ACIIDS SUBMISSION TO SENATE INQUIRY INTO LYME-LIKE ILLNESS

This is a submission by the Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS), a group of Australian doctors, primarily general practitioners, who specialise in the treatment of tick-borne diseases.

This organisation was formerly known as Australian Chronic Infectious Disease Society (ACIDS).

This document has been lodged by Dr Peter Dobie, ACIIDS secretary, on behalf of the ACIIDS board. The document is dated 10 March 2016 and signed by all members of the board.

There are 60 attachments.

The ACIIDS board comprises:

Dr. Richard Schloeffel	Chairperson
Dr. Peter Dobie	Secretary
Dr Sandeep Gupta	Finance Officer, Education Officer
Dr. Tania Ash	
Dr. Janet Kim	
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1. OVERVIEW

1. Many people are developing a Lyme-like illness (LLI) in Australia, often with chronic and debilitating symptoms.

2. In most cases this illness is acquired from a tickbite, but some patients appear to have acquired the illness from other arthropods such as lice and bedbugs.

3. The clinical features of this illness are similar to the clinical features of Lyme disease.

4. Many of these patients have positive laboratory tests for tick-borne infections such as Borrelia, Rickettsia, Babesia, Bartonella, ehrlichiosis and anaplasmosis.

5. The preponderance of the evidence suggests that the primary causative organism is a Borrelia bacterium.

6. Most of these patients respond to treatment with antibacterial agents; this is consistent with the illness being a bacterial infection.

1. EVIDENCE FOR A LYME-LIKE ILLNESS IN AUSTRALIA

There is strong evidence that a Lyme-like illness can be acquired in Australia.

The preponderance of evidence suggests that Borrelia is the primary causative organism responsible for this illness.

Borreliosis is a term that will be used at times in this submission; this term refers to infection with Borrelia bacteria, and is another name for Lyme disease.

The evidence for a Lyme-like illness in Australia is as follows:

1. Many people are becoming unwell, sometimes very unwell, after a tickbite in Australia.

2 .The clinical features of this illness are similar to the clinical features of borreliosis (Lyme disease).

3. Many of these patients have positive blood tests for tick-borne infections such as Borrelia, Rickettsia, babesiosis, bartonellosis, ehrlichisosis and anaplasmosis.

4. Most of these patients respond to treatment with the same antibiotics that are used to treat borreliosis. This suggests that the illness is a bacterial infection. The antibiotic treatment often needs to be continued for an extended period.

5. The members of ACIIDS are currently treating approximately 1500 patients with this illness, and have treated in total approximately 4000 patients.

Moat of these patients have positive blood tests for Borrelia at Australian and/or overseas laboratories. The overseas laboratories are fully accredited in their respective countries.

6. The members of ACIIDS have treated approximately 300 patients with positive blood tests for Borrelia who have never left Australia.

7. The first cases of Lyme disease being acquired in Australia were reported in the Medical Journal of Australia in 1982 (ref.1) and 1986 (ref. 2).

8. A study that found the bacteria that cause Lyme disease in Australian ticks was reported in the Medical Journal of Australia in 1991 (ref.4).

8. Russell and Dogget in 1994 studied Australian ticks; although they did not find B. burgdorferi, the bacterium that causes Lyme disease in the USA, they found “spirochetal objects” which may have been fragments of a different species of Borrelia (31).

9. Hudson in 1998 reported in the Medical Journal of Australia a case in which he had cultured (found definite evidence of) Borrelia in the skin biopsy of a patient. The patient had travelled to Europe, but the clinical details indicated that the infection may have been acquired in Australia (3).

10. Borrelia burgdoreri, the bacterium that causes Lyme disease, was found in skin biopsies of two patients bitten by ticks in Australia in 2014 (attachment 4).

11. Irwin in 2015 identified a species of Borrelia in Australian ticks (attachment 32)

12. Irwin in 2015 identified Anaplasma and Ehrlichia in Australian ticks; these bacteria are common co-infections seen in Lyme disease patients in the USA (attachment 33).

13. Mayne in 2014 described a series of 500 confirmed cases of borreliosis, 89 of whom had never left Australia (attachment 1).

