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MSIDS INC.
Multiple Systemic Infectious Disease Syndrome Inc.
Formerly WA Lyme Association

9 May 2016

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

community.affairs.sen@aph.gov.au

Dear Ms Radcliffe

Re: Responses to the Senate Inquiry into the growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients.

Regrettably, the MSIDS Inc. has been unable to complete our organisation's submission for the above inquiry within the generously extended timeline.

Although working consistently on our submission (which currently exceeds 20,000 words) for many months, due to illness and other life events adversely impacting on our team members, we have been unable to finalise the document to our satisfaction. Rather than tender an unfinished submission, we would prefer to submit a completed document when the Community Affairs Committee reconvenes following the pending election.

To register our intent, we would be happy for you to publish the documents supplied as background to our appearance at the inquiry hearing held in Perth on 14 March if this is still possible during the 'caretaker' period. (See documents re-attached.)

Our incomplete submission focuses on providing evidence to support the 13 recommendations for immediate action (as per the attached document). As a way forward in future, MSIDS Inc. continues to support the strategies outlined in the Patient-focused Action Plan (attached), which was drafted by WA Lyme Association and submitted in 2014 to the Chief Medical Officer via the LDAA's main patient submission in response to the Scoping Study.

We are sincerely grateful to the current Community Affairs Committee for their compassionate interest in the plight of Australian sufferers of Lyme-like illness. We thank them, too, for having prepared an Interim Report prior to the declaration of the election. We are also hopeful that this genuine interest will continue among those who are appointed to Community Affairs Committee following the election.

Yours sincerely

Kate Daniels

Kate Daniels

Chairperson
Multiple Systemic Infectious Disease Syndrome (MSIDS) Inc
(formerly WA Lyme Association)

Attachments:

1. MSIDS Inc Recommendations for Senate Inquiry into Lyme-like Illness
2. About MSIDS Inc (formerly WA Lyme Association)
3. Patient-focused Action Plan - developed by WA Lyme Association as an appendix to the LDAA's 2014 patient response to the Scoping Study.
4. WA Lyme Association 2014 submission in response to Scoping Study.

MSIDS Inc. – Senate Inquiry into Lyme-like illness

Recommendations:

Process

1. Broaden the Department of Health (DoH)'s focus beyond seeking microbial evidence of 'classical Lyme disease' *(Borrelia burgdorferi sl.)* to one of addressing the public health issue of an epidemic of vector-borne, multi-systemic infectious disease syndrome (MSIDS).
2. Review DoH policies relating to information dissemination and policy advice/guidelines to adopt a more proactive and visible public leadership role in addressing the emergence of a debilitating 'Lyme-like' illness of *as-yet-unknown* causative origins.
3. Develop a strategic plan and policy framework based on implementing aspects of the patient-submitted Strategic Action Plan that are not reliant on identifying a definitive causative agent.

Surveillance/Data Collection

4. Initiate a strategy for collection of data from clinicians, laboratories and government agencies to establish a foundation of data which will facilitate better understanding of the epidemiology, pathology and clinical features of Australian Lyme-like illness aka MSIDS.

Diagnosis & Testing

5. Conduct an independent review of Australian pathology accreditation processes, policies, practices and interpretation criteria with respect to 'Lyme disease' and co-infections.
6. Acknowledge pathology results obtained from accredited overseas laboratories, consistent with policy for other diseases.
7. Consult with Australian treating physicians to assist with developing a clinical case definition for Australian 'Lyme-like' illness aka MSIDS.

Treatment

8. Ensure the Australian public can access early-intervention, prophylactic treatment based on clinical presentation following tick bites.
9. Educate clinicians regarding the risks of tick-borne infections and provide guidelines for diagnosis and treatment.
10. Ensure Therapeutic Goods Administration (TGA) listing for drugs required to treat 'Lyme disease' and co-infections.
11. Ensure physicians treating according to evidence-based, overseas guidelines are not subjected to discrimination and sanctions.

Research

12. Facilitate and resource patient clinical studies focusing on Australian Lyme-like illness (MSIDS) inclusive of pathogens beyond 'classical Lyme disease'.

Prevention/Public Protection/Education

13. Ensure the public and medical front-line responders are provided with sound advice regarding the risks of tick-borne infection, prevention/risk minimisation and safe removal.

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WA Lyme Association

MSIDS Inc. was initially formed in 2012 as the WA Lyme Association (WALA) with the aim of providing peer support, information, research facilitation and advocacy on behalf of sufferers of Lyme-like illness in Western Australia.

When applying for legal incorporation in late 2014, it was decided to change the association's name to Multiple Systemic Infectious Disease Syndrome Incorporated (more easily pronounced as the acronym, *em-sids ink*). The term MSIDS has been used by Dr Richard Horowitz to describe the multi-systemic nature of the condition developed by patients suffering from chronic Borreliosis and associated co-infections.

This name was chosen with the aim of redirecting discussions stuck in semantic argument about whether classical 'Lyme disease' exists here toward a focus on the medical condition Australian *patients* are experiencing, which arises when a cluster of bacterial and parasitic pathogens cause debilitating illness following bites from ticks and other arthropods.

While 'classical Lyme disease' (*Borrelia burgdorferi* sl), as occurs in the northern hemisphere, has yet to be definitively identified in Australia, many of the ***tick-borne co-infections – such as Anaplasma, Babesia, Bartonella, Ehrlichia and Rickettsia – are already known to exist here.***

Stigma resulting from a concerted campaign by scientists and medical authorities to deny the existence of 'Lyme disease' in this country has resulted in health practitioners being too afraid to diagnose and treat even those infections known to occur from tick and other arthropod bites.

While our medical authorities continue to state there is no evidence of 'Lyme disease' in Australia, they deny the most incontrovertible evidence: ***Thousands of Australians are being struck down by debilitating – and sometimes life-threatening – illness following bites from ticks and other blood-sucking arthropods.***

The number of patients diagnosed with 'Lyme disease' in WA has risen, from approximately 150 in 2012, to in excess of 1000 in 2015. The growth of this figure is impeded only by the limited availability of medical practitioners willing to diagnose and treat 'Lyme disease' in WA. Hundreds of patients still wait for up to a year to see a Lyme-aware doctor while others incur huge expenses travelling to eastern Australia, the United States, Europe, South Africa and Asia to receive treatments unavailable in WA.

Since 2013, in Western Australia alone, there have been *five* seriously ill patients couldn't wait for the science to catch up with the reality of their unendurable suffering and ended their own lives. In February 2016, they were joined by another Queensland patient, making a ***total of six lives lost to Lyme-like illness.***

MSIDS Inc (as WALA) members were key contributors to the national patient task force that prepared the 2014 formal submission submitted through the Lyme Disease Association of Australia (LDAA) in response to the Scoping Study Report commissioned as part of the Chief Medical Officer's review of Lyme disease in Australia. The association also submitted a shorter complementary submission raising issues more specifically related to Western Australia.

MSIDS Inc (as WALA) took a lead role in developing the Patient-focused Action Plan that was appended to the LDAA's submission to the Chief Medical Officer (CMO) to provide government and medical authorities with a strategic blueprint for addressing the 'Lyme disease' problem in Australia. (Copy attached.)

In the two years since this plan was submitted, our governments have failed to implement even those strategies that are not reliant on identifying a definitive causative agent for the illness. Thus, existing patients continue to suffer discrimination and denial of adequate health services and the public remains at risk of infection from a preventable disease.

In September 2014, the association coordinated a Lyme Awareness Seminar in Perth that, while well-attended by affiliated health professionals and the general public, attracted minimal attendance from the hundreds of general practitioners and specialists who were invited and provided background information about Lyme disease.

With a number of other groups now providing patient support services and involved in public awareness-raising for 'Lyme disease' in WA, rather than duplicating, it was decided to prioritise the association's primary focus toward advocating for policy change and research facilitation.

Although the 300+ client network serviced by MSIDS Inc. is primarily WA-based, since early 2015 the organisation has extended membership Australasia-wide to include those in the 'Lyme' community who support these priorities.

