease fear retribution**

A handful of doctors have recognised Lyme-like symptoms in their patients and have commenced long-term treatment. They keep empirical evidence of the improvements in their patients and acknowledge that this is the only hope these patients have to achieve wellness. These doctors often
test their patients using specialist overseas laboratories as already described. These doctors educate
themselves through consultation with international Lyme disease experts and by attending national
and international conferences, which look at best practice approaches for treating the illness.

These doctors have legitimate concerns over the limitations that have been placed on others and
what that means for their own practices. It is probable that any Australian doctor that chooses to
treat Lyme-like disease will be investigated, given that they administer antibiotics for a longer period
of time than the approved one month treatment protocol, espoused in the now defunct IDSA
guidelines. These doctors are not confident in referring patients onto an infectious disease specialist,
given that Australian infectious disease specialists have a history of misdiagnosing, blatant
discrimination, or outright withholding patient treatment.

To date we have many anecdotal reports of Australian general practitioners who have stopped
treating Lyme-like disease for fear of retribution. This reduces the number of doctors who are willing
to take a risk and provide proper treatment and care for those who have tested positive for the
disease. When Australian doctors feel intimidated by the surveillance and remove themselves from
treating Lyme-like patients the problem is exacerbated for those doctors who remain committed.

If infectious disease specialists followed internationally recognised long-term treatment protocols,
showed Lyme-like patients some care and respect, were committed to reducing the symptoms of the
disease and could identify the disease through effective testing then Lyme-like patients would not
have to rely solely on scarce Lyme aware doctors for their diagnosis, long term treatment and care.
Doctors and patients alike would prefer to have infectious disease specialists in our hospitals that
are educated, compassionate and available to assist when the symptoms of this life threatening
disease escalate.

F 2.4. Patient data on treatment – are you currently on treatment
Our surveys ask patients about their treatment; 1,021 patients answered this question and 13%
(132) reported they were not undergoing treatment. We examined the free text answers provided
by patients who report they are not currently on treatment. A sample of what patients tell us:

- I took antibiotics for 5 weeks, starting 14 days after the bite. My blood might still be
  positive but I don't have any symptoms anymore
- I have severe chemical sensitivities and am unable to tolerate medication or antibiotics
- I'm trying to find a doctor who will be able to treat me
- I had to go off them because I am the carer for my husband who has chronic Lyme
disease and who is currently much sicker than me so we cannot afford the time or
money for me to continue treatment at present
- Cannot afford treatment for Lyme disease
FIGURE 17: NUMBER OF PATIENTS UNDERGOING CURRENT TREATMENT

F 2.5. For Australians with chronic illness, short term treatment isn’t effective

In the rare case that an Australian patient tests positive for a Borrelia pathogen, their infectious disease specialist will treat them with antibiotics for a month or less and tell them that their Lyme-like illness is cured. The infectious disease specialist will follow the IDSA practice guidelines, despite the fact they have been removed as they don’t meet the standard of evidence required for treatment guidelines.

In Australia this is rarely likely to produce any benefits for the patient. For those with chronic undiagnosed Lyme disease or Lyme-like illness, long term treatment is required for several reasons:

1. Medical practitioners will need to treat more than one pathogen;
2. Nearly all Australian patients reach chronic stage before they are even diagnosed – 10.7 year average time to diagnosis;
3. Lyme-like pathogens are hard to eradicate
   - Borrelia spirochetes cover themselves with a bio-film, a fibrous layer that protects them from antibiotics. Long-term treatment introduces drugs that breakdown biofilms so that the hidden spirochetes can be eradicated.\(^{73}\)
   - A recent study by Northwestern University also found that Borrelia forms dormant persister cells, which are highly tolerant to antibiotics. They recommend pulse dosing of antibiotics over time.\(^{74}\)
   - German scientists modelling Borrelia found that it “recovers from a strong initial immune response by the regrowth of an immune-resistant sub-population of the bacteria”. The chronic phase “appears as an equilibration of bacterial growth and adaptive immunity”. They note that their findings have major implications for the development of the chronic phase of Borrelia infections, as well as on potential protective clinical interventions.\(^{75}\)
   - In his review of evidence for immune evasion and persistent infection in Lyme disease, Berndston wrote, “The question is no longer whether LD (Lyme disease) can survive an

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\(^{74}\) http://www.northeastern.edu/news/2015/06/researchers-discovery-may-explain-difficulty-in-treating-lyme-disease/

antibiotic challenge in order to become a persistent infection. High quality studies show not only that it happens, but they also show how it happens.” 76

4. Long-term treatment is proving effective
   - More than 200 Australian patients report that significant improvement occurred with treatment beyond 30 days.
   - There are more than 700 studies that demonstrate verified persistent infection, even after antibiotic treatment, necessitating long term treatment. 77

Research into Lyme-like illness should not occur independently of research into co-infections. Global guidelines provide medical practitioners with long-term treatment protocols that include a proper investigation of co-infections; these should underpin Australian treatment protocols.

F 3. The treatment patients received from medical professionals

F 3.1 Minimally disruptive medicine: the burden of illness and the burden of treatment
The concept of minimally disruptive medicine was proposed by May et al in 2009. They suggested that each disease carries a burden of illness – as well as the physical effects of the disease there are also psychological impacts. The counterpart to the burden of illness proposition is that of the burden of treatment – relating to the workload delegated to the patient by health professionals in the care, monitoring and management of their illness.

A 2009 study of 2,400 Americans explored the burden of illness for people diagnosed with Lyme disease. The findings of the study are reported by Johnson in the paper Healthcare access and burden of care for patients with Lyme disease (Johnson, 2009). The study found the burden of illness, characterised by the number of people on disability support, to be substantial. It also found access to health care, characterised by the distance people have to travel to obtain treatment, the number of doctors they have had to visit, and the lack of access to medical insurance to be unacceptable. The study concluded that inadequate treatment of patients with Lyme disease, results in concomitant reductions in health benefits and increases in economic costs’.

The Australian situation is far worse.

For example, 47% of patients (vs. 25% in the USA) report receiving sickness or disability benefits and 35% had to access their insurance or superannuation.

**Figure 18: Economic burden of illness on patient income**

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77 ILADS- Chronic Lyme and Evidenced based review
In terms of access to healthcare, the US data reports that half of their patients saw more than seven doctors to obtain a diagnosis. In contrast, 46% of Australian patients report they had seen more than seven medical professionals, with the majority seeing ten or more prior to obtaining a diagnosis.

**FIGURE 19: NUMBER OF MEDICAL PROFESSIONALS SEEN PRIOR TO DIAGNOSIS**

In the USA nearly half their patients are reported to have travelled over 50 miles to receive healthcare, with 30% travelling more than 100 miles and 9% more than 500 miles. Again the situation in Australia is much worse, with 8% of patients travelling overseas and nearly 20% travelling more than 500kms to obtain healthcare for their Lyme-like illness.
The data presented in these charts is now nearly two years old; back in 2014, 70 people had reported seeking treatment overseas. Of those only 11 reported they had gone to Germany. In the past two years there has been a significant increase in the number of patients seeking treatment overseas. The majority travel to Germany where two 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.
Australian 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.

