

# Minutes from the All-Party Parliamentary Group on Lyme disease Round table meeting

Tuesday 23<sup>rd</sup> January 2018

Attendees

## *Parliamentarians*

Michelle Donelan MP (Co-Chair)  
Simon Hoare MP (Co-Chair)  
Teresa Pearce MP (Vice-Chair)  
Alex Chalk MP (Vice-Chair)  
Lord Astor of Hever (Vice-Chair)  
Kelvin Hopkins MP  
Sir Desmond Swayne MP  
David Simpson MP  
Lord King of Bridgwater  
Lord Greaves  
Mims Davies MP (Staff member)

## *Patient Charities and Support Groups*

About time for Lyme  
Caudwell LymeCo Charity  
Fight Lyme Now  
Justice for Lyme  
Lyme disease Action  
Lyme Disease Campaign for Change UK (Unable to attend but submitted statement included below)  
Lyme Research UK  
Lyme disease UK  
VIRAS  
Vis-à-vis symposiums  
Well One Clinic

## Introduction

Michelle Donelan MP (MD) opened the meeting by outlining the agenda and introducing the attending MPs and Peers to the assembled patient group representatives. Desmond Swaine MP, mentioned that his wife has had Lyme disease. Lord King mentioned that he had had a constituent who died of Lyme disease forty years ago, whom he had never forgotten. MD said that the APPG intends to hold an enquiry to begin its work, explaining that such enquiries are a key lobbying tool and have been used very effectively by other APPGs when lobbying in the past. They enable the members of the APPG to interview key Members of Parliament, decision-makers and experts. MD also told the meeting that she had met Health Secretary Jeremy Hunt, that he is very keen on the APPG for Lyme disease going ahead and that it has his full support. To have such support from the outset is a significant advantage. She also explained briefly how an APPG works. The group would be open to suggestions from patient groups regarding experts to interview and issues to consider etc, but the questions would be asked by the MPs and Peers, who would conduct the enquiry themselves. Finally, MD explained that the APPG was expected to run with little funding and that a crowdfunding page would be set up online to accept donations from the general public, with the stipulation that donations could only be accepted from declared sources.

Simon Hoare MP (SH) then reiterated that fact that Health Secretary Jeremy Hunt MP had called Michelle Donelan and himself, to ask what they saw as the key issues around Lyme disease. SH stressed that the APPG already has the ear of the Department of Health (DH) and that the DH is not "pretending that things are currently right", but acknowledges that there are problems which need to be addressed. SH then characterised the current situation amongst UK Lyme disease patient groups by making reference to the comedy film *The Life of Brian*, in which there are innumerable factions each advocating on broadly similar issues yet bitterly divided over finer details. He commented that the fragmentation is understandable but he stated, most emphatically, that we are only going to make progress if we focus on the important objectives and all "start to sing from the same hymn sheet and to the same tune". SH then issued a serious warning: if the Department of Health finds that taking any steps at the request of half the patients will result in a bitter backlash of objections from the other half, they may "file Lyme disease as too difficult to deal with" and simply do nothing at all. He stressed that the APPG itself wants to get results, not become the UN trying to broker peace between the factions.

The floor was then opened for the two representatives of each of the patient groups in attendance to speak for five minutes, in the following order:

## About time for Lyme

Hi, my name is Kellie Maher and I'm one of the co-founders of About Time for Lyme.

About Time for Lyme's aim is to increase awareness and education of the growing problem of tick-borne diseases in the UK. We are based in The New Forest, but our work covers the whole of the UK.

In tackling the problem of Lyme disease, the challenge we all face is two-fold. On the one hand we must find a way forward for the many thousands of patients who are already affected, whilst on the other, we must come up with an effective plan for the many thousands that are likely to be affected in the future. About Time for Lyme's focus is primarily on the latter. We do this by sharing vital information about ticks and the diseases they carry amongst the general public, with the aim of reducing the incidence of the disease through prevention or by encouraging early diagnosis and treatment. We are also, however, concerned with improving the understanding of tick-borne diseases amongst the medical community, and are proud to be working closely with the charity Vis a Vis Symposiums.

So why is it about time for Lyme?

In 1993, NATO held the Second European Symposium on Lyme Borreliosis in London, at which it was declared that *Borrelia burgdorferi* was being found in ticks in locations across the UK, including in urban parks. The need to make the British public aware of the risk, as well as the significant issue of unreliable serology testing, were two of the main issues highlighted. Today, 25 years later, we are facing the same issues, only they are now more acute.

In 2015, The Big Tick Project confirmed the significant increase in the UK tick population in recent years. Ticks were found to be present all across the UK, increasingly so in urban areas, and were found on 1/3 of dogs examined.

However, despite the fact that ticks can now be found on the doorstep of practically every UK citizen, there remains a common misconception that Lyme disease is a rare problem and one generally confined to rural areas.

If you ask any patient who is experiencing the often-devastating effects of Lyme disease, they will express their deep regret that they did not know more about the problem beforehand. The average British citizen simply does not know how to protect themselves against ticks, what to do if they are bitten and what the potential warning signs of Lyme disease could be. The government's failure to inform the British public of this risk to their health is resulting in many thousands falling ill each year.

Probably the most important factor contributing to us losing the battle against Lyme disease is delayed diagnosis or, more often, misdiagnosis. Awareness remains incredibly poor and serology tests remain unreliable, while doctors continue to rely solely on them due to the absence of any training offered to them by the NHS in the area of tick-borne diseases. Given these factors, the current Public Health England estimates of cases per year are likely to be a gross underestimation.

The recently drafted NICE guidelines have unfortunately failed to communicate the prevalence of the problem, as well as falling short in other key areas, such as testing and treatment. The conclusions have, for the most part, been drawn from a narrow and outdated pool of sources. The result is that doctors will not be able to appreciate the urgency of the situation.

Currently, both the general public and doctors are dramatically ill-equipped to face the increasing threat tick-borne diseases are posing to public health. Every year spent with doctors relying solely on serology testing will result in an unnecessarily high incidence of misdiagnosis. Therefore adequate provisions must be made to equip doctors to be able to implement clinical judgment where necessary.

More UK-specific research is also desperately needed. However, we must ensure that research is able to filter down into practice in a far more efficient manner than is currently the case.

There are clearly some specific areas that require attention and review as a matter of urgency. Perhaps equally important is the broader issue of taking control of the narrative surrounding Lyme disease. The absence of any government-led awareness initiatives has left the majority of the general public both ill informed and confused. We cannot allow debate about the areas of Lyme disease that we are still yet to fully understand, detract from the need to respond efficiently and effectively to this threat.

When the only information people are receiving about this issue comes from the media or word of mouth, they are more likely to be panicked by the situation than if the information had come from a reliable source on the matter. By delivering the basic information of how people can protect themselves and their families in a positive way, About Time for Lyme hope to leave people feeling empowered and more in control, rather than concerned. Our aim is to reach anyone and everyone whose activities take place outdoors and we hope to be able to do so through a range of channels.

We respectfully ask that this APPG help us reach a wider audience and push for greater awareness and educational initiatives at all levels, in order to help towards reducing the incidence and severity of tick-borne diseases.

We also ask that the key areas we have highlighted be addressed as a matter of urgency:

Training for doctors

Improvements in testing and treatment options  
Research that filters into practice effectively

We would like to express our sincere gratitude to MPs and Peers for getting behind this issue and we very much look forward to working together with you. Thank you for listening.

### **Caudwell LymeCo Charity Statement (with some additional information added)**

Caudwell LymeCo aims to help prevent Lyme disease and to improve the lives of people who suffer from Lyme disease. The charity raises money for Lyme disease research, and educates the public.