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LYME DISEASE
ASSOCIATION OF AUSTRALIA
For Lyme Disease Awareness & Action

Lyme disease in Australia

Scoping Study Submission: Appendix A
Patient Strategic Action Plan

Lyme Disease Association of Australia

JANUARY 2014

> *"Courage is what it takes to stand up and speak: courage is what it takes to sit down and listen" Winston Churchill*

Appendix A – Patient focused strategic approach to the Lyme problem

Patients scope the problem as follows:

- There is a rapidly increasing cohort of patients experiencing Lyme-like illness in Australia.
- More than a thousand patients have already been clinically diagnosed with a Lyme-like illness by reputable and knowledgeable GPs there are potentially many thousands more who remain undiagnosed.
- The majority of the clinically diagnosed patients have also had positive *Borrelia* spp. serology results via overseas laboratories and some in Australian labs.
- Most of these patients have also been diagnosed with a selection of Lyme-related co-infections, such as Babesiosis, Bartonellosis, Ehrlichiosis, Rickettsiosis, Mycoplasmosis, Chlamydophila pneumoniae.
- Some patients have travelled overseas; some have never left Australia.
- Some patients can confirm a history of tick bites; many cannot.
- There is sufficient anecdotal evidence among this cohort to suggest other modes of transmission, which warrants further scientific investigation.
- Many patients who have been receiving treatment based on protocols recommended by Lyme-aware GPs have already experienced significant health improvements.
- There are no formal policies for the proactive medical treatment of Lyme disease and Lyme-like illness in Australia.
- Most patients have experienced difficulties in readily accessing affordable, reliable diagnosis and treatment by Australian clinicians who are receptive and appropriately educated to treat their condition.
- Most patients have experienced significant impediments and many have experienced discrimination due to a lack of public awareness of Lyme-like illness and an official position that Lyme disease cannot exist here (since it was not located in a 1994 study of east coast ticks).
- There are no formal policies in place to ensure the protection of the Australian public as a whole from the possible spread of Lyme-like illness via various potential means of transmission.

Patients asked these questions:

1. What can be done to assist patients who are already infected with Lyme-like illness?
2. What are the impediments to accessing appropriate testing and treatment?
3. What can be done to prevent further infection among the general public?
4. What might be causing this illness (with totally open parameters, not focused only on ticks)?

Patients identified these Key Issues & Objectives:

1. Australian Patients experience difficulties obtaining a reliable diagnosis for Lyme-like illness in Australia.

> *Objective: Ensure patients can readily access affordable and reliable diagnosis and 'best practice' laboratory testing by 2016.*

2. Australian patients with Lyme-like illness experience difficulties accessing appropriate and affordable medical treatment for their condition(s) and often encounter discrimination.

> *Objective: Ensure patients with Lyme-like illness are able to access appropriate and affordable treatment by 2016.*

3. The Australian public has not been made aware of the potential risks of exposure to Lyme-like illness from ticks and other possible vectors nor has a national health policy been developed to address treatment issues.

> *Objective: Reduce the risk of an epidemic of late stage Lyme-like illness by ensuring the Australian public is aware of the potential risks of exposure to possible transmission(s) and by improving access to early intervention treatment protocols throughout Australia by 2016.*

4. Patients with Lyme-like illness experience discrimination because their medical condition is not formally recognised.

> *Objective: Ensure an end to discrimination by raising public awareness of Lyme-like illness by 2016.*

Patients identified these Priority Strategies:

1. Chief Medical Officer to issue a public statement acknowledging the existence of Lyme-like illness in Australia and ensure widespread dissemination throughout medical and public agencies, as well as through mass media.

2. Implement a broad scale Public Education Program, targeting medical community and sectors of the public identified as 'at risk'.

3. Implement an Interim Treatment Strategy for existing patients while further research into causative factors is conducted.

4. Review Australian laboratory testing processes to ensure reliability of testing.

5. Conduct a study of the unique patterns (epidemiology) of Lyme-like illness in Australia before making assumptions about its causes.

6. Pursue research into 'causative factors' ensuring an open focus to consider all potential sources of transmission.

Patient focused Strategic Action Plan

1. Diagnosis and Testing

Major Issue: Patients experience difficulties obtaining a reliable diagnosis for Lyme-like illness in Australia.

Objective: *Ensure Australians experiencing Lyme-like illness can readily access affordable and reliable diagnosis and 'best practice' laboratory testing by 2016.*

Target for Change	Impediments		Strategies	Refer to:
Australian clinicians GPs & Specialists	Clinicians discount the possibility of Lyme disease in their diagnoses because an entrenched scientific position, based on a single study of indigenous ticks, leads them to conclude Lyme disease cannot exist in Australia, regardless of travel history and symptom presentation in their patients. They are also reluctant to consider diagnosing Lyme disease because of the controversy surrounding the disease.	1.1 1.2	CMO re-issue official statement regarding the existence of Lyme-like illness and the possibility of *Borrelia* or similar pathogen causing illness in Australia. Revise dissemination strategy to be more effective in reaching GPs.	
Australian clinicians GPs & Specialists	Clinicians frequently misdiagnose and recommend inappropriate treatment protocols.	1.3 1.4	Develop educational guidelines. Develop training program for clinicians in diagnosis of Lyme-like illness.	See Education Action Plan
ICPMR, PaLMS and referring laboratories	Australian laboratory tests appear biased towards a high false negative rate (when compared to same-sample overseas testing). Positive test results are often dismissed as being erroneous	1.5 1.6	Conduct a thorough review of current Australian testing procedures. Study laboratory practices in all countries testing for Lyme-like illness to ascertain 'best practice'.	See Diagnosis & Testing Action Plan
CMO CACLD	Uncertainty about the causative factors for Lyme-like illness in Australia has meant most clinicians rule out Lyme disease as a differential diagnosis.	1.7 1.8 1.9	Conduct epidemiological research based on current patients with Lyme-like illness. Conduct retrospective research. Conduct clinical research.	See Research Action Plan
CMO CACLD	Research into Lyme disease appears to falter once simplistic causative factors have been identified, leaving many questions unanswered as to alternate potential causes of Lyme-like illness, and patients can be excluded when their presentations of the condition fall outside narrow definitions endorsed for diagnosis and treatment.	1.10	Study the unique presentations of Lyme-like illness in Australia before conducting research based on assumptions from other locations where Lyme disease and Lyme-like illness occurs.	See Research Action Plan

2. Treatment

Major Issue: Australian patients with Lyme-like illness experience difficulties accessing appropriate and affordable medical treatment for their condition(s) and often encounter discrimination.

Objective: *Ensure all Australian patients with Lyme-like illness are able to access appropriate and affordable treatment by 2016.*

Target for Change	Impediments		Strategies	Refer to:
CMO/CACLD	Attention to developing treatment protocols for existing patients has been delayed due to scientific focus on identifying causative agents before acknowledging medical condition.	2.1	Consult with clinicians with most experience treating Lyme-like illness in Australia and overseas.	See Treatment Action Plan for detail.
		2.2	Identify 'best practice'.	
		2.3	Develop interim treatment guidelines endorsed by CMO.	
		2.4	Ensure thorough dissemination of treatment protocols to all Australian clinicians.	See Education Action Plan for detail.
		2.5	Develop training for clinicians.	
Australian clinicians GPs & specialists	Patients attending GPs & specialists are prescribed inappropriate treatments, particularly antidepressants and steroids.		See Strategy 1.1 See Strategy 2.3	See Treatment Action Plan for detail.
Public hospitals	Patients attending public hospitals (particularly emergency departments) have been refused treatment when revealing a Lyme diagnosis in their medical history.		See Strategy 1.1 See Strategy 2.3	See Education Action Plan for detail.
GPs & Public hospitals	Patients presenting with a recent tick bite have been refused early intervention treatment with antibiotics, or incorrect antibiotics.	2.6	Implement early intervention strategy where infection is suspected. Administer antibiotic treatment (6 weeks minimum).	See Treatment Action Plan for detail.
PBS	Patients treating Lyme disease bear unsustainable expenses because many of the prescribed medicines they require are not covered under Pharmaceutical Benefits Scheme (PBS).	2.7	Authorise inclusion of pharmaceuticals regularly used in Lyme treatment protocols on PBS.	See Treatment Action Plan
Medical community	There is an acute shortage of Lyme-aware doctors available to treat patients with Lyme-like illness in Australia.		Implement Strategy 1.1 to reduce controversy and stigma associated with Lyme-like illness. Implement Strategy 2.5 - training for clinicians.	See Treatment Action Plan

3. Public awareness/Risk protection

Major Issue: The Australian public has not been made aware of the potential risks of exposure to Lyme-like illness from ticks and other possible vectors nor has a national health policy been developed to address treatment issues.

