REPORT OF THE
JOINT COMMISSION ON HEALTH CARE

STUDY OF LYME DISEASE PURSUANT TO SJR 347

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

SENATE DOCUMENT NO. 46

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Preface

Senate Joint Resolution (SJR) 347 of the 1999 Session of the General Assembly directed the Joint Commission on Health Care, in cooperation with the Virginia Department of Health, to examine issues relating to the incidence, reporting, treatment, and prevention of Lyme disease in the Commonwealth.

Specifically, SJR 347 directed the Joint Commission's study to examine: (i) the incidence of Lyme disease in Virginia; (ii) whether Lyme disease is underreported in Virginia; (iii) if Lyme disease appears to be underreported in Virginia, why, and what steps can be taken to ensure the accurate reporting of Lyme disease; (iv) what assistance is available from the federal government for prevention, e.g., from the Centers for Disease Control, and for treatment, e.g., through the National Institutes of Health; (v) the extent to which Virginia is accessing any available federal support for the prevention and treatment of Lyme disease; (vi) the most appropriate use of and access to all available support for prevention and treatment of Lyme disease in this Commonwealth; and (vii) the most appropriate and expeditious means of publicizing the availability and benefits of the new vaccine.

Based on our research and analysis during this review, we concluded the following:

- Lyme disease is a bacterial illness transmitted by infected ticks. Humans are infected with the disease through tick bites.
- Nationwide, Lyme disease is a rapidly emerging infectious disease. However, the incidence of Lyme disease in Virginia is lower than the national average. In 1997, there were 4.7 cases reported per 100,000 population; Virginia's rate was 1.16 per 100,000. The highest reported incidence of Lyme disease is in the northeastern region of the country.
- The Centers for Disease Control designates Virginia as a "low risk" state. The number of reported cases in Virginia has been very low, ranging from 54 in 1989 to 151 in 1991.
- There is general agreement that Lyme disease is underreported in Virginia. The actual number of cases could range between 432 and 1,080. However, CDC indicates that the underreporting of Lyme disease in Virginia is no greater than in other states. The Virginia Department of Health (VDH) indicates that the underreporting of Lyme disease is no greater than other reportable diseases.

- VDH would like to conduct more "active" surveillance of reportable diseases.
- Lyme disease support groups expressed concern about the level of public education, VDH's surveillance efforts, and underreporting of the disease. Lyme disease advocates also believe very few doctors are adequately trained to diagnose and treat Lyme disease.
- A critical problem related to Lyme disease is that there is no reliable serological test to determine with certainty whether someone has Lyme disease. The lack of a reliable test fosters continuing disagreement regarding the actual incidence and proper treatment of the disease.

A number of policy options were offered for consideration by the Joint Commission on Health Care regarding the issues discussed in this report. These policy options are listed on page 29.

Our review process on this topic included an initial staff briefing, which comprises the body of this report. This was followed by a public comment period during which time interested parties forwarded written comments to us regarding the report. The public comments (attached at Appendix B) provide additional insight into the various issues covered in this report.

On behalf of the Joint Commission on Health Care and its staff, I would like to thank the Virginia Department of Health, the Virginia Pharmacists Association, and the Lyme Information Center of Virginia for their assistance during this study.

Patrick W. Finnerty
Executive Director

December, 1999

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Authority for Study/Organization of Report

Senate Joint Resolution (SJR) 347 of the 1999 Session of the General Assembly directs the Joint Commission on Health Care, in cooperation with the Virginia Department of Health (VDH), to examine issues relating to the incidence, reporting, treatment and prevention of lyme disease in Virginia.

Specifically, SJR 347 requires that the Joint Commission's study include, but not be limited to, an analysis of:

(i) the incidence of lyme disease in Virginia;
(ii) whether lyme disease is underreported in Virginia;
(iii) if lyme disease appears to be underreported in Virginia, why, and what steps can be taken to ensure the accurate reporting of lyme disease;
(iv) what assistance is available from the federal government for prevention, e.g., from the Centers for Disease Control, and for treatment, e.g., through the National Institutes of Health;
(v) the extent to which Virginia is accessing any available federal support for the prevention and treatment of lyme disease;
(vi) the most appropriate use of and access to all available support for prevention and treatment of lyme disease in the Commonwealth; and
(vii) the most appropriate and expeditious means of publicizing the availability and benefits of the new vaccine.

A copy of SJR 347 is attached at Appendix A.

This Report Is Presented In Five Major Sections

This first section discusses the authority for the study and organization of the report. Section II provides background information regarding lyme disease. Section III examines the incidence of lyme disease in Virginia and the nation and the degree to which there is underreporting of lyme disease in the Commonwealth. Section IV examines a number of concerns and issues regarding the prevention and treatment of lyme disease. Lastly, Section V presents a series of policy options the Joint Commission may wish to consider in addressing the issue of lyme disease.