*Disclosure: LymeCo CEO Veronica Hughes, is a member of the currently running NICE Guidelines committee for Lyme disease. Everything she may currently say about the guideline is limited by the confidentiality agreement associated with the work. She may make factual statements regarding the Draft NICE guideline which has been in the public domain since September 2017, however she may not and has not expressed any opinion on this draft or the guideline in development, nor revealed to third parties anything said in committee meetings.*

The final guideline is expected to be published in April 2018.

Our requests to the All Party Parliamentary Group for Lyme disease

We would like to thank all the MPs who have joined the APPG for generously giving their time to support this group. We request that your group kindly considers working to further the following objectives:

- **Secure a budget for Lyme disease research from the Department of Health**
- **Create several "Centres of Excellence" for Lyme disease in NHS hospitals**
- **Design a public information campaign & professional information campaign**
- **Research and press for a more Lyme disease-supportive social security and education system**

Proposed agenda and manifesto for APPG

### **KEY OBJECTIVES**

#### **1. Secure a budget for Lyme disease research from the Department of Health**

Please campaign for a research budget from the Department of Health, to fund the Lyme disease research which was recommended in the Draft NICE guidelines, and supported in general terms by the DH's own independent enquiry. My own estimate is that the research recommended in these guidelines could feasibly be done for around £10 million.

The audit of research for preparation of the NICE guideline exposed a lack of unbiased and precisely-reported evidence on Lyme disease treatment, diagnostic tests, epidemiology and even on the clinical presentation. Many patients have expressed disappointment at the lack of specific advice in the Draft NICE guideline regarding, for example, how to help patients with ongoing symptoms after the recommended treatment. The guideline can only be updated if appropriate evidence is produced to inform it.

#### **Current situation**

The Health Protection Research Unit in Emerging and Zoonotic Infections (HPRU) based in Liverpool has a research budget from the National Institute of Health Research (NIHR) of which approximately £250k - £500k is allocated to Lyme disease. The UK government has so far allocated more resources to, for example, Malaria and Ebola than to Lyme disease.

#### **Why this objective?**

1. The NHS can only provide treatments and diagnostic tests that are scientifically proven to work. It has a duty of care to its patients, but also has a duty of responsibility to the taxpayers who fund it.
2. NICE guidelines are based on peer-reviewed, published scientific research papers which are ranked according to risk of bias and imprecision using the GRADE and QUADAS tools, amongst others. Recommendations cannot safely be made without this standard of evidence.
3. The audit and grading of evidence performed when preparing the NICE guideline exposed a lack of evidence, of this standard, on important questions. These include what is the most reliable diagnostic test for Lyme disease, test of cure, or the outcome of longer courses of antibiotics for chronically ill people, and whether Lyme disease can be transmitted congenitally or by other means besides tick bites.
4. NICE should not be asked to alter its research quality standards, as some patients have informally suggested, but DH funding should be sought for research of the right standards to be carried out.

How:

A research budget for Lyme disease should be allocated by the Department of Health to the Medical Research Council and/or the National Institute of Health Research to commission research projects outlined in the NICE guideline for Lyme disease.

The following research recommendations were expressed, in the Draft NICE guideline, as the most pressing:

- Can a core outcome set (symptoms list) be developed for clinical trials of management of Lyme disease?
- What are the incidence, presenting features, management and outcome of Lyme disease including in women with Lyme disease who are pregnant, in the UK?
- What is the current seroprevalence of Lyme disease-specific antibodies and other tick-borne infections in people in the UK?
- What are the most clinically-effective and cost-effective treatment options for different clinical presentations of Lyme disease in the UK?
- What is the most clinically-effective and cost-effective serological antibody-based test, biomarker etc. for diagnosing Lyme disease in the UK at all stages, including re-infection?

There are many medical professionals who treat UK Lyme disease patients privately, predominantly in the USA and Germany. Although their hands-on experience may nurture inspiring suggestions for future research, we first need to fund research into the absolutely basic questions listed above.

Result:

- This will enable the NICE guidelines, and thus NHS patient care, to be updated and improved.

## 2. Create several "Centres of Excellence" in NHS hospitals

Please seek funding and approval to create several Centres of Excellence in existing NHS hospitals, to serve as tertiary referral centres for Lyme disease patients. Currently, Lyme disease patients are either treated by their GP or referred to a local consultant (neurologist/infectious diseases/rheumatologist or other) and this doctor may only have treated a few or even no Lyme disease patients before. If he feels he lacks specific knowledge or experience, there is currently nothing he can do. For other conditions there are tertiary referral centres where people with rare conditions are referred from other hospitals, and the doctors there build up hands-on experience, as well as taking a focused interest in published research. Such centres would be obvious foci for clinical research.

Current situation

There are no Centres of Excellence for Lyme disease in the UK. Patients are currently referred to a variety of local consultants, many of whom have little or no experience of treating Lyme disease.

Centres of excellence are tertiary referral centres in large NHS hospitals, for patients who may require more expertise than regional hospitals can provide.

Why this objective?

1. With the current shortage of published medical evidence, the pragmatic way of helping patients currently would be to build up direct experience among some doctors.
2. The severe shortage of experts in Lyme disease was noted in the Department of Health's independent enquiry.
3. Such centres would be the obvious places to carry out clinical research projects such as antibiotic trials.

How:

- Examine examples of centres of excellence for other diseases which have been a success and try to emulate them. The National Heart Hospital at the Royal Brompton in London is an example of a world-leading tertiary referral centre which attracts expert doctors from across the world. Examine those which have been less helpful to patients and analyse the potential pitfalls, to avoid replicating them.
- All the necessary specialisations should be involved in treating patient. These would include neurology, rheumatology, infectious diseases, cardiology/electrophysiology, immunology and dermatology, amongst others.
- A research aspect to the centre's work should be incorporated from its inception, possibly collaborating with nearby universities.

Result:

- Gradually improving care for patients as teams of doctors focus deeply on Lyme disease patients and learn from experience.
- *Advisory resource nationally*: The doctors at the centres of excellence could become an advisory resource to practitioners throughout the NHS.
- *Analytical research resource*: Patient data could easily be aggregated from medical notes and produce statistical information.
- *Pool of UK patients for clinical research*.

## 3. Design and promote a public information campaign & professional information campaign

Please research and design a public information campaign. Overt government ratification would help the public distinguish between evidence-based reliable advice and the misleading and sometimes dangerous advice which currently abounds online and in the press.

Please also support the work of NICE and other medical bodies providing up-to-date information to medical professionals on the NICE guidelines, including the “known unknowns” which they should bear in mind.

Current situation

Misinformation is often shared in the press and online, including dangerous advice such as inappropriate tick removal.

There is an RCGP online course on Lyme disease for GPs, with very low uptake.

The DH's independent enquiry reported a pervasive lack of awareness of Lyme disease symptoms and general knowledge on the disease among medical professionals.

Why this objective?

1. Accurate and adequate public knowledge is clearly essential for effective Lyme disease prevention, diagnosis and treatment.
2. Some medical professionals lack up to date knowledge on Lyme disease and we have heard reports of some doctors apparently clinging to long-disproven assumptions.

How:

- An official public awareness campaign based on proven evidence should be designed, and championed by MPs and other trusted public bodies. This could include:
  - warning notices in particularly tick infested areas
  - informative material in GP surgeries across the UK on prevention and symptoms
  - educational projects in schools
- A professional campaign should encourage doctors and nurses to adopt the forthcoming NICE guideline for Lyme disease, including an awareness of the known unknowns.
- The campaign should foster:
  - the adoption of updated and fuller information on Lyme disease in university courses
  - the updating of medical text books.

