



MedStar’s New Center for Diagnosis Underscores Ongoing Work

MedStar Health, the largest healthcare provider in Maryland and greater Washington DC, has established a center devoted to diagnostic safety housed within the [MedStar Institute for Quality and Safety \(MIQS\)](#). The Center for Improving Diagnosis in Healthcare, one of five centers of expertise at MIQS, is focused on achieving the goals defined in the National Academy of Medicine’s (NAM) 2015 report, *Improving Diagnosis in Healthcare* through the following actions:

- *Convening* interested clinician, patient, family, and community stakeholders.
- *Collaborating* to identify and prioritize diagnostic challenges.
- *Creating* goal-directed strategies and tactics, training, tools, and effective improvement interventions.
- *Communicating* with the larger healthcare community through workshops, publications, enhanced training, and expanded research.

When it launched the Center for Improving Diagnosis in early 2018, MedStar was already a member of the Coalition to Improve Diagnosis. Combining committee work and collective Coalition actions with its own center underscores MedStar’s commitment to addressing diagnostic error and reducing harm.

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Diagnosis at the Center of the Lyme Wars

By Susan Carr

Controversy erupted soon after Lyme disease was discovered more than 40 years ago. Debates focused on both diagnosis and treatment are often characterized by heated exchanges and accusations. The existence of conflicting sets of clinical guidelines^{1,2}—with their own societies and communities of physicians—reflects the way Lyme disease has travelled on two separate tracks since the 1980s.

The disease was identified as a tick-borne illness by Alan Steere in 1975 and named for towns in Connecticut where it was studied by Steere and his colleagues.³ In 1980, other researchers linked a specific bacteria (*Borrelia burgdorferi*) to a species of ticks (*Ixodes scapularis*), which informed the use of antibiotics to treat the disease.⁴

By 1990, Steere was hearing about patients suffering from long-term symptoms associated with Lyme. He questioned both the diagnosis of a chronic version of the disease and long-term antibiotics used by some physicians to treat it, triggering a strong response from physicians and patients. During testimony before a US Senate committee in 1993, Steere was challenged by a physician and a young Lyme patient in a wheelchair who quietly pleaded that Steere help find a treatment for his affliction. People in the gallery shouted, “He’s wrong! He’s wrong!” as Steere spoke.⁵

The rancorous environment, often referred to as the “Lyme Wars,”^{6,7,8} continues, and patients seeking treatment for persistent symptoms must choose between sides engaged in an active battle. Most patients who are diagnosed and treated early respond well to antibiotic treatment. The controversy surrounds those who remain ill after treatment or those whose diagnosis is delayed, for whom treatment becomes more difficult.⁹

Patients seeking treatment for persistent symptoms must choose between sides engaged in an active battle.

People who find they or their children have been bitten by a tiny tick and turn to the internet for advice will find alarming information about where an untreated infection may lead. If they dig deep

enough, they will find ugly comments common on the internet but unusual in the medical community.

On a brighter note, some are attempting to work collaboratively on issues related to Lyme, in groups that represent a diversity of expertise and opinion. While this is a hopeful sign, the process of working together on issues related to research, diagnosis, and treatment is slow, with results not expected for years.

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SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

Diagnosis at the Center of the Lyme Wars

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Problems with Diagnosis

Diagnosis is central to the controversy. Lyme disease is diagnosed based on signs and symptoms that include a rash—sometimes but not always *erythema migrans* (EM)—and “flu-like” symptoms, including fever, chills, headache, fatigue, aches, and swollen lymph nodes, which occur within 30 days of infection.^{10,11,12} The patient’s history, including whether they have observed a tick bite or spent time outdoors in areas where Lyme is known to occur, may help the physician make a diagnosis. There is general acceptance that most cases of Lyme detected soon after infection are treated successfully with a 10-to-21-day course of oral antibiotics.¹³