II.
Background On Lyme Disease

Lyme Disease Is A Bacterial Illness Transmitted By A Tick Bite; Lyme Disease Is The Most Commonly Reported Vector-Borne Disease In the United States

Lyme disease is a bacterial infection that is transmitted to humans through tick bites. Lyme disease is caused by the bacterial spirochete called *Borrelia burgdorferi* which most commonly is carried by two types of ticks. In the eastern United States, the deer tick is mainly responsible for transmitting the disease; in the western region of the country, it is the western black-legged tick. As will be discussed in greater detail in Section III, the incidence of lyme disease as well as the number of geographic areas in which it is found have been increasing steadily throughout the United States. Lyme disease is the most commonly reported vector-borne disease in the United States.

While The Bacteria That Cause Lyme Disease Has Been In The United States For Over 100 Years, Lyme Disease Was First Recognized in 1975

Research has shown the bacteria which cause lyme disease have been present in the United States for over 100 years. However, the disease was first recognized in 1975 after researchers investigated why an unusually large number of children were being diagnosed with juvenile rheumatoid arthritis in Lyme, Connecticut and two neighboring towns. The investigators discovered that the affected children lived near a wooded area that harbored ticks and that the first symptoms appeared during the summer months coinciding with the tick season. Subsequently, the investigators determined that many of the children had developed a rash and that several recalled being bitten by a tick at the rash site. After further investigation, the researchers found that tiny deer ticks infected with a spiral-shaped bacterium (or spirochete) were responsible for the outbreak of arthritis. The bacteria was later named *Borrelia burgdorferi* after the discovering scientist (Dr. Burgdorfer).

Lyme Disease Is Transmitted By the Bite Of An Infected Tick; Typically, A Tick Must Be Attached To The Host For A Day Or More Before Transmission Of The Bacteria

Lyme disease is transmitted when an infected tick bites a human and takes a "blood meal." While attached, the tick transmits the bacterium to the host. Researchers indicate that an infected tick normally must be attached for a period

of 24 hours or longer to infect its host. However, if removed improperly, the infection can be transmitted much more quickly.

While tick bites can occur at any time of the year, they are more prevalent during the warmer months (April –September) along the east coast. Research indicates that the bacteria-carrying deer ticks are more prevalent around wetlands. Transmission of the bacteria that causes lyme disease often occurs when the tick is in the nymphal stage of its four-stage life span (egg, larva, nymph and adult). (However, adult ticks also can transmit the disease.) During the nymphal stage, the deer tick is no bigger than the size of a pinhead. Because these ticks are so small, persons often are not aware that the tick is on them or is attached.

There Are Three Stages Of Lyme Disease; Some Symptoms Of Lyme Disease Mimic Other Diseases

The bacteria that cause lyme disease can affect the skin, heart, nerves and/or joints. Lyme disease has three stages: (i) early lyme disease; (ii) early disseminated lyme disease; and (iii) late or chronic lyme disease. The symptoms vary according to each stage. Figure 1 summarizes the three stages and identifies the typical symptoms and problems associated with each stage.

As shown in Figure 1, with the exception of the erythema migrans rash, several of the other symptoms are common conditions and can be symptoms of other diseases or medical problems. The erythema migrans rash is the most distinctive symptom of lyme disease, and, if present, is the most helpful to physicians in diagnosing the disease. The rash generally appears within 1 to 30 days after an infected tick bite. It is rather distinctive in appearance and typically is shaped like a large red circle generally located at the site of the infected tick bite. The rash often grows in size with the center becoming clear or filled with tiny blisters giving the appearance of a "bull's eye" target.

While the erythema migrans rash is the most useful symptom in diagnosing lyme disease, various medical groups estimate that the rash does not appear on 15 to 40 percent of persons with lyme disease. In the absence of the rash, it is difficult to make an accurate diagnosis of lyme disease because the other symptoms (e.g., chills, fever, and headaches) can be symptoms of other medical conditions or diseases. If the rash does not appear and the patient is not diagnosed with lyme disease, the condition worsens and moves to the second stage (early disseminated lyme disease).

Figure 1

Stages and Symptoms of Lyme Disease

- **First Stage: Early Lyme Disease** is characterized by one or more symptoms that can occur days to weeks after the infection.
  - Potential Symptoms: fatigue, chills and fever, headache, muscle and joint pain, swollen lymph nodes, and erythema migrans (skin rash)

- **Second Stage: Early Disseminated Lyme Disease** is a function of the infection beginning to spread and affecting other body functions. This stage occurs weeks to months after the bite of an infected tick.
  - Potential Symptoms: numbness and pain in arms and legs, paralysis of facial muscles (usually on one side of the face), and meningitis (fever, stiff neck, and severe headaches)

- **Third Stage: Late or Chronic Lyme Disease** can occur weeks, months or even years after infection in patients who either never received treatment for early lyme disease or whose treatment did not kill all of the bacteria.
  - Potential Symptoms: chronic lyme arthritis (brief bouts of pain and swelling usually occurring in one or more of the large joints especially the knees), nervous system problems, including memory loss and difficulty concentrating, and chronic pain in muscles and/or unrestful sleep.