14. There have been numerous cases in Australia of patients who have developed an erythema migrans (EM or "bull's-eye") rash, as seen in Lyme disease in the United States, after a tickbite, and then developed LLI – examples of the rash are attachments 50,53,54,55.

While the preponderance of the evidence suggests that Borrelia is the primary causative organism, it is possible that the species of Borrelia primarily responsible for the illness in Australia has not yet been identified.

Some people have claimed, on the basis of three studies examining ticks (the study by Russell and Dockett and the two studies by Irwin) that borreliosis cannot be acquired in Australia. It is unreasonable to make such a claim on the basis of three studies.

2. PREVALENCE AND DISTRIBUTION OF LYME-LIKE ILLNESS IN AUSTRALIA

a) Prevalence

It is difficult to gauge the prevalence of this illness in Australia.

The members of ACIIDS are currently treating approximately 1500 patients with this illness, and have treated a total of approximately 4000 patients with this illness.

There are also other patients who
- have been treated by doctors who are not members of ACIIDS
- have been incorrectly diagnosed with other illnesses by other doctors
- have sought help from naturopaths rather than doctors.

ACIIDS estimates that there are tens of thousands of patients in Australia suffering from this illness.

Most people who are bitten by a tick in Australia do not develop LLI; ACIIDS believes that the proportion of Australian ticks that carries the causative organism is small.

b) Distribution

The illness is most common on the east and west coasts, but confirmed cases have been reported from every state and territory.

4. METHODS TO REDUCE THE STIGMA ASSOCIATED WITH LYME-LIKE ILLNESS FOR PATIENTS, DOCTORS AND RESEARCHERS

Discrimination against patients suffering from this illness, and the doctors who treat them, is rife.

Many patients have been traumatised by their experience with medical specialists and in hospital emergency departments; they have been subject to derision and verbal abuse.

Community nurses sometimes refuse to care for patients suffering from this illness.

Potential methods to reduce stigma could include the following:

1) A valuable intervention to reduce stigma would be for the Chief Medical Officer to contact all Australian medical practitioners stating that

- there is significant evidence of a Lyme-like illness in Australia (although the causative organism is yet to be determined)
- this illness is an important public health issue in Australia
- patients suspected of suffering from this illness should be offered appropriate diagnostic tests and support for this illness
- patients suffering from this illness should be treated with compassion and not be subject to discrimination
- further opinion should be sought from ACIIDS when doubt exists in the diagnosis or management of this condition.

2) Community nursing services should be informed that we have a LLI in Australia, and instructed not to discriminate against patients in whom this diagnosis has been made.

3) AHPRA should immediately cease placing restrictions on medical practitioners on the basis of diagnosis and treating Lyme-like illness.

4) Government funding should be allocated towards research into tick-borne diseases in Australia.

5. THE PROCESS FOR DIAGNOSIS FOR PATIENTS WITH LYME-LIKE ILLNESS WITH A SPECIFIC FOCUS ON LABORATORY TESTING PROCEDUES AND ASSOCIATED QUALITY ASSURANCE PROCESSES, INCLUDING RECOGNITION OF ACCREDITED INTERNATIONAL LABORATORY TESTING

The diagnosis of LLI is a three-step process comprising

1) taking a detailed history from the patient, with the use of questionnaires
2) thorough physical examination
3) laboratory tests.

While it is preferable that doctors perform laboratory testing for this illness, ACIIDS considers that a provisional diagnosis of LLI can be made without performing laboratory testing. There are two reasons why ACIIDS holds this opinion:

1) The Centers for Disease Control, Atlanta, Georgia, USA (CDC) states that Lyme disease is a clinical diagnosis, which means that a diagnosis that can be made on the basis of history and examination, without performing laboratory testing. The following is a quote from the CDC:

"Lyme disease is diagnosed based on symptoms, physical findings (eg rash), and the possibility of exposure to infected ticks."

The rash being referred to here is the erythema migrans (EM) rash. A diagnosis of Lyme disease can be made if this rash appears after a tickbite. This rash is sometimes seen in Australia after tickbites, although less commonly than in the USA.