Objective: *Reduce the risk of an epidemic of late stage Lyme-like illness by ensuring the Australian public is aware of the potential risks of exposure to possible transmission and by improving access to early intervention treatment protocols throughout Australia by 2016.*

Target for Change	Impediments		Strategies	Refs/Timeframe
DoH CDNA	There are currently no formal mechanisms in place to measure the incidence of Lyme disease or Lyme-like illness in Australia.	3.1 3.2	Monitor incidence of Lyme disease in the Australian population. Initiate a national surveillance program.	
The Australian Public	Australians are generally unaware of the potential sources of and risks associated with transmission of Lyme-like illness.	3.3 3.4	Develop and disseminate public awareness campaign. Erect warning signage in areas of potential high risk exposure.	See Education Action Plan for detail.
GPs & Public hospitals	There is no early intervention strategy in place for people being bitten by arthropods known to be potential vectors for Lyme-like illness.	3.5	Ensure all GPs are aware of risks and ready to administer appropriate treatment for early intervention.	See Treatment Action Plan for detail.
Red Cross & Organ Donation agencies	There is a risk of transmission through blood banks and organ donation, as opting out is voluntary and only an option for those who have been correctly diagnosed.	3.6 3.7	Screening of blood for *Borrelia*, *Babesia* and other known co-infections. Notification to organ donors to withdraw from program after suspected tick bites.	
GPs, public health facilities.	Mothers may be transmitting pathogens to babies during pregnancy and breast-feeding.	3.8	Issue public health warnings to prospective parents and treat expectant mothers to minimise transmission risk.	See Education Action Plan for detail.
Public Health Education Programs, Clinicians.	The general public is unaware of the possibility of sexual transmission of Lyme disease, particularly from partners who remain undiagnosed.	3.9 3.10	Issue public health warnings regarding potential risks of LD along with other safe sex warnings. Warn patients diagnosed with Lyme-like illness of potential risks to sexual partners.	See Education Action Plan for detail.

4. Social welfare & discrimination issues

MAJOR ISSUE: Patients with Lyme-like illness experience discrimination because their medical condition is not formally recognised.

Objective: *Ensure an end to discrimination by raising public awareness of Lyme-like illness by 2016.*

Target for Change	Impediments		Strategies	Refs/Timeframe
Australian clinicians GPs, Specialists & Public Hospitals	Patients attending GPs, specialists and public hospitals (particularly emergency departments) have been subjected to humiliation and refused treatment when revealing a Lyme diagnosis in their medical history.		See Strategy 1.1.	See Education Action Plan for detail.
Department of Human Services / Centrelink	Patients have been denied welfare income payments, as Lyme-like illness is not recognised as an official medical condition. Children are denied disability supports because their illness is not currently listed for consideration on Centrelink paperwork.	4.1	Raise awareness of Lyme-like illness in public institutions including the relapsing recurring nature of manifestations	See Education Action Plan for detail.
GP, Public hospitals, DCD, Child welfare agencies	Parents have been threatened with losing custody of their children due to school non-attendance and/or told their children's obvious symptoms are psychosomatic when revealing they are suffering from Lyme-like illness, or are accused of Munchausen's syndrome by proxy.		As per 4.1	See Education Action Plan for detail.
Schools	Children suffering from Lyme-like illness are unable to perform to their potential and are frequently unable to attend school.	4.2 4.3	Open up pathways for partial homeschooling options. Provide additional in-school support options.	See Education Action Plan for detail.
Workers' comp & Insurance companies	Workers' compensation and income protection insurance claims are frequently rejected due to official ambiguity over existence of Lyme disease in Australia.	 4.4	See Strategy 1.1. Improve diagnosis and testing.	See Education Action Plan for detail.
CMO/Medicare	Disparity of costs between patients in tests available to them for diagnosing and testing Lyme disease.	4.5	Implement diagnostic guidelines	See Diagnosis & Testing Actions Plan
Australian public	Patients suffer from social discrimination due to the invisible, and sometimes alarmingly visible, symptoms of their disability.		See Strategy 1.1.	See Education Action Plan for detail.

5. Education Action Plan – in further detail

Target audiences	**Tasks**
All Australians	CMO to make a formal announcement to the Australian public regarding the existence of Lyme-like illness among Australian patients and the need to take precautions while research into potential transmission sources are further researched.
All Australian clinicians	Develop and disseminate educational packages on the background, diagnosis and treatment of Lyme-like illness. (Refer to 7. Treatment Action Plan for further details.)
Radiologists, IDS, Neurologists, private and public practices of specialists	Develop and disseminate specialist diagnostic and treatment guidelines for clinicians involved in differential diagnosis.
Government agencies, Educational institutions, public health centres, Centrelink, DCS	Develop and disseminate education packages providing medical background, care considerations and risk protection information regarding Lyme-like illness.
General public Private health centres, National Parks, State forests, coastal recreation areas, public and private camping areas, school camps	Develop public risk awareness campaign identifying arthropods suspected as sources of infection. Including: print and electronic media packages; signage in public areas; advertising and media stories.
Occupations with high risk of vector exposure Farming, bush regeneration, land care, forestry, mining, outdoor recreation and tourism industries	Develop risk awareness information for inclusion in industry WHS guidelines. Prepare news articles for distribution in industry newsletters. Best practice example: http://www.aabr.org.au/aabrs-tick-guide-now-available/
Public, including prospective parents via GPs & Public Hospitals, sex education programs.	Develop awareness information brochures to advise of ‘potential risk’ via sexual and in utero transmission.

6. Diagnosis and Testing Action Plan – in further detail

Timeframe	**Tasks**
Immediate	CMO to establish Review committees/working groups for Diagnosis and Testing.
Interim step	Develop interim diagnostic guidelines in consultation with Australian doctors treating Lyme-like illness and based on local disease presentations.
By 2015	Research Brazil's diagnostic tools for BYS in the development of a diagnostic pathway.
By 2016	Common differential diagnosis symptoms should be developed for Australia once clinical studies have determined the most common aspects of Australian Lyme disease or Lyme-like illness.
By 2016	Develop guidelines for diagnosis of the most common Australian co-infections.
Medium	Full review of all Australian laboratories conducting Lyme disease testing to determine test method used, genospecies tested, actual testing practices compared to test kit guidelines.
By 2015	Study laboratory practices of all countries testing for Lyme-like illness to ascertain 'best practice'.
By 2015	Establish criteria for eligibility and standardise testing process for all Australian laboratories involved in testing for Lyme disease.
By 2015	Reference labs to be established based on a statement of requirement.
By 2015	Only reference labs testing for *B. burgdorferi, garinii and afzelii* will perform two-tier testing (ELISA and immunoblot).
Interim step	Local pathology laboratories cease performing screening ELISA tests until standardised testing processes are established..
Immediate	Testing process to outline steps to ensure samples are analysed within 3 days of collection.
Immediate	Changeover of ICPMR Lyme disease testing to European ELISA and immunoblot test kits.
Interim step	All Lyme disease testing to be performed by Australian Biologics or PaLMS until ICPMR has updated and verified their new testing procedures. Standardisation of criteria used to determine positivity on Western Blots.
Immediate	Patients and clinicians to be provided with details of which laboratory has performed their testing and the full results (showing species tested and bands detected).
Immediate	CMO to provide national clinician advice to reflect the testing process (revise the NSW Government version).
By 2015	Analyse historic immunoblot results to determine characteristic bands in patients with Lyme-like illness acquired in Australia and use to refine immunoblot interpretation guidelines.
By 2016	Testing capability to be developed for potential co-infections.
By 2015	Conduct studies into other diagnostic tools, including, but not limited to: • microscopy tests for detection of spirochaetes • latest culture methods • nested PCR in conjunction with DNA sequencing tools • lymphocyte transformation test (LTT) • SPECT scans
By 2015	Review /recall Westmead tests results in which 'false positive' result was given on basis of 5-bands requirement. Request these patients retest once processes are revised and refined.