Source: American College of Physicians; "Lyme Disease, A Patient's Guide," 1999

If diagnosed early and treated appropriately with antibiotics (discussed later), the vast majority of lyme patients are cured. However, if the disease is undetected and untreated, more serious problems arise. In the second stage of the disease (early disseminated lyme disease), patients may experience numbness and pain in arms or legs, paralysis of facial muscles and more serious conditions such as meningitis and abnormal heart beat. The paralysis of the facial muscles, a condition called Bell's palsy, is a result of the infection spreading to the nervous system.

If the disease goes untreated, or the treatment does not kill completely the infection, the disease can progress into the third stage called late or chronic lyme disease. In this stage, patients may suffer from chronic arthritic pain, nervous system problems and chronic pain in muscles. However, many medical experts believe that lyme disease is a rare cause of nervous system disease.

Steps Can Be Taken To Prevent Lyme Disease; Antibiotics Are The Most Common Form Of Treatment

Medical experts and epidemiologists offer several suggestions for preventing lyme disease. As one would expect, the best way to prevent lyme disease is to avoid tick-infested areas. When in infested areas, wearing light colored clothing is recommended as ticks become more visible; wearing long pants and long-sleeved shirts also is recommended. Certain insect repellents also can help prevent tick bites. Persons should check for ticks immediately after leaving an infested area. Pets also need to be checked for ticks to prevent exposure to humans.

If a tick has attached itself, it should be removed immediately. However, it is important to properly remove the tick by using tweezers to grasp the tick at the head as close to the skin as possible. Crushing a tick while still attached may cause the bacteria to be injected into the skin.

Antibiotics Are Used To Treat Lyme Disease: For patients with early lyme disease, the standard course of treatment is oral antibiotic treatment (generally, either doxycycline or amoxicilin) for 3-4 weeks. The vast majority of these patients respond very well to treatment. In general, the sooner therapy is begun following infection, the quicker and more complete the recovery. The American Medical Association indicates that 90-95% of children with early lyme disease symptoms recover completely after only one course of antibiotic treatment.

Patients with later stage lyme disease also are treated with antibiotics. However, the potency of the antibiotic may be stronger and the duration of treatment generally is longer. Moreover, the results of the treatment can vary considerably. Treatment of late stage lyme disease is an inexact science. While many persons respond favorably to treatment, in a small percentage of patients, the disease becomes a treatment-resistant chronic condition with symptoms persisting for many months, even years. Conversely, a significant percentage of patients have reported a slow improvement of these symptoms over an extended period of time. Those patients with recurring symptoms generally receive additional antibiotic treatments, sometimes over an extended period of time. Patients with more severe symptoms may require intravenous antibiotic treatment. Lastly, if the disease affects the brain or heart, which is rare, treatment in a hospital may be necessary.

III.
Incidence Of Lyme Disease In Virginia And The Nation

Nationwide, Lyme Disease Is A Rapidly Emerging Infectious Disease; The Greatest Number of Reported Cases Of Lyme Disease Is In The Northeast

Lyme disease is a rapidly emerging infectious disease, now accounting for more than 90% of all reported vector-borne illness reported in the United States. The annual total of reported cases increased 25-fold between 1982 and 1997, with a cumulative total of more than 112,000 cases reported during that period. A total of 12,801 cases of lyme disease was reported in the United States in 1997. (Centers for Disease Control, Jan., 1999).

Lyme disease cases have been reported in 48 states and the District of Columbia. However, there is a clear geographic concentration of reported lyme cases in the northeastern states, and to a lesser degree, in the north-central region. Figure 2 illustrates the incidence of lyme disease throughout the country based on reported lyme disease cases.

As seen in Figure 2, a large majority of states (33) have very few reported cases of lyme disease resulting in a very low rate per 100,000 population (less than 1 case per 100,000 population). In 1997, the rate of reported cases per 100,000 population ranged from 0.00 in Colorado, Hawaii, Montana, and North Dakota to 70.23 in Connecticut.