An important point to note is that Lyme-like illness once acquired in Australia does not always remain here; people travel. There are numerous cases of Lyme-like illness reported in our nearest neighbour, New Zealand. Patients in New Zealand seem to be even worse off than those in Australia as many New Zealander patients come to Australia for treatment.

We highlight the case of a seriously ill female child who, on a holiday in Australia in 2010, cuddled a small Eastern Grey kangaroo at a popular tourist park. Her name is Ruby and her story, in full, is available on the Ruby Red Trust website.

Briefly, Ruby’s mum removed a nymphal tick from Ruby’s hair as she walked away from the Kangaroo, but she missed another that was found in her scalp a few days later. A plethora of symptoms ensued; headaches, abdominal pain, encephalopathy, ataxia, seizures, status epilepticus, striae rashes, petechial and vesicular rashes, cyclical high fevers, lymphocytopenia, neutropenia, thrombocytopenia and mitral heart murmur.

Ruby’s family has lived through five years of medical neglect from paediatricians. They have routinely withheld treatment, support services and through the serious mishandling of Ruby while in a state of epilepticus, placed her life at risk. Ruby lives through daily seizures so life threatening that she has become a regular in the Intensive Care Unit of her local hospital, having breathing tubes stuck down her neck so she can breathe.

Ruby is 10 years old. She has no paediatric care as paediatric doctors refuse to treat her. Ruby’s parents are angry that the deprivation of treatment for Ruby has already stolen her childhood.

Parents like those in Ruby’s family and indeed many more across Australia often ask, ‘Where are the bureaucrats while I am sitting holding my child’s hand and hoping they do not die? Why don’t they come and witness these children who suffer so badly and wipe away their tears and tell them everything will be okay, until it happens again tomorrow, or next week or next month?’

F 3.2 the Severity of Lyme disease and Lyme-like illness

A more recent article by Johnson examined the Severity of chronic Lyme disease compared to other chronic conditions: a quality of life survey. 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 notes 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.

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78 See: [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3976119/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3976119/)
In addition to the burden of disease placed on patients through their symptoms, Australian patients report strong psychological impacts. Lyme disease and Lyme-like illness also has many personal impacts. Patients face significant decline in their quality of life, they have deficits in their ability to function, and many become dependent on their family and friends creating even more burden.

**FIGURE 22: BURDEN OF ILLNESS - QUALITY OF LIFE**

<table>
<thead>
<tr>
<th>Burden of illness - quality of life impacts</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>I rely on disability aids to perform daily functions (wheelchair, walkers etc)</td>
<td>15.02%</td>
</tr>
<tr>
<td>I require a carer</td>
<td>28.31%</td>
</tr>
<tr>
<td>I am unable to drive</td>
<td>25.50%</td>
</tr>
<tr>
<td>I am unable to leave my home unaccompanied</td>
<td>25.81%</td>
</tr>
<tr>
<td>I am unable to leave my home</td>
<td>25.82%</td>
</tr>
</tbody>
</table>

The quality of life impacts do not occur in isolation of families and friends. If the 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.

**FIGURE 23: BURDEN OF ILLNESS - SOCIAL AND FINANCIAL IMPACTS**

<table>
<thead>
<tr>
<th>Burden of illness - social and financial impacts</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have had to leave my school / job / study</td>
<td>64.83%</td>
</tr>
<tr>
<td>I have had to take extended time off school / work / study</td>
<td>84.38%</td>
</tr>
<tr>
<td>I have had to sell my home</td>
<td>10.68%</td>
</tr>
<tr>
<td>I have spent my savings and financial resources</td>
<td>64.54%</td>
</tr>
</tbody>
</table>
The burden of treatment for Australian patients is extremely disproportionate to other diseases, again compounded by the controversy and stigma, patients report that their illness has profound effects on their psychological wellbeing.

**FIGURE 24: BURDEN OF TREATMENT - PSYCHOLOGICAL IMPACTS**

<table>
<thead>
<tr>
<th>Burden of treatment - psychological impacts</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have suicidal thoughts</td>
<td>43.87%</td>
</tr>
<tr>
<td>I suffer bouts of depression</td>
<td>60.33%</td>
</tr>
<tr>
<td>My friendship circle has shrunk</td>
<td>64.25%</td>
</tr>
<tr>
<td>My immediate relationships are affected</td>
<td>64.07%</td>
</tr>
</tbody>
</table>

Tragically, of the 43.87% of patients (354 out 807 patients) who report having suicidal thoughts, four have taken their own lives in the past three years. Other submissions to this inquiry tell those stories. We ask the Committee to pay particular attention to the loss and devastation that the denial of, and stigma associated with, Lyme-like illness causes to some of the most vulnerable members of the Lyme community. The Submission made by patient [redacted], who tragically took his own life shortly after he lodged his submission, is heartbreakingly raw and tells of the shameful situation that exists for patients who recognise they need help, but for whom there is none.

Such are the tragic losses within the Lyme community that a movement called ‘Red Shoe Day’ was established in memory of Australian Lyme (previously ME/CFS diagnosis) patient, Theda Myint who took her own life on July 25, 2013. The group invites people to wear red shoes, Theda’s favourite, on July 25 each year in honour of those who have lost their lives to Lyme disease and Lyme-like illness.

The Red Shoe day page sums up well the invisibility of the illness, not only in Australia but also within society. ‘Invisible illnesses are those that are generally ‘invisible’, not only from the outward appearance of the person, but also seemingly invisible to appropriate research, treatment and care of ….. the thousands of people that are living with them. Many living with these illnesses are also “invisible” to society, as their health is such that they are confined to their houses, (and many to their beds) for months, even years’.

The page also outlines how ‘each death brings a heightened sense of anger at the injustice of their illness being ignored. It is also hard, as whilst many offer comfort to those affected, it also brings a sense of one’s own mortality (or that of the loved one you are caring for) to the fore’. These are the

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79 Red Shoe Day – Facebook page [https://www.facebook.com/events/253764474820850/](https://www.facebook.com/events/253764474820850/)
impacts that resonate throughout the entire community when a patient dies, or even more tragically takes their own life.

The LDAA’s volunteers, who monitor our mailbox and answer the desperate calls from people who are in a situation of depression or are suicidal are not trained in suicide prevention nor are they trained counsellors. They are patients who are trying to help each other when no one else will. We are at the limit of what we are able to do to help patients. Without dedicated support from people who understand their burden of illness, patient’s move online to forums where they seek help from the Lyme community in a more public way. This places a psychological burden on the community who are equally ill equipped to act or help. A recent and telling example of the way people are feeling is included in the Appendix 3 Figure 27: Patient expression of suicidal feelings. Patients like this need access to counselling and intensive support and they need it now.

