

DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE AGUS LEANAÍ

JOINT COMMITTEE ON HEALTH AND CHILDREN

Déardaoin, 21 Samhain 2013

Thursday, 21 November 2013

The Joint Committee met at 9.30 a.m.

MEMBERS PRESENT:

Deputy Robert Dowds,

Deputy Seamus Healy,

Deputy Billy Kelleher,

Deputy Sandra McLellan,

Deputy Mary Mitchell O'Connor,

Deputy Dan Neville,

Deputy Caoimhghín Ó Caoláin,

In attendance: Deputies Seán Kenny, Helen McEntee, Derek Nolan, Jonathan O'Brien, Peadar Tóibín and Jack Wall.

Senator Colm Burke,

Senator John Crown,

Senator John Gilroy,

Senator Jillian van Turnhout.

DEPUTY JERRY BUTTIMER IN THE CHAIR.

The joint committee met in private session until 9.55 a.m.

Prevention and Treatment of Lyme Disease: Discussion

Chairman: We will now commence in public session. I remind members, witnesses and persons in the Public Gallery to ensure their mobile telephones are switched off or in aeroplane mode as otherwise they interfere with the broadcasting of proceedings and cause difficulties for staff.

The purpose of this meeting is to discuss issues surrounding the prevention and treatment of Lyme disease, an infectious disease caused by bacteria transmitted to humans by the bites of ticks infected with those bacteria. I thank Deputies Ciara Conway and Derek Nolan who nominated the issue for discussion in our work programme. Members will know from the briefing circulated that there have been 19 notified cases of Lyme disease - a statutorily notifiable condition - so far this year. We will hear during the meeting about matters relating to the diagnosis, treatment and prevention of this debilitating disease. I take this opportunity to thank everybody who took the time to correspond and liaise with the committee prior to the meeting, including the experts whom we are delighted to have in attendance today. I remind the witnesses that presentations should take between four and five minutes. Given that we are holding two meetings and that there is a large number of witnesses, I urge the witnesses to be concise. There will be a question and answer session on the presentations. I again welcome Dr. Schwarzbach, Dr. Eoin Healy, Mr. Micheál Casey, Ms Lisa Vandegrift Davala, Ms Tracy Brennan and Ms Annette Moloney.

Before we commence I remind people regarding privilege. Witnesses are protected by absolute privilege in respect of the evidence they give to the committee. However, if they are directed by it to cease giving evidence on a particular matter and they continue to do so, they are entitled thereafter only to qualified privilege in respect of their evidence. They are directed that only evidence connected to the matters under discussion should be given and are asked to respect the parliamentary practice to the effect that, where possible, they should not criticise or make charges against a person or an entity by name or in such a way as to make him, her or it identifiable. Members are reminded of the long-standing parliamentary practice and ruling of the Chair to the effect that they should not comment on, criticise or make charges against a person outside the Houses or an official by name or in such a way as to make him or her identifiable.

I invite Dr. Schwarzbach to make his opening remarks.

Dr. Armin Schwarzbach: I thank the committee for its invitation. I will speak about the problems associated with the diagnosis, treatment and prevention of Lyme borreliosis in Ireland.

I am a clinical laboratory specialist, MD and PhD, founder and director of the first clinic for tick-borne diseases and medical director of Infectolab in Augsburg, Germany, which is registered as an official clinic at the Bavarian Medical Council. I am the international expert for the chief medical officer's clinical advisory committee on Lyme disease in Australia, CACLD, and also a director of the International Lyme and Associated Diseases Society, ILADS, in the USA.

I speak to the committee as a clinical laboratory specialist working with patients in diagnosing and treating Lyme borreliosis and co-infections in over 20,000 cases in the past ten years. More and more Irish patients attend me in the clinic to get the right diagnosis and treatment. Also, some Irish doctors have contacted me in recent years to get support in the diagnosis and treatment of Lyme borreliosis in Ireland.

Lyme borreliosis is a bacterial infection by a spirochete named *Borrelia burgdorferi*, which can move everywhere around the body and be the reason for many symptoms and syndromes. It is named the “known unknown” by Lyme borreliosis specialists, a chameleon-like bacteria that is difficult to diagnose and difficult to treat. Lyme borreliosis is the fastest growing vector-borne infection in the United States. A total of 300,000 patients get infected in the US according to the newest Centre for Diseases Control, CDC, USA reports, which means ten times more Americans than previously reported.

Up to 50% of the ticks in Lyme-endemic areas are infected with borrelia. The problem begins with the fact that just fewer than 50% of patients with Lyme borreliosis recall a tick bite. Fewer than 50% of patients with Lyme borreliosis recall any bull’s-eye rash - erythema migrans - as a typical sign for a fresh infection. Without the recall of a tick bite or a bull’s-eye rash, chronic Lyme borreliosis symptoms can be misdiagnosed as chronic fatigue syndrome, CFS, fibromyalgia, rheumatoid arthritis, carpal tunnel syndrome, Parkinson’s, Alzheimer’s disease, multiple sclerosis, motor neuron disease, depressions, autism and so forth. In Ireland and all other countries worldwide, doctors are forced to use the borrelia ELISA test for borrelia antibodies as a screening test and not the borrelia western blot, even though the western blot has a higher test sensitivity, which means fewer false negative results, and a higher specificity, which means fewer false positive results.

The common ELISA test, which one receives at the doctor’s office, misses 35% to 60% of culture proven Lyme borreliosis. The western blot finds about 60% of chronic infected patients, which means a lot of false-negative western blot results in the case of chronic Lyme borreliosis. The laboratory tests for borrelia antibodies are not standardised and cannot exclude chronic Lyme borreliosis. It is impossible. Therefore, the European Union has spent €1.1 million on the development of a highly sensitive and specific low-cost lab-on-a-chip system for Lyme diagnosis in the last two years by the Hilysens project. My clinic, the BCA clinic in Augsburg, was one of the scientific partners in the Hilysens project.

Lyme borreliosis is a clinical decision depending on Lyme-typical symptoms and differential diagnosis. The average patient sees five doctors over nearly two years before being diagnosed with the correct diagnosis, Lyme borreliosis. In Ireland and many countries, doctors are forced to treat a chronic Lyme patient for a restricted time with antibiotics. The allowed maximum is four weeks in general, so only four weeks are allowed to treat a patient with chronic Lyme disease. If the patient is not cured within four weeks, the diagnosis of post-Lyme disease syndrome, PLDS, is given and most patients are treated symptomatically, but the persistent infection is not treated. Many of these patients develop psychiatric disorders. Short treatment courses with antibiotics have resulted in a 40% relapse rate, especially if the treatment beginning is delayed. There has never been a study demonstrating that 30 days of antibiotic treatment cures chronic Lyme borreliosis. Documentation is available which demonstrates that short courses of antibiotic treatment fail to eradicate *Borrelia burgdorferi*. A total of 40% of Lyme patients end up with long-term health problems.

It is important to know and learn about each symptom which can be caused by *Borrelia burgdorferi* to make the right clinical diagnosis in time to start the antibiotic treatment as soon

as possible. The patient should be monitored by the doctor after the treatment of any fresh infection, but especially during and after the treatment of a chronic infection. The socioeconomic costs for Ireland regarding misdiagnosed or late-diagnosed patients can be exorbitantly high, in addition to the costs for symptomatic therapies by painkillers or immune-suppressive remedies such as corticosteroids and all of their side effects for patients. The earlier one treats a Lyme borreliosis patient, the better is the prognosis in general.

My conclusions and proposals are as follows: first, teaching medical students at universities about all Lyme borreliosis symptoms by a standardised anamnesis, which means symptomatology, and teaching them about problems with diagnostic tests and about treatment options, including the long-term treatment aspects; second, a basic course for general practitioners, GPs, about handling of tick bites, symptomatology by a standardised anamnesis - a patient's account of their medical history-problems with diagnostic tests and long-term treatment options including monitoring of the patient; third, initiation of studies about bacteria in the ticks or tick tests, improvement of diagnostic tests and long-term treatment and the development of new antibiotics against *Borrelia burgdorferi*; and fourth, information campaigns for the Irish population on how to prevent tick bites and about symptoms in fresh and chronic infections. The first step in that regard was taken by Jenny O'Dea, who is one of the first people I got to know here in Ireland. She published a fantastic booklet for children and their parents to inform them about the risks and possibilities of Lyme disease.