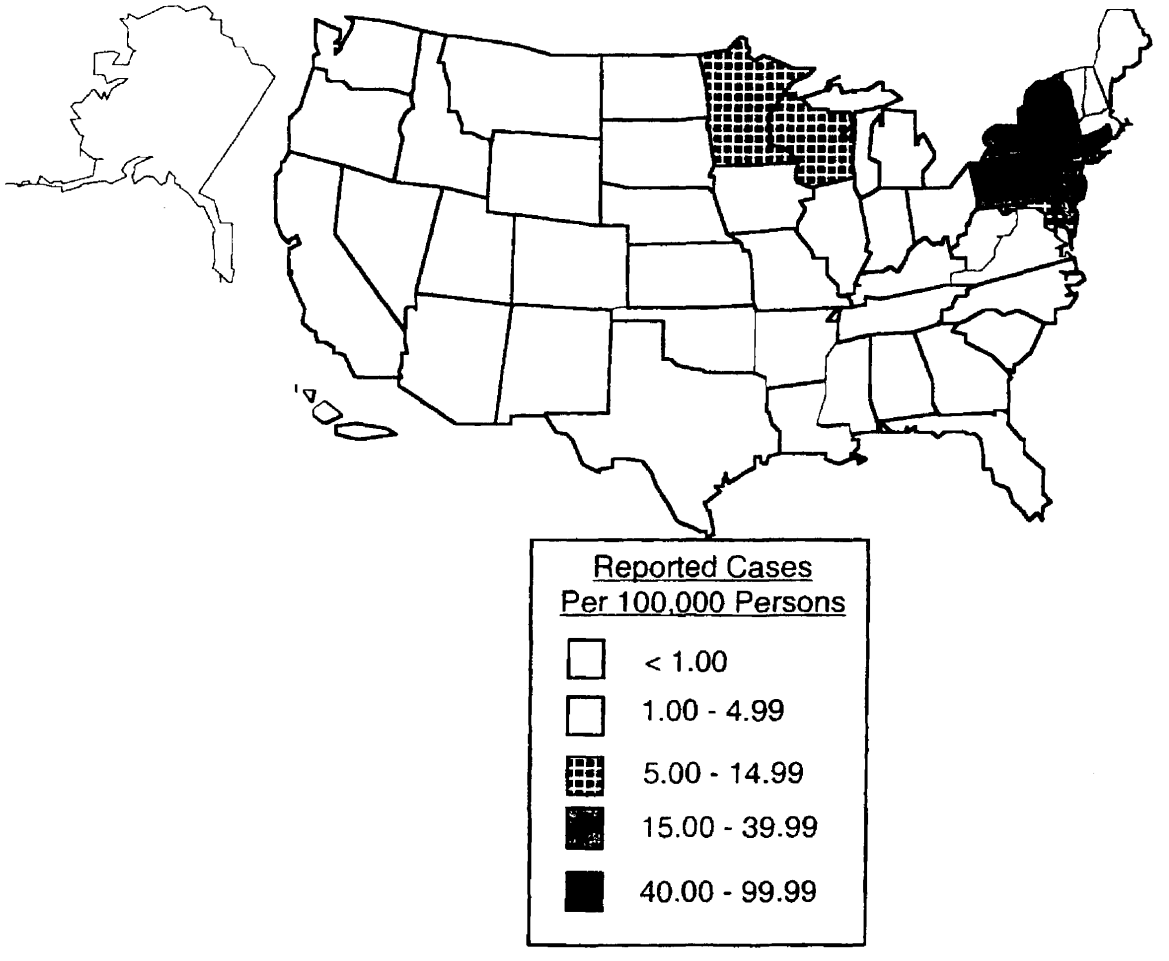
Virginia is one of 8 states that reported between 1.00 and 4.99 cases of lyme disease per 100,000 population. Three states (Maryland, Minnesota and Wisconsin) had rates between 5.00 and 14.99. Four states (Delaware, New Jersey, New York and Pennsylvania) reported rates between 15.00 and 39.99. Connecticut (70.23) and Rhode Island (44.5), by far, reported the highest rates of lyme disease.

Based On Reported Cases Of Lyme Disease, The Centers For Disease Control Designated Virginia As A "Low Risk" State

The Centers for Disease Control (CDC) monitors all notifiable diseases, including lyme disease, that are reported to it by the states. Based on data

Figure 2

Reported Cases Of Lyme Disease Per 100,000 Population (1997)



Source: American Lyme Disease Foundation, Centers for Disease Control

reported to CDC for the period of 1993-1997, Virginia was identified as a "low risk" state for lyme disease. Figure 3 illustrates how the CDC ranks all 50 states according to lyme disease risk. The rankings for each state are based on the following CDC methodology: (i) "high risk" states had annual incidences of reported lyme disease at the level of the national average rate (4.7 per 100,000 population) or greater; (ii) "moderate risk" states had an incidence of reported cases less than the national average rate but greater than half the national rate; (iii) "low risk" states are those with reported populations of vector ticks but