Result:

- Reduce the number of people who become infected with Lyme disease
- Reduce the number of infected people who delay going to their doctor or receiving treatment
- Increase doctors' knowledge
- Reduce the number of people left with lasting symptoms as a result of delayed diagnosis and treatment.

#### **4. Research and press for a more Lyme disease-supportive social security and education system**

Please make sure the APPG enquiry studies the welfare system to understand exactly why patients with severe chronic symptoms after catching Lyme disease are sometimes refused financial benefits or other forms of state-funded help. Please make appropriate recommendations based on the findings, possibly including alterations to the methods of assessment.

Please also speak to suitable experts in order to formulate official recommendations for schools on how to support children with long-term Lyme disease symptoms. Please seek to clarify with OFSTED why its school rating system encourages schools to penalise children for absences because of ill health. Please make recommendations on how the system should be refined to distinguish between problems of truancy and of ill health, and to handle each appropriately.

Current situation

Persisting symptoms after Lyme disease may be severe enough to prevent people from returning to employment or education, sometimes permanently. This is medically documented and stated in the Draft NICE guideline.

People in this position, or their carers, are sometimes denied sickness benefit, carers allowance or other forms of support.

School children who suffer chronic illness are sometimes punished, being denied participation in school trips or other events, while pupils who enjoy perfect health are awarded prizes. Ofsted ratings are based partly on overall pupil attendance, which has led to schools doing this.

Why this objective

1. In a first-world country the situations described above are unacceptable.
2. We are aware of some patients who have been reduced to penury or resorted to suicide as a result.
3. Psychiatrists have pointed out that children and adults with chronic physical illness may suffer more harm than help if their symptoms are mishandled as psychosomatic, which can be the implication of the situations mentioned above.
4. The Ofsted system encourages children to attend school even with colds or other contagious infections, which poses an additional risk for children weakened by Lyme disease or other chronic health conditions.

How

- An enquiry should be launched into the financial and practical support offered by the state for people disabled by Lyme disease and for their carers, to
  - clarify why many patients are denied support
  - assess what help is needed
  - assess how best to provide it.

- The APPG should press for the implementation of the changes recommended.
- The Ofsted system regarding attendance should be re-evaluated.
- Formal guidelines should be created on how schools should help children with long-term Lyme disease symptoms to continue their education to the best of their ability and to live without suffering isolation and loneliness.

## Result

- With adequate support, the suicide rate among Lyme disease patients might reduce.
- Lyme disease patients might be able to live with less stress and a quality of life closer to that of healthier people. With healthier food and help maintaining personal and domestic hygiene if needed, this may improve their chances of making health improvements.
- Children with Lyme disease could improve their academic performance if allowed and helped to work at a pace they can sustain, and if given emotional and practical support in living with the symptoms which impair their ability to study.
- Children with Lyme disease may convalesce faster if not repeatedly exposed at school to children with colds, flu or other infections.

## Fight Lyme Now Statement

- 1) Firstly we would like the APPG to help **identify how many blood samples are sent to regional laboratories for testing and what type of assay system is used in their testing.**
- 2) We would like the APPG to recognise the uncertainties in laboratory testing for the infective agent of Lyme disease (*Borrelia burgdorferi sensu lato*, Bb) and **to help in the direction of resources towards, a), testing strategies that allow the identification of a wider array of antigens to Bb and b), the direct detection of Bb in blood without or with culture.**
- 3) To help **direct resources towards establishment or specialist teams trained in the identification of Lyme disease and Tick borne disease in general.**

**‘Statement’ taken from LinkedIn post (Jan 12<sup>th</sup> 2018) entitled, ‘Synthesis of NICE recommendations, UCL’s reviews and FLN survey’**

[\(https://www.linkedin.com/pulse/synthesis-nice-recommendations-ucls-reviews-fln-survey-chris-newton/\)](https://www.linkedin.com/pulse/synthesis-nice-recommendations-ucls-reviews-fln-survey-chris-newton/)

NICE and UCL have now published their guidelines and reviews on Lyme disease. Our specific comments have been published at: <https://www.linkedin.com/post/response-draft-nice-guidelines-laboratory-diagnosis-lyme-chris-newton>  
<https://www.linkedin.com/post/fight-lyme-now-comments-ucls-systematic-reviews-disease-chris-newton>

Here we overview the recommendations for practice (NICE) and research (NICE and UCL) in light of our survey into the diagnosis and treatment of Lyme disease in the UK (<https://www.linkedin.com/post/fight-lyme-now-uk-disease-survey-diagnosis-treatment-cost-newton>).

Whilst NICE have focussed largely on peer reviewed studies, the UCL systematic reviews have been able to take into account the experiences and opinions of patients, clinicians and researchers. A fundamental conclusion from systematic review three, 'Stakeholder experiences of the diagnosis of Lyme disease' was that a diagnosis of Lyme disease is often difficult to make. There are two primary reasons for this; 1), symptoms overlap with many other conditions and 2), laboratory tests are not entirely reliable. The difficulty in making a diagnosis of Lyme disease was clearly apparent from the Fight Lyme Now (FLN) survey. When survey respondents were asked the question, 'When you first reported and/or presented your symptoms to the NHS, what INITIAL diagnosis were you given?', the most prevalent diagnoses given were: 1) CFS, 2) Fibromyalgia (Fmy), 3), Psychiatric disorder (Psy), 4) ME, 5) Post Viral Infection Syndrome (PVIS), 6) Irritable Bowel Syndrome (IBS), 7) LYME DISEASE, 8) Sleep disorder, 9) Autoimmune condition (Au), 10) Gastroesophageal Reflux Disease (the number of conditions that were diagnosed on initial presentation extended to 40 or more and these included rheumatoid arthritis, thyroid disorders, Alzheimer's disease and multiple sclerosis). At the time of the survey analysis (1100 survey respondents), around 800 individuals had their blood samples tested by the NHS. Of these, blood from around 200 individuals tested positive for antibodies to Borrelia, however, only 50 (25%) of these individuals received a clinical diagnosis of Lyme disease at first presentation of their symptoms to an NHS health care professional.

Whilst the FLN survey failed to identify when in the chronology of patient-professional interaction a test was undertaken, for 150 (75%) of individuals who tested positive (at some point during the interaction with the NHS), the most prevalent diagnoses initially made were CFS followed by a Psychiatric disorder (Psy), PVIS, autoimmunity (Aut), Fibromyalgia (Fmy) and IBS. For 75 individuals (38%), it took up to 5 years to obtain a diagnosis of Lyme disease and for the other 75 individuals, whilst it took between 5 and 10 years for some, a considerable number hadn't received a diagnosis of Lyme disease up to the time of completing the survey. The latter finding may be indicative of low confidence in the testing systems on the part of the medical professional; this was also one of the research outcomes from UCL review three.

Based on the FLN survey there are a large number of individuals who believe that they have Lyme disease despite testing negative at the NHS laboratory. Strictly, a diagnosis of Lyme disease can only be made when characteristic symptoms are linked to the presence of the pathogenic organism, *Borrelia burgdorferi sensu lato* (Bb). This is where the uncertainty in testing comes into play. Tests currently available on the NHS look for the presence of antibodies to Bb and not for the presence of Bb itself. NICE recommendation C1 for diagnosis (review C) suggests treating for Lyme disease without a test when an EM rash is present and also to, 'Consider treatment with antibiotics (see evidence reports D–L) before test results become available if there is a high probability that the person has Lyme disease' (recommendation C7). Therein lies the problem. It requires a great deal of knowledge and experience on the part of the medical professional to make a diagnosis of Lyme disease in the absence of a positive laboratory test. The authors of the UCL systematic review three have reflected this problem by stating that uncertainties surrounding diagnosis...*'were compounded by low-level knowledge among clinicians'*, and further go on to suggest that, *'these uncertainties appeared to undermine clinician-patient relationships'*.