I offer the committee my full support and will be delighted to answer any questions the members might have.

Chairman: Thank you, Dr. Schwarzbach. I invite Dr. Eoin Healy from University College Cork to make his presentation.

Dr. Eoin Healy: I hope I will not overlap too much with Dr. Schwarzbach's presentation. I will try to be as brief as possible and avoid the areas he has already covered.

Lyme borreliosis is an ancient condition. It affects humans in temperate parts of Europe and the United States. Although it is ancient, the disease was only discovered and described as recently as 1982. The first cases here were described in the mid-1980s and it is now accepted that the disease is endemic here. Cases are not due to somebody having contracted the disease abroad. A few might be, but the majority of cases are contracted here.

The disease is transmitted by the tick *Ixodes ricinus* in this country. It is commonly called the common tick, deer tick or sheep tick, and in the west of Ireland it is referred to as an scior-tán. It is the same beast. To call something a tick bite is probably a misnomer because the tick remains attached to the victim for several days while it sucks blood. There is no evidence that borreliosis can be transmitted by the bite of a flea, horsefly, mosquito, midge or anything other than a tick. Lack of awareness of the risk of tick bite and of the symptoms of the disease on the part of the public and of general practitioners is the main impediment to both the prevention of the disease and its treatment.

As Dr. Schwarzbach mentioned, the textbook first clinical sign of the disease is the bull's-eye rash, called the erythema migrans, which appears at the site of the tick bite. However, it only appears in approximately 70% of people who proceed to develop full-blown Lyme disease. As a critical symptom, it might not appear at all, so treatment may not be instigated. As the disease progresses, the nervous system in particular may be attacked, but there might also be joint and arthritic involvement as well as cardiac complications. As a result, disease symptoms

can vary from person to person. This can be confusing for patients who may share experiences and general practitioners, GPs, who find it causes problems for diagnosis.

There is an increasing risk of contracting Lyme disease in Ireland. The risk is strongly correlated with the density of ticks in a particular area. Persistence of the tick species transmitting Lyme disease in a particular area requires the presence of a sufficient number of large host animals on which the adult ticks can feed and obtain blood meals prior to producing a new generation of parasites. The animals involved are usually cattle, sheep, goat or deer. In Ireland up to 30 years ago, the particular tick species responsible for Lyme disease was, in relative terms, sparsely distributed. They would have been known by livestock farmers in particular parts of the country as transmitters of a few diseases such as redwater fever and louping-ill virus to domestic farm animals. The majority of urban dwellers would never have heard of a tick, let alone seen one.

Significant changes in the landscape have since occurred. Re-afforestation and the development of recreational forest parks have provided ideal habitats for expansion of the population size and distributional area of both the native red deer and the introduced sika deer. Escapees from fenced areas and parks, along with their reproduction in the wild, mean that deer are now widespread across much of rural Ireland. For example, between 1978 and 2008, the distributional area occupied by red deer has shown an overall increase of over 560%.

The behaviour patterns of deer together with their short fur result in them being able to feed far greater numbers of ticks than, say, sheep. As a consequence, we are seeing significant growth in tick numbers in areas where deer are common. In some places, tick numbers are as high as any on continental Europe. Greater use by humans of recreational forest parks and growth in outdoor activities such as hill-walking are resulting in increasing contact between humans and ticks. This increased contact inevitably increases the risk of tick bite and, therefore, the risk of contracting Lyme disease.

A lack of public and medical practitioner awareness of the disease means that a patient presenting with it is often initially overlooked or misdiagnosed. The delay is critical. The longer the delay, the worse the outcome. Most patients will have progressed to late-stage Lyme disease by the time they are treated. Many late-stage patients fail to respond to conventional treatment and the disease can persist in a chronic state.

Improved treatment of Lyme disease in Ireland requires early diagnosis. This demands an educational effort to make the public aware of the risk and potential consequences of tick bites and how to reduce this risk, as well as ensuring medical practitioners have the knowledge and competencies to detect, test for and treat the disease.

As things stand, deer numbers will continue to increase and will, therefore, serve to further amplify the growth in tick numbers. Climate change and farming practices are together creating more favourable conditions for tick survival. Increasing contact between ticks and humans will inevitably result in a rise in the incidence of Lyme disease. It is not possible to significantly reduce either the deer population or the tick population by human effort. In the absence of this, an educational approach will be the cheapest and most effective strategy.

Chairman: I thank Dr. Healy for his presentation. I call Mr. Mícheál Casey, veterinarian, Department of Agriculture, Food and Marine, to make his opening statement.

Mr. Mícheál Casey: Diseases transmitted by ticks are a major cause of economic loss,

disease and deaths in farmed animals worldwide. However, Lyme disease is not regarded as a significant economic tick-borne disease in farm animals.

Ticks are not distributed uniformly in Ireland, and even in regions where they occur in large numbers, they have particular habitat requirements. They need shelter from the elements and a moist microclimate which they find in under-grazed farmland and in rough vegetation such as rushes, bracken, and heather. Ticks have some fairly precise environmental requirements, especially when they leave the relative shelter of the base of the vegetation to find a new host. They find a new host by questing, where they climb to the tips of the vegetation and grab onto an animal or person going by. They need mild and moist conditions for questing, which are provided in late spring and in autumn in a typical Irish year. This results in clearly defined spring and autumn peaks in tick-borne diseases. On some farms the ticks have become adapted to one or the other season, while on other farms both peaks are seen. Understanding the type of habitats that ticks favour and the annual peaks of tick activity in spring and autumn is one part of preventing Lyme disease. We know when and where the highest risk of exposure will occur, along with the sub-populations of animals and humans most at risk.

Lyme disease is strongly associated with deer in the USA, whereas in Ireland, research has suggested field mice and some ground-feeding bird species are more important as reservoir hosts. In humans, we know Lyme disease causes a fever and a characteristic skin rash. This can progress to cause central nervous system disease, arthritis and blood vessel damage in humans. In animals, the same is true and the reported cases in the scientific literature worldwide have shown the main clinical signs associated with Lyme disease in animals consist of skin, neurological and arthritic syndromes, with some involvement of muscle.

Research in other countries indicates that this organism is capable of causing sporadic disease in dogs, cattle and horses. No confirmed cases have been reported from Irish animals to my knowledge. However, it is likely there have been occasional undetected cases in animals here, given how common the organism and the vectors are and how commonly animals are bitten by ticks.

There is some evidence that dogs are at higher risk of Lyme disease than other animals. However, this may reflect the amount of time they spend in tick habitats, the number of tick bites they get, and the close attention they receive if they get sick. As they are more likely to be exposed and affected, they are more likely to be detected.

There are many gaps in our knowledge of Lyme disease in Irish animals that need further research in terms of the impact of the organism and the prevalence of Lyme disease in Ireland. This year marks 21 years since barriers to trade in live animals between EU member states were lifted in 1992. It would be timely to survey our tick population to check for the incursion of exotic tick species and to re-survey ticks for the agent of Lyme disease to monitor its distribution.

Having said that, plenty of scientific evidence points towards widespread exposure to borrelia in Ireland. Blood-testing of farmers in Northern Ireland has revealed evidence of widespread occupational exposure to borrelia. This is likely to equally apply to other occupational and leisure users of marginal land and forestry. Surveys that captured and tested Irish ticks have shown that many are carrying borrelia.

Tick-borne diseases of Irish animals occur in well-defined areas and habitats. Within these areas, relatively little tick-borne disease is seen in animals despite apparently heavy exposure to a variety of tick-borne pathogens. This is because the exposure to ticks tends to occur from

shortly after birth when the young animal may be protected by maternal immunity passed on in colostrum, the first milk.

