

Senate Community Affairs references Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH PORTFOLIO

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

20 April 2016

Question no: 1

Topic: Borrelia Bacteria

Type of Question: Written

Senator: Senator Madigan

Question:

A species of *Borrelia* bacteria was discovered in an echidna by Dr Peter Irwin last year after many years of medical authorities denying that *Borrelia* bacteria of any sort was present in the wild in Australia. The Office of Health Protection is yet to publicly state that it recognises this published, peer-review scientific fact. Does the OHP recognise that a species of the *Borrelia* family of bacteria has been found in Australia?

Answer:

The Office of Health Protection (OHP) welcomed the research published by Professor Irwin and made the research publicly available on the department's website when it was first released on 25 June 2015¹. The paper was shared with former members of the CMO's Clinical Advisory Committee (which ceased July 2014) and it was mentioned by the department on 21 October 2015 during Senate Community Affairs Legislation Committee estimates hearings. See page 19 of the Senate Community Affairs Legislation Committee Hansard².

The Australian medical and scientific community have previously cited the presence of *Borrelia* bacteria in wildlife in Australia. Not only can species within the genus *Borrelia* be found naturally in the mouths and alimentary tracts of most mammals (including humans), potentially pathogenic *Borrelia* have been identified in introduced and possibly indigenous Australian wildlife from the mid-1900s. A recent publication by Chalada, Stenos and Bradbury³ provides a historical review of *Borrelia* found in introduced and native animals as well as migratory birds.

Irwin's research reveals the presence of a *Borrelia* sp. which probably aligns more closely with those *Borrelia* species that cause relapsing fever. Relapsing fever is distinct from Lyme disease. The clinical presentation and diagnosis of relapsing fever is different to that of Lyme disease. Whether this new bacterium can cause disease in humans is yet to be determined. It is not appropriate to make a link between discovery of a novel microorganism and a disease until pathogenicity studies can be performed.

There is no evidence to date that a bacterium in the genospecies complex of *Borrelia burgdorferi* sensu lato is present in Australian wildlife.

This is the basis for the statement that there is not yet an indigenous cause of Lyme disease in Australia. Should a bacterium in the genospecies complex of *Borrelia burgdorferi* sensu lato be discovered and verified as a human pathogen in Australia, the department would make such a discovery broadly known across the medical and patient communities.

¹ <http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-lyme-disease.htm#recent-aust-research>

² http://parlinfo.aph.gov.au/parlInfo/download/committees/estimate/e2ce0775-f59c-45f2-abff-96f7e8aa5e10/toc_pdf/Community%20Affairs%20Legislation%20Committee_2015_10_21_3927_Official.pdf;fileType=application%2Fpdf#search=%22committees/estimate/e2ce0775-f59c-45f2-abff-96f7e8aa5e10/0000%22

³

<http://www.sciencedirect.com/science/article/pii/S2352771416300039/pdfft?md5=7b40d15b4ade0e8a1d89f10ff792f30a&pid=1-s2.0-S2352771416300039-main.pdf>

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Question no: 2

Topic: Public Health

Type of Question: Written

Senator: Senator Madigan

Question:

What is the department's strategy to protect the health of the Australian public when a new emerging disease is found to be making people sick?

Answer:

The department's Office of Health Protection (OHP), in partnership with key stakeholders, especially state and territory health agencies, aims to protect the health of the Australian community through effective national leadership and coordination and building of appropriate capacity and capability to detect, prevent and respond to threats to public health and safety. Most of the work of OHP is around communicable and infectious diseases as well as the management of health emergencies.

OHP works closely with states and territories through the Public Health Laboratory Network and Communicable Diseases Network Australia on the development and maintenance of policies, systems for surveillance and analysis of communicable and emerging diseases.

An additional medical network available to the department for the sharing of valuable information includes the General Practice Round Table, which the Chief Medical Officer (CMO) has used frequently to discuss and disseminate information about emerging infectious diseases and other matters relating to health protection.