At the moment we don't have sufficient numbers of specialist-trained GPs and other medical professionals in the UK who would be able to say that 'there is a high probability that the person has Lyme disease'. This is borne out by our survey (as indicated above) as the most prevalent diagnoses for 200 or so individuals who tested positive for Bb antibodies were CFS, a Psychiatric disorder (Psy), PVIS, autoimmunity (Aut), Fibromyalgia (Fmy) and IBS. The UCL authors of review three have suggested that there is a need for, 'a more holistic approach'. In particular, it was suggested that, *'this could take the form of care provided by a multidisciplinary team, with one professional designated as the lead provider for the patient'*. We entirely agree!

Except in cases where there are very clear signs of neuroborreliosis (NICE review F) or Lyme arthritis (NICE review G) and/or the individual is examined by a specialist team, there is an absolutely pressing need for improved laboratory testing with 1), methods capable of detecting a wider array of antibodies (antibodies to the pleomorphic forms of Bb; see: Merilainen et al., 2016) and at a lower concentration in blood and 2), methods that are capable of determining current infection status. In terms of 1), serology systems should be developed with antigens from both spirochetes and round bodies (pleomorphic forms). To address 2), T-cell tests should be developed and validated along the lines of the EliSpot or MELISA and work must begin on direct detection methods.

With respect to the latter, arguments are nearly always put forward as to why these direct testing systems don't work; the usual one being lack of sensitivity. This is true for the current PCR-based systems, but there is some promising new technology that may get around some of the pitfalls in sample preparation prior to the PCR process. Another argument is that Bb remains in tissues or in biofilms. This is also true, but there will be a certain amount of interchange between tissue and blood compartments and there is evidence for Bb in red blood cells (Laane and Mysterud, 2013); as RBCs don't have the immunological capability of macrophages and other immune cells, they may travel through the body in RBCs relatively protected.

A final set of comments is directed to recommendations from NICE evidence review C, namely:

C11. Carry out tests for Lyme disease only at NHS-accredited laboratories that: use validated tests (validation should include published evidence on the test methodology, its relation to Lyme disease and independent reports of performance) participate in a formal external quality assurance programme. C12. When tests have been done in laboratories that do not fulfil the criteria in recommendation C11, do not diagnose Lyme disease, but carry out testing again using an NHS-accredited laboratory.

In our opinion, these recommendations are directed to the T-cell-type tests such as the EliSpot and the MELISA. There is documented evidence that a memory T-cell response is associated with active infection and that tests based on such a response have a role in difficult-to-diagnoses cases (see comments and references therein- von Baehr, 2014). As stated previously, we are heartened to learn that a research recommendation from NICE is:

*RR1. What is the most clinically and cost effective serological antibody-based test, biomarker 16 (such as CXCL13), lymphocyte transformation and ELISPOT for diagnosing Lyme in the UK at all stages, including reinfection?*

However, we take exception to C12 (see above). As far as we are aware, most of the non-NHS laboratories do take part in external quality schemes and are accredited by their state QC surveillance systems. At the time of our (FLN) visit to RIPL in the Summer of 2015, again, as far as we are aware, the UK reference laboratory for Lyme disease was not externally accredited (not GLP). Whilst we are not advocating that all (NHS) laboratories should necessarily have to go through these most onerous and costly of tasks (of obtaining GLP accreditation etc), we would suggest that it is not constructive 'for mud to be thrown' without 'one's own house (lab.) being similarly in order'.

Merilainen L, Brander H, Herranen A, Schwarzbach A, Gilbert L (2016) Pleomorphic forms of *Borrelia burgdorferi* induce distinct immune responses. *Microbes and Infection* 18: 484-495

Laane MM, Mysterud I. (2013) A simple method for the detection of live *Borrelia spirochaetes* in human blood using classical microscopy techniques. *Biological and Biomedical Reports* 3(1): 15-28 (for commentary see : [http://www.apollon.uio.no/english/articles/2013/2\\_borrelia.html](http://www.apollon.uio.no/english/articles/2013/2_borrelia.html) )

von Baehr V (2014) The lymphocyte transformation test for the diagnosis of Lyme borreliosis could fill a gap in the difficult diagnostics of borreliosis. *Clinical Microbiology and Infection*. European Society of Clinical Microbiology and Infectious Diseases, CMI, 20, O1155–O1156

## **Justice for Lyme Statement**

Our sister group was formed in 2009 Fibro, ME/CFS Babes and Guys supporting Fibro and ME. We then included Lyme disease in 2015. The lovely Sonia Poulton became our Patron 2012. Our primary aim is to represent the silent voices of Gloucestershire. We also help national Charities with their campaigning. We work locally with the NHS and Healthwatch. We have also produced medical packs for GPs and hospitals. More recently our focus has centred on Lyme. This was partly due to my personal experience of getting a diagnosis. I questioned the fact why this has taken nearly 17 years. I don't want future generations to suffer how others and I have. This resulted, in my MP Alex Chalk starting to take these issues seriously.

In addition, Deb Collins and I decided to set up a group Justice for Lyme, we feel that we need urgent change in this country. The purpose of the group is to represent silent voices nationally. My own personal experiences demonstrate how the UK is failing Lyme patients. Since University (2002) I have not been able to work. I have two degrees that I can't use. The two years up to my diagnosis I was under numerous consultants: mainly being orthopaedics, specialities included arms, knees, spine, and rheumatology. During 2014 -2015, I was under 4 different hospitals. I went to Bath hospital 36 times. How much does that cost the NHS? My health has led me into serious debt. I have a disabled mother and a severely mentally ill sister. I don't have a family that can fundraise for me to get treatment. Benefits don't cover your treatment costs. Patients with chronic Lyme need treatment not to be left to rot in the gutter. I have been under ID specialists the last two years, 2 hospitals. I am horrified how Lyme patients can be treated. Some quotes:

*"If you the Elisa is negative you don't have Lyme. It is a reliable test."*

*"You know more about Lyme than me"*

*"Graded exercise and CBT will help."*

*"All the bacteria has been killed. No ticks live in Oxfordshire."*

The APPG needs to be our voice. It needs to portray the reality of Lyme. It needs to work with the Lyme experts and not ignore the science. The NHS needs to accept accredited tests from overseas. They need to introduce Lyme literature doctors. Chronic Lyme needs treating. CBT and graded exercise can turn patients into cabbages. The DWP need to understand the implications of Lyme disease. I feel it is important to remind us why we need urgent change by reading some of the feedback we receive from those we support: On a weekly basis I am asked to speak to someone with suspected Lyme. All are desperate for answers to get their lives back on track. I can only help people who are able to afford private treatment through Germany.

Due to the life changing consequences of chronic Lyme disease I am now the primary carer for my once fit and healthy 28-year-old daughter. Previously a sport loving young woman with a degree and a bright future ahead of her, she is now housebound, uses a wheelchair and is reliant on me for the most basic tasks whilst dealing with daily constant pain with crippling fatigue. During the 4 years that she has been ill we have had very little help from the health service and constant denial that Lyme has caused the symptoms, despite the clear clinical diagnosis back up by tests from a reliable accredited German lab. As a parent with no support seeing my daughter's health continue to deteriorate and her future become more and more uncertain as time passes, us heart breaking and hugely stressful.