7. Treatment Action Plan – in further detail

Timeframe	Tasks
Immediate	Formally authorise doctors to treat Lyme disease or patients with Lyme-like illness, irrespective of where they are diagnosed, without repercussions.
By 2015	Develop interim guidelines, potentially based upon European guidelines, and disseminate to all hospitals, general practitioners and infectious disease doctors in Australia.
Immediate	Consult current treating practitioners in the development of any Australian treatment guidelines, either interim or final.
By 2015	Develop a standardised Australian 'criteria' for diagnosis to underpin the development of a diagnostic pathway.
By 2015	Develop educational material for doctors containing information on: • importance of differential diagnosis of Lyme disease and clear articulation of early, late and chronic stages of Lyme requiring different treatment strategies; • the Jarisch-Herxheimer reaction following administration of antibacterials; • chronic and relapsing nature of illness, also L-forms, cyst forms, cell wall deficient biofilms and the possibility of co-infections; • treatment of co-infections, where a 'layered' approach to treatment may be required, and non-bacterial co-infections (Babesiosis) require alternate treatment protocols; • the inappropriate prescription of steroids and /or anti-depressants (especially if the case is differential); and, • early intervention treatment strategies following a tick bite.
By 2015	Develop appropriate specification of the medications required to treat Lyme disease on medical schedules and the PBS.
By 2016	Conduct epidemiological studies (Rec 7) and clinical research into the unique Australian presentations of the illness (Rec 4) before developing final treatment guidelines in Australia.
By 2015	Review the range of complementary therapies currently being used in the treatment of Lyme-like illness to evaluate which may be efficacious and worthy of inclusion in recommended treatment protocols. For example, diet, detoxification, herbal, vitamin or mineral supplementation protocols.

7. Research Action Plan – in further detail

Patient community's priorities for research projects proposed in response to the Scoping Study.

Priority	Etiology	Patients	Pathogen	Testing
1	Epidemiological study (Rec 6)	Clinical study (Rec 4)	*Borrelia* search (Rec 1)	**Interim solution** for pathology testing & Treatment
2			Tick competence (Rec 2)	Testing (Rec 3)
3	Retrospective investigation (Rec 5)	Treatment guidelines (Rec 7)		

The LDAA agrees in principle to the research projects proposed in the Study and proposed two additional research proposals (at Rec 6 & 7). What follows is a summary of the noted considerations the LDAA would like to see implemented in research projects on behalf of patients:

Study 1: 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.	
1.	Samples should be collected from coastal, mountain and desert terrains and from areas where people are reported to have a Lyme-like illness.
2.	Collections and studies should not be limited to ticks; samples of all biting insects, fleas, mites, keds (biting flies), lice etc. should be considered.
3.	Other potential pathogens should be included in this study; *Babesia, Bartonella, Anaplasma, Ehrlichia, Rickettsia* and other pathogens and viruses should be included in the study along with *Borrelia*.
4.	*B. Queenslandica* should be acknowledged as a potential strain.

Study 2: Are Australian ticks competent to maintain and transmit B. burgdorferi s.l. genospecies or other Borrelia species associated with relapsing fever?	
1.	Vector competence studies should not be limited to ticks; where spirochaetal matter is discovered in other insects, their vector competence should be properly investigated.
2.	Evidence already exists to indicate that Australians are infected with more than one strain of *Borrelia*; research should investigate the multiple strains present within the samples collected and provide transparent calculations of the competence of those vectors to transmit multiple organisms, not simply *Borrelia.* Rates of transmission also necessitate investigation.
3.	Research on strains known to cause relapsing fever should be correlated with clinical evidence of patients who are presenting with relapsing fever syndromes.
4.	Native fauna should be considered in the examination of potential reservoirs and should be included to determine whether there is a native Lyme-like organism; it is important to understand the epidemiology, as there may be more than one vector involved. The Study should include identification of native Reservoirs for Lyme and Lyme-like disease and associated co-infections.

Study 3: Do we have the best reagents for detecting novel Borrelia species, including B. miyamotoi, especially in clinical specimens?	
1.	Interim testing arrangements and standardisation of testing protocols are urgently required.
2.	Some Australian private laboratories are already using sophisticated PCR techniques and isolating *Borrelia* and spirochaetal organisms. Every effort should be made to include any research evidence to continually improve the diagnostic and confirmatory testing protocols.
3.	The DoH should immediately conduct a formal review into the current test process in use at the public health laboratories, specifically in light of the sub-optimal testing materials currently in use at Westmead.
4.	The DoH should immediately, and formally, liaise with overseas testing laboratories that are providing positive tests to Australian patients to gain an understanding of their test processes, antigens used, primers and sequences.

Study 4: Clinical studies of patients presenting with symptoms suggestive of Lyme or Lyme-like disease.

1.	Prospective clinical studies of patients must include an inquiry on alternate forms of transmission, for example, from an infected person to a sexual partner, or to a foetus, or via breastfeeding, as well as blood-to-blood contact or via transfusion.
2.	A program of research needs to commence immediately to gather and collate symptom information from Australian treating doctors to underpin a detailed map of the constellation of symptoms unique to Australian patients.
3.	Samples from patients not presenting with an EM rash should not be excluded from investigation.
4.	The DoH should work collaboratively with the patient groups to assist with the longitudinal survey of patients conducted annually.
5.	Any clinical study must investigate the manifestations of disease, especially in regard to early and late stages and 'chronic Lyme'.
6.	The Indigenous population should be studied to ascertain whether there is a history of Lyme-like illness in Australia or possibility for immunity to develop.
7.	All clinical studies must abide by the strictest ethical principles, be conducted in an open and transparent manner, with full declaration of any conflicts of interest.
8.	All clinical studies must recognise the specific impacts that studies will have upon children, who are most at risk.

Study 5: Retrospective investigation of chronic cases of Lyme borreliosis

1.	Testing processes and considerations outlined in research project 3 must be a precursor to qualifying patients.
2.	Testing should not be limited to serological tests (ELISA and IFA), as many studies have shown negative serology in chronic cases with other indications of active infection, such as PCR positive and Elispot positive results.
3.	Evaluate the efficacy of SPECT scans in the diagnostic process.
4.	Samples used to qualify patients for any prospective studies must meet an agreed criterion and be conducted with the latest scientific knowledge and best laboratory technology available.
5.	Research should include patients from every demographic group who can share their stories, their medical results and their histories as part of a formal retrospective study as well as currently treating doctors who are prepared share their records.
6.	Any review of consolidated patient data, should not be limited to infectious diseases experts only and should include other independent experts.
7.	A panel of "experts" should include at least two physicians with extensive experience in diagnosing and treating chronic Lyme disease in Australia.
8.	All clinical studies and retrospective investigations conducted should be carried out with proper ethical approaches where full disclosure of any prior involvement in Lyme disease or Lyme-like illness is made transparent.

Study 6: Epidemiological research

1.	As a matter of urgency, the LDAA recommends a *full* epidemiological study that also includes, but is not limited to, the addition of the following:
a)	A baseline quantification of Australians with diagnosed Lyme disease or Lyme like illness, to satisfy the Terms of Reference of the Clinical Advisory Committee on Lyme Disease (CACLD). Data collected should include demographics such as prior travel history, geographical location, bite history, disease duration etc.
b)	Monitoring of Lyme and Lyme-like cases by the CDNA in light of the emerging incidence of Lyme-like illness occurring in Australians who have never left the country (LDAA 2012). A transparent and open disclosure of the criteria and processes used for monitoring and surveillance of Lyme disease or Lyme-like illness in Australia is required.

Study 7: Development of a treatment options pathway - is included in the Treatment Action Plan of this section.

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WA Lyme Association

Phone 0447 092 660

7 February 2014

Attention: Dr Gary Lum

Professor Chris Baggoley
Chief Medical Officer of Australia
Department of Health
Canberra

Dear Professor Baggoley,

Re: Submission of Additional Comment and Letter of Support for Lyme Disease Association of Australia's Response to *Scoping Study to Develop and Research Project(s) to Investigate the Presence or Absence of Lyme Disease in Australia*

I write on behalf of the WA Lyme Association (WALA) primarily to provide full endorsement for the Lyme Disease Association of Australia (LDAA)'s main patient submission in response to the Scoping Study commissioned by the Chief Medical Officer (CMO) as part of the review into Lyme disease in Australia.