The department, through the CMO, chairs the Australian Health Protection Principal Committee (AHPPC) which has amongst its membership the Chief Health Officers from all states and territories, as well as senior executive representatives from relevant Australian Government agencies. The AHPPC is made aware of health threats and provides the preeminent health emergency management advice for incidents of national consequence.

Australia has obligations under the World Health Organization's (WHO) International Health Regulations 2005. The department is the National Focal Point under these regulations.

As information on emerging threats are discovered and communicated through WHO member states, the department is made aware and shares the information with responsible bodies in states and territories, as well as relevant Australian Government agencies.

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Question no: 3

Topic: Research Evidence

Type of Question: Written

Senator: Senator Madigan

Question:

Given Lyme-like illness is an emerging disease, do you think the standard approach of evidence-based policy has achieved a successful outcome for Lyme-like patients?

Answer:

The department acknowledges that 'chronic' Lyme disease is controversial and has polarised the medical profession and patient groups here and overseas. The growing awareness of a chronic debilitating illness manifesting itself as a constellation of nonspecific debilitating symptoms is not a recent phenomenon and is not limited to Australia.

Unlike recent emerging communicable public health threats, namely, SARS coronavirus and MERS coronavirus, no one knows the cause of this chronic debilitating illness. The affected patient community and the medical practitioners working within this community are divided on the important matters of cause, spread and transmission. As yet there is no outcome for these patients.

It has been the department's aim to find, share and understand the relevant Australian research evidence relating to this illness. While the work of Peter Irwin and Edward Holmes (submission 546) and their teams is not conclusive, it is the best start in searching for a microbiological cause. It is also important to consider non-microbiological causes as well as other medical explanations.

Without an accurate definition of the disease and without a known cause, the department emphasises the value of a multidisciplinary team approach to investigation and care for these patients. Such an approach must be coupled with investigatory technology such as metagenomics as well as conventional approaches to consider other diagnoses and exclude certain causes.

This approach, which follows the evidence and keeps patients at the centre of the research, is the best strategy for helping these patients.

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20 April 2016

Question no: 4

Topic: Research Evidence

Type of Question: Written

Senator: Senator Madigan

Question:

Patients do not think this approach has been successful. Can you please advise what alternative approaches are available?

Answer: *(as per answer to question 3)*

The department acknowledges that 'chronic' Lyme disease is controversial and has polarised the medical profession and patient groups here and overseas. The growing awareness of a chronic debilitating illness manifesting itself as a constellation of nonspecific debilitating symptoms is not a recent phenomenon and is not limited to Australia.

Unlike recent emerging communicable public health threats, namely, SARS coronavirus and MERS coronavirus, no one knows the cause of this chronic debilitating illness. The affected patient community and the medical practitioners working within this community are divided on the important matters of cause, spread and transmission. As yet there is no outcome for these patients.

It has been the department's aim to find, share and understand the relevant Australian research evidence relating to this illness. While the work of Peter Irwin and Edward Holmes (submission 546) and their teams is not conclusive, it is the best start in searching for a microbiological cause. It is also important to consider non-microbiological causes as well as other medical explanations.

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Question no: 5

Topic: Borrelia Infection

Type of Question: Written

Senator: Senator Madigan

Question:

Given the committee heard evidence of Borrelia infection through unprotected sex and through the womb, is it possible that Borrelia could be acquired locally in people who haven't travelled?

Answer:

In terms of classical Lyme disease, there remains no verifiable and repeatable evidence for sexual or congenital (mother to fetus) transmission which results in disease. The department is aware of publications making such claims but the data in those publications in some cases is not complete and in other cases has not been verified. To date, a bacterium in the *Borrelia burgdorferi* sensu lato genospecies has not been discovered in Australia so infection within Australia is unlikely.