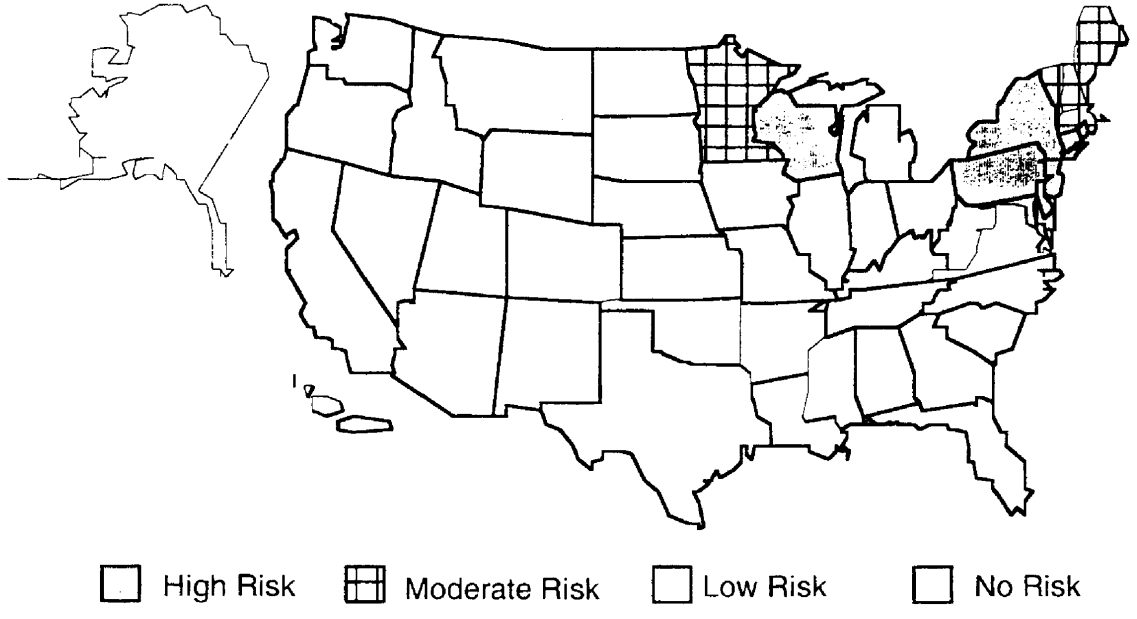
incidence rates of reported cases less than half the national rate; and (iv) "no risk" states have no know populations of vector ticks. (It is important to note that these rankings are based on "reported" cases of lyme disease. The actual incidence of lyme disease may be very different in each state depending on the degree to which the disease is underreported.)

The Virginia Department Of Health Is Responsible For Disease Reporting And Control In Virginia

Section 32.1-35 of the Code of Virginia requires the Board of Health to promulgate a list of diseases that must be reported to the Virginia Department of Health (VDH). Section 32.1-36 requires physicians and laboratory directors to report cases of these reportable diseases to the local health department serving the county or city in which the practice, facility or laboratory is located in accordance with the regulations promulgated by the Board. Physicians and laboratory directors report these diseases on a standard reporting form provided by the VDH. The form is relatively easy to complete and provides the necessary data for disease surveillance.

Figure 3

Lyme Disease Risk By State (1993-1997)



Source: Centers for Disease Control

The Office of Epidemiology within the VDH has primary responsibility for disease reporting and monitoring in the Commonwealth. This office coordinates the investigation of these diseases with the local health director and operations director. The Office of Epidemiology oversees a disease surveillance process that provides for the on-going collection, analysis, and interpretation of outcome-specific data for use in planning, implementation and evaluation of public health practice. The information on reportable diseases is used to: (i) develop disease control measures; (ii) detect outbreaks; (iii) document disease transmission; (iv) quantify morbidity and estimate trends; (v) identify risk factors for disease acquisition; and (vi) facilitate research. This office also submits state-level data to the Centers for Disease Control for use in developing national statistics on reportable diseases.

Lyme Disease Is One Of 61 Reportable Diseases Monitored By The VDH

As of January, 1999, the VDH regulations for disease reporting included 61 diseases, including lyme disease. Examples of other reportable diseases include AIDS/HIV, anthrax, botulism, chickenpox, diphtheria, hepatitis, influenza, malaria, measles, rabies, tuberculosis, and yellow fever.

Physicians are required by regulation to report cases of the 61 reportable diseases within 7 days unless the disease in question is among 18 diseases that the VDH requires more rapid communication. More rapid communication of these 18 diseases is required because of their extremely contagious nature or their potential for greater harm, or both. Examples include anthrax, botulism, diphtheria, rabies in man, Hepatitis A, small pox and tuberculosis. For these 18 diseases, regulations require that information be provided to the local health director by the most rapid means possible (e.g., telephone, or facsimile).