Members of the WA Lyme Association were active participants in the consultation process conducted by the LDAA and contributors to the research and writing that culminated in the document submitted on behalf of Australians suffering from Lyme-like illness.

In Western Australia, there are more than 400 people who have been diagnosed with Lyme disease since 2011. There are only a very small number of doctors courageous enough to challenge the controversy and stigma attached to Lyme disease and committed to providing appropriate diagnosis and treatment for Lyme-like illness in WA. Some of these doctors have closed their books because they cannot cope with any more patients; others have waiting lists out to eight or nine months for new patients. So the number of patients diagnosed with Lyme disease in WA is limited by the capacity of a few Lyme-aware doctors to meet the demand.

In addition, there are hundreds more Western Australians who have lived for years, and sometimes decades, with the symptoms of Lyme-like illness and who should be diagnosed and treated, but they simply cannot afford either the expense of pathology testing or the associated treatments, many of which are not covered by PBS.

The obvious and repetitive official counter to this has been received when our members have raised their concerns with their MPs and the WA Health Minister, who suggest patients should be referred to an infectious diseases specialist and have their testing via an Australian laboratory accredited to test for Lyme disease.

WALA members welcomed with gratitude the issuing of the CMO's Advice to Clinicians (on Lyme disease) in August 2013; however, it is clear this message has not filtered through to the clinicians themselves and many patients continue to complain of encounters with general practitioners and specialists who simply 'rule out' the possibility of Lyme disease in Australia. Patients have provided numerous accounts regarding the derision and misdiagnoses they have encountered when referred to infectious disease specialists, not to mention the fruitless expense.

It is also now well known in circles of chronic illness sufferers that it is not worth drawing blood for a Lyme disease test on the public health system in Australia, for the reasons elaborated on pages 25-29 of the LDAA's Response to the Scoping Study.

WALA therefore supports the urgent implementation of strategies 1.1 – 1.6 (page 45) and the detailed Diagnosis and Testing Action Plan (page 50) outlined in Appendix A – Patient-focused Strategic Approach to the Lyme Problem in the LDAA's submission.

WALA also strongly supports the LDAA's recommendation that Study 6. - Epidemiological Research should be included in the research component of the CMO's review of Lyme disease in Australia.

It seems only prudent that, before reaching a hypothesis about the *causes* of an illness, diligent scientists would:

- study the patients suffering from the syndrome;
- gather data from the patients and their doctors regarding disease presentation and medical history;
- undertake initial clinical studies with patients suffering from the illness to identify potential pathogens involved; and,
- observe the patterns of the dispersal to ensure any further research decisions and directions are based upon a well-informed foundation of scientific and anecdotal evidence.

The omission of uniquely Australian clinical evidence or reference to the Australian patient experience within the Scoping Study is of considerable concern. The narrowly confined scope of the CMO's review process occurred prior to Professor McKenzie's appointment, as reflected in the Terms of Reference for his consultancy brief.

WALA provided input to the public comment on the Terms of Reference for the Clinical Advisory Committee on Lyme Disease (CACLD) and this was incorporated within the LDAA's response presented by the patient representative, Rev. Nikki Coleman, at the second meeting of the CACLD in April 2013.

At this meeting, the CACLD agreed to adopt the first recommendation of the patients' submission, that is:

> **Draft Terms of Reference**
> "whether there is evidence of Borrelia spp causing illness in humans in Australia"
>
> **Recommendation 1:**
> It is, therefore, suggested that the wording of the first ToR be amended to read:
>
> 1. "the extent to which there is evidence of Borrelia spp causing illness in humans in Australia;"

> Reframing the wording of this first ToR would indicate to Lyme patients that the committee is approaching Lyme disease with the intention to open-mindedly explore and fully review the issue and not simply 'rubber stamp' the current policy status quo.

What was envisaged was not a mere *rephrasing* of the Terms of Reference document, but an actual *reframing* of the Terms of Reference for the CACLD. This would ensure the review process takes into consideration the factors introduced in supporting the LDAA's recommendations; namely the recognition that Lyme disease and/or Lyme-like illness *is* here in Australia, whether it is acquired overseas, through indigenous ticks or by some other means of transmission.

The CACLD adopted the changes in wording to the Terms of Reference and then agreed that the Committee's primary focus would be on identifying the causative agents for Lyme disease in Australia[i] and that ticks would be studied as the most likely vector. Given the composition of CACLD and the members' areas of professional expertise, it is understandable that they are inclined to promote approaches which support their own areas of research. However this presumptive approach has not been satisfactory to patients living with Lyme-like illness, whose presentations or suspected causes often fall outside these narrow parameters.

Forgotten within the CACLD's priorities appears to be the fact that we have yet to obtain unequivocal proof that *Borrelia* is the primary pathogen causing Lyme-like illness in Australia, nor has it been established that ticks are the only possible vectors or form of transmission.

The rationale presented by one member of the CACLD that "if we find *Borrelia* in Australian ticks, then our problems will be solved and research into other potential transmission modes will naturally follow" is unconvincing. To use a term very familiar to patients, *there is no evidence to suggest* this would be the case; in fact, the evidence elsewhere suggests that once *Borrrelia* is located in indigenous ticks, other modes of transmission are discounted. Countries with far greater research budgets have yet to fully investigate the potential for transplacental, sexual or blood exchange transmission, or via other vectors.

The CACLD's focus is evident in both the Scoping Study Terms of Reference instructing their colleague, Prof. McKenzie, and in the title chosen for his report. It is, therefore, not surprising his research supports the CACLD's focus on Lyme Borreliosis as it presents in other countries as the basis for evaluating *whether or not* Lyme disease exists in Australia, instead of making any attempt to describe or establish the *extent* of the Lyme-like disease as it presents in Australia.

The Study's lack of in-depth consultation with patient groups and the doctors treating Lyme disease in Australia makes a very clear statement. It is apparent that the author and those directing him consider the direct experience of Lyme disease and/or Lyme-like illness in Australia to be irrelevant, or lacking in credibility, while drawing upon information about Lyme disease as described by scientists, not sufferers, elsewhere. This is, quite frankly, insulting and demoralising to the primary stakeholders who live and work at the cutting edge of Lyme-like illness in *this* country.

In any study of Lyme disease in Australia there is a need for epidemiological (and clinical) data to be collected and analysed from Western Australia. The state's isolation and unique ecosystems could give rise to entirely different strains of

pathogens which may reveal different hosts capable of maintaining the pathogens as well as different vectors transmitting them.

Cases of Lyme disease have been diagnosed from all areas of Western Australia, in coastal and inland areas of the north and south west, as well as within the metropolitan area of Perth. In some cases, there was an obvious correlation with tick bite, whereas in other cases haematophagous (blood-sucking) insects such as stick fast fleas, sand flies and March flies were suspected.

Given Western Australia's proximity to SE Asia, there may be a correlation between coastal infections and the presence of migratory birds, as examined by Karen Smith in the web page *Role of Birds as Vector & Reservoir Hosts*[ii].

The historical prevalence of rodents escaping from ships in the port city of Fremantle, as well as squirrels and birds able to traverse the boundaries of the Perth Zoological Gardens, may be worthy of further investigation in terms of identifying potential reservoir hosts in the metropolitan area.

However a number of 'clusters' of Lyme disease cases following tick bites have also been observed in inland areas. In one of these, involving a small community 400 kilometres south east of Perth and containing only 250 families, eight people have been clinically diagnosed (and confirmed with overseas serology) while another three, who have yet to be diagnosed, are suspected of having Lyme-like illness. Four of those diagnosed, including three children, have never left the country.

Clusters such as this warrant further investigation. The example of Hong Kong's diligent approach to Lyme disease outbreaks[iii] was mentioned in the LDAA's response to the Scoping Study and could serve as a model to emulate.