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Question no: 6

Topic: Borrelia Infection

Type of Question: Written

Senator: Senator Madigan

Question:

Given the committee heard evidence of Borrelia infection through unprotected sex and through the womb, could Australians be acquiring Borrelia even if the causative agent is never found in an Australian vector?

Answer:

Please see answer to Question 5.

If the causative agent is not found in an Australian vector then an epidemiological analysis based on sexual and reproductive activity would be required to prove the hypothesis. The likelihood that all of these patients are connected sexually and genetically is low. There is no evidence for other human to human forms of transmission of classical Lyme disease such as through respiratory (either droplet or aerosol) or faecal-oral routes. The likelihood of not finding a causative agent in a vector if the causative agent can be characterised is remote.

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Question no: 7

Topic: Research

Type of Question: Written

Senator: Senator Madigan

Question:

Do you think the Lyme-like patients who do not have classic Lyme disease should have to wait years for scientific research to conclude before action is taken to help them?

Answer:

In many areas of medicine, the conclusion of research is not the starting point for medical assistance. While no immediate cure is at hand in the Australian situation for patients with chronic nonspecific debilitating symptoms, most of the symptoms can be alleviated to some extent and in some patients other diagnoses should be explored. It is not unknown in medical research for significant early findings to be translated into practical therapy before the planned conclusion of research. This does not mean, however, that patients should be administered multiple, long term oral and intravenous antibacterial agents without verifying a bacterial cause for the illness.

Patients who are suffering from medically unexplained illness should continue to seek medical assistance. Without an accurate definition of the disease and without a known cause, the department emphasises the value of a multidisciplinary team approach to investigation and care for these patients. Such an approach must be coupled with investigatory technology such as metagenomics as well as conventional approaches to consider other diagnoses and exclude certain causes.

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Question no: 8

Topic: Travel for Treatment

Type of Question: Written

Senator: Senator Madigan

Question:

Is the Department of Health satisfied that the Australian patients who do not have classic Lyme disease should have to travel internationally to receive treatment or seek alternative treatments?

Answer:

Patients who are suffering from medically unexplained illness should continue to seek medical assistance in Australia. The Australian medical profession would not regard alternative forms of therapy such as hyperthermia treatment or hyperbaric therapy as evidence-based forms of treatment. Likewise, in the absence of proof for persistent active infection, the use of long term multiple oral and intravenous antibacterial agents is difficult to justify knowing that the risk of harm associated with such therapy is real.

Without an accurate definition of the disease and without a known cause, the department emphasises the value of a multidisciplinary team approach to investigation and care for these patients. Such an approach must be coupled with investigatory technology such as metagenomics as well as conventional approaches to consider other diagnoses and exclude certain causes.

This approach, which follows the evidence and keeps patients at the centre of the research, is the best strategy for helping these patients.

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Question no: 9

Topic: Treatment Approach

Type of Question: Written

Senator: Senator Madigan

Question:

What can be done to help them in the interim period before research is concluded that isolates and identifies the causative agent that is making them sick?

Answer:

The department proposes that in conjunction with states and territories, multidisciplinary teams can be established to provide an investigation and treatment approach for patients. While no immediate cure is at hand, most of the symptoms described can be alleviated to some extent and in some patients other diagnoses should be explored by multidisciplinary teams.

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Question no: 10

Topic: Testing

Type of Question: Written

Senator: Senator Madigan

Question:

What has the Department done to assess the test results from overseas Lyme specialist labs that have mutual accreditation under the recently signed ILAC MRA? Is such a project being considered?

Answer:

The department has contracted the National Serology Reference Laboratory to evaluate classical Lyme disease assays. Specimens from Australian patients are being sought from laboratories overseas and in Australia which specialise in the diagnosis of so called chronic Lyme disease. Australian patient specimens are also being sought from Australian medical testing laboratories. Two German laboratories have been invited to participate and both laboratories fit within the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) framework. The success of this project depends on the cooperation of the invited participants to provide specimens of the required specifications in terms of volume, storage conditions and patient information.