the accuracy of CD4 counting [1, 5]. T cell enumeration was performed once on the day of venesection (baseline measurement) and once on each sequential day for a total of 4 days by an experienced operator. Samples were run on a FACSCanto II flow cytometer (Becton Dickinson). Blood samples were maintained at room temperature in the laboratory and treated the same as routine clinical samples.

The median age of the 19 subjects was 37 years (range, 23–63 years), and 11 were male. Mean absolute CD4 cell counts were 422 cells/μL (range, 260–890 cells/μL), and CD4 counts as a percentage of lymphocytes were 23% (range, 26%–35%). Each day, from day 2 through day 4, the mean coefficient of variation (CV, calculated from the baseline value and the value on that day for each sample) was <7% for all 8 parameters: CD4, CD8, and CD3 lymphocyte absolute and percentage counts; total lymphocyte count; and CD4:CD8 ratio (Table 1). There was no increase with time in mean CV from baseline measurement for any parameter (P > .4 for all comparisons; Student t test).

The mean CV from baseline across the 3 days was greater for CD4, CD8, and CD3 absolute lymphocyte counts (5.18%) than for percentage counts (2.72%). The mean CV for absolute CD4 was 5.07%, and the mean CV for CD4 as a percentage of lymphocytes was 3.33%. This is different from the mean CV for same-day intra-assay variability for our laboratory of 4.84% for absolute CD4 (P = .85; Student t test) and 4.47% for CD4 as a percentage of lymphocytes (P = .27; Student t test). The largest mean CV was for CD8 absolute counts (5.68%), and the smallest mean CV was for CD3 as a percentage of lymphocytes (1.75%). There was no consistent trend for any parameter with time. The CVs over the 4-day time course are consistent with previous flow cytometry studies that used in-house protocols and that were published by us and others from the developed [5] and developing [6] world. Our findings indicate that T cell enumeration can be reliably conducted by flow cytometry 3 days after venesection and therefore on Mondays after weekend clinics.

Acknowledgments

Financial support. GlaxoSmithKline (clinical research fellowship to C.A.M.).

Potential conflicts of interest. All authors: no conflicts.

Anna E. Seeley,1 Peter R. Richardson,1 Timothy Plant,1 Kaveh Manavi,1
Sylvie Freeman,1 Mark T. Drayson,1 and Calman A. MacLennan1,2

1Medical Research Council Centre for Immune Regulation and Clinical Immunology Service, School of Medicine and Dental Sciences, University of Birmingham, and 2HIV Services, University Hospitals Birmingham National Health Service Foundation Trust, Birmingham, United Kingdom

References


To the Editor—Truth in science is established through open debate in an independent process. The scientific process fails when one side of a debate sets the rules, controls the arena, and ensures that its viewpoint prevails. Sadly, this is what the Infectious Diseases Society of America (IDSA) has done in the “vindication” of its beleaguered 2006 Lyme disease guidelines described in the final report of the Lyme Disease Review Panel [1].

The Review Panel was mandated by an antitrust settlement agreement with the Connecticut Attorney General, who found substantial flaws in the IDSA Lyme guidelines development process [2]. Yet the guidelines review was far from independent. It was run by the IDSA, which selected the Review Panel members (7 of 8 were members of the IDSA), selected the chair (a past president of the IDSA), chose the speakers, and essentially acted as judge and jury [3, 4].

An ethicist paid by the IDSA screened panel members for financial conflicts of interest but failed to consider classic organizational bias: given the IDSA’s stake in vindicating its guidelines to reduce potential litigation exposure, maintain its reputation, and silence competitors, how could IDSA members be impartial? Selecting panel members with organizational conflicts of interest while systematically excluding the physicians who treat the majority of Lyme disease patients resulted in a biased review panel [3].
It is not surprising that this biased panel upheld all of its own Lyme guidelines recommendations, which ignore clinical judgment and treatment options [3]. In dismissing 1600 pages of peer-reviewed studies as “anecdotes,” the Lyme Disease Review Panel disregarded evidence that the number of patients in all controlled trials of persistent Lyme disease totals a mere 221 [5], that studies of these patients have yielded mixed results [6], that the risk of extended antibiotic therapy is extremely low [7], and that a key study by Klemper et al [8] was seriously underpowered and therefore inadequate to deny extended treatment to patients with persistent Lyme disease symptoms [9]. When the science is uncertain, guidelines panels should not usurp risk/benefit decisions that properly belong to clinicians and patients.

Perhaps the most glaring manipulation of the review process was the Review Panel’s handling of its 4:4 split vote on Lyme testing [10]. The guidelines clearly state that commercial Lyme testing is mandatory for the diagnosis of Lyme disease, despite the insensitivity of the tests. The Review Panel first claimed that the mandatory testing requirement was an “admonition” rather than a true recommendation, rendering the split vote irrelevant. Then, taking refuge behind boilerplate disclaimer language drafted for legal rather than clinical purposes, the Review Panel effectively upheld the mandatory testing recommendation [3].

The role of a medical society is not to “call the science” according to the vote of a panel that represents one side of a debate. Every guidelines panel should acknowledge diversity of opinion, defer to clinical judgment, and respect patient autonomy. Failure to do so may produce a short-term benefit in terms of upholding the status quo and protecting the society from litigation, but the ultimate cost may be severe damage to patient care and the society’s reputation as an impartial authority on good medicine. A Pyrrhic victory indeed.

**Acknowledgments**

**Financial support.** None.

**Potential conflicts of interest.** R.B.S. serves without compensation on the medical advisory panel for QMedRx, Inc. He has no financial ties to the company. L.J.: no conflicts.

Lorraine Johnson and Raphael B. Stricker
International Lyme and Associated Diseases Society, Bethesda, Maryland

**References**


Reprints or correspondence: Dr Raphael B. Stricker, 450 Sutter St, Ste 1504, San Francisco, CA 94108 (stricker@usmamed.com).

Clinical Infectious Diseases 2010;51(9):1108–1109 © 2010 by the Infectious Diseases Society of America. All rights reserved. 1058-4838/2010/5109-023951.00 DOI: 10.1086/656690

**Reply to Johnson and Stricker**

To the Editor—The statement “The scientific process fails when one side of a debate sets the rules, controls the arena, and ensures that its viewpoint prevails” [1] is particularly odd coming from Dr Stricker and Ms Johnson, both of whom were invited witnesses at an all-day hearing held by the Lyme Disease Review Panel in July 2009 with the express purpose of hearing all points of view on controversies concerning Lyme disease. Fully half of the 18 witnesses at that hearing were proponents of long-term antibiotic treatment for “chronic Lyme disease” [2].

The hearing, like all aspects of the extensive, 18-month process undertaken by the Review Panel, was conducted under the ever-watchful eyes of the Connecticut Office of the Attorney General, hardly an apologist for the Infectious Diseases Society of America (IDSA). All aspects of the review process were conducted in strict accordance with the action plan written and agreed to by the Attorney General and the IDSA—including the selection of the ethicist whose function was to guard against conflict of interest, the criteria that the ethicist used when screening applicants, the selection of the Review Panel members and hearing witnesses, the 80-day public input period during which approximately 150 individuals and organizations submitted materials for the Panel to review, the hearing itself, the process used to weigh the evidence and vote on the recommendations, and the writing and publication of the Panel’s final report [3]. One wonders whether any process will satisfy Stricker and Johnson unless it results in support of long-term, intravenous an-