Our child became too ill to attend school at the age of 14 with a condition which caused difficulty walking, constant headache, fatigue, brain fog and all over body pain. All blood tests came back normal. Treatment consisted of graded exercise and cbt and psychology sessions with a promise that the child would recover despite not having a firm diagnosis. However, during the treatment the child continued to decline, eventually becoming totally bedbound and tube fed and unable to speak. The child's symptoms were disbelieved, with suggestions from paediatricians of being all in the mind, a school phobia or fabricated/induced illness. Both the parents and the child felt abandoned by the local medical profession. They closed their mind to anything other than a psychological cause and psychological treatments. Social Service were brought in and it was suggested that the child could be forcibly removed from the family home.

Change is paramount! Don't let deaths continue!

## **Lyme disease Action Statement**

Who we are

LDA registered as a charity in 2003. Funded entirely by donations, and run by volunteers, we have been working with the public, clinicians and health providers to improve the understanding of Lyme disease, to promote a greater awareness of tick-borne infections and to stimulate research. Despite years of lobbying, including 2 early Day Motions, we were unable to get the Department of Health to listen to us.

In 2011 LDA achieved accreditation to NHS England's Information Standard so the Department could not deny what we had been saying.

In 2012 LDA funded and organised a project with the James Lind Alliance, part of the National Institute for Health Research. The aim of this was to prove to the authorities that, contrary to what they believed, there were scientific uncertainties in the diagnosis and treatment of Lyme disease. In 2013 LDA published a list of 69 verified uncertainties.

These two initiatives led to a change within the Department of health and Public Health England, but little change amongst health professionals. To address this, LDA funded and developed an on-line training module for GPs with the Royal College of General Practitioners which was launched in 2014 and LDA continues to fund and maintain it.

Throughout this time, LDA's Help Desk has been addressing questions from health professionals as well as from the general public. LDA's Medical Director and Chairman are in contact with national and international researchers and clinicians through conferences and personal contact. We also run an annual conference which enables patients to get together and hear national and international speakers.

However, in discussions across the country with those professionals who should be concerned with Lyme disease, the only people who have shown any curiosity and interest in the uncertainties in the science are a few researchers in other fields. This needs to change if progress is to be made.

## LDA's view of current difficulties

### 1. Diagnosis and Testing for Lyme disease

■ Although the incidence of Lyme disease is increasing in the UK it is still not common, so symptoms may go unrecognised by GPs and emergency care physicians, who may not consider it as a possible clinical diagnosis needing immediate treatment or further investigation.

■ There is no test which can guarantee to diagnose or rule out Lyme disease. Although there are some promising research possibilities, these are not yet proved through trials and are some way from commercial realisation.

■ There is a lack of understanding amongst health professionals and a failure throughout most of the NHS to recognise the inherent limitations of the current antibody based serology tests which are relied on for diagnosis.

■ Into this vacuum have come some private laboratories abroad, using various over the counter tests which are not specific for Lyme disease and which are less accurate for confirming diagnosis.

■ Patients who seek help in this way spend money, and invest considerable emotional resources, on tests which are not helpful. Test results from these laboratories are not accepted by the NHS or Public Health England, will not be believed by doctors, and do not result in effective treatment.

### 2. Treatment of Lyme disease

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■ As shown by LDA's project with the James Lind Alliance, and the draft NICE guideline, there is insufficient evidence on the best treatment except in early Lyme disease. Trials on European neurological Lyme disease show a treatment failure rate of about 30%.

■ Because of the relatively recent spread of Lyme disease in the UK, and the concerted influence of a UK microbiologist who was regarded as the single UK expert which informed medical education, UK doctors, including specialists have little knowledge and experience of complex cases of Lyme disease. They generally believe that it is a simple bacterial infection and have shared faith that current treatment regimens achieve cure.

### 3. Health professionals

■ Health professionals contacting the LDA Help Desk frequently ask for the name of a specialist they can refer to.

■ Currently LDA is not aware of any Lyme disease experts or centres of expertise within the UK. There appears to be complete reliance on the blood test and a single course of treatment.

■ The reference laboratory for England and Wales and that for Scotland appear to have insufficient resources to adequately address the issues while dealing with a significantly increasing volume of test requests. The England and Wales reference laboratory is the Rare and Imported Pathogens laboratory with other high priority diseases to deal with, such as the Ebola epidemic.

## LDA's priorities

LDA acknowledges that the development of a NICE Guideline with research recommendations demonstrates some progress in recognition and awareness. However LDA is concerned that the Department of Health, NHS England, policy makers and, critically, hard-pressed frontline clinicians, will feel it is a case of "job done". This is emphatically not the case. The draft NICE Guideline drew attention to the inadequacy of evidence on which policy and research decisions,

and diagnostic and treatment recommendations, are being based. This is not the time to “take the foot off the accelerator”. Therefore LDA will continue to press hard for the priorities of:

1. Investigating tests appropriate for UK infections.
2. The commissioning of a pilot national clinic to develop UK specialist expertise prior to a roll out of regional clinics.
3. Increasing the knowledge base of UK clinicians.
4. Increasing awareness of ticks and tick-borne disease amongst the public.

To achieve change

It is important to understand the context of Lyme disease in this country. A single microbiologist, previously in charge of the testing reference laboratory engaged with an activist group of doctors from the USA and Europe. This resulted in the prevailing view of Lyme disease being easy to diagnose and easy to treat being accepted by UK clinicians, despite evidence to the contrary. No doctors had the time and inclination to do their own reading. We have a lack of definitive tests, little evidence on the best treatment and a lack of specialists to diagnose & treat in the absence of tests.

Into this vacuum have come some private laboratories abroad, using various over the counter tests which are not specific for Lyme disease and which are less accurate for confirming diagnosis of disease.

Patients who seek help in this way spend money, and invest considerable emotional resources, on tests which are not helpful. Test results from these laboratories are not accepted by the NHS or Public Health England, will not be believed by doctors, and do not result in effective treatment. However, private treatment is sometimes the only option for people with a good probability of Lyme disease, denied treatment by the NHS.

We have a situation in which

- there are doctors who have been misinformed by their peers
- there are patients who have been misinformed by their peers

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Everyone suffers.

What LDA would like the APPG to achieve

1. First and foremost: improved awareness and education of parliamentarians so they are in a position to respond to constituents and to influence ministers and the Department of Health. The APPG needs to act on the basis of well-informed knowledge in order to avoid some traps that doctors and the public have fallen into over the past years. It will not be possible to influence the Department or NHS England unless arguing from a very sound base.
  2. Help towards regional specialist clinics. These need the cooperation of NHS specialists and this will only be achieved from a sound platform. There is a high risk in the current climate that if specialist clinics are established too fast, without sufficient preparation, that they will turn into ME/CFS clinics as this is what many existing infectious diseases clinics perceive as the main problem.
  3. Lobbying government and government agencies to engage in research to increase the knowledge of UK tick-borne infections.
- Lyme disease Campaign for Change UK Statement (Submitted in absentia)

## **Lyme Disease Campaign for Change UK Statement**

We are the UK arm, of the ‘Worldwide Lyme Disease Awareness Protest’, an International Community, set up to raise awareness and to campaign, so that Lyme Disease and the issues related be made public, by planning and executing a grassroots effort to spread Lyme Disease awareness.