Other factors that impact on whether an animal is infected by a tick-borne disease include the phenomenon of co-infection. If a tick is carrying a pathogen as well as an immunosuppressive disease like tick-borne fever, then the chances that pathogen causing disease are increased. Many of the animal tick-borne diseases depend on these cold infections with tick-borne fever to cause the pathogen to multiply. Prevention of tick-borne diseases in animals consists of preventing and reducing the risk of tick bites. Preventive treatment of animals against ticks is commonly employed in high risk areas to kill ticks or to prevent the organism from multiplying in the animals. These measures are probably controlling tick numbers on animals and may be preventing us from seeing more Lyme disease in Irish animals, but Lyme disease is not the reason for applying these treatments. Rather, it is for other tick-borne diseases such as Redwater and Louping-ill and other such diseases.

Treatment is reported in literature to be straightforward, with antibiotic treatment in the acute phase. The important thing is awareness from an animal point of view and ensuring veterinary practitioners are aware of the possibility of Lyme disease as a differential diagnosis when dealing with an animal showing suggestive clinical signs. This is an area where information campaigns and continuing education can increase the awareness and responsiveness of veterinary practitioners to possible cases.

Chairman: Our next speaker is Ms Lisa Vandergrift Davala, who has done extensive research on the issue.

Ms Lisa Vandergrift Davala: I thank the Chairman and the committee for this invitation. During the past two and a half years, I have had a chance to do extensive research in preparation for a documentary on Lyme disease. Twenty-three years ago I contracted the disease and it took 20 years for the diagnosis. We have arrived at an interesting moment in time as regards Lyme disease and tick-borne illnesses in Ireland. Thanks to the joint efforts of patient advocates and this committee, we have seen Lyme disease made a notifiable disease in 2011. Many Irish doctors are now willing to acknowledge the disease, to speak openly about their limited knowledge, to ask questions, to ask for information and educational resources and to suggest that patients give presentations to medical personnel. Lyme disease has been the subject of two Seanad debates, in 2009 and 2012, acknowledging not only the burgeoning problem, but arguing that if resources did not yet exist in Ireland for patients to be diagnosed and treated, they must be given the support to seek help abroad. Ms Jenny O’Dea, who must be credited, co-founded Tick Talk Ireland and its excellent resource *ticktalkireland.org*. Individual Lyme patients, through enormously supportive friendships, create the largest resource of all, by offering telephone and Skype support to each other during the harrowing effects of the disease and referrals to foreign testing and clinics. A virtual underground railway has criss-crossed Ireland and most parts of the world. We now have the beginning of recognition, of awareness, and of a willingness to have dialogue and to collaborate for progress.

Equally, we must acknowledge the difficulty that foreign-tested sero-positive and clinically diagnosed Lyme patients are having in ensuring their diagnoses by world-leading experts will be upheld when they return home to Ireland. Difficulties also arise in having their disability status recognised or in being listed as having a notifiable disease, which needs to be considered when assessing the validity of those figures.

Today, our focus must be to move forward and to contribute to resolving these medical

conditions, which can only be denied at great cost to our nation's health, to the health of our agricultural industries and to Ireland's financial condition overall. Last month, Britain's Lady Mary Mar asked attendees of the London Lyme conference what was the cost to the taxpayer of welfare benefits, social care, NHS provision and loss of income tax of maintaining these men, women and children in a state of health that precludes them from working and being active members of society. Recent ESRI studies reveal skyrocketing numbers of children from birth to 19 years of age being diagnosed with MS in Ireland, with as much as 191% increase in a year, while experts, researchers and clinicians around the world have credited the very clear evidence that what we may have assumed were neurological or neurodegenerative diseases are actually patients who test positive for Lyme borrelia, which can resolve with appropriate treatment.

A pathologist, Dr. Alan B. McDonald, has shown that seven out of the ten brain samples taken from diseased Alzheimer's patients after death from the Harvard Brain Bank and were positive for Lyme DNA. Dr. Dieter Klinghardt revealed that 100% of his neurodegenerative patients have tested positive for Lyme and progress occurs with treatment. Michael J. Fox, the actor famously diagnosed at a very young age with Parkinson's, has now been found to have Lyme. A study by neurologists at University College Hospital Galway found that the Republic of Ireland has one of the highest rates of Lyme disease in Europe. According to the World Health Organization, Lyme disease is the world's fastest-spreading infectious disease but we cannot begin to discuss the numbers of infected people in Ireland without broaching the issue of accurate testing and availability of treatment.

We have all been called here today to make a contribution to progress the awareness and treatment of Lyme and tick-borne diseases in Ireland. The Oireachtas is the forum in which to ask bold questions and suggest even bolder solutions. In the spirit of nothing ventured, nothing gained, I ask whether we have an epidemic of neurodegenerative diseases in Ireland or whether it is the ever-growing numbers of tick and vector-borne infections, which have progressed without prior detection and treatment in a country whose natural environment is a perfect habitat for these diseases and where the level of infected ticks is well documented.

In view of the research and clinical evidence from around the world pointing to the relationship between neurodegenerative diseases and the presence of borreliosis, can Ireland justify financially the expense of what may be needless disability? Would we be willing, with the help of fellow European experts and highly sensitive testing, to test a sample portion of Irish sufferers diagnosed with MS, ALS, Parkinson's, Alzheimer's, motor neuron, etc., or to test an anonymous cross-section including these patients? What if this small effort yielded a resoundingly positive correlation that could lead to a progressive way forward? Most importantly, after today, if committee members or their family members were now diagnosed with a neurodegenerative disease, would they not be consulting one of the overseas Lyme-literate medical doctors and having their blood accurately tested before accepting a sentence to a wheelchair and a diagnosis, often made without the benefit of any laboratory testing, of having an incurable disease? If we even thought we could help such patients, what would stop us? Why not ensure a future that is not burdened with an ever-growing number of misdiagnosed, neurologically crippled patients who have no choice but to depend on a collapsing social welfare and health system? It makes humane sense and it could also make financial sense.

Our Irish doctors just want to heal people but they need to be trained in this disease and they must be told the truth that Lyme disease is in Ireland and that our only testing method, the enzyme-linked immunosorbent assay, ELISA, which was developed to test for HIV originally, is a seriously flawed remnant from tainted guidelines from the Centers for Disease Control and

Prevention, CDC, and the Infectious Disease Society of America, IDSA, on the testing and treatment of Lyme disease that has now been publicly exposed as such through the investigations of Connecticut Attorney General Richard Blumenthal in 2008. It is hoped that upcoming Washington hearings may finally lead to the prosecution of several individuals instrumental in the drafting. Ireland need not have any obligation to use this misleading test, especially as we have excellent testing available now in Europe and the US and very exciting new testing on the near horizon in Europe, which will cost less than our current ELISA to administer and has an almost 100% sensitivity and specificity.

None of the Irish doctors I have spoken to had known that the ELISA test's own manufacturer's paper insert, which stays in the lab and is never seen by doctors, states clearly that this test cannot disprove Lyme disease and that a clinical diagnosis must outweigh a negative ELISA. However, it has been the failure to score on the test that has shut Irish Lyme patients out of treatment and forced them abroad. Doctors need to be shown that paper insert as legions of Irish patients' futures depend upon it. Furthermore, it is impossible for late-stage Lyme patients to test positive on the ELISA, as we are too immunosuppressed. Today, very fortunately, we are honoured to have with us, one of the world's leading experts on Lyme disease, Dr. Armin Schwarzbach, who is generous with his information.

It took 20 years to get my diagnosis and treatment. By that time, I was unable to walk, I had Bell's palsy on one side of my face, I had nearly lost my life and almost all of what was in it. I experienced symptoms of dementia and full paralysis. That person, from two and a half years ago, could not have made this presentation. I chose to know the truth rather than to be mothballed in a wheelchair with a neurodegenerative diagnosis and to suffer the horrors of my own body being eaten alive by bacteria until my demise. My greatest wish and the dream I have for Ireland is that we will now give that choice to all who need it.

Chairman: I thank Ms Vandegrift Davala for her very moving testimony. I welcome Ms Tracy Brennan and Ms Annette Moloney, two Lyme disease patients and advocates, and thank them for being here.