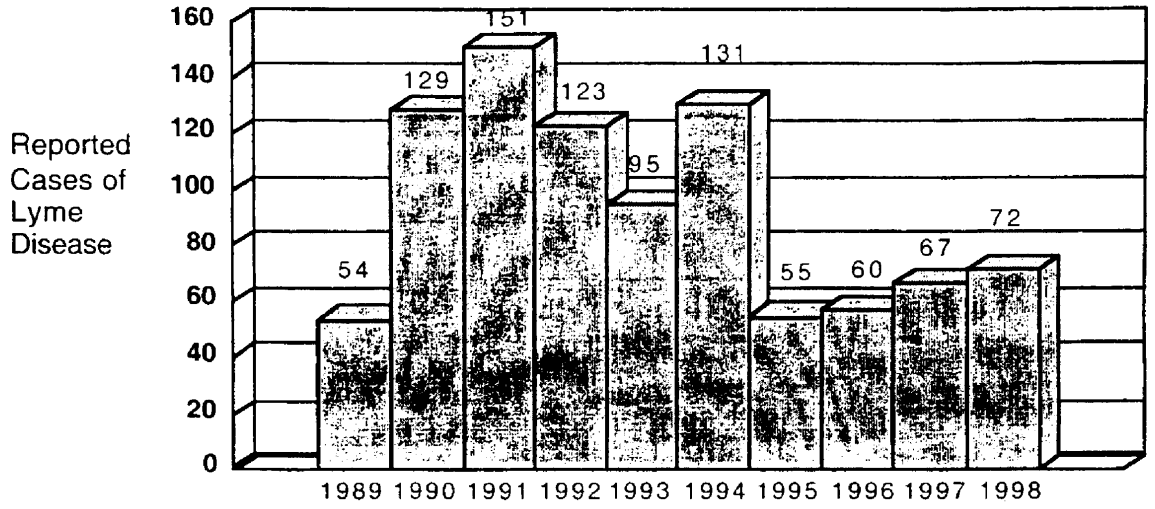
The Number Of Reported Cases Of Lyme Disease In Virginia Is Low

As discussed earlier, the number of reported cases of lyme disease in Virginia is low. According to statistics published by the VDH, the number of reported cases of lyme disease in 1998 was 72, or, 1.16 cases per 100,000 population.

The number of reported cases of lyme disease in Virginia has ranged from a low of 54 cases in 1989 to a high of 151 in 1991. Figure 4 illustrates the number of reported cases of lyme disease in Virginia from 1989 through 1998.

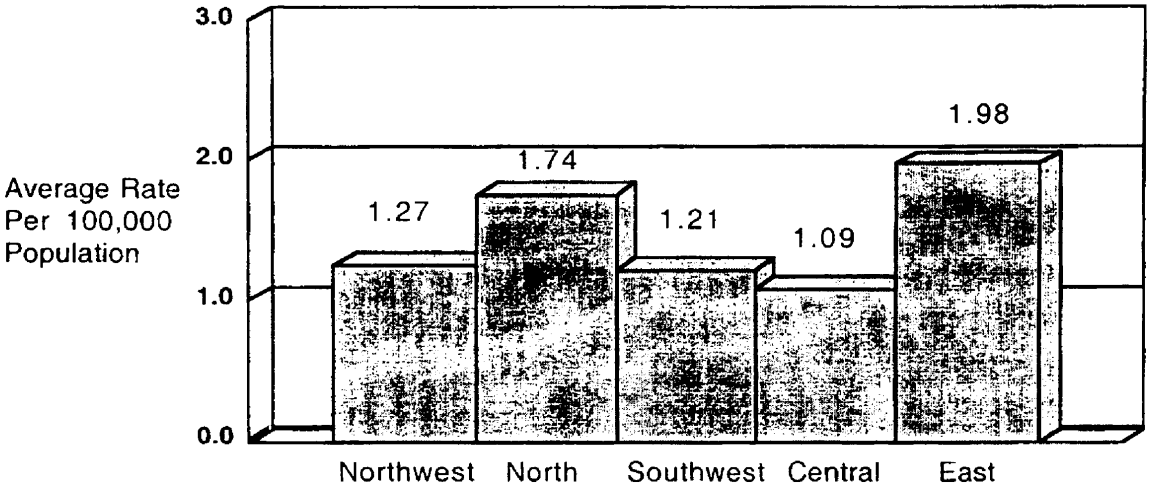
Lyme Disease Has Been Reported In All Regions Of The Commonwealth; The Eastern Region And The Northern Regions Have The Highest Rate Per 100,000 Population

Figure 4
Reported Cases Of Lyme Disease In Virginia
(1989-1998)



Source: Virginia Department of Health

Figure 5
Lyme Disease In Virginia: Average Rate Per 100,000 Population
(1989-1997)



Source: Virginia Department of Health

According to VDH reports for the period 1989 through 1997, there have been cases of lyme disease reported in all regions of the Commonwealth. Over this period of time, the Eastern Region has had the highest rate of reported lyme cases per 100,000 population. However, the rates per 100,000 population are fairly similar across the region with relatively minor variations. Figure 5 illustrates the average rate per 100,000 population for the five health planning regions during the period of 1989-1997.

While the Eastern Region has the highest rate per 100,000 population over the past nine years, the Northern and Northwest Regions have reported a higher rate per 100,000 population in recent years, with lower rates being reported in the Eastern Region. Figure 6 depicts this recent change in lyme disease rates.