Many sufferers, who are part of our group, are too unwell to lobby their MP. Many are house/bed-bound. We work collectively to allow those patient’s voices to be heard and to be a supportive network for patients, suffering from Lyme Disease & co-infections (and their care-givers) who are currently unsupported in all aspects of diagnosis, treatment and research funding.

Our activities involve realising the issues affecting individuals and the larger UK Lyme Disease community. We carry out actions so that we may highlight the issues publicly, using social networks to organise.

### **1. Lack of Public Awareness;**

using social media to educate the public on ‘tick safety’.

### **2. The transmission of tick-borne pathogens can occur via NHS blood transfusion (NHSBT) –**

Raising awareness to Public Health England (PHE).

### **3. Not listed as a notifiable infection;**

Campaigning for Notifiable status allowing incidence and spread of disease to be monitored.

### **4. Lack of NHS Practitioner knowledge;**

Campaigning for experts, from overseas to train our Clinicians about all aspects of **Testing, Diagnosis, Treatment & Transmission** methods, of LD and Co-infections.

#### **(4a) testing, (4b) diagnosis & (4c) treatment**

#### **4a. Limitations of Serological Testing, via RIPL;**

Campaigning for tests from accredited laboratories, overseas, to be accepted by NHS.

#### **4b. Clinical Diagnosis being ignored where Erythema Migrans (EM) rash is present;**

Campaigning for NHS Medical Practitioners become familiar; positive serology is NOT required, for ‘clinical diagnosis’.

#### **4c. NHS Treatment of Lyme Disease and Co-infections & NICE draft Guidelines;**

Campaign to NICE for the ‘Guidelines’ to be abolished, to allow for information/evidence gathering, which should commence immediately.

Many Stakeholders raise shared issues with NICE draft Guidelines.

Contains Inadequate treatment.

Contains no recognition of Chronic LD.

Contains no detail of Co-Infections.

### **5. Patient Misdiagnosis;**

Campaigning that LD should be included as a differential diagnosis when considering other illnesses that are reliant on subjective clinical presentation/have no known cause. Eg; Myalgic Encephalomyelitis (**ME**), Fibromyalgia, Motor Neurone Disease (**MND**) also known as Lou Gehrig’s disease or Amyotrophic lateral sclerosis (**ALS**), Multiple Sclerosis (**MS**), Alzheimer’s, Chronic Fatigue Syndrome (**CFS**), Parkinson’s Disease, Sarcoidosis.

10’s of 1000’s patients currently misdiagnosed.

### **6. Funding for Research into Tick-borne Diseases.**

Campaigning for funding for medical research, into accurate Lyme testing and treatment.

Campaigning for funding for research into vectors and reservoir hosts to determine what diseases they may carry/transmit.

### **7. Health Human Rights violations;**

Campaigning for recognition of the Health Human Rights violation;

Including obstruction of access to treatment options. Denied access, violates the Availability, Accessibility, Acceptability, Quality (AAAQ) of Health Human Rights imperatives, for "non-discriminatory" practices and medical ethics.

### **8. Global Issues – Medical Misdiagnosis/Inadequate Test & Treatment Protocols**

Patients in America and France have recently (January 2018) filed class antitrust action, for Health Human Rights Violations.

These filings are against their respective Public Health Organisations, Clinical Practice Guidelines Organisations, Insurers and Drs.

**France** –Lawyers claim the responsibility of the “actors of public health”, but also want \$611,345 of damages per patient.

USA – Within weeks of the lawsuit filing, the U.S. Centers for Disease Control and Prevention removed its website reference & links care guidelines.

A CDC statement explained: “It has been over a decade since the IDSA guidelines on treatment of Lyme disease, developed in 2006, were published. Since then, additional published research further informs Lyme disease treatment.”

### **Lyme Research UK Statement**

LymeresearchUK was set up to explore policy and practice Lyme disease and its impact on patients in the UK. It was started by Kate Bloor who his areas of expertise spanned from research methods in social sciences including policy research, operational research, as well as an understanding of epidemiology public health and health sciences research etc. Her academic background covers human sciences, the sociology of health and science and technology policy.

This, and experience in education and teaching and learning is also mirrored in the work and approach of LymeresearchUK - which has often been to educate and help other groups in understanding research and knowledge etc.

LymeresearchUK would like to suggest the APPG develops (through its work) and understanding of the range and complexity of problems experienced by patients (as a result of policy and practice) and that this is done, in a systematic way.

In this respect the use of social research methods and data will be of paramount importance including areas like policy analysis and impact research - as well as potentially other things like risk analysis, reviews and critical enquiry, patient centred research etc.

In particular we would like the APPG to be aware (and work towards resolving) issues around the mismatch between clinical trials and what happens in actual practice. To explain this, clinical trials are very 'limited experiments' done in a laboratory setting - which may or may not mirror the kinds of situations that arise in actual real-world situations. Therefore they do not reflect (as experiments) the real outcomes from the real experiences of treatment in the field.

We therefore need what is now called 'real-world data' and 'real-world research' - to demonstrate that difference. Patient centred outcomes are also very useful, and increasingly important in health services research now, since they reflect new or different parameters, perspectives, indicators etc that go beyond those defined narrowly by clinical research or other types of knowledge that is used in evidence based medicine.

### **Lyme disease UK Statement**

Thank you for the opportunity to attend and speak at this meeting today. We are spokespeople for LDUK and also Lyme patients ourselves.

Lyme Disease UK is a non-profit organisation with an Online Community of over 8000 members, the majority being from the UK. As well as supporting our members, Lyme Disease UK campaigns for **better awareness, diagnosis and treatment of Lyme disease.**

The situation in the UK is dire. We see continual examples of mistakes in diagnosis, testing and treatment. We see patients being dismissed if they have negative UK tests, some even with a history of both tick bite and EM rash people becoming housebound, disabled and even suicidal. We also see patients driven to self-treating or paying for expensive private treatment abroad. This represents an unacceptably high cost for individuals, society and the economy.

We are grateful to all of you for showing an interest and the determination to improve the situation. We believe that the APPG should push for change in the following areas: **public awareness, education of medical staff, and research** so that better testing and treatment protocols are made available.

The recognition of Lyme disease as a serious illness, which can be caught in British back gardens, with effects on a par with AIDS and cancer, is essential to give impetus to the drive for change.

**Public awareness of the risk of Lyme is appalling and needs to be addressed, immediately**, by government-sponsored media campaigns and obligatory information notices in relevant locations accessible to the public.

**Change is needed in the medical system** to ensure that front-line staff, including pharmacists, practice nurses and A&E staff, are able and equipped to remove ticks safely, and can recognise an EM rash and other early symptoms.

Doctors need to be aware of, and compliant with, current guidance and best practice and especially need to be made aware of testing limitations. The information received by them from the RIPL lab should be explicit on this point. Until we have a better test, it is not possible for a diagnosis of Lyme disease to be made on blood tests alone. Change is needed in the medical system to give greater emphasis to clinical diagnosis, only supported, not limited, by testing. Establishing better tests is of paramount importance.

There should be a precautionary **halt on blood and organ donation** by Lyme sufferers until safety is unequivocally established.

**Concerning treatment of patients**, the draft NICE guideline made it abundantly clear that there is an alarming dearth of good quality evidence for effective treatment protocols at all stages of disease. Until there is better primary evidence, we would like to see clinicians encouraged to exercise professional judgement in diagnosis and treatment decisions.

We would recommend that UK doctors are encouraged to visit, observe and learn from established **ILADS American and European Lyme specialists**. LDUK would be pleased to use its contacts to facilitate such opportunities. It is critical to explore innovative ways to improve care for current Lyme disease patients as soon as possible.