F 3.3. Impacts upon young people with Lyme-like illness living in aged care environments
The inquiry have been provided with several submissions from patients, either themselves or from other people on behalf of them, who live permanently in aged care facilities as they are unable to care for themselves. The average age of these patients is 30.

The impact upon young people who reside in nursing homes is well reported by the Young People In Nursing Homes National Alliance. It is of little utility to repeat the issues young people face in this situation since it was the subject of a Senate Inquiry on the Adequacy of existing residential care arrangements available for young people with severe physical, mental or intellectual disabilities in Australia. The Senate Committee tabled their report in June 2015.80

What is important is the additional layer of complexity that Lyme-like illness places on the aged care system and those young people who reside within it. Many aged care facilities don’t have the ability to provide IV antibiotics, few have intensive care facilities and many of the staff, while highly trained geriatric nurses, are ill equipped to deal with the complex array of symptoms and issues associated with someone so disabled by Lyme-like illness.

Nursing homes are also not immune to the Lyme associated stigma either. They operate within the same medical system that stigmatises patients wherever they are. They are not equipped to support the added psychosocial impacts on young people without family and community support. The young patients are too ill to ‘stand up for themselves’, nor should they have to. For young Lyme patients in nursing homes, the situation is dire; many end up with ‘medical abuse syndrome’, which results in their complete isolation, unable to trust the very people they depend on for their daily care and medical treatment.

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F 3.4. 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 indeed 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 and 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. It’s a despicable situation that does nothing to help the children who in this situation have no voice.

As part of the Lyme Awareness events held each year in May, Australia participated in a world-wide event to draw attention to the plight of people with Lyme disease and Lyme-like illness. The Australian campaign featured patients who contributed a series of photographs that outlined what patients had already lost to Lyme disease and also what they really want. We share with the Committee some of the children with Lyme who really just want to enjoy their childhoods Lyme free and do the same things as other children.
Children with Lyme-like illness tell us what they want

<table>
<thead>
<tr>
<th>Name</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sophie</td>
<td>“I want to be just like other kids and eat ice cream without getting a rash. I don’t want to be sick anymore, no tummy aches, no band-aids for my sore head, no sore arms and legs and no more medicine. Yuk!” Sophie is 4. She lives in NSW</td>
</tr>
<tr>
<td>Amber</td>
<td>“I want to never go to hospital again. I want to not have any more needles and no more hurts. I want doctors to help me because it hurts and I don’t feel very well.” Amber is 4. She lives in SA</td>
</tr>
<tr>
<td>Coby</td>
<td>“I want to read and write just like other kids. To play like other kids and not be tired all the time. I don’t want to fall asleep on the bus anymore. I want to see a Doctor who will make me well.” Coby is 6. She lives in NSW</td>
</tr>
<tr>
<td>Ben</td>
<td>“I want to fly planes and go outside and play on the grass with my dog. I hate being sick all the time. I need to play with more than just lego” Ben is 4. He lives in NSW</td>
</tr>
<tr>
<td>Name</td>
<td>Age</td>
</tr>
<tr>
<td>---------</td>
<td>------</td>
</tr>
<tr>
<td>Francesca</td>
<td>11</td>
</tr>
<tr>
<td>Jamie &amp; Jessica</td>
<td>5</td>
</tr>
<tr>
<td>Matilda</td>
<td>5</td>
</tr>
<tr>
<td>Phoenix</td>
<td>3</td>
</tr>
</tbody>
</table>

Francesca is 11. She lives in NSW.

Jamie and Jessica live in SA.

Matilda is 5. She lives in NSW.

Phoenix is 3. He lives in SA.
Growing evidence of an emerging tick-borne disease that causes a Lyme like illness for many Australian patients

Submission 528

Charlize

"I miss so much school because I am sick all the time. I didn’t go to school for 6 months. It’s not fair!"

Charlize is 9. She lives in SA

Noah

Noah is just 2 years old.

Noah’s Mum has Lyme disease, she hopes that Noah doesn’t have it too.

Noah lives in QLD

Katie

“I want to be able to do sport without collapsing. I want to be able to go to school for a WHOLE week. I want to wake up FIRST on Christmas morning."

Katie is 11. She lives in WA

Shannon

“I don’t want to feel sick every minute of my day. I want to go to school and do all the things my friends can do. I want the pain and sadness to go away. I don’t want to be scared anymore."

Shannon is 13. She lives in NSW
F 3.5 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.

It is important that the Committee gain an understanding of the associated expense of treatment for patients. Each component of the treatment cost is outlined below:

- **Accessing health care** – the majority of patients have to travel more than 100km to see a medical practitioner (see *Figure 20: Distance travelled to access treatment*)
  - 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 underpin the 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; as noted earlier 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 even 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 (see *Figure 22: Burden of illness - quality of life*)

It is easy to see the financial impact of the illness in the burden of treatment.

At the Inquiry into Chronic Health, referenced earlier, Dr Richard Schloeffel told the Committee that there ‘is enormous cost in the investigation’. We earlier outlined the lack of confidence Lyme treating doctors have in the local pathology tests, so they ask patients to be tested in overseas laboratories. Using the IGeneX data presented earlier, and assuming that 80% of the test kits we have fulfilled have been used; we can calculate a cost to Australian patients of over $2.4 million. Add to that the 718 Elispot and 672 *Borrelia* blot tests performed at Infectolab and you have another $260,000 spent on investigations alone.\(^{81}\)

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\(^{81}\) Calculations: IGeneX 2465 x $1000 (\$2,465,000) Infectolab 718 x $215 + 672 x $158 (\$260,546)
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’. 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, they 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. Other common treatments for Babesia include Malarone, in which a 30-day supply is $600.

An example of the type of medications used to treat Lyme-like illness in a 3 year-old is illustrated in Figure 25; 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 25: THERAPEUTIC TREATMENT EXAMPLE FOR A CHILD**

When Committee member Hall asked about the average cost of treatment per year per patient at the Inquiry into Chronic health, both Dr Schoeffel and patients told her the costs were $50,000 - $60,000. The LDAA suggests there would be very few Australians who could afford that type of expense yearly, even if they did have an income.

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. This is detrimental to Lyme patients who are in the chronic 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.

F 4. Costs to government
On the opposite side of the patient costs are the costs to government for Lyme disease and Lyme-like illness. In the preparation of this submission we shared some of the patient reported data with a patient who undertook a study of the potential costs to government for both chronic long term Lyme disease and early stage disease. The data is not represented here as it resides within another submission in more detail; but the costs are alarming.

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.

It is our recommendation that the Committee seek 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. The review should include a calculation of the burden of disease for Australians and assess the Disability Adjusted Life Years for Australians with long term Lyme-like illness and their consequential disability.