Ms Annette Moloney: I thank the committee for the opportunity to be here today. I am a Lyme disease patient from Limerick. I am here to offer my own patient experience and also to give the committee a perspective on behalf of a number of patients who are experiencing difficulties in the diagnosis and treatment of Lyme disease in Ireland. Lyme disease is like the escape artist of diseases. It is very difficult to find, even in blood tests. Lyme disease is complicated for doctors to diagnose and is often misdiagnosed and under-diagnosed. For patients, it is a painful and debilitating disease and it also presents a serious public safety issue in Ireland. Lyme disease has more than 100 varied symptoms, including muscle and joint pain, back pain, headaches, muscle twitches, breathing difficulties and heart problems, and can at times result in paralysis and loss of sight. For patients, the disease can feel like an intense mixture of a bad flu, severe arthritis and exhaustion but what differs is that symptoms can last for months or years. In some cases, children are born with the disease. The longer it is left untreated, the more damage Lyme disease can do.

I would like to begin by giving the committee my personal experience of Lyme disease. In July 2012 I got a tiny tick bite. While I would like to be able to tell the committee this happened in a far-off tropical location, it did not. It happened to me at home in Pallasgreen, County Limerick. I found the tick attached and removed it carefully but within three weeks I started to experience what I now know are typical acute Lyme disease symptoms. I went to my general practitioner and had a range of tests carried out in Ireland, which all came back negative.

Looking back, one could say I was lucky that I found the tick bite and I was able to connect it to the fact that I became ill quite quickly. I also knew of the dangers of tick bites. Although I had a strong suspicion what was going on, Lyme disease was repeatedly ruled out by doctors. In February 2013, I had specialist testing carried out in Germany, which confirmed that I had Lyme disease plus two co-infections.

In some ways, my story is an example of how complicated and fast acting the Lyme disease bacteria can be. Before the tick bite, I was a keen amateur runner. I was a voluntary coaching assistant with two athletics clubs in Limerick where I encouraged others to take up leisure running as a way to improve their health and well-being. A month before the tick bite, I had won four medals at the Limerick county track and field championships, which to me was as good as, if not better than, winning Olympic gold. I used to run approximately 20 to 25 miles a week and led an active, healthy lifestyle. Within three weeks of the tick bite, I could not run at all and I have not been able to return to running since but, in many ways, that is the least of my worries.

Apart from dealing with the disease itself, patients often face real challenges in the diagnosis and treatment of Lyme disease in Ireland. There are a growing number of patients who have tested negative for Lyme disease in Ireland who have subsequently tested positive through a specialist doctor or laboratory, for example, in Germany, Switzerland, Belgium or the USA.

Unfortunately, patient experience shows that some Irish hospital-based consultants refuse to acknowledge a diagnosis from a specialist Lyme disease doctor or laboratory from another country. Without the support and expertise of these consultants, the Irish medical system finds it difficult, if not impossible, to help patients to deal with the disease. This affects patients in a number of ways. They are denied a diagnosis for a debilitating condition. They have to find the money to travel to other EU states or countries to access treatment and, ultimately, their lives are at risk.

While it is important to note that some patients who happen to test positive in Ireland, thankfully, get treatment but medical approaches vary considerably. In preparing for today's meeting, Ms Brennan and I initially contacted 25 Lyme disease patients experiencing difficulties in accessing treatment in Ireland. This number has since grown to more than 100 people - men and women from a range of ages, including young children, and from almost every county. Information and a range of patient profiles was included in the longer submission sent to the committee in advance of today's meeting.

Apart from these personal impacts, Lyme disease is also a serious public safety issue in Ireland. By denying a specialist diagnosis of Lyme disease, patients are often tested for a range of other conditions, involving further blood tests, scans and referrals to other hospital consultants, leading to huge costs for the HSE or else paid for privately by patients. Furthermore, there is evidence that Lyme disease can be transmitted sexually, congenitally from mother to baby and through blood donations. The Irish Health Protection Surveillance Centre's disease surveillance report of April 2013 is of note here. It states: "surveys of blood donors indicate significant levels of sero-positivity in certain parts of the country (particularly in the West of Ireland): this suggests that a figure of 50 Lyme Borreliosis cases countrywide per annum could be a considerable underestimate."

As patients, we are concerned that there is dangerous lack of accountability and governance with regard to the comprehensive diagnosis and treatment of Lyme disease in Ireland. There is an urgent need to increase levels of awareness among the general public on the dangers of tick bites. Prevention and early intervention improves a patient's chance of recovery.

What needs to happen next? As patients and citizens, we recommend a number of positive steps, some of which can be developed in partnership with the HSE. The issue of Lyme disease should be addressed by the HSE at its next meeting with the committee. The committee should appoint a rapporteur to carry out a detailed examination and report on the situation in regard to Lyme disease in Ireland and for patient representatives to be consulted as part of this process. Patients feel there is a need for the HSE to establish a Lyme disease task group. This group should include a range of expertise, including infectious diseases consultants, GPs, international Lyme disease experts and patient representatives. It should also consult a number of other experts relating to patient symptoms, including chronic pain specialists, neurologists, rheumatologists, paediatricians, obstetricians, etc. As patients, we are aware that Lyme disease is a very complicated illness. We can understand that for doctors at all levels it also presents challenging and confusing scenarios where patients can present with a multitude of symptoms, in a variety of places, over a long period of time.

We, as patients, feel the diagnosis and treatment of Lyme disease in Ireland needs to be more patient-centred and more evidence-based. Ireland has a real opportunity to work with up-to-date international best practice to improve this situation for patients and the public. Lyme disease is very much an orphan illness. It is a minority illness and is not socially understood. Patients with complex cases of the disease know that if they want to return to health, they must rely on international expertise. While it could be said that Lyme disease is not overly prevalent in Ireland currently, due to increased travel by the population, this situation may change in the future and, from patient experience, we are also seeing more cases being contracted at home. Furthermore, because so many patients are misdiagnosed with other illnesses, it is also impossible to say how many actual Lyme disease patients there are. We do understand it is a relatively new disease within the Irish medical system and, as patients, we are encouraged by the leadership shown by joint committee in discussing this issue today. We hope this issue will form part of further dialogue with the committee, the HSE and the Department of Health and are keen to be part of that positive development. Again, we thank the committee for the opportunity to be here today.

Chairman: I thank Ms Moloney for her very sobering and challenging presentation.

Ms Tracy Brennan: I am very grateful that the committee has taken on board the seriousness of Lyme disease in Ireland and that I have the opportunity to make this presentation to it. I am 39 years old and I live in Dublin with my husband and our three small children. In August 2011, three weeks after my youngest daughter was born, I developed an ear infection. Over the next six weeks, I had three such infections. I was extremely weak and had a dreadful feeling I would just collapse. Over the next 12 months, the weakness continued and I suffered daily from a multitude of symptoms. The complete list of symptoms is simply too long to read out and the most important ones are included in my longer submission document.

The worst symptoms were: burning pain in all of my muscles, where climbing stairs was near impossible; pain in all of my joints and, in particular, sacral joint pain which meant walking was often very painful; and relentless, excruciating inner and outer ear pain. For months I attended ear, nose and throat, ENT, clinics in Beaumont hospital on a weekly basis and was frequently at accident and emergency in the Royal Victoria Eye and Ear Hospital. I saw more than nine different ENT doctors. Steroid ointment was being put in, then taken out and put back in. Sometimes I got relief and other times it was all pointless. I was referred to a pain management specialist who prescribed nerve pain medication which did not help. It was endless pain for months and I was so frustrated that we could not get to the bottom of the problem. My ENT

consultant was so baffled as to why I was not responding to treatment that he arranged for a second opinion for me. I also had regular chest infections, bouts of 'flu, episodes of streptococcal throat and kidney infections. I was constantly at my GP's practice or at the VHI SwiftCare clinics late at night needing antibiotics for the latest dose that came at me.

Managing the aforementioned symptoms and ongoing physical weakness on a daily basis was an enormous challenge. Imagine trying to hold and feed a newborn infant while battling a feeling that your legs were about to give from under you, with two other small children, aged four and two, at your feet. As a family we required enormous levels of help from grandparents in order to function. The number of hospitals and clinics I had to attend was starting to increase. These appointments were starting to exhaust me physically and mentally and left me wondering who could I turn to. In total, I attended 11 hospitals and clinics in Ireland as a public and private patient, some on a very regular basis, looking for answers. My medical bills in Ireland started to eat in to our savings but we had no answers to show for the money we were spending.

