

A milestone reached

There **are** uncertainties in the diagnosis and treatment of Lyme disease. You knew that, we knew that and researchers have said so in peer reviewed literature, but some have been slow to acknowledge it. Now this is confirmed by our current project with the James Lind Alliance (JLA).

A search through systematic reviews has revealed that only 7 of the questions raised by clinicians and patients have known answers. These were on homoeopathy, the diagnostic certainties of the erythema migrans rash, and a couple of questions on testing - the [website has details](#).

The JLA Lyme Disease Priority Setting Partnership has reached its conclusion on the top 10 priorities for research. These are shared priorities for both patients and clinicians.

81 potential uncertainties
of which:
7 have known answers
5 are the subject of a current trial
69 questions need further research

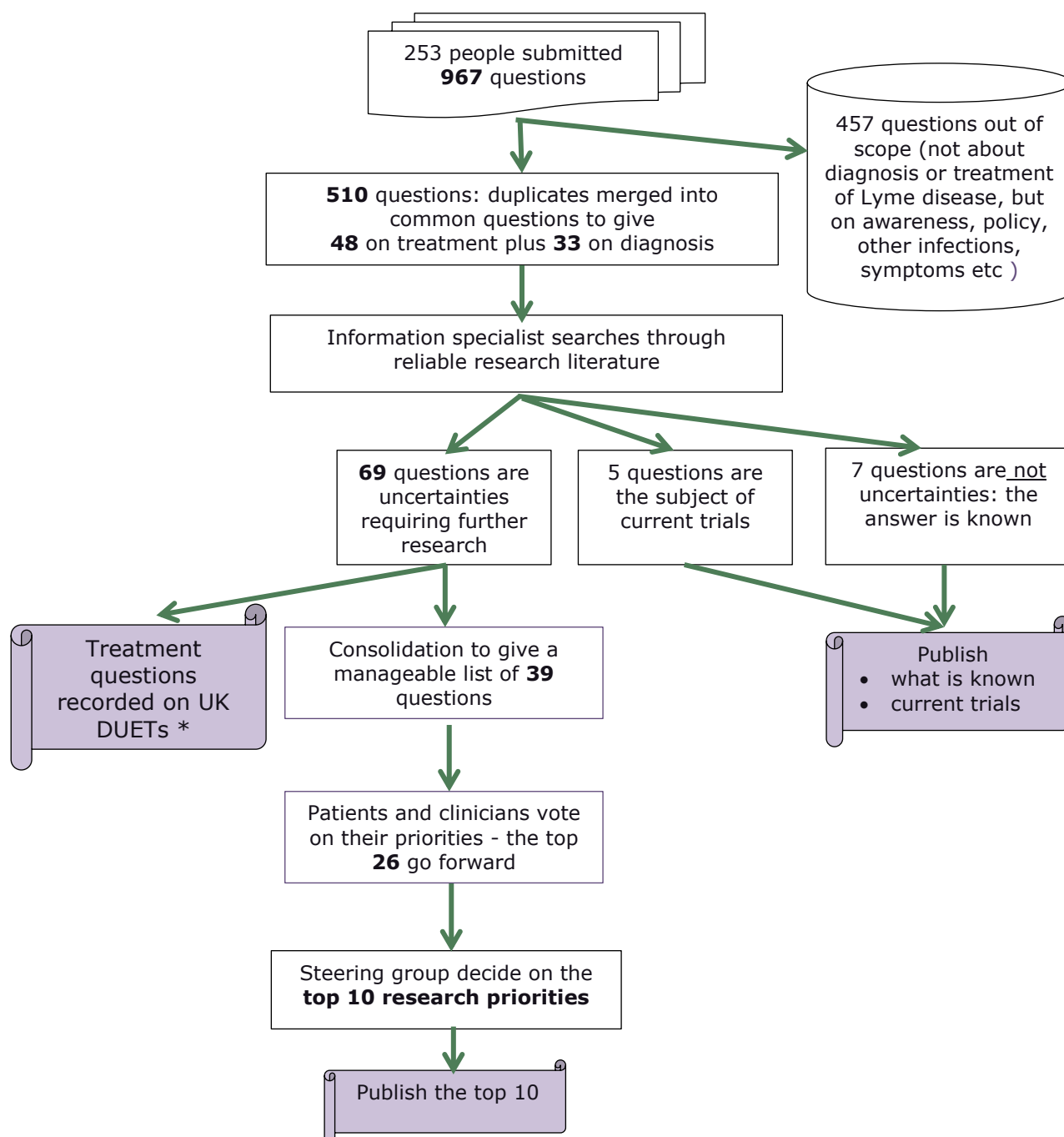
The top 10 priorities for research:

- What is the best treatment for children and adults presenting with a) early Lyme disease without neurological involvement and not including erythema migrans and b) late Lyme disease of any manifestation? To include consideration of drug(s), dose, duration.
- What key questions (clinical and epidemiological) should be considered to help make a diagnosis of Lyme disease in children and adults in the UK and would a weighting table be useful?
- How effective are the current UK tests in detecting infections due to the genospecies and strains of *B burgdorferi* s.l in the UK and which single test and what combination of tests performs best in diagnosing or ruling out active Lyme disease. Should stage of the disease and patient age be taken into account when interpreting these tests?
- What are the outcomes of cases where long term treatment has been used?
- What is the optimal course of action if symptoms relapse after a treatment course is finished?
- What is the optimal course of action if symptoms persist after initial treatment: should antibiotic treatment be continued until all symptoms have resolved or should a different dose or different antibiotic be used and what is the course of action if treatment appears to fail completely?
- Are continuing symptoms following conventional recommended treatment due to continued infection, or an immune response or other process?
- How common is relapse and treatment failure and is it related to disease stage, gender, co-infections or any other factor?
- Are there long-term consequences if treatment is delayed?
- Can Lyme be transmitted via other means: person to person sexually, transplacentally or by breast feeding; through organ donation; through blood transfusion?

See [Deciding the Priorities](#) for a description of how we arrived at the top 10.

The route we followed

We started this journey in September 2010 when the James Lind Alliance agreed to work with us. In August 2011 we had convened a steering group and in October 2011 we launched the first survey to gather potential uncertainties.



* The [UK Database of Uncertainties about the Effects of Treatments \(UK DUETs\)](#)

Fellow Travellers

This was a partnership between patients and clinicians and we had to work very hard to engage clinicians, many of whom thought there were no uncertainties. There are, after all, evidence based guidelines - so what more does a doctor need? The fact that these guidelines clearly state uncertainties is not always recognised.

Many patients contributed and a lot of doctors also submitted their own uncertainties to the on-line survey - how do we recognise Lyme disease and how do we treat it?

At the final workshop just before Christmas 2012 there were 4 doctors and 5 patients. We are very grateful to the GPs and patients who gave up their day to help. We also had some observers. The Netherlands is following a similar process for Lyme disease and we invited members of that focus group to watch this final workshop.

In addition to that we had representatives of those UK bodies most concerned with the outcome: the Health Protection Agency and the Department of Health.

The participants split into two groups and, facilitated by staff from the James Lind Alliance, discussed, argued and sorted their way through the 26 uncertainties.

After lunch the two groups came together to share ideas and to produce a final top 10.



A card for each uncertainty

All the observers were able to appreciate the rigour and transparency of the JLA methodology and could see that all the participants were agreed on the final outcome of the top 10 priorities.

Participants

Patients:

- Michael Cook
- Rowena Jolly
- Stella Huyshe-Shires
- Gail Lowe
- Stephanie Woodcock

Clinicians

- Alastair Miller, infectious diseases consultant
- Sandra Pearson, consultant psychiatrist
- Caroline Rayment, GP
- Sally Silsby, GP

Facilitators

- Lester Firkins, JLA
- Sally Crowe, JLA
- Mark Fenton, NICE
- Matthew Hall, Information Specialist

Observers

- Health Protection Agency
- Department of Health
- Health Council of the Netherlands
- STZ, Netherlands Patient organisation
- Vrije University, Amsterdam

The road ahead

This might be a milestone, but it is only one along the way: there is a long road ahead. We need not only to disseminate these results, so that clinicians and patients know where the uncertainties lie, but also to stimulate some research to find some answers.

Several things happen now in parallel:

- The outcome of this project will be publicised: above all the fact that there are uncertainties critical to diagnostic and treatment decisions.
- The top 10 research priorities will be publicised.
- All the uncertainties will be registered with the National Institute for Health Research (NIHR).
- The treatment uncertainties are being added to [UK DUETs](#), the UK Database of Uncertainties about the Effects of Treatments.
- LDA will consider its research strategy and decide what the charity can fund, or what studies it can initiate.
- LDA will consider how it can engage with UK universities and institutions such as the [Cochrane groups](#) to perform some of the systematic reviews which are lacking.
- LDA will see how it can help UK medical professional organisations to convey some of the critical messages to health professionals.
- LDA will use the outcomes from this project to help patients provide targeted information to doctors who are diagnosing and treating them, through the LDA patient help email service.

National Institute for Health Research NIHR

NIHR Evaluation, Trials and Studies Coordinating Centre ([NETSCC](#)) is home to a growing number of research programmes and from April 2013 will coordinate the work of the JLA Priority Setting Partnerships (PSPs).

UK government support for medical research is channelled primarily through NIHR and the Medical Research Council, and the two bodies work closely together.

Funding

This project had been funded by LDA. We have spent several thousand pounds on this JLA PSP - several thousand pounds of **patients'** money, as almost all donations to LDA come from patients and the public.

Although LDA will continue to use the charity income to pursue its aims, we are hoping that, now the uncertainties are documented and the priorities made clear, other organisations will realise there is work to be done.

It is not just research to find some answers: if we pull together we can use these known uncertainties to help clinicians and to help patients.

A New Year; a new beginning.