



For Lyme Disease Awareness & Action

LYME DISEASE  
ASSOCIATION OF AUSTRALIA  
ABN 46 417 706 647

29<sup>th</sup> April 2013

Professor Chris Baggoley  
Chief Medical Officer of Australia  
Department of Health and Aging  
Executive Department  
Department 14<sup>th</sup> Floor  
Scarborough House  
Atlantic Street  
Woden ACT 2606

Dear Professor Baggoley,

Thank you for inviting the Lyme Disease Association of Australia (LDAA) to represent the patient community on the Clinical Advisory Committee on Lyme Disease (CACLD). A national approach to Lyme disease provides renewed hope for Australian suffering with Lyme disease.

We were disappointed that we were unable to participate in the discussion on the committee's Terms of Reference (ToR), and were subsequently excluded from its drafting due to administrative errors, but we thank you for allowing us the opportunity to provide feedback on the draft prior to its finalisation.

The LDAA invited comments on the draft ToR from the wider Lyme patient community, through online forums and email groups, and discussed them with the LDAA executive. A number of recommendations are outlined for your consideration as follows:

## 1. Evidence of *Borrelia* in Australia

Draft ToR - "*whether there is evidence of Borrelia spp causing illness in humans in Australia*"

Implicit in the wording is the suggestion that the existence of *Borrelia* spp remains *in doubt* and, as such, is insulting to the many Australians already clinically diagnosed with borreliosis/Lyme disease who have confirmatory lab tests. The use of this wording in the ToR reflects the rationale by which Australian government health policy is currently defined. That is, because no evidence of *Borrelia* spp was found in a single study of Australian ticks<sup>1</sup>, it can be concluded that Lyme disease does not exist here.

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<sup>1</sup> Russell, Doggett, Dickeson et al- "Lyme disease : a search for a causative agent in ticks in south eastern Australia. [Epidemiol Infect.](#) 1994 Apr;112(2):375-84.

Additionally, narrowing the terms of reference to be defined as transmission **only** via locally acquired tick bite, denies the existence of alternate potential forms of transmission. These may be acquired via tick bites obtained overseas, other animal/insect vectors, and as yet unconfirmed and under-researched potential transmission modes such as sexual, *in utero* and blood supply contamination.

This rationale has been perpetrated throughout the country defining it as the 'official position' and has been repeatedly reflected in correspondence received by patients from government health agencies and Members of Parliament. It has also been adopted by the medical profession and has resulted in negative patient experiences in which Lyme sufferers have been advised that, as Lyme disease doesn't exist here, their diagnosis is invalid or they cannot be treated here and should "go overseas for treatment".

Lyme disease patients in Australia have repeatedly been denied their rightful access to appropriate health services for their condition simply by virtue of uncertainty about the possibility of transmission via Australian ticks; even when they state the legitimate fact of having been bitten by ticks in another country.

### **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*.

### **2. Lyme disease vs Borreliosis**

There is nothing about 'Lyme disease' in the Terms of Reference, although we note the header on the Department of Health and Ageing webpage page is titled Lyme Disease. The LDAA believes that this is inappropriate and would like to note our dissatisfaction on the name change – even though the aim of the name change was to link with the more scientific data, we believe that it is absurd to change the name within the public sphere when people have been diagnosed with Lyme disease in Australia for the past 30 years.

At the very least the ToR, in regard to education of the medical community and the public, should refer to borreliosis/Lyme Disease.

### **Recommendation 2:**

It is, therefore, suggested that the wording of the current fourth ToR be amended to read:

4. the most appropriate ways to disseminate information to health professionals and the general public on borreliosis/Lyme disease.

### 3. Co-infections

Dr McManus recently commenced discussion on the online Lyme disease Australian community forums foreshadowing the CACLD decision to change the name of Lyme disease to borreliosis; it caused considerable distress, partly because there was no patient consultation, and partly because the term borreliosis does not encompass all the facets that the name Lyme disease encompasses. As indicated in the *LDAA Australian Patient Situation 2012 Report*, the majority of Lyme disease patients in Australia have multiple co-infections which are common with tick borne diseases. Co-infections such as Babesia, Bartonella, Rickettsia, Ehrlichia, Mycoplasma Fermentans, Chlamydia Pneumonia were reported.