2) Borreliosis can be seronegative (this means that patients can develop borreliosis with negative blood tests).

Laboratory testing for borreliosis is complex and controversial. There are two opinions here - the opinion promulgated by the Infectious Diseases Society of America (IDSA) and CDC, and the different opinion promulgated by the International Lyme and Associated Diseases Society (ILADS) and ACIIDS.

ILADS is an international interdisciplinary group of physicians and researchers dedicated to improving the diagnosis and treatment of tick-borne diseases. Members include neurologists, rheumatologists, internists, general practitioners, paediatricians, immunologists, ophthalmologists, dentists, and psychiatrists.

ILADS has guidelines for the diagnosis and treatment of borreliosis (attachments 25,34). The views of ACIIDS are closely aligned with those of ILADS.

IDSA and CDC maintain that the so-called "two-tier" protocol should be used for the laboratory diagnosis of borreliosis. This protocol involves firstly performing the ELISA serology test; if the ELISA test is positive then the Western Blot or Immunoblot serology test is performed.

According to this protocol, the diagnosis of borreliosis can only be made if both the ELISA and Western Blot/Immunoblot are positive.

The two-tier protocol for testing for Borrelia is not universally accepted. This protocol was established for disease surveillance, but pathologists and infectious disease specialists have misused the surveillance criteria for diagnosis.

ILADS and ACIIDS consider that the two-tier protocol should be abandoned because of the poor sensitivity of the ELISA test. The ELISA is not sensitive enough to detect most cases of borreliosis.

There is a large body of scientific opinion that the first-line laboratory test for borreliosis should be the Western Blot or Immunoblot. This is the position held by ILADS and ACIIDS.

Recent studies by the group responsible for the Lyme disease proficiency testing for the College of American Pathologists came to the conclusion that the currently available ELISA tests do not have adequate sensitivity to meet the two-tiered approach recommended by the CDC for surveillance (28).

The CDC has cautioned that this surveillance case definition was developed for national reporting of Lyme disease, and that it is not appropriate for clinical diagnosis (30).

The CDC further notes that it is inappropriate to use surveillance case definitions 'for establishing clinical diagnoses, determining the standard of care necessary for a particular patient, setting guidelines for quality assurance, or providing standards for reimbursement' (30).

The test performed by most Australian labs for borreliosis is the ELISA test. This is one of the reasons that borreliosis is under-diagnosed in Australia.

The members of ILADS and ACIIDS also consider that polymerase chain reaction (PCR) testing is valuable in the diagnosis of borreliosis.

Australian doctors treating borreliosis frequently use overseas laboratories for testing. There are three reasons for using overseas laboratories:

1) Only two Australian laboratories (Australian Biologics and Australian Rickettsial Reference Laboratory) will perform Western Blot/Immunoblot testing without first performing the ELISA test.

2) Only two Australian laboratories (Australian Biologics and Australian Rickettsial Reference Laboratory) will perform PCR testing for borreliosis.

3) Patients with LLI should be tested for co-infections as well as Borrelia. These co-infections include babesiosis, bartonellosis, Mycoplasma, Rickettsia, human monocytic ehrlichiosis (HME) and human granulocytic anaplasmosis (HGA). Comprehensive testing for bartonellosis and babesiosis is not available in Australia.

The three overseas laboratories most commonly used are IGeneX (USA), Arminlabs (Gemany) and BCA-Labs (Germany) (formerly known as Infectolab). These laboratories are fully accredited in their respective countries.

IGeneX is a reference laboratory recognized by the American College of Pathologists, and it is also Clinical Laboratory Improvement Amendments (CLIA), Medicare, and Medicaid approved, thus satisfying licensing requirements for testing throughout most of the United States to perform highly complex clinical testing. The US Food and Drug Administration and CDC oversee the performance of the CLIA. IGeneX has also met licensing requirements for testing in the states that require additional licensing: California; Florida; Maryland; New York; and Pennsylvania.

Both Arminabs and BCA-Lab are accredited with DAKKS, the German pathology accreditation authority. Arminlabs co-operates with Gartner Laboratories, one of the largest German pathology providers.