Small town communities are often close-knit and likely to exchange information about their health conditions, so awareness about appropriate diagnosis and treatment pathways can be quickly disseminated. Hence, this cluster might be attributed to higher levels of Lyme disease and tick risk awareness. If this is the case, the high levels of diagnosis in this tiny remote community could also provide an alarming indicator of the potential *extent* of the Lyme 'epidemic' once Lyme disease awareness penetrates the mainstream population.

Contrast this to a larger inland south west town with a population of around 4,000 where the community is not generally aware of Lyme disease but casual conversations reveal concerning anecdotes of a series of farmers retiring with a 'mystery illness' or having been diagnosed with Motor Neurone Disease via a local medical practice where Lyme disease is categorically ruled out as a possible or differential diagnosis.

The personal attitudes and beliefs of general practitioners play a major role in the discovery (or lack of discovery) of patterns of Lyme disease dissemination. These beliefs are currently informed by official "there is no Lyme in Australia" statements propagated through the Communicable Diseases Network Australia, and frequently result in Lyme disease sufferers enduring painful, costly and unnecessary misdiagnosis.

WALA recommends that epidemiological studies also include collection and analysis of data in relation to any high incidence of diagnoses for diseases that *mimic* Lyme disease, such as Motor Neurone Disease, Multiple Sclerosis, Parkinsons' Disease, ME/CFS, Fibromyalgia and Alzheimer's disease.

Another factor worthy of investigation, particularly where clusters are occurring in rural areas, is the potential for cross contamination from livestock, particularly livestock imported from overseas and from other tick-endemic regions of Australia.

In the past, cattle, horses, deer, alpacas, llamas, goats and sheep have been imported to Australia from all parts of the world. Deer imports were suspended in 1993 and cattle imports were suspended between 1997 and 2003. Imports from New Caledonia were suspended in 2011, although cattle had not been imported from there for a decade. Live animal imports currently include horses (multiple countries), alpacas (multiple countries), cattle (Norfolk Island only) and goats and sheep (NZ only)[iv].

Although Australia maintains some of the most stringent customs and quarantine processes in the world, these are not foolproof. Biosecurity issues remain a concern in all areas of agriculture and outbreaks involving diseases, parasites and insects have occurred. The policy of 'adequate level of protection' is not a guarantee of protection against animals serving as hosts for human diseases, or for zoonosis.

Australia's current import requirements for live horses, for example, rely on the self-disclosure of overseas exporters during pre-export veterinary certification checks as the primary screening mechanism for ascertaining whether the horse has been kept in an area where Lyme disease has been found in the previous 90 days.[v] Under circumstances where a breeder is in the process of exporting a very expensive horse, it would be easy to simply 'overlook' an asymptomatic animal or the fact that a farm employee or neighbour may have been suffering from a Lyme-like illness.

From the information available on the Department of Agriculture, Fisheries and Fauna (DAFF) import database[vi] and preliminary email communications with their veterinary staff, it would appear that no serological testing is required with respect to *Borrelia* (even though *Borrelia burgdoferi* is known to occur in horses[vii]), and testing for *Babesia* and *Theileria* is constrained to equine strains[viii]. Similarly, there appears to be no requirement for serological testing specific to *Borrelia* for camelids (alpacas, llamas etc) and goats[ix], which are also potential hosts[x].

Livestock imported from overseas are required to be closely examined for tick infestation and to be treated with a parasiticide effective against ticks and a broad-spectrum anthelmintic. However acaricide resistance is an ongoing and well documented[xi] [xii] issue, of which people living in agricultural areas are well aware.

Frozen semen and ova from livestock (including species for which live imports have been suspended) can still be imported to Australia and *Borrelia* is not listed as one of the diseases requiring risk management. It is possible that pathogens causing Lyme disease and Lyme-like illness can remain viable after freezing.[xiii]

In summary, based on a preliminary investigation, it appears that most screening processes on imported livestock are primarily directed toward protection from *diseases affecting livestock rather than humans*. Other than the previously mentioned self-disclosure requirement on overseas exporters of live horses, Lyme disease (Borreliosis) does not appear to be specifically mentioned in any of the requirements or pre-export veterinary screening processes. Nor is there reference to any of the other tick-borne pathogens associated with Lyme disease as co-infections, other than Brucellosis. On the basis of these concerning discoveries, it becomes questionable how Lyme disease (and other pathogens with potential to harm humans) could *not* have already entered Australia via the importation of infected livestock from endemic areas.

WALA recommends that the CMO arranges for discussions to be held with the Department of Agriculture, Fisheries and Fauna (DAFF) to ensure more stringent quarantine controls are adopted to reduce the possibility of Lyme disease (and co-infections) being conveyed into Australia via imported livestock and biological products.

Interstate and intrastate transporting of livestock involves (for WA) individual inspection of livestock at quarantine points in Kalgoorlie and Kununurra. Livestock being transported from known cattle tick zones in the north of Australia are required to undertake full immersion dipping before being transported. However animals arriving from other states known to have endemic tick populations of other genera will only be intercepted and drenched (twice with Bayticol) if ticks are observed during inspections at quarantine entry points. Although quarantine officers provide assurances that their inspections for ticks are very thorough[xiv], the system is not entirely foolproof in ensuring the non-transference of tick-borne illness from endemic regions.

One such non-endemic outbreak has recently occurred in the southern coastal area of WA where cattle have been infected with bovine anaemia through the tick-borne parasite, *Theileria orientalis* variant buffeli (previously known as *Theileria buffeli*). The WA Department of Agriculture fact sheet for veterinarians[xv] indicates that *Haemaphysalis longicornis*, the bush tick, is considered the principal vector, however notes that "native ticks such as *H. bancrofti* and *H. Humerosa* may also be important. *H. longicornis* is primarily a parasite of cattle, but readily infests many other warm-blooded animals including other livestock, wildlife, birds, dogs and cats" (and presumably humans). It also notes that other unidentified means of transmission may be occurring, such as biting insects and livestock management techniques that potentially transmit infected blood between animals.

While the outbreak above relates to a tick-borne parasitic infection *in cattle*, it is indicative that the current inspection processes on movements of livestock cannot be *guaranteed* to exclude the transportation of other tick-borne pathogens, including those that cause Lyme-like illness.

Migratory birds may be a risk factor here as well because they are not required to undergo any customs inspections and it is unreasonable to expect that they would all pass through Christmas Island or an inland quarantine inspection point to shake off their ticks before traversing Australia.

It is worth noting that the recent *Theileria* outbreak has occurred in a region of WA where *H. longicornis* has previously been discovered. The potential for *H. longicornis* to act as a vector for *Borrelia* and other co-infections is further examined by Australian Lyme patient, Karen Smith, on her webpage entitled *Mammals as Vector and Reservoir Hosts*[xvi].

In this same region, there are also populations of feral deer[xvii] and pigs[xviii], both potential hosts for Lyme and co-infections, not to mention the as-yet-unknown and unquantified potential native hosts.

WALA is aware there are at least four diagnosed Lyme disease cases in this region, at least two of whom spent their working lives in agricultural industries.

Livestock breeders are often reassured by industry veterinarians that there is little risk to humans of cross contamination due to host specificity, both of ticks and pathogens, particularly with parasitic pathogens such as *Babesia* and *Theleiria*. This reassurance again relies on "there is no evidence to suggest" when, closer to the truth would be to say, "It is not known" - because thorough investigations of all the possibilities have not been conducted.

Far too little is known about zoonoses[xix] and vector-borne diseases in relation to human hosts in Australia. Little is known because no one is looking and no-one is likely to look for pathogens related to Lyme disease, which they are told *is not here*. Other than A/Prof Peter Irwin's research projects focusing on Lyme disease (and co-infections) in human companion animals at Murdoch University, there appears to be little similar research being undertaken by veterinarians or scientists exploring human disease relationships with larger animals, or with indigenous species, that could serve as potential hosts in tick breeding cycles.

WALA recommends adopting a multidisciplinary approach to an epidemiological study of Lyme disease and co-infections, which would include veterinarians, entomologists and optometrists (who are able to supply information which may be of assistance in diagnosing and monitoring Lyme disease).