In the summer of 2012, I was very lucky to be seen by an Irish GP who had spent 30 years working in the US and he recognised the symptoms of Lyme disease. He referred me for an appointment with an infectious diseases consultant in Ireland who sent my blood to the UK. The results from an ELISA test were negative and I was told I did not have Lyme disease and to go back to my GP. With the support of the GP I learned of the Borreliose Centrum in Augsburg, BCA, Germany. I had spent five years living in Frankfurt in my 20s and I felt very comfortable travelling to Germany for treatment as I am very familiar with the quality of their medical work and their approach to patients. My blood tests for Lyme disease through BCA returned positive results. It was such a breakthrough for my whole family that at last we knew why I was so unwell and why I was in so much pain. There was immense hope for my future.

I then travelled to Augsburg in Germany. For two hours a German Lyme disease specialist talked to me about all of my symptoms from my ears down to my toes. We discussed all of my possible exposure to ticks. Although we will never know when I was infected, it is highly likely it was when I was living in Montauk on Long Island in the US on a J1 student visa, as I lived in a wooden chalet surrounded by deer. We were shown ticks and told to be careful. Unfortunately, I never developed the classic bull's eye rash. The borrelia bacteria that causes Lyme disease can lie dormant in a patient's body for months or years and only become active when the patient has become immunosuppressed. For me, the immune system suppression of pregnancy gave the dormant borrelia a chance to take over.

I started my treatment in October 2012 with two weeks in Germany having intravenous antibiotics. Thereafter, I had 16 weeks of intravenous antibiotic treatment with a VHI Homecare team who looked after me so well in my own home. I never thought I would ever have to call on such a service but I did. I am so thankful it was available to me as it was excellent and played a pivotal role in my recovery. Treatment brought such relief. Within weeks my ear pain lifted and this gave me a glimpse of what life could be like. The neurological symptoms like noise and smell sensitivities also quickly disappeared. So that members can really understand the difference this treatment has made to my life, I will draw comparisons between October last year and this year. Last year, I needed a carer with me and a wheelchair for the walk through Dublin Airport for my flight to Germany. This October I flew to Gatwick by myself for a conference. My life is now filling up with social events that simply were not possible for me before treatment.

My treatment for Lyme disease through BCA has restored my health and my life, which had been completely shattered for almost two years by this awful debilitating disease. The money

spent has been the best money I or my family have ever spent. One of the best moments on this journey was going to see my ENT consultant. I handed him my German results and he fell back in to his chair. “Lyme disease, I had never even thought of it”, he exclaimed. He was delighted for me as we now had the answer to the ear pain. He congratulated me on persisting and getting to the bottom of my ill health, but most importantly for getting to the bottom of it all in only one year. His own brother, a doctor in the US, had also had Lyme disease, but it took him two years to get his diagnosis.

I am now in contact with over 20 Irish people who are travelling to Germany for treatment, some of whom have had a much worse experience than me. The system here is delivering for some but not for others. That is why I ask that this committee continues its engagement with us, as patients, in order to improve the lives of those who struggle with this relatively new and complicated disease. As Annette mentioned, engaging with the HSE would be an excellent start. A rapporteur to look at Lyme disease across the country, taking into account increased travel over the last number of years, and a Lyme disease task group in Ireland could mean fewer people having to endure the experience I had.

Chairman: I thank Ms Brennan and now call Deputy Kelleher.

Deputy Billy Kelleher: I thank the witnesses for their submissions and particularly for sharing their personal experiences with us. The more I read about Lyme disease and the more I have heard about it through the awareness campaign that the witnesses are engaged in, the more confused I become about the actual process of diagnosis. Is it a very difficult disease to diagnose or is the problem a lack of understanding of the disease, whereby doctors here simply do not look for it in the first place? I ask the witnesses to elaborate on that issue because it seems to be central.

The witnesses spoke about educating general practitioners and clinicians in general and that must be done through awareness campaigns. We should also invite the Chief Medical Officer and others from the Department of Health to appear before this committee to determine their views on how we should address this issue. Indications are that because of the changing landscape, the increase in the numbers of people engaged in recreational pursuits in the countryside, through hill walking, for example, and the increase in the deer population, this disease will become more prevalent in the future. Figures from the United States and elsewhere suggest that the incidence of Lyme disease will increase.

Mr. Casey said that animals develop a form of immunity to Lyme disease. Is that correct?

Mr. Mícheál Casey: “No, I said that because there are other tick-borne diseases, too little Lyme disease is seen here.

Deputy Billy Kelleher: I asked that question because I read somewhere that blood testing can sometimes yield false results whereby people are diagnosed as having Lyme disease when actually they are carrying the antibodies to the disease. In that context, I am wondering if blood testing sometimes gives false indications of the prevalence of the disease. I ask for clarity on that question. Is it a notifiable disease?

Ms Annette Moloney: Yes, it is notifiable.

Deputy Billy Kelleher: The key question, then, is whether it is always notified. Is there a follow-up system in place after diagnosis? If GPs and clinicians in general are unaware of the disease, then they are probably also unaware of the fact that it is a notifiable disease. I ask the

witnesses for their observations on that issue.

On the broader issue, home care packages were mentioned. Witnesses also spoke of the need for the HSE to have a better understanding of the needs of sufferers. Why is it that one has to go to Germany for antibiotic treatment? Such treatment does not seem to be too technically complicated and I do not understand why it cannot be provided here. Why do patients have to go to Germany? Is it because we do not understand the disease or because we cannot provide the necessary treatment for it here?

Chairman: I call Deputy McLellan. Deputy Caoimhghín Ó Caoláin has sent his apologies. He is in the Dáil at present, debating a Bill.

Deputy Sandra McLellan: I thank the witnesses for their presentations and for sharing their very personal experiences with us today. The witnesses made reference to the borrelia ELISA and the borrelia Western Blot tests. They suggested that the latter test results in a higher rate of detection. Would they recommend that this test be available in Ireland and how important a tool is it?

The witnesses said that if people are not cured of Lyme disease within four weeks, they go on to develop psychiatric problems. I ask them to elaborate on that point. The need for more awareness and public education was stressed by the witnesses, which is very sensible. How do they think such an initiative could be rolled out? I ask them to give practical examples of how it might work.

I have a lot of sympathy for Ms Moloney's predicament. What she went through was absolutely dreadful. It is also dreadful that Lyme disease is not included in the long-term illness scheme. Some consultants seem to have an unhelpful attitude to detection and obtaining second opinions. Would a Lyme disease task force assist in changing that situation?

Will Mr. Casey describe the symptoms of Lyme disease in animals? Are they different from the symptoms presenting in human beings? What curricular changes would be required to educate veterinary surgeons on Lyme disease? How aware are they of this disease?

Having read the submissions, I was quite upset to learn that doctors considered that patients presenting with symptoms which they were not able to identify as Lyme disease were putting it on, so to speak. I think that is heart-rending.

The Borreliose Centrum Augsburg, BCA, seems to be a good institution. We should consider adopting some of its practices and treatments in the short term. Did the witnesses suffering from Lyme disease receive financial support from the State to travel abroad for treatment? Would they encourage people to seek treatment abroad for this disease?

Ms Lisa Vandegrift Davala made a number of salient points, including the shortcomings of the ELISA test. What countries with high exposure to Lyme disease have dealt with it well? How can we learn from what they did to combat it?

Senator John Crown: I welcome the witnesses. It was very interesting for me, as a doctor, to hear the presentation. I feel I have had a CME exercise in infectious disease today. I wish to focus on specific medical issues which are troubling me greatly. If I understand what has been said correctly, the consensus of four members of the panel is that the ELISA blood test to diagnose Lyme disease does not work. I would like to hear Dr. Healy's and Mr. Casey's opinions on that. I would like Dr. Schwarzbach to tell me the alternative blood test he is using to make

the diagnosis of Lyme disease if he does not accept the ELISA blood test.