Accreditation and licensing documents for IGeneX, BCA-Lab and Arminlabs are attached:

IGeneX: CLIA certificate and licenses for California, Florida, Maryland, New York, Pennsylvania and Rhode Island: Attachments 36, 37, 38, 39, 40, 41, 42, 60.

Arminlabs: Attachments 6,7

BCA-Lab: Attachments 8,9

There is a mutual recognition arrangement between DAKKS and NATA (National Association of Testing Authorities, Australia). Both DAKKS and NATA are signatories to the International Laboratory Accreditation Cooperation (ILAC); there is thus no justification for Australian doctors to reject results from Infectolab, BCA-Lab or Arminlabs.

ACIIDS considers Australian Biologics (Sydney) to be an excellent laboratory, with high standards. We suspect that the reasons why NATA accreditation has not been granted to Australian Biologics are political.

Immune suppression and dysregulation by Borrelia is an important issue, and one of which many clinicians are unaware.

Borreliosis can be seronegative because it an immunosuppressive organism; this means that the bacterium suppresses the immune system.

There are many references in the scientific literature relating to seronegativity and immune evasion in borreliosis, and the fact the Borrelia is an immunosuppressive organism (17,19, 20, 21, 34, 35, 36); attachments 10, 12, 13, 14, 15, 16, 17, 18, 20, 21, 22, 23, 29 and 30.

One particularly pertinent article published in the New England Journal of Medicine concludes that:

"…the presence of chronic Lyme disease cannot be excluded by the absence of antibodies against B. burgdorferi..."

(B. burgdorferi is the species of Borrelia that causes Lyme disease in the USA) (Attachment 35).

This article in such an esteemed journal is also relevant for the acknowledgement of the existence of chronic Lyme disease (the existence of chronic Lyme disease is denied by IDSA – see below).

Recent studies have shown that tick saliva carries immunosuppressive substances that enable tick-borne agents to invade tissues while paralysing the local immune response (22,23).

There are several reasons why seronegativity might occur in borreliosis:

• Serologic tests may be performed too early (before antibodies are formed); B. burgdorferi may not be present in the blood (it may be in tissues) or may have eluded the immune system by adopting a cell wall-deficient L–form.

• Antibodies in the patient's blood may be bound into immune complexes.

• Antibodies may not be present in the patient's blood for other reasons (e.g., the use of antibiotics early in the course of the disease or systemic steroid therapy may abrogate the immune response to B. burgdorferi, and late in the disease, antibody levels may fall to very low levels) (24,25,26,27).

It has been the observation of ILADS and ACIIDS doctors that borreliosis patients sometimes do not become seropositive (ie develop antibodies) until after they have been commenced on treatment, and that IgM antibodies may persist for months or years.

In 2013, Virginia Governor Bob McDonnell signed the Lyme Disease Testing Disclosure Act, which mandates that all physicians who suspect and test patients for Lyme disease must disclose that a negative test result does not necessarily mean that the patient does not have Lyme disease.

6. EVIDENCE OF INVESTMENTS IN CONTEMPORARY RESEARCH INTO AUSTRALIAN PATHOGENS SPECIFICALLY ACQUIRED THROUGH THE BITE OF A TICK AND INCLUDING OTHER POTENTIAL VECTORS

1) The Tick Borne Disease Unit at Sydney University is currently undertaking a research project to determine the diagnostic criteria for Australian LLI. Validation of appropriate pathology in the Australian context is the initial focus of the study. ELISA testing, Western Blot and PCR are being assessed for their diagnostic rigor. The project is hampered by lack of funding.

2) Dr Peter Irwin of Murdoch University has undertaken valuable research and published his findings (attachments 32 and 33). Dr Irwin is continuing his studies into ticks and his findings are expected to give more insights into Australian tick-borne diseases.

7. POTENTIAL INVESTMENT INTO RESEARCH TO DISCOVER UNIQUE LOCAL CAUSATIVE AGENTS CAUSING A GROWING NUMBER OF AUSTRALIANS TO DEVELOP A DEBILITATING ILLNESS

ACIIDS has commenced planning a retrospective study on a group of patients that have been diagnosed with LLI and treated for this illness.