**Co-infections** have been found in the UK and yet the ignorance surrounding the possibility of these other tick-borne infections is even worse than that of Lyme disease. More attention and publicity needs to be given to these infections so that they can be treated as well.

**A research budget** needs to be established urgently to fund the NICE research recommendations and other gaps identified. Improvements in research, treatment, education and awareness must be mutually supportive and mutually dependent, each increasing the effectiveness of the other. There is otherwise a danger that they are addressed in an ad-hoc fashion with no cross-fertilisation or resource-sharing.

Centres of excellence of some kind should be considered as engines of this integration of different strands. More patients seen in a virtual or real-world centre would allow for longitudinal research studies, concentrated doctor experience, faster accumulation of expertise and treatment trials.

We need the APPG to push for progress in all of these areas. However, we believe **immediate focus should be on preparing for the next tick season, improving treatment for existing patients and pressing for a generous research budget**.

Individual APPG members can learn more about the Department of Health Reviews on Lyme Disease as well as the draft NICE guideline, and see comments from stakeholders, on all our various websites. Reaching out to sufferers in your own constituencies and helping them negotiate current provision would also inform you on the effects of the disease.

The UK has, for a long time, been behind other countries in tackling Lyme disease. We now have an opportunity to take the lead and coordinate a world-leading approach to the care of Lyme disease patients, which will both reduce the cost to individuals' lives and the taxpayer.

We would be happy to respond to any queries you might have, either now in person or via contact through our website. We leave with you a short handout detailing the suggestions that we have outlined. Thank you for your attention and interest.

**One LDUK spokesperson:**

*“On a personal note to give you an example of this, I have two sons with Lyme disease from UK tick bites; both bitten at different ends of the country - one in the South and one in the Highlands.*

*My youngest son had a large bone tumour removed at the site of the bite. My eldest son was bitten at the base of his spine, and all his discs have now herniated, causing ‘multi-level disc space narrowing’. Just before Christmas, he was also diagnosed with type 1 diabetes, an autoimmune disease, which a few of our NHS consultants believe may have been triggered by the Lyme infection.”*

**VIRAS Statement**

VIRAS share the main objectives of our fellow groups and in particular, we are determined that chronic Lyme disease should be recognised. To understand why it is NOT, it is necessary to know a small part of the history of the disease.

In the nineteen eighties and early nineties, Lyme disease was recognised as a threat to public health. Medical scientists were alarmed by how difficult it was to detect and diagnose the infection and frustrated by how often patients could not be cured with standard antibiotics.

In 1993, in recognition of this threat, both NATO and the World Health Organisation convened experts from around the world. Among their findings were that there were major problems with immunoblot tests which were described as “far from reliable”. The World Health Organisation recommended using varied diagnostic methods, even specifying 9 different laboratory procedures which should be used. They also sent the message that: “Scientists all over the world are called on for close cooperation and participation in global activities against Lyme borreliosis”.

But then, in 1994 a NEW narrative emerged, firstly from the CDC and then others followed. Now we were told that the same problematic immunoblot tests were reliable, that Lyme disease was rare and not easily caught, and for those that did get infected, it was easy to diagnose, and straightforward to treat with a short course of antibiotics. There had been no medical or scientific breakthrough to transform this crisis. Nothing had changed except for the way that Lyme disease was portrayed.

A possible explanation for this U-turn was recognition of a burgeoning epidemic for which the authorities had no answer and which was anticipated to be extremely expensive for insurance companies. The USA has a current median estimate of 340,000 NEW cases of Lyme disease per year. With medical costs of over \$1 billion dollars per year, and sickness payments for those that do not recover quickly, easily matching that figure. Money is obviously an issue.

Furthermore, it is believed that 5 to 10 percent of Lyme disease patients become chronically ill when their treatment fails. This creates an ever increasing pool, year on year, of chronic Lyme disease patients who might never regain their health and productivity.

This extremely expensive problem of chronic Lyme disease has been denied, even though it CAN be demonstrated by a host of methods including those recommended by the World Health Organisation.

So the denial of chronic Lyme disease has been sustained by discouraging, disparaging and by all other means suppressing alternative methods for confirming chronic infection. This is what the CDC, PHE and former HPA have done, with outstanding success.

This manipulation of the Lyme disease narrative has been so effective, that 25 years after the World Health Organisation recommended the use of multiple test methods, NICE are about to publish a guideline for Lyme disease, which only recommends inaccurate immunoblot tests for the vast majority of patients and does not even acknowledge the existence of chronic Lyme disease.

This denial of chronic Lyme disease must be changed and VIRAS ask the APPG to help to bring this about.

### **Vis-a-vis Symposiums Statement**

The Vis a Vis charity holds educational seminars on Lyme and associated diseases and invites recognised experts from around the world to speak on the science and latest research. We thank you for this opportunity to speak.

Ticks are cess pits of the world. They carry pathogens which cause more than 30 human diseases. Many ticks carry multiple infections and one bite can transmit not only Lyme borreliosis but bartonella and mycoplasma for example. Only about 1000 cases of Lyme disease are reported annually by Public Health England. An estimate 4 years ago for Scotland gave an incidence of 54 cases per 100,000 people. Ticks don't recognise political borders and are not campaigning for independence so this rate represents more than 40,000 cases each year in England.

Where are the 39,000 people not counted by PHE? They are constituents, friends and for some, family members. Some are diagnosed by primary care trusts, others are diagnosed with “stress”, chronic fatigue or arthritis. Probably a large number are diagnosed with Alzheimer's. In 12 Alzheimer studies borrelia infections varied from zero to 90% with an average of 30%. This would represent about 15,000 Lyme disease cases misdiagnosed as Alzheimer's, per year. This under-recognition every year is creating an ever larger group of patients languishing with untreated debilitating disease.

During development of the current draft NICE guidelines they identified and published over 800 pages of independent studies of test accuracy. These demonstrated poor sensitivity of the C6 and Western Blot tests used in the UK. Included but also ignored was the fact that the two tier test that NICE require for diagnosis can generate over 500 times more false negative results when compared to HIV testing.

In all major respects the draft guideline is a copy of those published by the Infectious Diseases Society of America. These were called into question by the Connecticut Attorney General, and after a senate investigation it was determined that the authors were biased, had conflicts of interest including financial interests in patents for Lyme disease tests and vaccines, acted for insurance companies, and acted against doctors that did not follow their guidelines.

The IDSA were forced to remove them and replacements are still not published. The IDSA guidelines have also been adopted in other European countries. As in America these are now being challenged. Last December the judge in a Berlin court issued an injunction to stop publication of guidelines by the German Society of Neurology. She said that the society should return to the negotiating table and take note of important lessons learned from patients and treatment studies regarding the efficacy of prolonged and repeated antibiotic treatments, and that the previous guidelines resulted in erroneous and misleading diagnosis and refusal of therapy. I'm sure this will sound familiar to all those presenting today.

In France Professor Perronne is heading a group of 100 doctors to challenge the official position. Also an international group headed by Jenna Luche-Thayer has lobbied the World Health Organisation to include relevant Lyme disease diagnostic codes, and placed on record evidence of Human Rights abuses with the United Nations.

How can the APPG help? By considering the evidence ignored by the NHS and PHE in the development of current NHS/PHE diagnosis and treatment protocols and support the following.

