Patients Need Treatment Options

Challenge to 2006 IDSA Lyme Disease Guidelines

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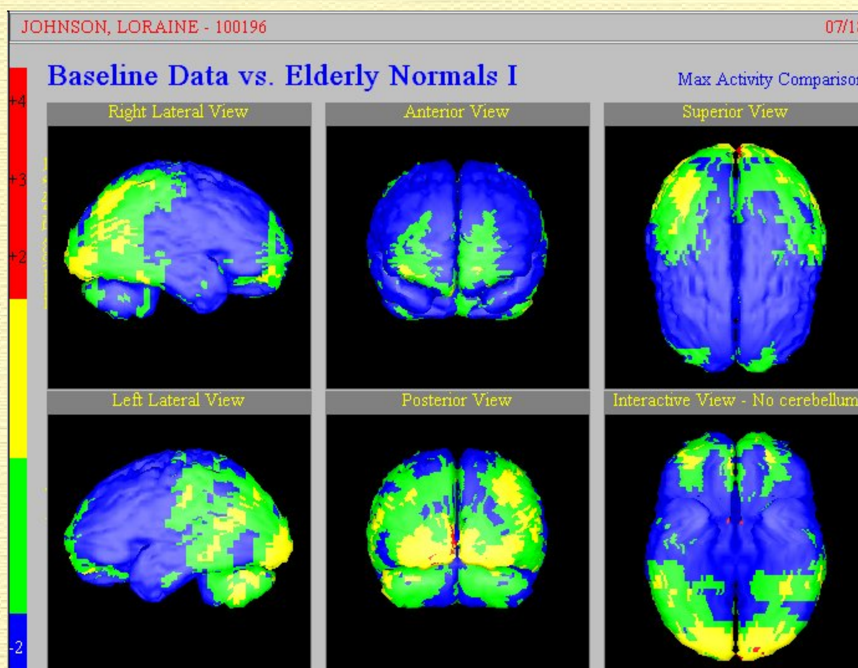
Credentials

- JD, MBA
- Chief Executive Officer California Lyme Disease Association (oversees 46 internet state groups)
- Professional advisory board national Lyme Disease Association (represents 35 groups in 23 states)
- Officer and member of the Board of Directors of ILADS
- Member of the Cochrane Consumer Network for Cochrane evidence based reviews in health care
- Publications in medical ethics and Lyme disease*

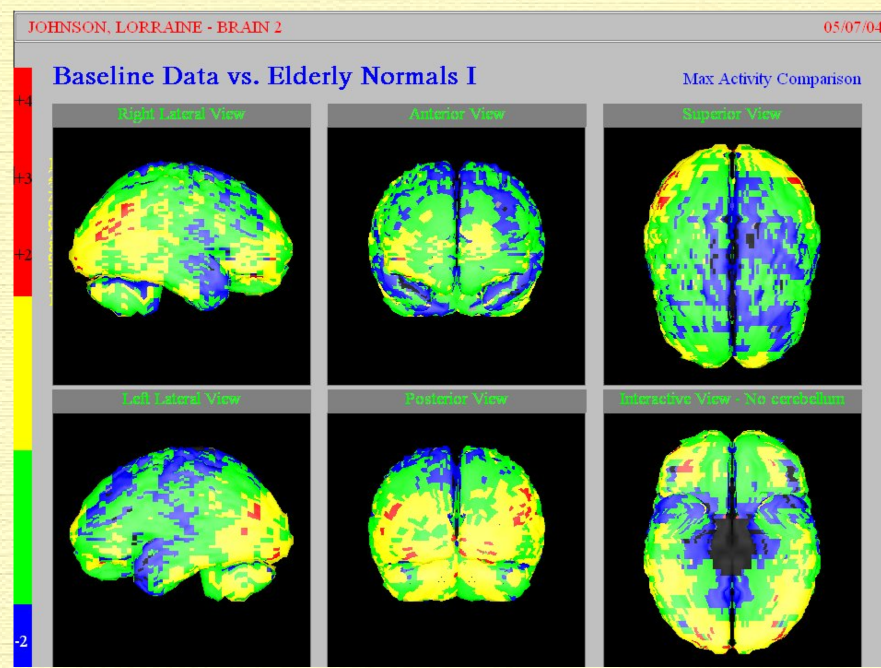
*See Bibliography

SPECT Scan: Before and After

2002
"extensive hypoperfusion" (Blue)



2004
"marked improvement"



Guidelines Goal: Medical Quality

"At its most basic level, quality is doing the right thing, at the right time, in the right way, for the right person.

Did people get better?

Was disease or disability reduced?

Was it reduced as much as it could have been, given what we know is scientifically possible?"

John Eisenberg

Director US Agency for Health Care Policy and Research

Eisenberg (1997) Legislative Testimony

The IDSA Guidelines are Mandatory

- IDSA Guidelines are highly restrictive
  - Preclude the meaningful exercise of clinical judgment
  - Deprive patients of treatment options
- IDSA Guidelines are treated as mandatory by:
  - health insurers
  - disability insurers
  - medical boards
  - physicians
  - pharmacists
  - hospitals, and
  - even school systems and child custody agencies

Results of CALDA 2009 Survey

- 73% diagnosis delay > 1 year, and 49% saw 7 or more doctors before being diagnosed;
- 90% difficult to find a physician to treat , and 53% traveled out of state for diagnosis or treatment;
- 41% can't afford to purchase the medications they need;
- 58% remained ill after treatment under IDSA protocols, and > 60% of these improved with additional courses of antibiotics;
- 88% had to cut down on normal activities such as work or school and 50% were not able to go to work or school.