Please interrupt me if I am wrong. My understanding is that the thrust of the argument is pointing in the direction that there are people who have the somewhat controversial chronic Lyme disease. The first, fourth, fifth and sixth witnesses would be advocates for the position that there is chronic Lyme disease which requires long-term antibiotic therapy which is not given in Ireland and which necessitates people travelling. It must be stated for the sake of balance that this is not a uniquely Irish phenomenon. It is not because Irish doctors are uncaring but because there is about 95% international consensus that the entity is not well-substantiated and leading bodies, including the Infectious Disease Society of America, the American Academy of Pediatrics and the National Institutes of Health, have denied the evidence in favour of a diagnosis of chronic Lyme disease infection. In a major *New England Journal of Medicine* review article in 2007, there was substantial criticism of Blumenthal as having been intimidatory. Individual researchers that have adopted the position that chronic Lyme disease is not yet validated have been personally threatened. It is important we understand there are two sides to the argument and the position on whether chronic Lyme disease exists. I would like specifically to get the opinions of Dr. Healy and Mr. Casey on whether they think the ELISA is not a valid test, and I would like to get Dr. Schwarzbach's information on the alternative blood test he is using.

Senator Colm Burke: I thank the witnesses for the very good presentations. I grew up on a farm and this reminds me of the time in the 1970s when people working on farms were being diagnosed with brucellosis, particularly chronic brucellosis. At the time, it took GPs some time to become familiar with the symptoms of this disease and from what the witnesses have said, their experience sounds very much like that. Ms Annette Moloney and Ms Tracy Brennan spoke about their experience in the different hospitals they went to in Ireland. Have they spoken to the hospital personnel about the need for one hospital to focus on Lyme disease and develop the necessary structure to deal with the low number of patients who contract it? Have those who have had the disease considered looking at that?

Mr. Casey might be able to comment on whether it is possible to reduce the level of ticks carried by the deer population? Can a course of action be taken in that regard in light of the future growth of the deer population? Mr. Casey referred to the analysis of the blood testing of farmers in Northern Ireland. Have the universities in the South considered taking on a research project on that topic to follow on from what has done in Northern Ireland? Would UCD or UCC be in a position to consider a joint project of research in conjunction with the veterinary college?

Deputy Mary Mitchell O'Connor: I thank the witness for their presentation. I did not know very much about Lyme disease until I was contacted by a mother whose son has it. This lady was in the lucky position that she could bring her son to Germany to undergo the tests and buy the medication. There must be people who cannot afford that. Do we know the number in this position?

In arriving at a diagnosis, doctors may first consider fibromyalgia or other diseases instead of Lyme disease. The fibromyalgia groups have appeared before the committee but they never mentioned Lyme disease. Do the different groups that support people suffering pain from this group of symptoms co-ordinate their effort and knowledge?

Deputy Dan Neville: I thank the witnesses for their presentations. There is a debate in the medical profession on the recognition of Lyme disease.

I have experienced something similar previously on the recognition of attention deficit hyperactivity disorder, ADHD, when it was strenuously denied that such a condition existed. It took a great deal of campaigning to get the medical profession and the psychiatric services to accept that ADHD was a treatable condition. I would detect that we are at a very early stage of having Lyme disease accepted internationally as a condition. While we do not have the benefit of listening to those putting the other side of the argument, it might be interesting to challenge them on their views on the matter as well. While both Ms Brennan and Ms Moloney have recovered, have they recovered fully such that they no longer need treatment?

Deputy Peadar Tóibín: I thank the witnesses for their moving and heartbreaking accounts of their experience. It must be very difficult to be extremely ill and to have to fight a health service. The witnesses have had the resources to be able to deal with Lyme disease, but imagine the case of those depending on the public service who must face a complete brick wall to try to find health. The question has been posed whether the diagnosis of Lyme disease is settled science and, if it is, why there is an ignorance among the medical profession about this disease? This lack of knowledge is leading to a personal negative experience as well as major costs within society. It is frustrating to hear that it was debated in the Oireachtas - in the Seanad - in 2009. Given that people are living with this disease every day as time ticks on, it is frustrating that the Oireachtas has failed to do more on it. Some interesting suggestions have been made about the research that needs to be carried out. I am not a member of this committee, but I think it would be great if it were to support the calls that have been made for increased research.

Chairman: The committee can only deal with the present. We are dealing with that. That is what we have been charged with.

Deputy Helen McEntee: Like Deputy Tóibín, I am not a member of this committee. I have come across this issue in my constituency. I thank everybody for their presentations. The debate that has taken place on this matter in recent years needs to be stepped up. Obviously, this is what is happening. Many questions have been asked. As far as I am aware, none of the insurance companies in Ireland provide cover or assistance to patients with this disease. As it is not a long-term illness, it does not have disability status. What is the position in other countries? It is obvious that better diagnosis and better medical help is available in other countries, but what level of financial assistance is available elsewhere? How can we learn from those countries as we move on?

Chairman: There is approximately half an hour remaining in this meeting, so I will give all the witnesses approximately five minutes each in which to respond.

Dr. Armin Schwarzbach: I thank members for their questions. We could spend two or three hours discussing all the points that have been made. I will focus on the key points. A clinical diagnosis is needed in this case. The diagnosis must be made on the basis of the symptoms, which is very difficult. One needs to give time to the patient. An hour or more is needed to ask him or her about his or her medical history. One must then find a correlation with a possible tick bite or other differential diagnosis. That means it is a speaking medicine. This is not done in universities or hospitals because of a lack of time. This is done by general practitioners or by ambulance personnel. That is how it is done in Germany.

The doctors trust the ELISA technique. The HIV ELISA was founded in 1980. The antigenicity of *Borrelia burgdorferi* is so complicated that it was a big problem to develop a good ELISA that is sufficiently sensitive. There are several working groups in this area. The EU knows about the problem. That is why €1.1 million was provided to improve the sensitivity

of the test. We developed new antigens as part of this new test system. More subspecies have been found. *Borrelia* is not one bacteria. It consists of several subspecies. *Borrelia miyamotoi* is a brand new subspecies which has been detected in Russia and the USA.

We have to look for several subspecies. The ELISA technique is a very weak technique because one could just put some antigens on the ELISA particle. The immunoblot technique is a better technique. On the other hand, not all patients develop antibodies in the body. The next problem can arise if the patient is treated at an early stage with doxycycline, which is normally used. In such circumstances, no antibody production will start in the body, which makes it complicated to diagnose. If a clinical diagnosis is required, one must do a good anamnesis and a good symptomatology, including the differential diagnosis. One needs to give the patient time. It is not possible to do all of this in ten minutes.

University studies that were done in the 1980s and 1990s do not accept chronic Lyme disease because they do not see chronic Lyme disease. If patients go to their GP, rather than a hospital, with symptoms like those of fibromyalgia, rheumatoid arthritis or multiple sclerosis, they will be sent to a neurologist for spinal fluid analysis. If that test is negative for Lyme disease, it will be excluded from consideration. Neurologists also use spinal fluid for a very weak ELISA technique to exclude this. That is impossible. It cannot be diagnosed by laboratory tests. A clinical diagnosis is required. This needs experience. It cannot be done by a normal GP without any experience.

The universities do not teach students about Lyme disease. Like other doctors of my age, I did not hear anything about this when I was a student. Lyme disease is a very young disease. It started in 1981. The oldest patient is a 5,000 year old iceman. It has existed for a very long period. There are two different tendencies in the medical world. The first of them relates to those with chronic infections. The second of them relates those in the acute or subacute stages, who tend to go to hospitals. In the other cases, they tend to go to GPs. We have to care more for those with chronic infections rather than those in the acute or subacute stages. It would be good to do this.

The therapies are definitely too short. One cannot tell someone they have been healed of a bacteria after four weeks. This is what we do not see in our patients' group. If one treats a patient with doxycycline for two or three weeks, one has to monitor the patient. One cannot leave the patient alone. One has to keep an eye on what happens afterwards. It can be a very traumatic disease. The committee has heard some examples. This is my daily work in the hospital and the laboratory.

Ireland is not alone in having this problem. There is a strong move in this direction in the Czech Republic, Poland and Finland, which I will visit soon. Each of those countries plans to do something about this problem to help chronically infected patients who have received tick bites. Not everybody sees the tick bite. That is what it makes it complicated. Not everybody has the typical symptoms. Some 10% of patients have the summer flu, for example. Nobody asks whether one has received a tick bite when one has the summer flu. It is not a typical question for a GP. One has to know about this. One has to learn about it.

