Comment on IDSA/AAN/ACR Lyme Disease Guideline Project Plan

Lyme Disease Action (LDA) would like to submit the following comment in response to the IDSA/AAN/ACR Lyme Disease Guideline Project Plan. LDA is a UK based not for profit organisation representing the interests of patients, treating clinicians and researchers. Although the planned guidelines are intended for the USA, it is likely that they will be extrapolated for use elsewhere and that they will prove highly influential throughout the world.

In writing this comment LDA has read the proposed Project Plan and referred to the Standards for Developing Trustworthy Guidelines developed by the Institute of Medicine (IOM)[1]. In the UK we have been accustomed to increasingly greater user involvement in healthcare and a more democratic approach to guidelines development as used in NICE guidelines[2] and exemplified by the standards and transparency of the AGREE II enterprise[3].

Background (Page 3)

4/5: A recently published estimate of 300,000 cases per year in the USA provides a more realistic idea of the number of people affected [4]. A recent study on the financial and healthcare burden of Lyme disease in the USA highlighted the demonstrable need for better healthcare provision and outcomes for Lyme disease patients[5]. LDA believes that a primary aim of any new clinical guideline should be to improve patient care, address unmet needs and provide clear and measurable benefit.

14/15: Re: 'The clinical complexity of Lyme disease and the breadth of specialties involved'. Whilst this is true, it is also the case that there are many key uncertainties in the prevention, diagnosis and treatment of Lyme disease. Within the UK, LDA commissioned a Priority Setting Partnership with an independent body, the James Lind Alliance, to establish and prioritise these key areas of uncertainty[6]. LDA believes that the process of guidelines development would be made more transparent if the underlying uncertainties were made clear and explicit as key determining factors in clinical decision making.

16-22: There appears to be an emphasis on meeting the needs of a small group of medical societies with shared values, allegiances and prejudices rather than the diverse needs of the wider range of key stakeholders. LDA believes that important groups such as treating clinicians and professional groups such as ILADS appear to have been excluded from this process without any explanation or transparency. It is likely that the current wide variation in practice is underpinned by the core uncertainties referred to in 14/15 together with the unmet need of many patients who are currently experiencing poor outcomes when subjected to the current guidelines. LDA's view is that IOM Standard 3.1 is not met by the current project plan. The group of professionals appears unbalanced and weighted towards those who have co-authored papers on Lyme disease and are therefore likely to share opinions and a common position, leading to bias. It is important to balance the evidence from the published literature with the wider experience of clinical practice in the field, or there is a risk that the guidelines will be detailed, over simplistic or even irrelevant for this target audience.

Notes on Panel Composition (page 2 and 4)

Page 2: 3 out of 4 Panel Leaders are members of the sponsoring organisations and 15 of the 25 professional panellists are also members. It is notable that there is only one representative from AAFP representing the whole of family medicine and unclear as to any prior interest in Lyme disease.

Page 4. Line 40: IOM Standard 3.2 is not met since the guideline development group has only one consumer representative who we understand has has never had Lyme disease and has no experience or knowledge of the issues affecting Lyme patients. The IOM Standards explicitly state the need to include a current or former patient together with a patient advocate or

patient/consumer organization. There are many informed expert patients in the USA supported by well-informed and organized advocacy groups, so it is unacceptable to patients that their voice appears to have been excluded in this way and indeed sidelined by the inexplicable use of a token patient. The views and experiences of patients and their representatives are vital if these guidelines are to be effective in improving the care and treatment of patient as well as appearing credible and trustworthy.

Objectives and Scope (Page 5)

42-45: LDA believes that it should be made explicit that these guidelines are being developed within the context of the American healthcare system and are not intended to be applicable elsewhere.

Methods of summarizing and rating the quality of evidence and strength of recommendations (Page 6)

68/69: 'This guideline will primarily focus on patient-important outcomes'. This begs the question as to why these guidelines have not involved a valid patient voice and patient advocacy from the outset. The current guidelines development project plan does not comply with IOM standards and is not fit for purpose in its current form.

70-94: The date range of studies is not specified.

Population/Patients, Intervention/Treatment, Comparator and Outcomes (PICO) (Page 9)

131: The proposed list of clinical questions is probably different from the questions that are important to patients. The panel cannot know this since it did not include an expert patient with knowledge and experience of Lyme disease.

147- 153: LDA recognizes Lyme disease falling into categories of early localized, early disseminated and late disseminated. We do not understand the differentiation into *acute* localized/ *acute* neurological and wonder if consistent use of terminology would be helpful at this stage.

157: This question would be better phrased, 'Should patients with Lyme disease and raised intracranial pressure be treated with….' Since papilledema is a proxy indicator of raised ICP and there may be raised ICP without papilledema.

External review

There appears to be no provision for external review.

Summary

If IDSA intends to adopt an ethical approach to producing credible guidelines, a more democratic approach to development is needed. The current project plan does not comply with IOM Standards of guideline development group composition and falls short of the standards for guidelines development used by the rest of the developed world. In particular, in this controversial field, evidence from published literature needs to be balanced by the underlying uncertainties and wider experience of clinical practice or there is a danger that the guidelines will fail to deliver precisely where they are most needed.

References

1. http://iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx
2. The guideline development process: an overview for stakeholders, the public and the NHS. NICE (2007) https://www.nice.org.uk/guidance/cg62/documents/the-guideline-development-process-an-overview-for-stakeholders-the-public-and-the-nhs-third-edition2
3. AGREE II (2010) http://www.agreetrust.org/agree-ii/
4. http://www.cdc.gov/lyme/stats/humancases.html
5. Adrion ER et al. Health Care Costs, Utilization and Patterns of Care following Lyme Disease 2015. *Plos One*, 10, p.e0116767.
6. LDA 2013 http://www.lymediseaseaction.org.uk/what-we-are-doing/research/