Existing laboratory blood tests for Lyme disease are problematic especially in patients with acute Lyme.¹³ The lack of a dependable laboratory test and reliance on common signs and symptoms often mean that the diagnosis is missed or delayed, which can lead to more serious illness.^{14,15,16,17} In addition to the EM rash, which can emerge or recur long after infection, symptoms of untreated Lyme disease include chronic

pain, fatigue, neurocognitive and behavioral problems.¹¹

The existence of other tickborne diseases that cause

similar symptoms and can co-infect with Lyme further complicate diagnosis.¹⁸

Diagnosis of disease in patients with long-term symptoms is a central issue in the controversy. One side believes that Lyme disease is an acute infection and short-term treatment is curative. They conclude that on-going symptoms reflect “post-treatment Lyme disease” symptoms or syndrome (PTLDS).^{13,19,20} The other side believes that Lyme disease with persistent symptoms—“chronic Lyme”—requires longer treatment durations or a combination of antibiotics to effect cure.

Those in the PTLDS camp say that most patients diagnosed with chronic Lyme either don’t have the disease—have something else—or have relapsed after initial treatment. The PTLDS camp says there is no evidence that the infection persists following treatment and recommend against long-term use of antibiotics.¹⁷ Some

believe that individuals with chronic symptoms may have had an autoimmune response to the initial Lyme infection.

Patient Community Working on Research

Lyme is quite common—the CDC estimates that more than 300,000 people in the US are infected each year (see sidebar page 3)—but being common doesn’t mean the disease is well understood. Lack of definitive, large-scale clinical treatment trials leaves many questions unanswered.

Inspired by the experience of community and patient advocates who influenced developments in AIDS and cystic fibrosis, the Lyme patient community is working to accelerate progress in diagnosis and treatment

According to Lorraine Johnson, chief operating officer of LymeDisease.org and one of SIDM’s patient partners (see p5), the National Institutes of Health has funded only four studies of patients with persisting symptoms of Lyme disease, the largest of which had 129 enrollees. LymeDisease.org is conducting a research project called MyLymeData, which includes patient-reported health information for more than 10,000 Lyme patients (personal communication with Lorraine Johnson, March 23, 2018).

The large number of patients in MyLymeData will allow researchers to study biomarkers and treatment effects in subpopulations, potentially helping to understand why some patients respond well to initial treatment and others don’t. Patients involved in this research are long-term Lyme disease patients diagnosed by physicians. Johnson says that, in addition to conducting on-going observational data, MyLymeData will serve as a research platform to help conduct clinical trials—including trials that might lead to better diagnostic tools. The National Science Foundation has awarded an \$800,000 3-year grant to a team of big-data researchers to explore predictive data analytics using the more than 2 million data points collected in the registry.²³

Johnson takes heart from the experience of the cystic fibrosis (CF) community. During the 1960s and 1970s, without a definitive diagnostic test or initial agreement about optimal treatment regimens, physicians in a handful of hospitals were able to improve the quality of life

The existence of other tickborne diseases that cause similar symptoms and can co-infect with Lyme further complicate diagnosis.

How common is Lyme disease?

The CDC made news in 2013 when it increased its estimate of Lyme disease cases per year from 30,000 to 300,000.²¹ Thirty thousand was the number of cases reported by state health departments, which CDC acknowledged represent a small fraction of the number of Lyme disease diagnoses each year. CDC increased the number based on results from three studies:

- A survey of clinical laboratories, which found approximately 288,000 people tested positive for Lyme in 2008.
- A large database of medical insurance claims that showed approximately 329,000 physician-diagnosed cases of Lyme annually.
- Self-reported cases of Lyme in a survey of the general public.²²

Those studies led CDC to estimate 300,000 annual cases of Lyme disease. Geographic information in the new data supported CDC's previous observation that a huge majority (96%) of cases occur in the Northeast and upper Midwest.²²

ImproveDx is a bimonthly publication of the not-for-profit Society to Improve Diagnosis in Medicine. The opinions expressed in this publication are not necessarily those of the Society to Improve Diagnosis in Medicine or its Board of Directors.