Members of the Lyme community frequently joke about wishing they could consult vets instead of doctors for their own Lyme-like illness. Underlying this humour is a far more concerning situation wherein patients have observed that their pets' illnesses are taken far more seriously than their own and they can have intelligent and open-minded conversations with veterinarians about Lyme disease, but not with their medical practitioners. This situation arises because, in general, *veterinarians approach Lyme disease as an infection* and not as a political controversy to be avoided.

WALA has received numerous accounts regarding doctors who either refused outright to see Lyme patients or who were hasty in referring to other clinicians those patients who requested diagnosis and treatment for Lyme disease, including patients whose infections had obviously been contracted outside Australia. Some doctors can't get Lyme patients out the door quickly enough! The stigma associated with treating patients for Lyme disease generates a kind of embarrassment in many GPs, almost as if they are being asked to admit they believe in astrology or elves.

This stigma regarding Lyme disease is so well established and deeply embedded into the consciousness of the Australian medical profession that it has become like a systemic mythology: founded on the legendary Russell and Doggett 1994 tick study; modelled on commercially and politically influenced American policy guidelines; and cemented by public laboratory testing procedures that preclude positive diagnoses.

The Lyme community would like to see the Australian medical profession begin to approach Lyme disease and Lyme-like illness as a systemic infection or illness syndrome that is affecting Australian patients, divested of the stigma, mythology and political controversy with which it is currently approached.

As noted in the LDAA's response to the Scoping Study, the American "Council of State and Territorrial Epidemiologists (CSTE) considers a county to be endemic for Lyme disease if there are at least two confirmed human cases that were acquired in (not just reported from) that county".[xx]

In the case of the outbreak of a tick-borne *Theilieria* infection in cattle mentioned above only two farms were affected. Appropriate notices were duly disseminated to alert veterinarians, inform them about the disease and advise how to deal with the livestock. This is a professional and responsible approach to a disease outbreak.

There are over four hundred cases of diagnosed Lyme disease in Western Australia and more than a thousand nationally, so where is the equivalent response to the outbreak of human Borreliosis in Australia?

WALA would like to encourage the CMO to carefully consider the Patient-focused Strategic Action Plan submitted as Appendix A in the LDAA's response to the Scoping Study and to implement as many strategies as are feasible within the jurisdiction of his office.

Of the 400-plus patients in WA, some patients who have completed a full Lyme treatment protocol under the guidance of Lyme-aware clinicians have already been 'clinically cured'. Many of those who have been following treatment protocols in which the initial focus has been treatment of Lyme co-infections have already experienced noticeable improvements in their health conditions and quality of life. This information could be relevant to both the Australian Lyme disease epidemiology and to developing treatment pathways, but was not sought in the Scoping Study.

The WA Lyme Association was founded in August 2012 with the intention of providing peer support, information sharing and advocacy toward policy change. Although other Perth-based Lyme groups have been involved in publicising Lyme disease, WALA deliberately elected not to focus on public promotion of Lyme awareness for fear of generating a public demand that exceeds the capabilities of existing Lyme-aware doctors. Our decision not to actively publicise Lyme disease or seek media attention was based on a belief that only top-down policy change will create the paradigm shift needed to remove the stigma from treating Lyme disease and Lyme-like illness in this country.

In July 2013, Western Australia lost a beautiful and intelligent young woman to Lyme disease[xxi]. Theda Myiint was not a member of our Association but her passing has deeply impacted the Lyme community Australia-wide[xxii]. Theda was 37 years of age and should have been out in the world enjoying her life, being a wife and mother and/or at the peak of her career as a television journalist. Instead she had already lost 14 years to Lyme disease and was a prisoner to her bed, wracked with intolerable physical pain and emotional suffering. When she was well enough, Theda was a devoted crusader for Lyme awareness.

Theda's death will not be counted as an 'official' Lyme statistic, but she was nonetheless a casualty of Lyme disease in an even more shameful way. Theda gave up the fight and ended her own life because she could no longer tolerate the suffering of Lyme disease when compounded by repeated demoralising encounters with physicians who asserted that her condition was a mental illness.

Theda eventually gave up the fight *because she couldn't wait any longer for a policy change* that might re-educate these ignorant attitudes, recognise her illness and provide her with access to appropriate treatment to take away her pain.

There is a strong feeling in the Lyme community that *time's up!* In fact, the time is well overdue for the Lyme denial to end in this country and for the medical community to start doing its job in understanding, diagnosing and providing treatment to alleviate the relentless suffering that can often accompany Lyme-like illness.

Yours sincerely

Kate Daniels

Chairperson
WA Lyme Association

<u>Post script</u>

Re: Additional information and minor amendment to original WALA submission on CACLD Scoping Study

The academic originally cited as the reference for the statement in WALA's original submission regarding the possibility of *Borrelia burgdoferi* pathogens remaining viable in frozen semen has now provided a copy of a previously inaccessible research paper on this topic.

The research paper (Kumi-Diaka, J. and Harris, O, (1995) *British Veterinary Journal*, Mar/Apr 1995. v. 151 (2)) appears to confirm WALA's assertion: "It is possible that pathogens causing Lyme disease and Lyme-like illness can remain viable after freezing" is correct.

WALA's original submission has therefore been amended to include a change in referencing to verify this statement.

A copy of the paper (Kumi-Diaka) is available from WALA.

However the following excerpts from the Kumi-Diaka study are of relevance to WALA's submission in relation to concerns expressed about imported livestock semen.

Continues next page....

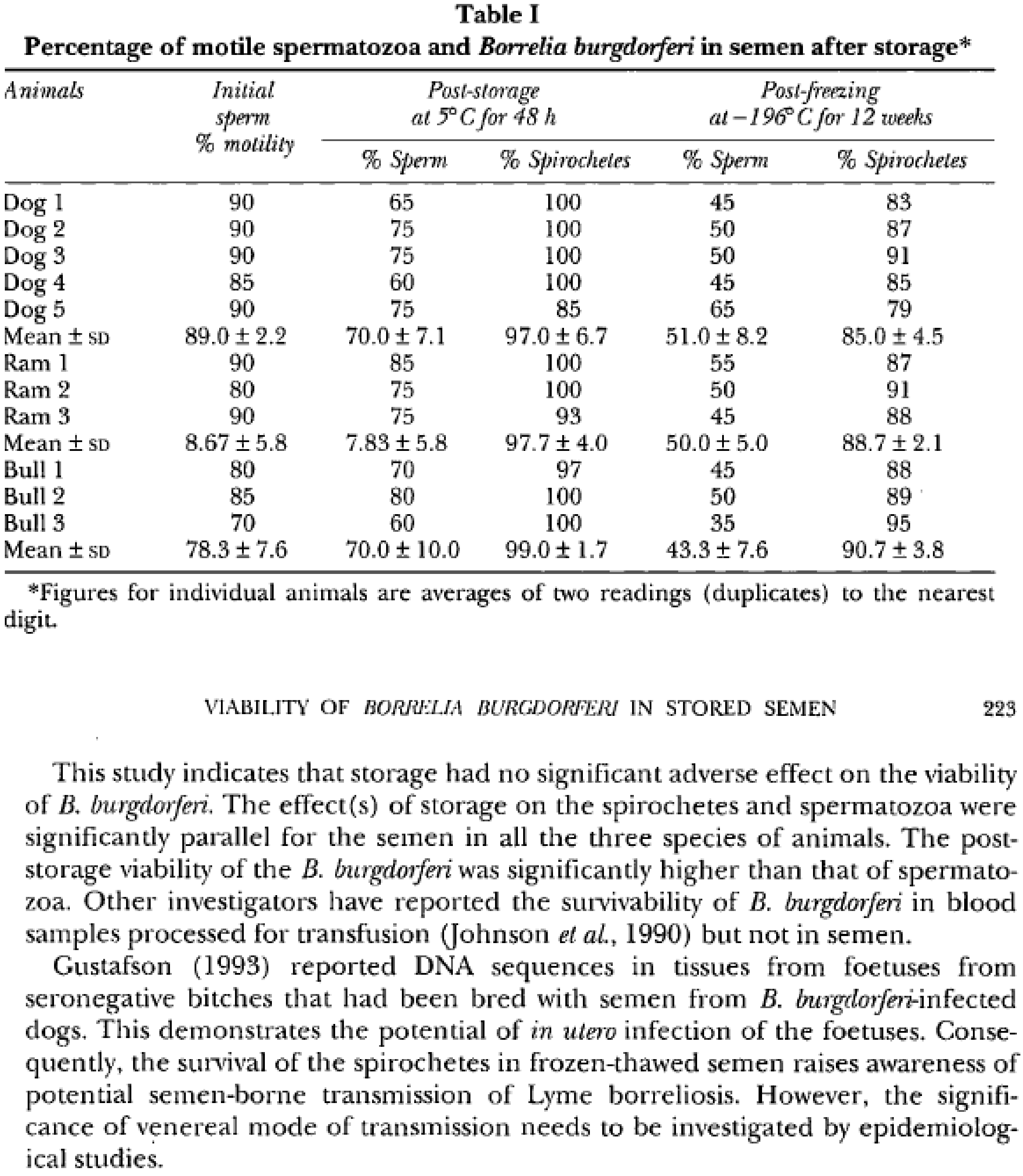

Table I

Percentage of motile spermatozoa and *Borrelia burgdorferi* in semen after storage*