Compared To Other Reportable Diseases, Lyme Disease Is Not One Of The More Frequently Reported Diseases In Virginia

According to a table of selected reportable diseases (33 of the 61 reportable diseases) prepared by VDH, lyme disease is not one of the more frequently reported diseases in Virginia. Of this group of selected diseases, the number of reported cases in 1997 ranged from 1 case of measles to 11,604 cases of chlamydia. In 1997, the average number of cases reported for these 33 selected diseases was 925; 67 lyme disease cases were reported. In 1997, the number of reported cases of lyme disease was greater than the number of cases reported for 13 of the other 32 diseases; the number of lyme disease cases was smaller than the number of reported cases for 18 of the other 32 diseases.

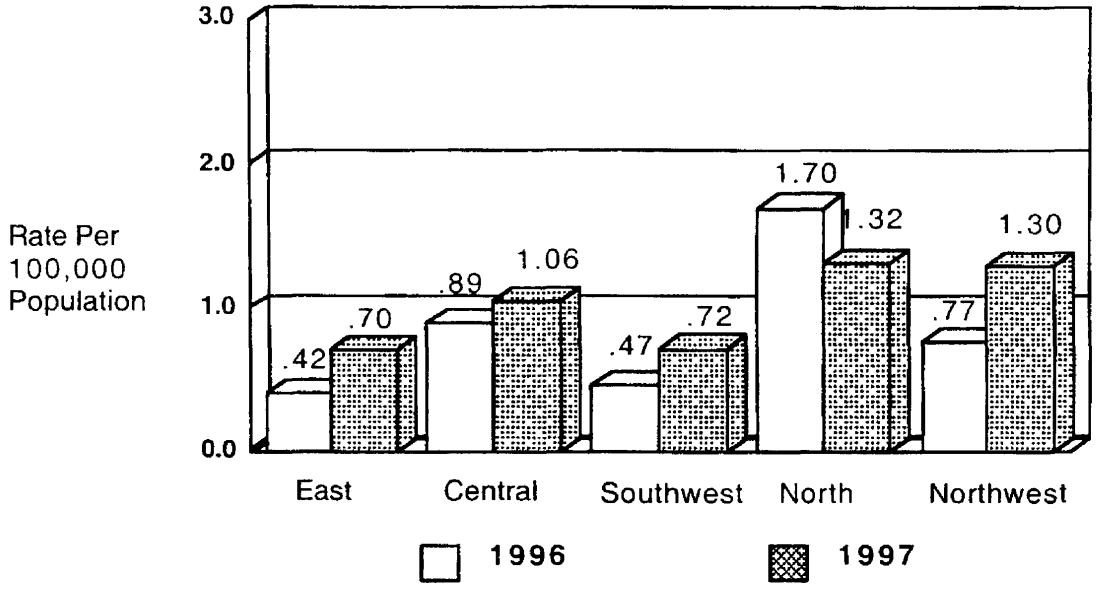
There is ongoing discussion and debate over the degree to which the relatively small number of lyme disease cases is a function of: (i) general underreporting by physicians, (ii) Virginia truly being a low risk state with few actual cases of lyme disease; or (iii) or a combination of both factors. While many public health officials, researchers, and medical experts believe it is more a function of both factors, some lyme support groups and patient advocates believe that underreporting is the most significant factor causing the small number of reported cases.

There Is General Agreement That The Number Of Lyme Disease Cases Is Underreported Both In Virginia And Nationally

While there have been no definitive studies or research that quantifies the degree to which lyme disease is underreported in Virginia, there is general agreement among researchers, patient advocates, and epidemiologists that there is some degree of underreporting. The underreporting of lyme disease occurs not only in Virginia but also across the nation.

Figure 6

Lyme Disease In Virginia, By Region: Rate Per 100,000 Population (1996-1997)



Source: Virginia Department of Health

The degree to which lyme disease is underreported in Virginia is relatively unknown because no specific research has been conducted in the Commonwealth. Nationally, there have been only a few published studies on this topic. A study published in 1996 in the Journal Of Infectious Diseases examined the public health impact of lyme disease in Maryland. One of the central issues addressed in the study is the degree to which lyme disease is underreported. Based on a survey of Maryland physicians, the researchers concluded that lyme disease is underreported 10-12 fold in Maryland. Another study published during 1996 in the Journal of Public Health Management and Practice examined the underreporting of lyme disease by Connecticut physicians. This study concluded that reported incidences of lyme disease may have been underestimated six-fold.

The Lyme Foundation, a national lyme disease advocacy group, estimates that the actual number of cases is likely to be 13-15 times higher than the number of reported cases. The bases and supporting research of this estimate were not immediately known.

If the range of underreporting of lyme disease included in these estimates (between 6 and 15 fold) is applied to the number of reported cases in Virginia in 1998 (72), the actual number of lyme cases would be somewhere between 432 and 1080, producing a lyme disease rate between 6.94 and 17.34 per 100,000 population. However, it is important to recognize that these are only estimates and were not based on Virginia-specific data.

Assuming there is some degree of underreporting of lyme disease in Virginia, then the actual incidence of the disease is higher than the number of reported cases. However, if one assumes that the same level of underreporting occurs in other states, Virginia's position relative to other states should remain essentially the same . . . . that Virginia is a relatively low risk state.