F 5. Conclusions on the signs, symptoms and treatment of patients
Similar to the outcomes recommended by Dr Leigner in his letter to Congressman Gibson, patients ‘disabled by Lyme disease might benefit from a dedicated unit with staff fully educated about Lyme disease to help them recover. Additionally, there is a definite need for a combined medical and psychiatric in-patient unit where psychiatrically disturbed persons with Lyme disease requiring intensive medical and psychiatric treatment can be cared for safely by well-informed staff’.

With vastly more experience than Australia, researchers in the USA are discovering better ways to treat Lyme disease. This progress must be taken into account and funds must be allocated to Australian research to address the specific nuances of Lyme-like illness and find ways of treating the disease for a population that is already in the chronic stage of illness.
(G) ToR any other related matters

**G 1. Risk of transmission through blood transfusion**

There is growing evidence that suggests that vector-borne pathogens can be spread through blood transfusion. As *B. burgdorferi* survives storage under blood banking conditions, transmission of *Borrelia* by blood transfusion is theoretically possible. As reported in the USA, a nine-year-old boy was infected with a Lyme-like co-infection, *Ehrlichia* after a blood transfusion. A number of other studies in the USA indicate there were 159 known cases of *Babesiosis* caused by transfusions where blood bank officials were able to trace back to 136 donors. Alarmingly, 30 of the cases reported were traced to only 12 donors because blood supplies were split and used in multiple recipients.

In response to the increasing awareness, many Australian Lyme-like patients have contacted the Australian Red Cross seeking information about their donation eligibility and have received correspondence stating that the Australian Red Cross is unable to accept blood donations as ‘Lyme disease is a chronic condition and the organisation needs to protect the health and safety of recipients’. However some patients also report a conflicting response where they’ve been informed that as long as they are in good health; they will be able to donate their blood.

Many Australians with Lyme-like illness have reported that they have donated blood to Australian blood banks prior to testing positive for Lyme-like pathogens. The Australian Red Cross does not test donated blood for Lyme-like pathogens, and given the issues with the current Australian testing processes there would be no certainty in the efficacy of the screening anyway.

There remains considerable public health risk for the many blood recipients, as there are likely many donors with Lyme-like illness who are as yet undiagnosed or potentially misdiagnosed. The LDAA have been unable to successfully communicate these risks to those operating placental cord or blood banks. This means that anyone in Australia receiving blood transfusions from any blood source is at risk of acquiring Lyme-like illness.

**G 2. Other forms of transmission**

It is important to highlight that, to date, it has never been proven beyond a doubt that transmission through a tick bite is the ONLY form of possible transmission of Lyme disease. The LDAA patient surveys indicate that 10% of patients offered alternate explanations for their acquisition of Lyme disease. 6.5% of patients report they may have contracted Lyme-like illness congenitally through placental transmission and 3.5% of patients report possible sexual transmission.

Research has shown *B. burgdorferi* spirochaetes can be transmitted transplacentally from mother to foetus (MacDonald, Benach & Burgdorfer 1987). While a causal link is yet to be established, maternal Lyme disease has also been implicated in miscarriage after first trimester, stillbirths and

---

birth defects (Gardner, 2001). Many Australian patients report their entire families have been diagnosed with Lyme-like disease. This is too coincidental and requires investigation.

Furthermore, newly published research also provides evidence that *B. burgdorferi* may be transmittable through both vaginal secretions and seminal fluid, raising the very real issue of sexual transmission (Middleveen et al, 2014). In an interview on this research, Australia’s Dr Mayne said “the presence of the Lyme spirochete in genital secretions and identical strains in married couples strongly suggests that sexual transmission of the disease occurs”. It is therefore important to ensure that clinicians are aware there may be other forms of transmission should their Lyme presenting patient have a history that does not correlate with a known tick bite or travel to an endemic area, especially if they are babies or infants.

The LDAA recommends the Committee place a particular emphasis on researching alternate modes of transmission and that it also includes animals other than arthropods.

**G 3. Australia’s international obligations**

As a founding member of the United Nations, Australia is and has always been a major participant in developing the international legal framework created in response to the horror and misery of the Second World War. By entering these fundamental agreements, the state of Australia has recognised, on a non-discriminatory basis:

- the right to life;
- the right to a standard of living adequate for health, including access to medical care; and
- the enjoyment of the highest attainable standard of physical and mental health

Further, 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; and
- create conditions to assure to all medical service and medical attention in the event of sickness

These obligations fall upon the state of Australia. The state cannot absolve itself of responsibility by leaving these matters to individual medical practitioners. Nowhere in the agreements does it state that the obligation of Australia to act depends upon the advice of any board or other body, or upon the advice of particular medical practitioners.

Australia is a founding member state of the United Nations, and was an original signatory to the UN Charter in 1945. Read together, Articles 55 and 56 of the Charter require Australia to take joint and separate action to, amongst other things, promote both higher standards of living, and solutions of international health problems.

The Universal Declaration of Human Rights was in part drafted by DR HV Evatt, the Australian who was third President of the UN General Assembly. Proclaimed in 1948, under his presidency, it provides that everyone is entitled without distinction to the rights and freedoms set forth in the Declaration (Article 2). Those rights include the right to life (Article 3); the right of equal access to

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public service (Article 21 (2)); and the right to a standard of living adequate for their health, including medical care, and the right to security in the event of sickness (Article 25 (1)).

The Universal Declaration is one of three fundamental documents which together comprise the International Bill of Human Rights. The other two are the International Covenant on Economic, Social and Cultural Rights, and the International Covenant on Civil and Political Rights.

The International Covenant on Civil and Political Rights entered into force in 1976, and was ratified by Australia in 1980. Each State Party undertakes to respect and ensure the rights recognised within the Covenant to all individuals within its territory without distinction of any kind. Those rights include an inherent right to life (Article 6 (1)).

The International Covenant on Economic, Social and Cultural Rights entered into force in 1976, and was ratified by Australia in 1975. Article 2 (1) provides that:

Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures (emphasis added)

Of greatest interest here is Article 12:

(1) The State’s Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health

(2) The steps to be taken by the State’s Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for:

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

It is obvious from the rest of this submission that the state of Australia is not meeting its obligations, certainly not to the extent required, in respect of Lyme-like illnesses, and those suffering from Lyme-like illnesses. It cannot be suggested that the state of Australia is (certainly not to the maximum of its available resources, nor even to a lesser standard), progressively realising the right of those suffering from Lyme-like illnesses, to the highest attainable standard of physical and mental health. Australia has not taken the steps necessary for the prevention, treatment and control of Lyme-like illnesses.
Appendices
APPENDIX 1.

FIGURE 26: QUEENSLAND DEPARTMENT OF HEALTH LETTER 1990

State Health Building
141-163 Charlotte St.
B.P. Box 399
Brisbane 4001

20th August, 1990

EARLY TREATMENT URGED FOR TICK BITES

A tick-borne disease which can cause chronic arthritis and neurological problems is likely to become more common in Australia.