- 1) Tests with superior sensitivity already exist and should be introduced, reports from internationally accredited laboratories that use these tests should be accepted as evidence by the NHS. The two tier test requirement must be removed.
- 2) Ensure that all Lyme testing laboratories are accredited by UKAS to the International Standards Organisation ISO 15189. This should help avoid the problems confirmed by the Parliamentary Health Services Ombudsman investigation of the Lyme Reference Laboratory at Southampton which was closed in 2012.
- 3) Help prevent the release of the flawed NICE guidelines which do not recognise the potential complexity of multiple infections, persistent form of borrelia, poor sensitivity for targeted borrelia species, unknown sensitivity for other species, and individual responses to treatment.
- 4) Ensure that all front line doctors are trained in tick-borne disease diagnosis and treatment and able help their patient by treating based on clinical diagnosis, and that with care and patient consent can prescribe appropriate courses of antibiotic with prolonged or repeated courses if they are responding positively.
- 5) Support research into tests that match the supreme sensitivity of HIV testing and research for optimum treatments for both early and disseminated disease.

## **Well One Clinic Statement**

I am Dr Beryl Beynon from the Well-One Clinic in Beverley, East Riding of Yorkshire I worked as a GP in Beverley from 1971 to 2000 when I retired from the practice. However I had founded a Medical Charity, Jacob's Well Appeal, in 1982 to help Polish hospitals during the Solidarność time and by the year 2000 we were also working in Romania, Ukraine and Afghanistan where the need for help was very great and we had extended our aims to include medical research and education.

By 2008 I had set up and registered an independent health clinic as a social enterprise in the hope that I would be able to leave behind me something that could help the charity to continue to work when my husband and I were no longer able to. It was only then that I started to get my first Lyme disease patients as they could get no help from the NHS. I had to learn from scratch with my patients teaching me a lot. I realised that the laboratory testing was inadequate and all the patients were desperate to know what organisms were making them so ill and they needed the back up of a lab test to persuade the authorities that they were not benefit frauds.

At this point I asked for help from Dr Chris Newton who did set about trying to find a method that could be used. I will leave him to tell you what we tried and the difficulties we had. The research provision of Jacob's Well was very helpful and helped us to get started at this time. Chris came up with the idea of making a Rife machine after reading about the work of Royal Raymond Rife many years ago and we realised that this has been widely used in the past.

We decided to offer a group session to start Rife treatment. This worked well and we were soon seeing some success and we quickly could see health improvements though it was slower in many cases. Our biggest problem was the distance that many of the patients had to travel to get to us and weekly attendances were impossible for all except the local patients.

As a GP I had to look carefully at backing up this work with antibiotics and I was very reluctant to go down the path of using three antibiotics for a long period of time as I realise the risk of incurring drug resistance with overuse, and I have seen recurrences after this method.

I have opted to back up the Rife treatment with short bursts of pulsed Metronidazole with magnesium for a few days prior to this as first choice. Our aim is to put the disease into remission. This can happen sometimes in a month but is often 6 months or even a year. The support of the other patients in the group is equally helpful.

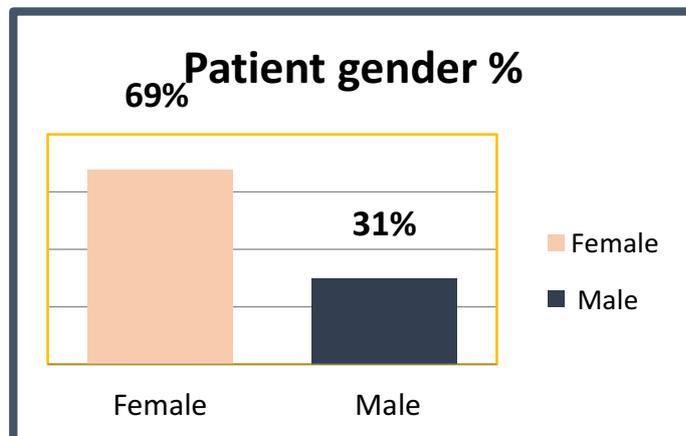
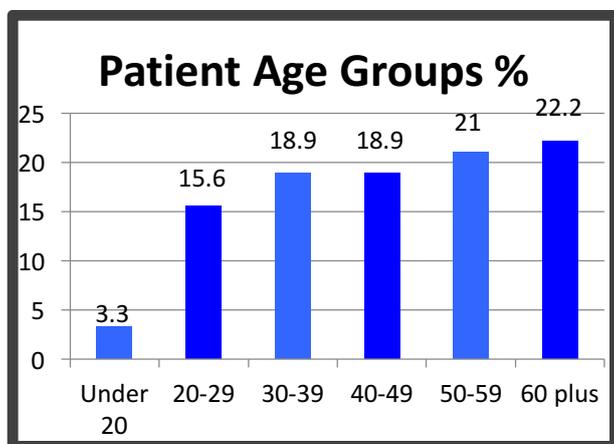
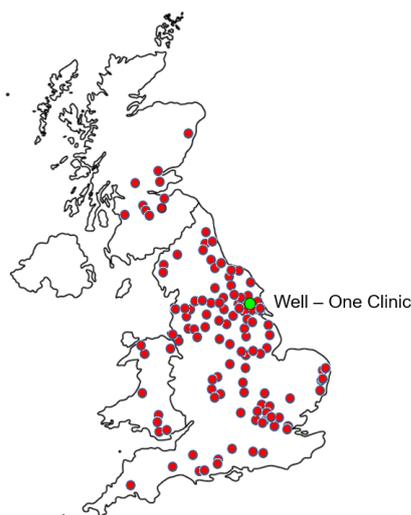
Our GPs are this year being monitored on their use or overuse of antibiotics. They will be reluctant to prescribe many. Their hands are tied. They are no longer free to divert from Nice Guidelines and their work is becoming more confined, they have lost their freedom to use their scientific and clinical knowledge to treat patients now. Pope Francis prayed for those who are enslaved we can only pray that God will allow our medics to follow their Hippocratic oath and free us to practice the art of medicine again. The basic principle of the oath that I took being that a doctor must always cure patients, but never harm them, respecting teachers, passing medical knowledge to new generations and keeping patients' secrets.

What we would like the APPG to achieve

- Improved, and more routine testing e.g. full blood counts, biochemical profiles, flow cytometry such as CD 57s and elispot testing.
- More treatment for Lyme patients, the draft nice guidelines are 35 pages long but in many cases early Lyme that could have been stopped will persist after this treatment has stopped.
- To date we have offered over 3,000 free rife sessions. We have seen patients improve and seemingly enter full remission, but we do not have the capacity to research this further ourselves. If the APPG could provide us with a suitably qualified researcher we feel this could be of a great benefit to Lyme patients going forwards.
- Specific Lyme treatment centres across the UK to reduce travel for sick patients.

#### Patient Travel Distances

Distance	Percentage
0-10 miles	15
11-49 miles	16
50-99 miles	27
100-149 miles	16
150-199 miles	8
Over 200 miles	18



#### Brief Discussion following statements

Lord Greaves said that he thought it had been a very useful meeting and that there was momentum building within Parliament on the issue and a growing recognition that it is a much bigger problem than previously thought. He added that chronic Lyme disease remains a huge mystery and that there is clearly a need for more research.

Teresa Pearce said that we should look at methods for patients who are too ill to attend meetings in Parliament to be able to give evidence via video link.

Kate Bloor from Lyme Research UK stated that her MP Caroline Lucas was interested in Lyme disease and asked any of the Members of the APPG if they could bring it up with her in person if they had a chance.

Michelle Donelan then closed the meeting and said that the minutes would be sent round and that the APPG would now concentrate on planning for an enquiry later in the year. She thanked everyone for attending and said she had also thought it had been a very useful meeting.