8. THE SYMPTOMS AND SIGNS OF AUSTRALIAN LYME-LIKE ILLNESS, AND THE

TREATMENT PATIENTS RECEIVE FROM MEDICAL PROFESSIONALS

A) SYMPTOMS AND SIGNS OF AUSTRALIAN LLI

The clinical features (symptoms and signs) of LLI can mimic the clinical features of many other illnesses.

i) Symptoms

The symptoms of LLI are similar to those experienced by patients diagnosed with Lyme disease in the United States and Europe.

Most ACIIDS members use a patient questionnaire to help define the totality of a patient's symptomatology.

It is important to differentiate between about acute symptoms, which are experienced within 48 hours of the tickbite, and the symptoms of chronic LLI, which are experienced months or years after the tickbite.

This infection can sometimes lie dormant or latent for an extended period; patients sometimes do not develop symptoms until months or years after the tickbite. Not all patients develop acute symptoms.

The symptoms of acute LLI typically include fever, fatigue, headache, joint pain and muscle pain. Some patients also develop a distinctive skin rash known as erythema migrans (EM); this is often referred to as a "bulls-eye" rash. Patients may occasionally develop encephalitis or meningitis.

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

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

Other symptoms of chronic Lyme-like Illness can include sharp pains, numbness or pins and needles in the limbs, sensitivity to light and sound, sore throat, swollen glands, sleep disturbance, palpitations, limb weakness, muscle twitching, non-epileptic seizures, anxiety, depression, panic attacks, constipation, dizziness, vertigo, fainting episodes, double vision and tinnitus (ringing in the ears).

Some patients suffering from LLI have committed suicide. There are several reasons why some patients with LLI develop severe depression. The infection can have a direct effect on the brain causing depression, anxiety, panic attacks, personality disorders and psychosis (40). Patients also often become depressed because they have seen many doctors and have received no diagnosis or treatment, despite debilitating symptoms.

ii) Signs

Signs are clinical features of an illness observed by the physician on physical examination.

Signs in acute LLI can include fever and skin rash. Occasionally patients may develop signs of acute neurological involvement, with signs of encephalitis or meningitis.

A wide variety of signs can seen in chronic LLI:

Neurological system: Signs of cranial nerve involvement (such as Bell's palsy), peripheral nerve signs such as reduced sensation in the extremities and absent reflexes, nystagmus, fasciculation, poor coordination, muscle weakness, ataxia, difficulty walking, positive Babinski response, clonus.

Cardiovascular system: ECG changes; arrhythmias due to borrelia carditis; POTS (Postural Orthostatic Tachycardia Syndrome).

Dermatological system: The skin rash of acrodermatitis chronic atrophicans (ACD); dermatological manifestations of bartonellosis may also be seen.

Gastrointestinal system: Enlarged liver or spleen, gastroparesis, loaded colon due to slow transit constipation.

Musculoskeletal system: Swollen joints, muscle weakness, muscle tenderness and trigger points.

Differential diagnosis includes the following disorders: Multiple sclerosis, amyotrophic lateral sclerosis (ALS), Parkinson's disease, Alzheimer's disease, Chronic Fatigue Syndrome, fibromyalgia, rheumatoid arthritis, polymyalgia rheumatica, polymyositis, autism and complex regional pain syndrome.

B) TREATMENT PATIENTS RECEIVE FROM MEDICAL PROFESSIONALS

1. Treatment received from ACIIDS members

The members of ACIIDS, who are primarily general practitioners, are the Australian experts in the diagnosis and treatment of tick-borne diseases and LLI. We have more expertise and experience in this field than any other doctors in this country.

ACIIDS has formulated consensus-based treatment guidelines for the treatment of borreliosis and related co-infections (attachment 24).

These guidelines are based on the guidelines of similar organisations overseas, as well as the peer-reviewed literature and expert opinion. The mainstay of treatment is antibiotics (either oral or intravenous), but many supportive measures are also used.

It is the experience of ACIIDS doctors that most patients with Australian LLI respond to the same treatment as is used internationally for the treatment of Lyme disease.