The disease, known as Lyme Disease, is caused by an organism, Borrelia, transmitted by the common bush tick. The Queensland Department of Health has included the disease as one that must be notified by laboratories and general practitioners to determine the actual incidence of the disease in the State.

The first indication of Lyme Disease is a round bite and migratory rash. The rash then becomes generalised and if left untreated, can impair joint movements and be a continuing illness.

Queensland Department of Health, Director of Environmental and Occupational Health, Dr Ron Ramm, says doctors may not be recognising the disease. He urges early treatment of tick bites where a rash manifests. Treatment includes intravenous penicillin and other antibiotics.

While to date only four clinical cases of Lyme Disease have been recorded in Australia, the disease is known to spread rapidly and of 488 people sera tested for the disease in Queensland last year, 30 per cent tested positive.

Lyme Disease was first recognised in Lyme, U.S.A., in 1977 and has since spread across the United States. Between 1982 and 1987, 13,825 cases were reported. The disease has also spread through most of Western Europe.

FOR MORE INFORMATION, PLEASE CONTACT DR RON RAMM ON (07) 2340941.
## APPENDIX 2

Table 8: Incidence of Borreliosis in 39 countries

<table>
<thead>
<tr>
<th>Country</th>
<th>% of population w/Borreliosis</th>
<th>Population in Data Year</th>
<th>Data year</th>
<th>Estimated infected citizens</th>
<th>Notes</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belarus</td>
<td>7.50%</td>
<td>10,070,000</td>
<td>1998</td>
<td>755,250</td>
<td>7.5% of the general population (<em>Borrelia afzelii</em>)</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Bolivia</td>
<td>1.30%</td>
<td>7,464,000</td>
<td>1994</td>
<td>97,032</td>
<td>Statistic from the towns of Camiri, Boyuibe, and Gutierrez.</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>16.50%</td>
<td>8,444,000</td>
<td>1994</td>
<td>1,393,260</td>
<td>15 to 18% of forestry and animal workers.</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Croatia</td>
<td>7.50%</td>
<td>4,426,000</td>
<td>2000</td>
<td>331,950</td>
<td>7.5% of persons in north western Croatia</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Country</td>
<td>% of population w/Borreliosis</td>
<td>Population in Data Year</td>
<td>Data year</td>
<td>Estimated infected citizens</td>
<td>Notes</td>
<td>Reference</td>
</tr>
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<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>2.00%</td>
<td>10,520,000</td>
<td>2013</td>
<td>210,400</td>
<td>1% to 3% of blood donors from Prague (the capital city)</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Denmark</td>
<td>2.00%</td>
<td>5,707,251</td>
<td></td>
<td>114,145</td>
<td>2% of blood donors infected</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Egypt</td>
<td>23.00%</td>
<td>55,210,000</td>
<td>1989</td>
<td>12,698,300</td>
<td>23% of screened blood donors and STD clinic patients in Fayoum, Egypt</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Estonia</td>
<td>3.00%</td>
<td>1,381,000</td>
<td>1999</td>
<td>41,430</td>
<td>3% of randomly selected people in the Karksi Nuia region</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>France</td>
<td>2.23%</td>
<td>65,680,000</td>
<td>2012</td>
<td>1,463,449</td>
<td>Average of 26,584 cases per year for the period 2009 to 2012</td>
<td><a href="http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20883">http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20883</a></td>
</tr>
<tr>
<td>Germany</td>
<td>6.03%</td>
<td>82,100,000</td>
<td>1999</td>
<td>4,954,500</td>
<td>German National Reference Centre for Borrelia says 80,000 to 100,000 new cases per year based on a 1999 study</td>
<td><a href="http://www.lgl.bayern.de/gesundheit/infektionsschutz/infektionskrankheiten_a_z/borreliose/lyme_index.htm">http://www.lgl.bayern.de/gesundheit/infektionsschutz/infektionskrankheiten_a_z/borreliose/lyme_index.htm</a></td>
</tr>
<tr>
<td>Greece</td>
<td>1.10%</td>
<td>10,930,000</td>
<td></td>
<td>120,230</td>
<td></td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Hungary</td>
<td>3.50%</td>
<td>9,853,000</td>
<td></td>
<td>344,855</td>
<td>2 to 5% of blood donors</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Ireland and Northern Island</td>
<td>15.00%</td>
<td>4,841,943</td>
<td></td>
<td>726,291</td>
<td>15% of blood donors</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Italy</td>
<td>5.93%</td>
<td>60,795,612</td>
<td></td>
<td>3,602,140</td>
<td>4.3% of blood donors in the central region; 1.5% in Lazio; 10.9% in Sicily; 7% in Piemonte</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Japan</td>
<td>6.10%</td>
<td>126,800,000</td>
<td></td>
<td>7,734,800</td>
<td>6.1% of military personnel</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Country</td>
<td>% of population w/Borreliosis</td>
<td>Population in Data Year</td>
<td>Data Year</td>
<td>Estimated infected citizens</td>
<td>Notes</td>
<td>Reference</td>
</tr>
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<td>-------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Latvia</td>
<td>2.70%</td>
<td>1,984,456</td>
<td>2005</td>
<td>53,580</td>
<td>2.7% of Latvians in high risk occupations</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Mongolia</td>
<td>6.27%</td>
<td>3,000,000</td>
<td>2006</td>
<td>188,000</td>
<td>Serological evidence for tick-borne encephalitis, borreliosis, and human granulocytic anaplasmosis in Mongolia. Int J Med Microbiol 2006 May; 296 Suppl 40:69-75.</td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>5.73%</td>
<td>16,320,000</td>
<td>2005</td>
<td>935,850</td>
<td></td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Poland</td>
<td>11.05%</td>
<td>38,230,000</td>
<td>2002</td>
<td>4,224,415</td>
<td>11% to 13% of blood donors (2002 publication)</td>
<td><a href="http://web.gideononline.com/web/eb.php?f=r">http://web.gideononline.com/web/eb.php?f=r</a> &amp;id=12150065&amp;s=p</td>
</tr>
<tr>
<td>Portugal</td>
<td>1.50%</td>
<td>10,110,000</td>
<td>1997</td>
<td>151,650</td>
<td>1% to 2% of blood donors, and 4% to 6% of military populations (1994 to 1997)</td>
<td><a href="http://web.gideononline.com/web/eb.php?f=r">http://web.gideononline.com/web/eb.php?f=r</a> &amp;id=12081110&amp;s=p</td>
</tr>
<tr>
<td>Slovakia</td>
<td>0.83%</td>
<td>5,426,000</td>
<td></td>
<td>44,805</td>
<td>15 new cases per 100,000 population</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Country</td>
<td>% of population w/Borreliosis</td>
<td>Population in Data Year</td>
<td>Data year</td>
<td>Estimated infected citizens</td>
<td>Notes</td>
<td>Reference</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>3.45%</td>
<td>46,121,000</td>
<td></td>
<td>1,591,175</td>
<td>3.45% of humans in Madrid</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Switzerland</td>
<td>15.75%</td>
<td>8,298,000</td>
<td></td>
<td>1,306,935</td>
<td>9.5% to 22% in the general population</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>Taiwan</td>
<td>3.00%</td>
<td>21,087,000</td>
<td>1994</td>
<td>632,610</td>
<td>Rates were 3% and 13% in the sera collected from Taiwan and Orchid Island, respectively.</td>
<td><a href="http://www.ncbi.nlm.nih.gov/pubmed/9747351?dopt=abstract">http://www.ncbi.nlm.nih.gov/pubmed/9747351?dopt=abstract</a></td>
</tr>
<tr>
<td>Turkey</td>
<td>2.50%</td>
<td>72,140,000</td>
<td>2010</td>
<td>1,803,500</td>
<td>2.5% of blood donors in Erzurum Province (2010 publication)</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>3.25%</td>
<td>64,100,000</td>
<td></td>
<td>2,083,250</td>
<td>2.5% to 4.0% of blood donors in South England</td>
<td>Lyme disease: Global Status 2015 edition</td>
</tr>
<tr>
<td>United States of America</td>
<td>5.55%</td>
<td>318,900,000</td>
<td>2010</td>
<td>17,700,200</td>
<td>Incidence of Clinician-Diagnosed Lyme Disease, United States, 2005–2010’. Estimate that annual incidence is 106.6 cases/100,000 persons and that ≈329,000 (95% credible interval 296,000–376,000) LD cases occur annually.</td>
<td><a href="http://wwwnc.cdc.gov/eid/article/21/9/15-0417_article">http://wwwnc.cdc.gov/eid/article/21/9/15-0417_article</a></td>
</tr>
<tr>
<td>Totals</td>
<td></td>
<td>2,738,845,262</td>
<td></td>
<td>158,958,082</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (average) global incidence of Borreliosis:</td>
<td>5.804%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 3