As some of these infections require specific treatment beyond the recommended antibiotic protocols for borreliosis; and recovery from Lyme disease is hampered unless co-infections are also treated, any narrowing of the ToR to focus on only one bacterium would be a disservice to Lyme patients. We recommend an addition to the ToR that common co-infections associated with borreliosis also be addressed in the work of the committee.

#### **Recommendation 3:**

It is, therefore, suggested that another ToR be added as the second item:

2. the prevalence of co-infections with borreliosis/Lyme disease be examined, in regard to diagnosis and treatment.

### 4. Discrimination

There is a large amount of discrimination that Lyme disease patients are experiencing in Australia. Discrimination is reported in every aspect of a Lyme disease patient's journey from obtaining a diagnosis in the medical system, to the pathology tests available, to accessing medications supported by the PBS and obtaining access to disability services and payments to long term treatment. This discrimination affects those people who are most vulnerable and often unable to advocate on their own behalf, compounding the difficulties they face in accessing adequate medical care and support services.

#### **Recommendation 4:**

It is, therefore, suggested that the following be added to the ToR

“to develop and disseminate policy recommendations to government and non-government agencies dealing with potentially Lyme-infected patients.”

**In addition to the recommended amendments to the draft ToR, we have other general issues we'd like to have some clarity on. These are outlined below.**

## 5. Terms of Reference

Typically government committees<sup>2</sup> have ToR's that clearly state the **role and responsibility** of both the Chair and the committee members. In this instance there is no role or responsibility specified. As such it is difficult to understand what role members will have and more importantly where the authority for decision making is vested.

Similarly, there is no framework surrounding how potential **conflicts of interest** will be addressed, or even if conflicts of interest are required to be declared and at what point. We note that financial conflicts were sought and none declared at the first meeting, however the issue relates to general conflicts of interest. Conflicts of interest are not simply financial; they can be real, potential or perceived.

The LDAA asserts that there will be real and perceived conflicts of interest relating to the membership of the committee. For example, members of the Committee may be vested in their own, or dated, research which supports current policy and may be required to provide opinions on evidence which may conflict. Furthermore the Public Health Laboratory Network have a vested interest in their policy for two –tiered test processes. As such it remains extremely challenging to see how a committee of this stature, and in light of the previously held dogma, will operate without disclosing any real or potential conflicts of interest.

Conflicts of interest with an expert committee are inevitable but properly declaring conflicts and managing them in a totally transparent way will help avoid perceived conflicts of interest. The LDAA believes that it is unethical to not address these issues, as it will dramatically influence the discussion and decisions of the committee.

In addition, there is no stated **deliverable** nor a stated **time frame** for an outcome in the ToR, or on the webpage. While we note the Minutes of the meeting state that an outcome is expected within four meetings, there is no timeframe provided for meetings and hence no end date. While Australians are suffering with debilitating health crises caused by their Lyme disease, it is unacceptable to not provide a timeframe for the committee's outcomes to the wider public. It may be useful in the interests of transparency to include this information on the webpage.

### Recommendation 5:

It is, therefore requested that the LDAA receive feedback on these issues in regards to the general ToR and how they will be addressed.

## 6. Monitoring of Lyme disease

The statement ***The Australian Government is monitoring Lyme disease, in consultation with the states and territories, through the Communicable Diseases Network Australia***, also repeated at the end of the section on Lyme disease on the Department of Health and Ageing (DoHA) website, needs further explanation. The LDAA would like the monitoring and reporting process explained, so that the entire Lyme disease community can understand it.

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<sup>2</sup>

[http://www.health.gov.au/internet/main/publishing.nsf/Content/5D0F9F4CA81570D9CA257B3C0006D332/\\$File/NTRAC%20Terms%20of%20Reference.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/5D0F9F4CA81570D9CA257B3C0006D332/$File/NTRAC%20Terms%20of%20Reference.pdf)

The point is that the stated monitoring claim is **likely** to be based upon the current two-tiered testing process which requires a positive ELISA response as a pre-cursor to a Western Blot.

Dr Armin Schwarzbach MD PhD, Specialist for laboratory medicine at the Borreliose Centrum Augsburg – Infectolab, also a committee member, , provides significant evidence in his paper on *Problems and Future in the Testing of Lyme Disease*<sup>3</sup> that highlights the absurdity of that approach. Dr Schwarzbach proposes the average sensitivity of an ELISA test is approx. 43%; as such the two-tiered test process produces a large number of false negatives because Australian tests are not progressed to Western Blot. It borders on immoral to continue to use a flawed testing process as the method to provide ‘monitoring’ data to this committee to demonstrate the evidence, or not, of borrelia in Australia.