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and outcomes, including life expectancy, for cystic fibrosis patients. Working outside the box of traditional guidelines and in partnership with patients and families, physicians experimented with treatments, focused intently on patient response, and openly shared data about their results.²⁴ Following those improvements and discovery of the gene that causes CF, stakeholders including patients and advocacy groups have continued to find synergies that promote research and learning beyond what would be possible acting alone.²⁵

HHS Collaborative Working Group

The US Department of Health & Human Services' Tick-Borne Disease Working Group currently represents the best hope of national collaboration for improvement in Lyme disease. Established in 2016 as part of the 21st Century Cures Act, members of the working group—13 members plus many more serving on subcommittees—represent a diversity of opinions and experience. The group is chartered to monitor and guide federal research and to provide expertise to research and prevention efforts. The group had its first meetings in December 2017 and February 2018 and is expected to issue its first report to Congress in December 2018. It will continue to report every other year until its charter expires in 2022.²⁶

No one expects quick solutions to the challenges posed by Lyme and other tick-borne diseases. In addition to working on better options for diagnosis and treatment, many groups, including federal and local agencies, advise preventing tick bites through the use of insect repellent, checking for ticks after

being outside, and seeing a physician quickly if symptoms develop. Patients with chronic symptoms associated with Lyme, whether or not they have been treated previously, must choose among competing expert opinions. Some will feel they need to become experts themselves and perhaps work with one of the patient-led information and advocacy groups.

Lyme activists cite the AIDS movement as a model for patient expertise and activism that fought against the medical establishment and ultimately affected the science of diagnosis and treatment.²⁷ AIDS has been called the first “large-scale conversion of disease ‘victims’ into activist-experts.”^{28(p8)} Reviewing a 1996 book about power struggles that occurred during the early years of the AIDS epidemic, David Rochefort says:

Epstein shows that scientific findings are seldom ‘definitive’; rather, they are constructed as such on the basis of complicated, sometimes contradictory evidence that is filtered through a politics of knowledge in which a variety of persons, organizations, and institutions compete to control the outcome.^{29(p262)}

It will not be clear for some time who will win the Lyme Wars. It seems certain, however, that patients and their organizations will have played an important, perhaps leading, role in the final outcome. And even if the traditional medical establishment turns out to be correct in its appraisal of long-term Lyme symptoms, the Lyme Wars may be seen as a challenging and pivotal episode in the development of patient expertise and power.

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Conference applies for CME Credits

MedStar’s New Center for Diagnosis Magnifies Ongoing Work

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Christine Goeschel, ScD, MPA, MPS, RN, is assistant vice president for quality at MedStar Health and director of the Center for Improving Diagnosis. Goeschel served on the expert panel for the NAM report on diagnosis and has been a leader in safety and quality improvement efforts at the Keystone Center for Patient Safety in Michigan and in the United Kingdom and across Europe. She has taught at the School of Public Health at Johns Hopkins and worked on research at the Hopkins Armstrong Institute.

Goeschel notes that providers throughout MedStar Health have been interested in improving their diagnostic skills since before the NAM report. Some of the new center’s efforts involve providing a “diagnosis-related lens” through which to view and support improvement work already underway across the system, engaged in by staff members in many different roles.

In addition to ongoing work, the Center for Improving Diagnosis is currently pursuing a number of incubator actions:

- Provide a cognitive reasoning program for internal medicine residents studying diagnosis.
- Conduct surveys to understand gaps in provider and staff awareness and knowledge about diagnostic error.

- Quantify problems related to diagnosis through surveillance of data coming from existing MedStar research.
- Study “good catch” reports to identify how often those reports reflect problems related to diagnosis and to examine who reports and who the players are in the catch. The Center expects to demonstrate that diagnostic teams at MedStar already include many non-physician staff members, and to further leverage the stories as part of the Center’s work.

Some of the new center’s efforts involve providing a “diagnosis-related lens” through which to view and support improvement already underway across the system, addressed by staff members in many different roles.

Good Catch Reflects Best Practice

Goeschel describes a good catch that was not labeled “diagnostic teamwork,” but clearly exemplifies a best practice: A patient was about to be discharged when a fairly new nurse happened to look at an EKG tracing and thought it didn’t look right. She detected a change since the previous EKG. Goeschel explains:

Because we have been working on high reliability culture and encouraging everyone to speak up, the nurse felt confident she could raise this concern with the physician even though the discharge orders had all been written and everyone had signed off.