FIGURE 27: PATIENT EXPRESSION OF SUICIDAL FEELINGS

Excerpt (no corrections):

I [redacted] have decided that if the senate inquiry doesn't help us in getting proper treatment, I will be getting my affairs in order, and I have nominated another Lymie to speak on my behalf once or if I pass. I understand that some people can live dibilitated for many years BUT not me.

I take my wedding vows very seriously and have chosen til death do us part. This illness has taken a huge toll on my family, our finances etc and for what.......no progress and now no abx tmnt to maintain this disease. I myself refuse to become a burden to my family, in all aspects.......physically, emotionally, financially etc.

I know that they will grieve and that is painful but then they can move on, instead of me living and being more dibilitated and cause them more strain. I believe my llmd has been bullied not to treat us. And i am so angry at the health dept for doing so. [redacted] is kicking arse along with all the other ld associations n foundations but I am not sure this inquiry will be enough to change the current mentality n stigma in the health community.

I am a positive person and if i end my life it is because i have a clear mind n out of future suffering to my family, do so. I am not commiting suicide, there is a difference when your terminally ill to shorted your life. I chose to end my life on my terms, not stuck in a hospital ward tubed up.

My will and letter of my wishes is with our solicitor. My kids know if anything happens to me they can live with their cousin [redacted]. So other than writing personal letters to my kids n hubby etc will be done when my time has come.

I dont wish to upset anyone but i need the world to know that it is because i cant get proper tmnt in australia that i have chosen to shorten my life rather than let my family be burdened watching my body dibilitated by this disease. I refuse to spend thousands of dollars on treatments that do not work on late stage lymies. Enough is enough.

So that is my reason should i chose to end my life early. I am not suidal just letting the lyme community know ahead of time, why i chose to die. Instead of wondering you now know.

Love all you lymies to the moon n back.

Please do not comment to this post. I just wanted ya all to know from me if or when i pass, the real reason. — feeling annoyed.
## APPENDIX 4