Animals	*Initial sperm % motility*	*Post-storage at 5°C for 48 h*		*Post-freezing at −196°C for 12 weeks*	
		% Sperm	*% Spirochetes*	*% Sperm*	*% Spirochetes*
Dog 1	90	65	100	45	83
Dog 2	90	75	100	50	87
Dog 3	90	75	100	50	91
Dog 4	85	60	100	45	85
Dog 5	90	75	85	65	79
Mean ± SD	89.0 ± 2.2	70.0 ± 7.1	97.0 ± 6.7	51.0 ± 8.2	85.0 ± 4.5
Ram 1	90	85	100	55	87
Ram 2	80	75	100	50	91
Ram 3	90	75	93	45	88
Mean ± SD	8.67 ± 5.8	7.83 ± 5.8	97.7 ± 4.0	50.0 ± 5.0	88.7 ± 2.1
Bull 1	80	70	97	45	88
Bull 2	85	80	100	50	89
Bull 3	70	60	100	35	95
Mean ± SD	78.3 ± 7.6	70.0 ± 10.0	99.0 ± 1.7	43.3 ± 7.6	90.7 ± 3.8

*Figures for individual animals are averages of two readings (duplicates) to the nearest digit.

This study indicates that storage had no significant adverse effect on the viability of *B. burgdorferi*. The effect(s) of storage on the spirochetes and spermatozoa were significantly parallel for the semen in all the three species of animals. The post-storage viability of the *B. burgdorferi* was significantly higher than that of spermatozoa. Other investigators have reported the survivability of *B. burgdorferi* in blood samples processed for transfusion (Johnson *et al.*, 1990) but not in semen.

Gustafson (1993) reported DNA sequences in tissues from foetuses from seronegative bitches that had been bred with semen from *B. burgdorferi*-infected dogs. This demonstrates the potential of *in utero* infection of the foetuses. Consequently, the survival of the spirochetes in frozen-thawed semen raises awareness of potential semen-borne transmission of Lyme borreliosis. However, the significance of venereal mode of transmission needs to be investigated by epidemiological studies.

A mean figure of 90%+ viability for *Borrelia burgdorferi* spirochetes in semen frozen for 12 weeks should be of sufficient concern to warrant further investigation by both medical authorities responsible for public health protection and the livestock industry.

Documents supplied by DAFF indicate that frozen semen and ova are required to undergo cleaning and washing processes to eradicate pathogens; however it is not known if these processes are effective in removing *Borrelia* pathogens or other affiliated pathogens capable of infecting humans because these are not listed for risk management on DAFF's site. These 'cleansing' processes, too, bear further investigation from those at a level where responses may be more forthcoming than in WALA's initial inquiries.

Additional information re testing of Australian livestock for Borrelia burgdoreri

In addition, WALA has made inquiries on behalf of a person who believes her horse may be infected with Lyme disease. WALA's preliminary inquiries regarding the availability of testing within Australia for *Borrelia burgdorferi* in livestock revealed that this could be extremely difficult, if not impossible. These inquiries included calls to Murdoch University Vet School, the Australian Veterinary Association and the CSIRO's Australian Animal Health Laboratory in Geelong, all of which are unable to readily refer to a testing process available in Australia.

So even if owners of livestock suspect Lyme-like illness in their animals, they would have to be willing to go to considerable lengths (possibly involving overseas pathology testing) to have this scientifically confirmed or denied.

Large animals and the tick breeding cycle

In overseas research it is generally accepted that larger animal species are considered to be 'end hosts', meaning that they serve as a blood meal for adult ticks, which then cannot pass on the infection. It is believed only tick larva and (mostly) nymphs are the stages that feed from reservoir hosts (rodents, birds and possibly, marsupials) and can pass on the infection to the next life cycle stage.

While this is the accepted theory in countries where Lyme disease is known to occur, the ability of ticks in Australia to carry and transmit infection (and their breeding cycles relative to this) remains uncertain at this time.

Also unknown are the potentials of non-tick vectors and uniquely Australian reservoir animals in hosting pathogens for Lyme-like illness or the potentials of blood, urine or venereal transmission between livestock, or indeed livestock and humans. In short, there are many more questions that can be listed as 'gaps in our knowledge' than those outlined in the Scoping Study.

The additional information supplied here and minor amendment to WALA's original submission serve only to reaffirm recommendations regarding the need for a full and thorough epidemiological study to be conducted and for further investigation into Australia's quarantine and animal importation procedures to be undertaken.

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[i] http://www.lymedisease.org.au/wp-content/uploads/2010/11/20130528CACLDMtg2NikkiNotes.pdf

[ii] http://www.lymeaustralia.com/birds-as-vector--reservoir-hosts-including-examination-of-iuriae-seabird--iauritulus-bird-ticks.html

[iii] http://www.chp.gov.hk/files/pdf/prevention_of_lyme_disease_in_hong_kong_r.pdf

[iv] Email communication with DAFF quarantine veterinary officer.

[v] http://apps.daff.gov.au/icon32/asp/ex_QueryResults.asp?Commodity=horses&Area=All+Countries&EndUse=All+End+Uses&QueryType=Search

[vi] http://apps.daff.gov.au/icon32/asp/ex_querycontent.asp

[vii] http://www.thehorse.com/articles/10200/lyme-disease-in-horses

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[viii]

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.05.08_EQUINE_PIROPLASMOSIS.pdf

[ix] http://apps.daff.gov.au/icon32/asp/ex_querycontent.asp

[x] http://www.aaem.pl/pdf/aaem0223.pdf

[xi] Wharton, RH (1967) Acaricide resistance and cattle tick control, *Australian Veterinary Journal,* Volume 43, Issue 9, pages 394–398

http://onlinelibrary.wiley.com/doi/10.1111/j.1751-0813.1967.tb04892.x/abstract

[xii] University of Glasgow (2013) Secret of cattle ticks' resistance to pesticide, ScienceDaily, 7 October 2013. www.sciencedaily.com/releases/2013/10/131007122556.htm

[xiii] Kumi-Diaka, J. and Harris, O, (1995) *British Veterinary Journal*, Mar/Apr 1995. v. 151 (2)

[xiv] Personal communication, livestock inspectors, Kalgoorlie Quarantine Inspection Station of AgWA.

[xv]

http://archive.agric.wa.gov.au/objtwr/imported_assets/content/pw/ah/dis/cat/batog_veterinarian_factsheet.pdf

[xvi] http://www.lymeaustralia.com/mammals-as-vector--reservoir-hosts-including-examination-of-hlongicornis-scrubbush--hbispinosa-ticks.html

[xvii] http://www.feral.org.au/wild-deer-density-2007-western-australia/

[xviii] http://www.feral.org.au/feral-pig-density-2007-western-australia/

[xix] http://www.dpi.nsw.gov.au/__data/assets/pdf_file/0011/334001/Zoonoses-animal-diseases-transmissible-to-humans.pdf

[xx] http://www.cdc.gov/lyme/faq/#endemic

[xxi] http://www.youtube.com/watch?v=U29UAqR2RfE

[xxii] http://www.lymeaustralia.com/theda-myint---july-2013.html