We request the committee immediately propose alternative methods of collecting statistics on ‘Lyme like’ illness in Australia by accessing information: -

- a. from the medical community, based on case records of Doctors clinical observations;
- b. by contacting overseas reference Labs running tests on Australians (IGeneX, InfectoLab);
- c. working with the Lyme disease patient community to collate existing laboratory test results for patients already diagnosed.

There is already much data available from which spatio-temporal data analysis can occur to provide greater insights into Lyme disease, co-infections and associated illnesses in Australia. The fact that the government is currently failing to access and consider this data to solve chronic health issues is reprehensible. The Department of Health and Ageing have many data assets that could be used to help model clusters of Lyme like illness; PBS data, Australian Refined Diagnosis Related Groups (AR-DRGs) statistics, and Medicare data could be overlaid with Veterinary and spatial information to indicate geographic clusters of tick borne pathogens in both humans and animals. Our concern is also that it is not acknowledged in the ToR that borrelia is a zoonotic, vector borne disease.

#### **Recommendation 6:**

Even though the monitoring of Lyme disease is not a part of the ToR, it is a stated aim on the DoHA. It is, therefore, suggested that the forms of monitoring by the Communicable Diseases Network Australia to include not only blood test results from the PHLN but also information:

- a. from the medical community, based on case records of Doctors clinical observations;
- b. by contacting overseas reference Labs running tests on Australians (IGeneX, InfectoLab);
- c. working with the Lyme patient community to collate existing test results for patients already diagnosed.

### **7. Blood Supply and Organ Donation Systems in Australia**

In relation to the potential for Lyme disease (and other co-infections such as Babesiosis) to be spread through the blood and organ donation systems, the LDAA would like to raise this as a major issue that should cause alarm in terms of the government’s legal liability.

Policy needs to be developed to ensure Lyme disease is not passed on through blood or organ donation (currently suffering from Lyme disease does not exclude you from blood or organ donation). The fact

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<sup>3</sup> <http://xa.yimg.com/kq/groups/4321767/1707244727/name/LiteratureSchwarzbach.pdf>

that there is a committee convening to determine the existence of Lyme disease in the Australian population, then government policy needs to be proactive and err on the side of caution in protecting the population from further transmission.

Overseas, many jurisdictions have implemented donor deferral policies for donors with Lyme disease or Babesia.

**Recommendation 7:**

It is, therefore, suggested that the government immediately implement a blood donor deferral policy, and an organ donation permanent deferral policy, as a prudent precautionary measure until the findings of the committee are known.

**8. Communicable Disease Network Australia (CNDA)**

According to LDAA members previous correspondence with the DoHA on the CDNA's role in monitoring diseases, especially zoonotics, they stated *'CDNA and the National Arbovirus and Malaria Advisory Committee include members from animal health agencies or with animal health expertise. Information-sharing mechanisms between the human health and veterinary spheres (such as the information sharing protocol between the Department of Agriculture Fisheries and Forestry and the Department of Health and Ageing) ensure that Australia is well prepared for a disease event at the animal-human interface.'*

Currently the membership of the CACLD does not include any veterinarian, or anyone representing the zoonotic aspects of borrelia. Associate Professor Peter Irwin, of Murdoch University Perth, is currently looking at the role of dogs as sentinels for Lyme disease in Australia. He also assisted in confirming the recent case of Babesiosis in a NSW patient and co-authored a paper with Doctors from The Canberra Hospital on the first reported case of Babesia in Australia. Dr Irwin would be an asset to the committee given his current investigations into Lyme disease from a veterinary perspective. Note: the LDAA does not have any relationship with Dr Irwin, nor have we contacted him to see if he is available for the committee, we are simply aware of his current research through our member's participation.

**Recommendation 8:**

It is, therefore, recommended that the committee be expanded to include an expert on the zoonotic aspects of borrelia – particularly a researcher currently working in this field.

Once again, I would like to thank you for giving patients a voice on the CACLD, and look forward to working with you and other members of the committee in the future. Please feel free to contact me should you wish to discuss or clarify any of the suggestions of the LDAA.

Sincerely,



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Rev. Nikki Coleman  
Past President  
Lyme Disease Association of Australia