### TABLE 9: LISTING OF KNOWN *Borrelia* SPECIES

<table>
<thead>
<tr>
<th>No.</th>
<th>Group</th>
<th><em>Borrelia</em> species and year of discovery</th>
<th>Geographical Region/s. List not complete.</th>
<th>Known association with human disease</th>
<th>Test for it under Australian Medicare?</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>LD</td>
<td><em>B. afzelii</em> (1994)</td>
<td>Sweden, China, North America, Europe, Asia</td>
<td>Yes. Lyme borreliosis</td>
<td>Available but unreliable Refer to Note 3</td>
<td>1a, 1b, 18a, 51a, 51b</td>
</tr>
<tr>
<td>2</td>
<td>LD</td>
<td><em>B. americana</em> (2010)</td>
<td>North America</td>
<td>Yes. Lyme borreliosis</td>
<td>No</td>
<td>2a</td>
</tr>
<tr>
<td>3</td>
<td>LD</td>
<td><em>B. andersonii</em> (1995)</td>
<td>North America</td>
<td>Yes. Lyme borreliosis</td>
<td>No</td>
<td>3a, 3b</td>
</tr>
<tr>
<td>4</td>
<td>RF</td>
<td><em>B. anserina</em> (1891)</td>
<td>Worldwide</td>
<td>No. Avian borreliosis</td>
<td>No</td>
<td>4a, 4b, 12a</td>
</tr>
<tr>
<td>5</td>
<td>RF</td>
<td><em>B. baltazardii</em> (1979)</td>
<td>Middle East</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>17a, 17b</td>
</tr>
<tr>
<td>6</td>
<td>LD</td>
<td><em>B. bavariensis</em> (2009)</td>
<td>North America, Europe</td>
<td>Yes. Lyme borreliosis</td>
<td>No</td>
<td>18a, 1a</td>
</tr>
<tr>
<td>7</td>
<td>LD</td>
<td><em>B. bissetti</em> (1998)</td>
<td>North America, Canada, Europe</td>
<td>Yes. Lyme borreliosis</td>
<td>No</td>
<td>25a</td>
</tr>
<tr>
<td>8</td>
<td>RF</td>
<td><em>B. braziliensis</em> (1952)</td>
<td>South America</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>8a</td>
</tr>
<tr>
<td>9</td>
<td>LD</td>
<td><em>B. burgdorferi</em> (1984)</td>
<td>Worldwide. Sweden, China, Eastern United States, Western United States, Europe, Asia, Japan, North America, Canada, Europe, Australia</td>
<td>Yes. Lyme borreliosis. “Classic Lyme”</td>
<td>Available but unreliable Refer to Note 3</td>
<td>9a, 9b, 12a, 51a, 51a, 51b, 18a, 1a</td>
</tr>
<tr>
<td>11</td>
<td>LD</td>
<td><em>B. carolinensis</em> (2009)</td>
<td>North America</td>
<td>Yes. Lyme borreliosis</td>
<td>No</td>
<td>11a</td>
</tr>
<tr>
<td>12</td>
<td>RF</td>
<td><em>B caucasia</em> (1945)</td>
<td>Caucasus (north-western Russia, Georgia, Armenia and Azerbaijan) to Iraq Iran and Central Asia</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>12a</td>
</tr>
<tr>
<td>No.</td>
<td>Group LD - Lyme Disease RF - Relapsing Fever</td>
<td>Borrelia species and year of discovery</td>
<td>Geographical Region/s. List not complete.</td>
<td>Known association with human disease</td>
<td>Test for it under Australian Medicare?</td>
<td>References</td>
</tr>
<tr>
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<td>----------------------------------------</td>
<td>------------------------------------------</td>
<td>-------------------------------------</td>
<td>--------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>13</td>
<td>RF</td>
<td>B. coriaceae (1987)</td>
<td>North-eastern Africa, Middle East, Southern Europe, Western United States</td>
<td>No. Epizootic bovine abortion</td>
<td>No</td>
<td>12a, 13a, 4b, 46a</td>
</tr>
<tr>
<td>14</td>
<td>RF</td>
<td>B. crocidurae (1917)</td>
<td>West Africa, North Africa, Morocco, Libya, Egypt, Iran, Turkey, Senegal, Kenya</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>4b, 12a</td>
</tr>
<tr>
<td>15</td>
<td>RF</td>
<td>B. dipodilli</td>
<td>Morocco, Libya, Egypt, Iran, Turkey, Senegal, Kenya</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>12a</td>
</tr>
<tr>
<td>16</td>
<td>RF</td>
<td>B. duttonii (1949)</td>
<td>North America</td>
<td>No</td>
<td>4c</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>RF</td>
<td>B. duttonii (1906) Ref 17b. This paper concluded that B. microti and B. duttonii might be same species.</td>
<td>Central, Eastern and Southern Africa, Sub-Saharan Africa, Middle East</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>4b, 4c, 12a, 17a, 17b</td>
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<td>18</td>
<td>LD</td>
<td>B. finlandensis (2011)</td>
<td>Finland, Europe, Unknown Novel species isolated from a tick.</td>
<td>Unknown</td>
<td>No</td>
<td>18a</td>
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<td>19</td>
<td>LD</td>
<td>B. garinii (1992)</td>
<td>Sweden, China, North America, Europe, Australia, Asia, Japan</td>
<td>Yes. Lyme borreliosis</td>
<td>Available in one lab only- unreliable – S See note 3</td>
<td>51a, 51b, 18a, 1a, 1c</td>
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<tr>
<td>20</td>
<td>RF</td>
<td>B. groinigeri (1953)</td>
<td>Mombasa</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>20a</td>
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<tr>
<td>21</td>
<td>Unknown.</td>
<td>B. harveyi (1947)</td>
<td>Kenya</td>
<td>Yes.  'produces a mild infection in man'.</td>
<td>No</td>
<td>21a</td>
</tr>
<tr>
<td>22</td>
<td>RF</td>
<td>B. hermsii (1942)</td>
<td>Canada, North America, Western United States</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>22a, 12a, 4b, 4c</td>
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<td>No.</td>
<td>Group</td>
<td>LD - Lyme Disease RF - Relapsing Fever</td>
<td><em>Borrelia</em> species and year of discovery</td>
<td>Geographical Region/s. List not complete.</td>
<td>Known association with human disease</td>
<td>Test for it under Australian Medicare?</td>
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<tr>
<td>23</td>
<td>RF</td>
<td><em>B. hispanica</em> (1926)</td>
<td>Spain, Portugal, Morocco, Algeria, Tunisia, North Africa, South Europe, Iberian peninsula and North-western Africa</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>4b, 12a, 23a, 46a</td>
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<td>24</td>
<td>LD</td>
<td><em>B. japonica</em> (1994)</td>
<td>Japan</td>
<td>No</td>
<td>No</td>
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<td>26</td>
<td>RF</td>
<td><em>B. latyschweii</em> (1941)</td>
<td>Iran, Central Asia, Middle East</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>12a, 17a</td>
</tr>
<tr>
<td>28</td>
<td>LD</td>
<td><em>B. lusitaniae</em> (1997)</td>
<td>Sweden, Europe, Asia</td>
<td>Yes. Lyme borreliosis</td>
<td>No</td>
<td>28a, 28b, 51a</td>
</tr>
<tr>
<td>29</td>
<td>LD</td>
<td><em>B. mayonii</em> (2016)</td>
<td>United States America</td>
<td>Yes. Lyme borreliosis</td>
<td>No</td>
<td>29a, 29b</td>
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<tr>
<td>30</td>
<td>RF</td>
<td><em>B. mazzottii</em> (1956)</td>
<td>Southern United States, Mexico, Central and South America</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>12a</td>
</tr>
<tr>
<td>31</td>
<td>RF</td>
<td><em>B. merionesi</em> (1974)</td>
<td>Morocco, Libya, Egypt, Iran, Turkey, Senegal, Kenya</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>12a</td>
</tr>
<tr>
<td>32</td>
<td>RF</td>
<td><em>B. microti</em> Ref 17b. This paper concluded that <em>B. microti</em> and <em>B. duttonii</em> might be same species.</td>
<td>Middle East, Morocco, Libya, Egypt, Iran, Turkey, Senegal, Kenya</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>12a, 17a, 17b.</td>
</tr>
<tr>
<td>33</td>
<td>RF / LD</td>
<td><em>B. miyamotoi</em> (1995) Refer to Note 1</td>
<td>Japan, Netherlands, Russia, USA, Europe, North America, Eurasia, Asia, Sweden</td>
<td>Yes. Relapsing Fever / Lyme Disease. Refer Note 1.</td>
<td>No</td>
<td>33a to 33k, 51a</td>
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<tr>
<td>34</td>
<td>RF</td>
<td><em>B. parkeri</em> (1942)</td>
<td>South America, Western United States</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>8a, 12a</td>
</tr>
<tr>
<td>35</td>
<td>RF</td>
<td><em>B. persica</em> (1913)</td>
<td>Central Asia, From west China and Kashmir to Iraq and Egypt, USSR, India, Middle East, Greece</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>4b, 12a, 17b, 46a</td>
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<td>36</td>
<td>RF</td>
<td><em>B. queenslandica</em> (1962)</td>
<td>Australia</td>
<td>Yes. Relapsing Fever</td>
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<td>No.</td>
<td>Group</td>
<td>LD - Lyme Disease</td>
<td>RF - Relapsing Fever</td>
<td><em>Borrelia</em> species and year of discovery</td>
<td>Geographical Region/s. List not complete.</td>
<td>Known association with human disease</td>
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<td>37</td>
<td>RF</td>
<td>B. recurrentis (1874) (syn. B. obermeyeri, B. novyi)</td>
<td>Worldwide. Africa, South America, Middle East, Europe and Asia</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>4c, 17a, 12a, 46a</td>
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<td>38</td>
<td>LD</td>
<td>B. sinica (2001)</td>
<td>China, Nepal, Asia</td>
<td>No</td>
<td>No</td>
<td>1c, 38a</td>
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<td>39</td>
<td>LD</td>
<td>B. spielmanii (2006)</td>
<td>Europe</td>
<td>Yes. Lyme borreliosis</td>
<td>No</td>
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<td>40</td>
<td>LD</td>
<td>B. tanukii (1997)</td>
<td>Japan</td>
<td>No</td>
<td>No</td>
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<td>41</td>
<td>RF</td>
<td>B. theileri (1903)</td>
<td>Worldwide. West Africa</td>
<td>Bovine Borreliosis</td>
<td>No</td>
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<td>42</td>
<td>RF</td>
<td>B. tilla (1961)</td>
<td>Cape Province South Africa</td>
<td>No</td>
<td>No</td>
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<td>43</td>
<td>RF</td>
<td>B. turcica (2004)</td>
<td>Turkey, Jordan, Romania</td>
<td>No</td>
<td>No</td>
<td>43a</td>
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<td>44</td>
<td>LD</td>
<td>B. turdi (1997) (formerly B. turdae)</td>
<td>Japan, Korea, Portugal</td>
<td>No</td>
<td>No</td>
<td>44a, 44b, 44c, 44d</td>
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<td>45</td>
<td>RF</td>
<td>B. turicatae (1933)</td>
<td>North America, Southwestern United States, Mexico, Central and South America</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>4b, 4c, 8a, 12a, 46a</td>
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<td>46</td>
<td>RF</td>
<td>B. uzbekistana</td>
<td>Central Asia</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>46a</td>
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<tr>
<td>47</td>
<td>LD</td>
<td>B. valaisiana (1997)</td>
<td>Sweden, China, Europe, Asia, Japan</td>
<td>Yes. Lyme borreliosis</td>
<td>No</td>
<td>47a, 51a, 51b</td>
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<td>48</td>
<td>RF</td>
<td>B. venezuelensis (1921)</td>
<td>Central America and norther South America</td>
<td>Yes. Relapsing Fever</td>
<td>No</td>
<td>12a</td>
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<tr>
<td>49</td>
<td>LD</td>
<td>B. yangtzensis (2015) (formerly proposed as B. Yangtze)</td>
<td>Asia, China, Japan</td>
<td>Unknown. Has not been examined in humans.</td>
<td>No</td>
<td>51b</td>
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<tr>
<td>50</td>
<td>RF</td>
<td>(Unnamed Species, 2015)</td>
<td>Australia</td>
<td>Unknown. Has not been examined in humans.</td>
<td>No</td>
<td>50a &amp; Submission 497</td>
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<td>No.</td>
<td>Group</td>
<td>Unnamed (year)</td>
<td>Geographical Region/s.</td>
<td>Known association with human disease</td>
<td>Test for it under Australian Medicare?</td>
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<td>52</td>
<td>RF</td>
<td>Unnamed (2015)</td>
<td>Middle East</td>
<td>Yes. Novel <em>Borrelia</em> relapsing fever bacteria sequenced from 2 patients.</td>
<td>No</td>
<td>17a</td>
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<tr>
<td>53</td>
<td>RF</td>
<td>Unnamed (2016)</td>
<td>Bolivia</td>
<td>Unknown. Novel tick borne relapsing fever <em>Borrelia</em> identified. Unable to determine if this <em>Borrelia</em> was the incompletely described <em>B. mazzottii</em>.</td>
<td>No</td>
<td>8a</td>
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</table>