CALDA Survey of 3,000 Patients (2009)

Opposition to IDSA Guidelines Growing

- 40,000 people signed petition opposing IDSA guidelines
- Physician groups opposing guidelines or supporting physician protection laws:
  - The International Lyme and Associated Diseases Society
  - The Association of American Physicians and Surgeons
  - The New Jersey Psychiatric Association
  - The German Lyme Borreliosis Society
  - The UK-based Lyme Disease Action
  - Connecticut Medical Society supports physician protection
- States with physician protection laws
  - Connecticut
  - California
  - Rhode Island

Simple Reason for Guideline Opposition

- IDSA guidelines extend well beyond what is known in science
- And they restrict clinical care based on expert opinion.

Panel Charge is Medical//Scientific

Panel is charged with making :

"an individual determination whether each of the recommendations in the 2006 Lyme disease guidelines is medically//scientifically justified in light of all of the evidence provided".

Any contested recommendation will require a 75% supermajority vote by this panel to stand.

Authority Base of EBM

"The anchoring authority of the guideline process is the belief that guidelines are evidence based, not opinion based, and therefore their conclusions flow directly from the conclusions of studies. Accordingly, the outcome is perceived to be impersonal and inevitable."

Sniderman (2009) JAMA

Uncertainty Due to Lack of Biological Markers

Without an objective surrogate (preferably biological) marker . . . every attempt to address clinical questions in the realm of PLD is doomed, almost by definition to leave these questions unanswered.. . .

- What is the definition of the condition?
- What are the diagnostic criteria?
- What is the pathogenesis of PLD?
- If . . .persistent infection, how long [should it be treated]
- What end point should be [used]
- How do we assess the response of subjective complaints to treatment?

Steiner (2003) Neurology

Uncertainty Caused by Strains

"[I]dentification of the strain a person is infected with could help guide therapy [and] [s]ome strains may call for a longer course of antibiotics. The problem is isolating the microbe out of the patient to see what strain it is. . . . any isolate of Borrelia burgdorferi from a patient would mean a diagnosis of Lyme disease."

---Alan Barbour

Director of the Pacific-Southwest Regional Center of Excellence for Biodefense and Emerging Infectious Diseases at the University of California Irvine

Weintraub (2009) Experience Life Magazine

Uncertainty and Tradeoffs Require Clinical Flexibility & Treatment Options

Flexibility key to guidelines

"As a rule, good practice guidelines make strong recommendations only when there is strong evidence to support them. . . Good guidelines acknowledge situations where clinical decisions are not clear-cut, and offer flexibility in these situations."

Lin & Slawson (2009) American Family Physician .

Options are common when there is uncertainty

- Prostate cancer
- Ischemic heart disease
- Breast cancer
- Benign prostatic hyperplasia
- Back pain
- Hormone replacement therapy
- Hip and knee replacement
- Herniated disk
- Silent gallstones

Gaps in Research Should Not Prevent Treatment of Patients

"[I]n those situations in which an otherwise applicable treatment guideline is considered inappropriate based on the evidence, the 'default' standard of treatment must be covered treatment that reflects individualized medical judgment, not no treatment."

Sarah Rosenbaum, Chair of the Department of Health Policy at George Washington University School of Medicine and Law

Rosenbaum (2002) J of Law, Med & Ethics

Summary

Scientific evidence in Lyme is limited and uncertain;

Different diagnosis and treatment approaches to Lyme exist;

Treatment outcomes for Lyme are variable, and

Quality of life trade-offs in Lyme are significant

Accordingly, guidelines should

- Accurately reflect the state of the science,
- Acknowledge legitimate scientific controversy regarding diagnosis and treatment
- Permit flexibility and clinical judgment, and
- Provide treatment options to patients

Sniderman (2009) JAMA ; Lin (2009) American Family Physician; Wennberg (2002) Wake Forest L Rev

Revised Recommendations

- While laboratory tests can confirm a diagnosis, they are too insensitive to rule out a diagnosis.
- Treatment failures under early and late Lyme disease are unacceptably high under IDSA guidelines. Optimal treatment agents and duration have not been determined. Clinical judgment in determining the optimal course of treatment for the individual patient is advised.
- Requirements of specific objective findings for a diagnosis or treatment of Lyme disease are premature. Clinicians believe that although objective findings do exist, they are highly variable and the best markers have not yet been determined.

Revised Recommendations

- Treatment modality restrictions: These are based on level III evidence and many are supported by science. Hence, restrictions should be removed from the guidelines.
- Post Lyme disease definition should be expanded to include patients with subjective symptoms who fail standard treatment regimes. The optimal treatment agent and duration has not been determined; and restrictions on treatment agents or duration are inappropriate.

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