This can be a life-threatening disease at the end. Chronic Lyme disease is not a disease for the hospital. It is a matter for rheumatologists and neurologists. The psychiatric question is very important at the end. If one spends one's whole life suffering from pain, if one uses many painkillers and immunosuppressive medicines and if there is an explosion of bacteria in one's body, one will feel hopeless, particularly if one loses one's place in the workforce. We need to

consider what happens in such circumstances from a psychiatric perspective. It is typical for patients to be sent to a psychiatric specialist. I have seen thousands of such cases - not just in Ireland - in recent years. It is not an Irish problem.

I was also asked about the definition of a post-Lyme disease symptom. Most doctors postulate. That is not an explanation for me because I do some special tests. I have been asked about these tests. They came from the tuberculosis world. One such test is the lymphocyte transformation test, which is the gold standard for tuberculosis. Many patients - I do not know the exact number - do not react on the antibodies used in the immunoblot or ELISA techniques. They react on the T cells. I think we have to look increasingly at the T cells in the coming years. There is a tendency in the scientific world and in laboratories-----

Chairman: Is there an awareness and a willingness among Dr. Schwarzbach's profession to change its methodology?

Dr. Armin Schwarzbach: Yes. This mentality is shared in the USA. An increasing number of studies are coming about. One must read into this field to find out what the experts are saying. It is not just done by GPs. One could compare our experts to specialists in oncology or HIV. Prevention is also an important aspect of this matter. It is not just a question of the ELISA technique. People need to be educated about prevention. There should also be an information campaign about how to diagnose it in the first and second stages.

Dr. Eoin Healy: Dr. Schwarzbach has dealt with the issue of testing. I might make a few points about the incidence of the disease. I will also comment on the question of whether it is a notifiable disease.

Chairman: I would like to ask about mapping in Ireland. Dr. Healy mentioned in his presentation that it is prevalent in certain parts of the country, such as Limerick. Are the locations where patients are found mapped? Is there a concentration in any particular area?

Dr. Eoin Healy: Yes, there is. I have seen such mapping. One cannot always rely on it. Those who live on the east coast and take their holidays in the west might develop symptoms when they return. The Health Protection Surveillance Centre states on its website that "likely estimates suggest that there are between fifty and a hundred cases each year". The data I have seen from the Cork and Kerry region suggest that this number of cases is encountered in that region alone each year. I have estimated, based on the population size for that region extrapolated for the country as a whole, that there are more than 250 cases in this country each year. If we come at it from a different angle, it is reckoned that there are 65,000 new cases of Lyme disease appearing in Europe every year. Based on the population size in Europe of approximately 735 million and on a *pro rata* basis of 4.58 million, that would give us about 400 cases a year. Dr. Armin Schwarzbach might be able to comment on this but certainly American testers would reckon that they are possibly picking up something in the order of one in ten cases; in other words, they are missing nine cases for every one they pick up. If we were to take a somewhat more conservative view and say we are catching, say, one in four and if we have 400 new cases per year, that means that there are 1,600 cases a year in the country. If we accept that there is such a thing as chronic Lyme and that a certain percentage are not responding to treatment and that their disease condition persists over a number of years, we must think about the burden of illness that is building up over a period of, say, five or ten years and the cost to the families, the sufferers themselves and the whole health system.

As to whether we could do anything about reducing the number of ticks in the environment

or ticks on deer, it is an impossible situation. There are deer everywhere. I am not recommending a deer cull or anything like that but it is just that the situation with deer is out of control. To wipe out ticks on one acre of land would almost be impossible. If one thinks about the west of Ireland it is-----

Senator John Crown: Does Dr. Healy believe there is an entity of ELISA-negative Lyme disease?

Dr. Eoin Healy: I am not a microbiologist and I would not be competent to answer that question.

Senator John Crown: What are you?

Dr. Eoin Healy: I am a zoologist.

Chairman: In your experience of dealing with the issue from a HSE point of view, the testimony given by the patient advocates tells us there is not, perhaps, a recognition or a willingness to change along the way. Would that be Dr. Healy's experience?

Dr. Eoin Healy: That would be my experience. People who I know have suffered from Lyme disease have had poor experiences in dealing with medical practitioners and an unwillingness to accept their condition. Often I believe this is because it is not within their own area of expertise. Infectious disease consultants are not used to Lyme disease. They are specialists in other areas. The Lyme disease patient gets, perhaps, not 100% treatment.

Chairman: I call Mr. Casey.

Mr. Micheál Casey: I thank the Chairman. A wide number of points have been raised. Deputy Sandra McLellan asked if the symptoms were similar to those of humans. The clinical signs described for animals are very similar to what is described as acute Lyme disease. To take up the point raised by Deputy Dan Neville, acute Lyme disease is not a controversial diagnosis. It is a well established condition. The controversy is probably over what Senator John Crown identified as the ELISA negative chronic Lyme disease. That is a controversial area. That is not my area of expertise. I am open certainly to testimony of the type we have heard here today. There are other pieces of what one could call circumstantial evidence that could support it. It has been shown in peer review publications that the organism can persist for years in the brains of mice. In all of this we need to work towards a case definition, which would combine clinical science, test findings and pathology. To that extent, that package has not been put together so far as I have read. Certainly, in animals there is no suggestion of a syndrome of chronic Lyme disease but, I think, in animals we are missing acute Lyme disease. I think many cases are being missed. The points made by Dr. Eoin Healy are absolutely correct that there is much under-diagnosis of Lyme disease in both animals and in humans.

On the research front, there is a huge gap in our knowledge. Some of the work done on the distribution of ticks and on mapping probably needs to be replicated. Dr. Annetta Zintl and Dr. Theo de Waal in UCD are interested in doing further research on the distribution of ticks. If we progress that on to ticks that are collected as part of that survey could be tested for some of the organisms that cause some of these tick borne diseases, including borrelia, it would add significantly to our knowledge.

On the ELISA test, it seems to be uncontroversial from an animal point of view that it would do well in acute infections. The controversy is over whether, in untreated infections when the

antibody response drops and the ELISA is no longer detecting antibody, the organism is still present and still causing disease. Again, we have to be mindful that 25 years ago stomach ulcers were not treated with antibiotics and a bacterial cause was not recognised. An open mind is important. I would think that scientifically the jury is still out in terms of peer review publication. I am not contradicting what people have said here today but in terms of what is in the published literature, and it is not my area of expertise, certainly on the animal side we have not seen the chronic Lyme case proven. One hears compelling testimony from people. I think we have to keep an open mind on that.

Ms Lisa Vandegrift Davala: First of all we have to talk about the vilification of patients. It is something that came up in one of the questions, the horror of being told by a physician or a consultant that one must be making it up. Unfortunately, this is a scenario that happens too frequently. I have been loth to talk too much about my personal situation but in view of the questions this morning, it is compelling that I say something. Two and a half years ago I attended a top hospital in Dublin with the two top neurologists. One turned to my husband and said, "I think you ought to consider a psychiatric evaluation for your wife". I sat in the wheelchair, having failed numerous neurological tests, yet what we were being told to do was to go the psychiatric route. What happens when a disease is vilified and is not given sanction? If I told somebody I had Parkinson's disease or if I said that to friends, family and community, there would be a collective "ah" and support would be given immediately. It is a disease and a name - warm and fuzzy - and lots of support is provided. When one says one has Lyme disease, one can hear the crickets twitter and people look at one. There is not the sense of "we know what to do, we know you have a disease for which nothing can be done, so we will surround you and take care you and one should not worry about a thing".

Too often the situation for Lyme patients is that once they receive the diagnosis, and they have had to work very hard to do so, even their own families can reject. It is such a horrifying situation to know that one's own Government's health system and most of the doctors in it do not recognise the thing for which one is now being treated successfully. I would argue that whatever controversies there are with the idea of chronic Lyme disease or the diagnosis using the ELISA, we are three of thousands in this country with this disease. Without the treatment we have received I doubt that any of us would be able to lift our heads up to a microphone this morning. At least two of us have been in a wheelchair within recent years. We would welcome evidence based and peer reviewed work on this and surely that will come, but we are the canaries in the coalmine. As with H. pylori and as with ADHD, I take that point very seriously: do not shoot the messenger.

