Shared Medical Decision Making and the Two Standards of Care in Lyme Disease

(HHS TBDWG June 18, 2018 comments submitted on behalf of LymeDisease.org by Lorraine Johnson, CEO)

There is considerable uncertainty in the diagnosis and treatment of Lyme disease. Most patients know that they should be told the risks and benefits of different diagnostic and treatment approaches of Lyme disease. They also know that they should be told the risks and benefits of different treatment options and be able to make the determination of the best approach in collaboration with their physician. This process is called shared medical decision making and is most often used when science is uncertain, there is no single "best" approach, and trade-offs exist between their benefits and risks and their associated quality of life consequences. Shared decision making is increasingly being promoted by different government agencies and rigorous evidence assessment protocols. LymeDisease.org believes that the time has come for the government, medical specialty groups, and physicians and to promote shared decision making with Lyme disease patients.

In healthcare, the primary goal is to improve healthcare outcomes that are important to patients. In 2001, the National Academy of Medicine (previously the Institute of Medicine) (NAM) defined patient-centered care as care that is respectful of and responsive to individual patient preferences, needs, and values and that ensures patient values guide all clinical decisions.[1] Patient-centered care focuses on achieving treatment outcomes that patients value, including the restoration of health, prevention of health deterioration and the provision of treatments that have the potential to improve quality of life.[2] To facilitate the development of treatment plans addressing the unique circumstances and values of individual patients, patient-centered care encourages shared medical decision-making.

Shared medical decision-making is an integral part of evidence-based medicine. Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values.[3] Evidence assessment protocols recommended by the NAM, such as Grading of Recommendations Assessment, Development, and Evaluation (GRADE) value the evaluation of outcomes of alternative management strategies and the distribution of values and preferences in patients considering those alternatives as well as shared decision making in encounters between physicians and patients.[4,5]

The importance of shared medical decision making when different treatment options exist is also being embraced by government agencies. For example, the Patient Centered Outcomes Research Institute,[6] the Food and Drug Administration,[7] the National Quality Forum, and the Agency for Health Research and Quality[8] have each embraced shared-medical decision making as a component of patient centered care.[9] It is also one of the aims of the U.S. Department of Health Services Healthy People 2020 program.[10]

Most recently, the Centers for Medicare and Medicaid Services has begun requiring shared medical decision making for reimbursement of certain procedures.[11] As the CMS explains: "Shared decision making can ensure that treatment decisions, for the many medical conditions that do not have one clearly superior course of treatment, better align with beneficiaries' preferences and values."[12] Under shared decision making, clinicians are viewed as the experts in the evidence and patients are the experts in what matters most to them.[13]

Shared decision making is ideal when there is medical uncertainty and treatment choices involve trade-offs between the risks and benefits of different treatment approaches. For example, breast cancer and prostate cancer patients have tough choices to make. No one knows whether it is better to do watchful waiting, surgery, or hormone therapy for prostate cancer. But we do know that the patient is the one who has to live with the decision and that the medical decision made may significantly affect the course of their life. Often this occurs when there is more than one standard of care for the condition.

Medically recognized standards of care are those accepted by medical experts as appropriate treatments for a disease or condition and commonly used by healthcare professionals. Medical recognition of standards of care is typically represented by publication in a peer-reviewed journal or some form of recognition by a professional medical society.[14] According to the National Guidelines Clearinghouse conflicting guidelines are not uncommon. It has posted conflicting guidelines for over 25 medical conditions and notes that these arise most often when the evidence base for a disease is weak and the guidelines panels hold different values.[15]

There have only been only four high level GRADE assessments of the evidence for treating persistent Lyme disease: one by the International Lyme and Associated Diseases Society (ILADS)[16], one by the Hayes and Mead[17] of the Centers for Disease Control, one by Cochrane[18], and one by England's National Institute for Health and Care Excellence (NICE)[19]. All four have acknowledged that the evidence-base for making treatment decisions in Lyme disease is weak.

The National Institute of Health has only funded three small clinical trials for persistent Lyme disease. Sample sizes in these studies were extremely small, ranging from 37 to 129. Nevertheless, two of the three studies demonstrated that retreatment improved some patients' measures, such as fatigue and pain.[20]

In addition, current diagnostic testing for Lyme disease is of poor quality and is unable to detect active infection or cure. Further uncertainty results from the high rate of treatment failure for all stages of Lyme. Some studies of early Lyme disease suggest the treatment failure rate for early Lyme disease may be as high as 36%.[21] In late Lyme disease, treatment failure rates may exceed 50%.[22] Because of the lack of guidance from high quality evidence and the poor quality of diagnostic testing, doctors and patients are uncertain about the best way to diagnose and treat the disease.

This uncertainty is compounded by the fact that persistent Lyme disease can be long lasting and significantly impair patient quality of life. It also may be costly to patients, employers, healthcare systems, and society. In a study of more than 5,000 patients with persistent Lyme disease, half report that they have been ill for more than 10 years.[23] These patients suffer a worse quality of life than those with most other chronic illnesses, including congestive heart failure, diabetes, multiple sclerosis and arthritis. Over 43% report that they had to stop working, and 25% report that they have been on disability at some point in their illness. They are five times more likely to visit healthcare providers and twice as likely to be seen in emergency rooms compared to the general population. The cost of this increased healthcare utilization continues until patients are restored to health.

The diagnostic and treatment uncertainty combined with the significant quality of life impairment suffered by patients who remain ill, has given rise to two medically recognized standards of care that are used by healthcare professionals for diagnosis and treatment. Both standards are reflected in peer-reviewed published guidelines—one by the ILADS[24] and the other by the Infectious Diseases Society of America (IDSA).[25] The ILADS guidelines are more current and adhere to the rigorous GRADE evidence assessment standards recommended by the Institute of Medicine.

The main difference between the IDSA and ILADS guidelines is that in the face of scientific uncertainty, the ILADS guidelines defer to clinical judgment and shared medical decision-making. Those of the IDSA severely restrict the use of clinical judgment and strongly recommend against treatment, regardless of the disease severity, complexity, prior treatment response, or functional impairment of the patient.

The IDSA leaves patients without treatment options when short term therapy fails, as it does in far too many cases. This is why over 95% of patients with persistent Lyme disease are treated by either an ILADS-trained physician, or a family practitioner or internist.[26] Only 3% report being treated by an infectious disease specialist. Similarly, a recent CDC HealthStyles national survey found that only 39% of patients with Lyme disease were treated in accordance with blanket short term recommendations in the IDSA guidelines. The majority were treated for longer periods.[27]

For diseases that lack the research base essential for evidence-based decisions, shared medical decision making with patients should be encouraged as part of good practice. This involves a discussion between the patient and the physician that presents risks and benefits of alternative treatments in a balanced manner, identifies the individual patient's preferences and values, and engages patients in decision making among treatment trade-offs.[28] Together, they choose a course of action.

Because two medically recognized standards of care exist for Lyme disease, LymeDisease.org, which represents thousands of patients nationally, believes that:

- Government agencies should provide unbiased public information regarding both standards of care and treatment approaches;
- Physicians should provide information regarding the risks and benefits of all available treatment options and decide with their patients which actions to take; and
- Insurance reimbursement should be available for treatment by either standard of care.

LymeDisease.org has created a shared medical decision-making form that is available for download for physicians and patients to use specifying the different treatment approaches and their associated risks and benefits.[29] This shared decision-making form was also included in the report of the Access to Care subcommittee of the TBDWG.

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