Based on the nurse’s concern, the physician re-evaluated the patient and decided to get an additional diagnostic test. It turned out, the patient was on the verge of having a heart attack and promptly received a cardiac catheterization and stent. The physician submitted this as a good catch. Goeschel says:

It was a great example of a nurse’s contribution to the diagnostic process based on work already being done. This diagnostic teamwork did not come from something different or new; it was due to MedStar’s ongoing commitment to safety.

In addition to its work as a member of the Coalition to Improve Diagnosis, MedStar Health and MIQS will continue to support healthcare improvement by addressing the quadruple aim—better care, better health in communities, lower costs, and healthcare workforce support—and sharing what it learns with other interested organizations. ■

The March 2018 issue of *Diagnosis* includes:

Sepsis as a model for improving diagnosis

Graber ML, Patel M, Claypool S

Becoming a teacher of clinical reasoning

Trowbridge RL, Olson APJ

Identification of facilitators and barriers to residents’ use of a clinical reasoning tool

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New Efforts Give Patients a Voice in Diagnosis Research

Patients Improving Research in Diagnosis—a joint project of the Society to Improve Diagnosis in Medicine (SIDM), [Medstar Institute for Quality and Safety](#), and [Project Patient Care](#)—will develop and evaluate an innovative curriculum over the next 18 months to train patient partners in diagnostic research. These partners will then be prepared to participate in the design, execution, and dissemination of future research in the field of diagnostic accuracy. Funded by a Eugene Washington PCORI Engagement Award from the [Patient-Centered Outcomes Research Institute \(PCORI\)](#), the initiative will also form the basis for a sustainable Academy for Patient Partners in Diagnosis.

“Though many programs have prepared patients for participation in research design and execution directed towards treatment, no programs currently focus on the unique requirements of research in the process of diagnosis and the choices that patients face during that process,” said Sue Sheridan, director of patient engagement for SIDM. “This is where Patients Improving Research in Diagnosis comes in.”

The Society to Improve Diagnosis in Medicine recognizes corporate members and organizations that support the society and its mission of attaining better outcomes through better diagnosis.

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with the patients to evaluate the effectiveness of the program. So far, the program has recruited 20 patient partners from a diverse set of organizations including the Chronic Disease Coalition, the American Cancer Society Cancer Action Network, the Sepsis Alliance, the American Heart Association and the Medstar Georgetown Patient and Family Advisory Council for Quality and Safety. Notable mentors signed on to the program include Rob El-Kareh, MD, MPH; Prashant Mahajan, MD, MPH, MBC; Kathryn McDonald, PhD; and Gordon Schiff, MD.

The program works toward 6 goals:

1. Engage a diverse set of disease-based and other healthcare organizations in diagnostic research.
2. Train patient partners to be ready to collaborate in diagnostic research.
3. Mentor patient partners to provide an effective support network.
4. Promote patient partners to active researchers in diagnosis.
5. Evaluate the project to inform future work.
6. Develop a plan to sustain the patient partner training initiative for diagnostic research through an Academy for Patient Partners in Diagnosis.

“I believe this cohort of patient leaders can contribute to the reduction of misdiagnosis by helping to ensure that research designs truly represent the research questions and outcomes that matter most to patients,” said Sheridan. “I’ve been a patient partner in research, so I’ve seen how our perspective can transform research design and lead to more meaningful and useful information.”

At a face-to-face meeting this spring, patient partners and research mentors will complete training based on a curriculum they are co-producing with Project Patient Care in collaboration with the MedStar Institute for Quality and Safety. Additionally, SIDM will host a Patient Summit and a Research Summit during

the Diagnostic Error in Medicine Conference on November 4-6 in New Orleans, Louisiana. At this event, patient partners and research mentors will be integrated into the broader SIDM patient and research community.

For more information on this program and to learn how to become a Patient Partner, contact Sue Sheridan at Sue.Sheridan@ImproveDiagnosis.org or 208-867-3479. ■

Patient Partners

Patient partners are recruited from organizations representing patients and other leading healthcare organizations. Each patient partner is assigned to a research mentor who helps guide their engagement in research activities. The mentors will also work

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Kelley Skeff—Professor in Medicine, Stanford University School of Medicine
C. Michael Armstrong—former CEO, AT&T; Armstrong Institute for Patient Safety

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