As far as a long-term illness scheme is concerned, I would love to hear about that. I know Senator Marie Moloney spoke about something similar in the Seanad debate in 2012. I am destitute financially as a result of this. I have spent well over €200,000. In terms of insurance coverage, Aviva was good enough to cover much of my testing in the initial phases of my treatment. However, some of the treatment is so new that the substances and treatment could not be covered.

Chairman: I do not wish to invade anyone's privacy, but may I ask whether all of the witnesses are still on medication or are they off everything?

Ms Lisa Vandegrift Davala: If even one spirochete remains in the body, it will replicate. Therefore, even if one resolves the Lyme disease, the thought of going through the horror of the disease again means that many of us will stay on a prophylactic dose of whatever antimicrobial we are using. In my case, it is a non-pharmaceutical agent, but in-----

Chairman: Is that by choice?

Senator John Crown: May I ask what that agent is?

Ms Lisa Vandegrift Davala: It is called the Byron White Formulas.

Senator John Crown: I am appalled that people have to spend this much money on their health - €200,000. Where has that money gone?

Ms Lisa Vandegrift Davala: It has been spent over 20 years of pursuing this diagnosis and treatment. It has taken me 20 years to find treatment.

Senator John Crown: Can Ms Davala spell out the name of the formula for me?

Chairman: Perhaps the Senator could talk to the witness after our meeting about that. We have two other speakers to come back in and other work to do.

Ms Lisa Vandegrift Davala: I would caution people to keep an open mind on this. Some of these people are fighting for their lives and they have had to be independently motivated. One cannot say to a group or any of the individuals within that group that the choices they made were wrong. They made these choices to save their lives.

Ms Annette Moloney: In regard to the other possible cases of Lyme disease, Dr. Healy has indicated clearly the possibility on the European level. We might only pick up on one out of every ten cases, but hopefully we are a bit better now and are picking up on one out of every four. Some time ago I came to think that there are probably four different types of patients in Ireland connected to this area. We have the Lyme disease patients who tested positive and who were, perhaps, able to access treatment, although that treatment could be varied and limited. There are those of us who tested negative and who decided to pursue another option and to get an international diagnosis. In my case, it was clear, as, luckily, I had found the tick bite and pursued another course of research. There are also patients who tested negative and who did not get a second opinion. They probably believed the ELISA test or the western blot test and think they are clear of Lyme disease. There are also probably patients who have never been tested for this at all and who have no idea that their possible condition could be caused by it.

On the option of second opinions and whether there is a facility to work with existing hospitals on this issue, unfortunately, patient experience is that this is not a good option. We know of one patient who was told by an infectious disease consultant, despite the availability of hi-tech diagnostic information from Germany and with seven cases backing up the evidence, that he could try and seek a second opinion on it but that there were four or five people working in this area in Ireland and they were all agreed on it.

Chairman: Why is that the case?

Ms Annette Moloney: In my experience, some infectious disease consultants have a broad range of experience, but perhaps they do not have specialist experience in the area of Lyme disease. They may not have had the positive experience other clinicians have had of seeing somebody come through a long treatment with a positive outcome. There are complications around the fact that one of the long-term treatments for Lyme disease is long-term antibiotics. Almost everything else in the health system tells us that the over-prescription of antibiotics is a big problem. We then say that we have done our research and would like to request long-term antibiotic treatment, or in some cases IV antibiotic treatment, but this is blocked.

There are also scenarios where when that knowledge and further referrals are not available, patients are told they will be referred to a rheumatologist for this other condition and that they should take a course of steroids in the meantime. Giving steroids is like giving Red Bull to a patient with Lyme disease. They will increase the level of the infection hidden in the person's connective tissues throughout the person's system. In my case, I believe the fact I was fit and healthy in my early 40s meant the Lyme disease had a better chance of getting access to my connective tissues. Looking back, this was unfortunate. Also, due to the psychiatric aspect of the disease, some patients have been recommended anti-depressants.

Some members have asked about the Western Blot test and the ELISA test. I failed both of those tests here, but my tests came up positive in Germany. There is a conundrum there in terms of international expertise. Lyme disease is a notifiable disease, but neither of the two GPs I tried to work with here could notify my case of Lyme disease because it was based on an international diagnosis and was blocked by an Irish hospital-based consultant. There is a great will on the part of GPs who see cases of Lyme disease on a regular basis. We had a fantastic GP who was available to meet with us today, but he is in the same predicament in terms of lack of support.

On insurance, I pay a significant amount in family health insurance per year, again because of my treatment being blocked by a hospital-based consultant. I cannot get any support in that regard. In terms of my status, I endured five and a half months of oral antibiotics during the summer. Treatment for Lyme disease often makes symptoms worse. Patients require ongoing ECG tests and liver analysis to ensure their systems can deal with the treatment. I must now be retested in January, and based on my current symptoms, it is quite likely I will need longer term treatment, which could involve travelling to Germany for IV treatment.

We are keen to look at the positives. There are opportunities for Ireland to get involved in pharmaceutical research and collaboration in this area. Today is the beginning of that discussion and that is very positive.

Ms Tracy Brennan: A question was asked about the ELISA test and why I had to go to Germany. I had two ELISA tests done in Ireland, one through a private hospital which went to France for analysis and one through a public hospital which went to the United Kingdom for analysis and because both tests returned a negative result, my blood was not put through the western blot test. I did not have a positive result in Ireland and was not offered treatment and that is why I went to Germany.

Deputy McLellan mentioned awareness. An awareness campaign that would be rolled out to children also would be a great way of educating the public, children, parents and teachers. I received no financial support for my treatment. I did not ask the Government for support. I had the money and spent it. Deputy McEntee pointed out that some people do not have the money to travel and asked who was helping those people. They do not get support from the Government and many of them have to fund-raise to cover their expenses.

Deputy Neville asked if I was better now. Thankfully, I am 95% better. The evidence the IV and oral antibiotics have worked is the fact I am here today. This time last year it would not have been possible for me to be here or speak here today. With regard to medical insurance, I submitted my expenses to the VHI, but unfortunately they could not be covered. The VHI could not cover my blood tests in Germany, my flights, accommodation, or doctor's appointments because I did not have a sign-off from an Irish consultant for my treatment. I knew I was not going to get that sign-off and decided to travel myself. However, the VHI's Homecare team

did look after me at home.

Dr. Eoin Healy: The neuroborreliosis form of the disease is notifiable. Studies conducted in NUIG indicate that only 50% of the cases it has examined have neurological symptoms. In other words, half of the cases have other symptoms, such as arthritic or cardiac involvement or whatever. Therefore, only half of all cases passing through GP surgeries are notifiable.

Senator Jillian van Turnhout: I have a very short question, because I know we are under pressure for time. I came here to learn about this and I thank everyone involved. Some of the evidence we have heard refers to how much the symptoms being experienced must be articulated by somebody. Obviously, children do not have the same ability to do that as a fully developed adult. Are those figures presented evenly spread?

Senator John Crown: When folks who come to Dr. Schwarzbach are negative for ELISA, is he then making the diagnosis on western blot or on the clinical questionnaire?

Dr. Armin Schwarzbach: It is a clinical diagnosis supported by antibodies and by some other T cell tests.

Senator John Crown: Would Dr. Schwarzbach's questionnaire ever be positive for somebody who is negative by both ELISA and by western blot?

Dr. Armin Schwarzbach: Yes. The correlation is very, very high.

Dr. Eoin Healy: There is a higher incidence in children than in other age groups; I think there is a higher incidence in the seven to 12 age group. There is a simple enough explanation for that as young children are wearing shorts, they are running into woodland and so on.

Chairman: I thank Deputy Nolan, who brought this to our attention. I also thank all the people in the Gallery for being here this morning. You are all very welcome. I thank all the witnesses for coming here this morning, particularly Dr. Schwarzbach, who travelled a long distance to be with us. Today is the start of what we will examine. The committee will reflect upon our hearings today and we will formulate a response arising from those hearings. It is fair to say that we may have to revisit it again next year, but we will reflect on today's testimonies and the questions and answers. I also thank the witnesses for their substantive written submissions.

The joint committee adjourned at 11.05 a.m. until 5.15 p.m. on Tuesday, 26 November 2013.