Table notes:

1. *B. miyomatoi* disease does not fit into categories of Relapsing Fever or Lyme Disease, but shares characteristics of both.

A 2010 study undertaken of *Borrelia* in ticks found in Sweden (Reference 51) identified *Borrelia* of unknown type in 9 ticks. Primer solution was designed to detect *B. burgdorferi, B. garinii, B. afzelii, B. valaisiana, B. lusitaniae, B. spielmani, B. andersonii, B. hispanica, B. miyomatoi, B. turdi, B. parkeri, B. crocidurae, B. tanukii, B. duttonii, B. hermsii, B. theileri, B. perscia, B. anserina, B. turicatae, B. turcicam B. japonica, B. coriaceae, B. recurrentis, B. lonestari.*

2. Can be identified using Western blot test in two-tier process.
Table References

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<td>3</td>
<td>a</td>
<td>Ataliba, Alexandre C.; Resende, Jose’ S.; Yoshinari, Natalino; Labruna, Marcelo B. (October 2007). “Isolation and molecular characterization of a Brazilian strain of Borrelia anserina, the agent of fowl spirochaetosis”. Research in Veterinary Science 83 (2): 145–149.</td>
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<td>b</td>
<td>Kang, Jun-Gu; Kim, Heung-Chul; Choi, Chang-Yong; Nam, Hyun-Young; Chae, Hee-Young; Chong, Sung-Tae; Klein, Terry A.; Ko, Sungjin; Chae, Joon-Seok (March 27, 2013). &quot;Molecular Detection of Anaplasma, Bartonella, and Borrelia Species in Ticks Collected from Migratory Birds from Hong-do Island, Republic of Korea&quot;. Vector-Borne and Zoonotic Diseases 13 (4): 215–225.</td>
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Growing evidence of an emerging tick-borne disease that causes a Lyme like illness for many Australian patients

**Table 10: Patients Like Me Website**

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<th>Conditions</th>
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<tr>
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<td>PatientsLikeMe.com, CC BY-SA 3.0, <a href="https://commons.wikimedia.org/w/index.php?curid=16252932">https://commons.wikimedia.org/w/index.php?curid=16252932</a></td>
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<td>Profile Activity</td>
<td>136828 Views</td>
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<tr>
<td>Comments</td>
<td>29 Comments</td>
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<tr>
<td>Forum Activity</td>
<td>5 posts</td>
</tr>
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<td>Helpful Marks</td>
<td>4 helpful marks</td>
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</table>

About Me
Stephan Heywood passed away at Thanksgiving of 2006. His wonderful wife and amazing son still live in Newton, MA. Stephan is the inspiration for PatientsLikeMe and his story is profiled in the documentary **SO MUCH SO FAST**. You can donate to the Stephen Heywood Fund at ALS TDI. 

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References


Mackenzie, J Prof, 2013, Scoping study to develop a research project(s) to investigate the presence or absence of Lyme disease in Australia, 30 September 2013, p. 4, http://www.health.gov.au/lyme-disease

May C, Montori VM, Mair FS. We need minimally disruptive medicine. BMJ 2009;339:b2803