The views of ACIIDS regarding the treatment of borreliosis are closely aligned with those of ILADS.

ACIIDS doctors follow the ACIIDS treatment guidelines and also refer to the guidelines laid down by

- ILADS (attachments 25,34)
- German Lyme specialists (attachment 2)
- Dr Joseph Burrascano (32) and Dr Richard Horowitz (33), two of the leading Lyme disease specialists in the United States.

The 2014 ILADS guidelines are intended to assist clinicians by presenting evidence-based treatment recommendations, which follow the Grading of Recommendations Assessment, Development and Evaluation system.

Treatment of Lyme disease is controversial. There are two schools of thought – the views promulgated by IDSA, and the views promulgated by ILADS.

There are two principal differences between the points of view of IDSA and ILADS:

1) IDSA claims that no case of Lyme disease requires more than four weeks of treatment with antibiotics, whereas ILADS considers that much longer courses of antibiotics are needed in cases of chronic Lyme disease.

2) IDSA claims that there is never a need to use more than one antibiotic at a time to treat Lyme disease, whereas ILADS doctors hold the opinion that it is often necessary to use a combination of antibiotics.

IDSA does not address the issue of the patient who acquires Lyme disease from a tickbite but does not receive initial treatment. This is a glaring omission. Four weeks of antibiotics is probably sufficient if patients are treated soon after the tick bite, but patients who acquire the infection and do not receive initial treatment will often develop chronic Lyme disease.

ACIIDS considers that there are two reasons why it is often necessary to use a need to use a combination of antibiotics:

- The Borrelia bacterium exists in three morphological forms in the human body (a cell-wall form, a cell-wall deficient or L-form, and an encysted form); different antibiotics are required to treat each of these three forms.

- Most cases of borreliosis require antibiotics to treat co-infections as well as the borreliosis.

It appears that IDSA is unaware of the pleomorphic nature of the organism, or chooses to ignore this issue.

There are many studies supporting the practice of ILADS and ACIIDS doctors to use a combination of antibiotics to treat the three different morphological forms of Borrelia (27, 37, 38, 39); see also attachment 31.

It is also the opinion of ACIIDS that biofilm is a major issue in this illness.

Co-infections that may require treatment in patients suffering from LLI include Bartonella, Babesia, Rickettsia, ehrlichiosis, anaplasmosis and Mycoplasma. The principal treatment for these co-infections is antibiotics. In some patients it appears that the bulk of their symptoms are due to the co-infections rather than the borreliosis.

There are a large number of scientific studies that attest to the need for, safety of, and efficacy of, long-term antibiotics (including IV antibiotics) in the treatment of chronic borreliosis. Some are attached to this submission – see attachments 5, 26, 27, 28, 29.

ACIIDS doctors are aware of the possible dangers of long-term antibiotic treatment, such as the development of hepatotoxicity, pseudomembranous colitis or drug resistance. Our patients are closely monitored and any side-effects of antibiotic treatment are dealt with in the early stages before they become problematic.

ACIIDS considers that the risk of not treating this illness is greater than the risk of potential adverse reactions to treatment.

Chronic borreliosis is not the only condition that requires treatment with long-term antibiotics. Other conditions include

- osteomyelitis
- leprosy
- tuberculosis
- severe acne
- prophlyaxis for recurrent urinary tract infections
- endocarditis
- Reiter's syndrome
- prophylaxis of at-risk populations such as asplenic children and young children with sickle cell disease.

Most cases of borreliosis and Australian LLI can be treated with oral antibiotics, but there is a role for intravenous antibiotics upon failure of oral medications in patients with persistent, recurrent or refractory illness, and in cases where there is neurological involvement (attachments 34 and 27).

The controversies relating to chronic Lyme disease in the USA are relevant to the Australian situation with regard to LLI.

IDSA has always maintained that chronic borreliosis does not exist; ACIIDS is however in agreement with ILADS that chronic borreliosis is a real clinical entity and a major public health issue, causing widespread illness in the community – in some cases profound disability - and a drain on medical resources (see attachments 34, 43, 45).

It is important to note here that a summary of the ILADS guidelines for the treatment of Lyme disease was recently posted on the website of the National Guidelines Clearinghouse (NGC), and the IDSA guidelines were removed. The NGC is an initiative of the US Department of Health and Human Services which is used as a reference for physicians and healthcare practitioners in treating patients (49) (attachment 58).

2. Treatment received from other medical practitioners

Patients suffering from this illness generally receive little or no treatment from medical specialists and hospital emergency departments. Patients have usually been dismissed by specialists, and often given a psychiatric or non-specific diagnosis. Many patients have been considerably traumatised by their interactions with doctors.

9. OTHER RELATED MATTERS

(A) SOCIAL & POLITICAL CONSIDERATIONS

1) Several general practitioners treating this illness have been told by the Australian Health Practitioners Regulatory Agency (AHPRA) that they are no longer permitted to diagnose or treat Lyme disease.

2) It appears that AHPRA and the state Medical Boards have taken disciplinary action against some general practitioners treating Lyme disease on the basis of complaints made by, and evidence given by, medical specialists, particularly infectious disease specialists.

As a result, ill patients are being denied treatment.

3) Most infectious disease specialists deny the existence of Australian LLI and will not treat patients suffering from this illness; it appears that these specialists are also seeking to prevent general practitioners from treating this illness.

4) Australian general practitioners should be free to treat this illness without fear of disciplinary action.

5) It is disturbing that AHPRA and the state medical boards consider the opinions of infectious disease specialists to be more relevant than those of the general practitioners treating the illness.

6) When considering cases of general practitioners who have been treating borreliosis, AHPRA and the state medical boards have not called peers of those doctors (other general practitioners treating this illness) to give evidence.

7) It is the experience of ACIIDS doctors that Australian infectious disease specialists, when presented with a positive laboratory test for borreliosis, invariably consider the result to be a false positive, regardless of which laboratory the test was done at, and regardless of the clinical presentation.

8) It has been suggested in some quarters that general practitioners should refer to infectious disease specialists any patients suspected of suffering from this illness. ACIIDS rejects this advice. Patients with this illness typically receive little or no treatment from specialists, whereas the members of ACIIDS generally get good results treating these patients according to the ACIIDS guidelines.

9) General practitioners are highly skilled at treating infectious diseases and their opinions should not be dismissed by specialists and regulatory authorities.

10) Patients suffering from this illness have frequently seen 10-30 doctors before being given the correct diagnosis.

11) There is a high human cost to patients suffering from this illness:

- Patients often experience debilitating long-term symptoms
- Patients experience difficulty obtaining a diagnosis and treatment because there is only a small number of doctors treating the illness.
- Patients experience difficulty meeting medical expenses.
- Patients experience difficulty with relationships due to financial burden, high rates of mental and emotional symptoms and impact on social function.
- Patients are often too unwell to work and often are dependent on Centrelink disability allowance, or on financial support from spouses and relatives.
- Patients have often been treated with contempt by medical practitioners.
- A small number of patients have committed suicide.
- There is a risk that untreated and severely ill patients might die from this illness.

12) There is a high economic cost to the community because of the expenses involved with medical treatment, and the fact that many patients are too unwell to work. The longer that a patient does not receive treatment, the longer they take to rejoin the work force.

(B) IDSA CONFLICT OF INTEREST

In 2008 Connecticut Attorney General Richard Blumenthal uncovered serious flaws in the IDSA process for writing its 2006 Lyme disease guidelines (6):

Blumenthal's findings included the following:

- Several of the 2006 Lyme disease panelists had conflicts of interest;
- The IDSA's 2000 and 2006 Lyme disease panels refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease, once removing a panelist from the 2000 panel who dissented from the group's position on chronic Lyme disease to achieve "consensus";
- The IDSA blocked appointment of scientists and physicians with divergent views on chronic Lyme who sought to serve on the 2006 guidelines panel by informing them that the panel was fully staffed, even though it was later expanded.

Blumenthal added:

"The IDSA's 2006 Lyme disease guideline panel undercut its credibility by allowing individuals with financial interests -- in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies -- to exclude divergent medical evidence and opinion".

(C) PREFERENTIAL TREATMENT BY CDC OF IDSA GUIDELINES FOR LYME DISEASE

In October 2014 a petition was filed by the Mayday Project Lyme patient advocacy group claiming that CDC provides preferential treatment to the IDSA by promoting IDSA's 2006 guidelines for diagnosis and treatment of Lyme disease while withholding information from the public about more recent guidelines from the ILADS,

The petition claimed that "CDC's preferential treatment of IDSA harms chronically ill patients, who are frequently misdiagnosed and denied medically necessary treatment because of restrictions imposed by the IDSA guidelines." It added that "CDC's failure to provide equivalent exposure for the ILADS guidelines compounds the harm by limiting access to information about evidence-based treatments that could help these severely ill patients recover from this devastating disease."

(D) TRANSPLACENTAL AND SEXUAL TRANSMISSION

Transplacental transmission of borreliosis has been documented, and confirmed by CDC (41,42, attachments 51,52).

Other references pertaining to transplacental transmission are listed are listed in attachment 49.

Congenital transmission means that children are born with existing illness, leading to significant undiagnosed morbidity. Some ACIIDS members are diagnosing and treating children presenting with Chronic Fatigue Syndrome, failure to thrive, learning difficulties and autism.

There is evidence of sexual transmission of borreliosis and some of the co-infections. Stricker and Middelveen have summarised the evidence (attachment 47); see also the paper by Middelveen, Burke et al (attachment 48).

Some ACIIDS members have diagnosed generations of family members with both sexual and transplacental transmission of this disease.

(E) POSSIBLE TRANSMISSION BY BLOOD TRANSFUSION

There is concern in the scientific community that it may be possible for Lyme disease to be transmitted by blood transfusion, although there are no confirmed cases (48). It is known that the Lyme disease bacterium can survive in blood that has been stored for donation (43,45).

B. miyamotoi, a species of Borrelia that has been implicated in Lyme disease, can survive standard storage conditions of most human blood components (attachments 56,57).

There are confirmed cases of babesiosis and ehrlichiosis being transmitted by blood transfusion (44,46,47).

(F) RECOMMENDATIONS

A) Clinicians and researchers need to work together to further clarify the pathogen(s) involved in this illness; government funding should be allocated towards this research. As a matter of urgency, funding for the research project by the Tick Borne Diseases Unit at Sydney University should be a priority.

B) AHPRA should be prevented from stipulating that any doctor is not permitted to diagnose or treat Lyme disease.

C) AHPRA, the state medical boards and the Chief Medical Officer should be required to recognise the members of ACIIDS as the Australian experts in the diagnosis and management of tick-borne diseases and LLI.

D) AHPRA and the state medical boards should be required to call a member of ACIIDS as an expert witness in cases involving general practitioners who have been treating LLI.

E) A program should be put into place to educate general practitioners in the diagnosis and management of tick-borne diseases and LLI; ACIIDS is willing to supervise this education program.

F) There should be expanded financial assistance from the government for patients suffering from this illness.

G) There is a need for a case definition for Australian LLI. ACIIDS would be willing to work with infectious disease specialists to develop such a definition.

H) ACIIDS recommends that the front-line laboratory tests for Lyme disease/borreliosis should be Western Blot (or Immunoblot) and PCR.

I) When reporting the result of an ELISA test for Lyme disease, Australian pathology

laboratories should be required to add a note that a negative ELISA test does not exclude a diagnosis of Lyme disease or borreliosis.

J) ACIIDS recommends that all blood donors be screened for borreliosis and associated co-infections.

K) ACIIDS recommends that Chief Medical Officer write to all Australian medical practitioners stating that

- there is significant evidence of a Lyme-like illness in Australia (although the causative organism is yet to be determined)
- this illness is an important public health issue in Australia
- patients suspected of suffering from this illness should be offered appropriate diagnostic tests (not the ELISA test for Lyme disease) and treatment
- patients suffering from the illness should be treated with compassion and not be subject to discrimination
- further opinion should be sought from ACIIDS when doubt exists in the diagnosis or management of this condition.

SIGNED BY THE ACIIDS BOARD

See attachment 59.

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