State And National Health Officials Believe The Underreporting Of Lyme Disease Is No Greater Than Most Other Reportable Diseases

Officials both at the VDH and the Centers for Disease Control (CDC) indicated that while there is some level of underreporting of lyme disease in Virginia and across the nation, the level of underreporting does not appear to be any greater than that of most other reportable diseases. VDH staff did indicate that for the most serious diseases (e.g., most contagious and/or most severe health consequences) such as AIDS/HIV, rabies, and meningitis, there is less underreporting given the serious consequences of not appropriately reporting such cases. Some patients with chronic lyme disease must endure persistent and often serious medical problems associated with the disease. However, most medical experts agree the disease is not fatal.

CDC officials interviewed by JCHC staff indicated they have no evidence to suggest that the underreporting of lyme disease in Virginia is any different than that in other states.

The U.S. Army Has Conducted Lyme Disease Risk Assessments At Several Virginia Military Installations And Concluded Some Are High Risk Areas

Because military personnel often train in wooded areas and other locations where ticks live, the U.S. armed services has had an ongoing interest in lyme disease. In the late 1980s and early 1990s, the U.S. Army conducted lyme disease risk assessments at a number of military installations, including several in Virginia.

The risk assessments conducted by the U.S. Army evaluated several aspects of lyme disease to determine if personnel assigned to a particular

military facility were at risk of being infected with lyme disease. To determine the level of risk, the U.S. Army evaluated the following four elements:

- history of lyme disease in the area;
- the presence of the tick vector and a host population needed to sustain a viable population of the vector;
- the presence of the lyme disease causing spirochete (*Borrelia burgdorferi*) in the tick population; and
- the presence of antibodies to the *Borrelia burgdorferi* bacteria in the mammalian host population (e.g., deer and small mammals).

Once these four elements were assessed, researchers classified each facility as being a low, moderate, or high risk facility. A "low" risk facility was one at which some elements of the lyme disease cycle were identified in the nearby area, but not on the installation. A facility was considered a "moderate" risk if some elements of the lyme disease cycle were identified on the installation or human cases of lyme disease were reported from the local area. And, lastly, if all elements of the lyme disease cycle were present on the installation, the facility was considered to be "high" risk.

The findings of the U.S. Army lyme disease risk assessments conducted at Virginia installations are presented in Figure 7.

As seen in Figure 7, 4 of the 8 installations were assessed as a "high" risk area for lyme disease; the other 4 were assessed as "moderate" risk areas. While this information indicates that, at least in these areas, Virginia has a higher risk for lyme disease than that indicated by the information published by the Centers for Disease Control (CDC), it is important to remember that "risk" is defined differently in the two methodologies. The CDC risk classification is based solely on the number of reported cases of human lyme disease infection. The U.S. Army definition included not only human lyme disease infection, but also three other elements. As such, the U.S. Army risk classification is based more on the "potential" of being infected with lyme disease, whereas the CDC risk classification is based only on the actual rate of human infection. Therefore, while the two risk classifications produce different results, they are not necessarily inconsistent.

VDH Has Taken Steps In The Past To Address Underreporting Of Lyme Disease Including A Three-Year CDC Grant-Funded Project

The VDH periodically publishes the "Epidemiology Bulletin" as a means of communicating with local health departments, physicians, laboratories, and other providers about reportable diseases. In 1997, VDH dedicated an issue of

the "Epidemiology Bulletin" to tick-borne diseases in Virginia. This issue contained information regarding various aspects of lyme disease including prevention, diagnosis, treatment and the number of reported cases.

Figure 7

Lyme Disease Risk Assessment Of Virginia Military Installations (1993)

Military Installation	Lyme Disease Risk Assessment
Fort A.P. Hill (Caroline Co.)	HIGH
Fort Belvoir (Fairfax Co.)	HIGH
Fort Eustis (James City Co.)	HIGH
Fort Lee (Prince George Co.)	MODERATE
Fort Pickett (Nottoway Co.)	MODERATE
Marine Combat Dev. Command (Quantico)*	HIGH
Naval Service Warfare Center (King George Co.)*	MODERATE
Woodbridge Research Facility (Prince William Co.)	MODERATE

* Risk assessment conducted in 1991

Source: U.S. Army Lyme Disease Risk Assessments in Virginia, April, 1998

In January of this year, the "Epidemiology Bulletin" was devoted to highlighting the importance and purpose of disease reporting and control. The issue also reviewed recent changes in the regulations regarding disease reporting.

During the early 1990s, the VDH submitted a grant proposal to the CDC to increase, improve and evaluate surveillance for human lyme disease cases in Virginia and to monitor progress toward a better understanding of the ecology and epidemiology of the disease. The grant was funded for a 3-year period.

The major activities of the lyme disease project included:

(i) reviewing CDC surveillance forms, laboratory reports and Virginia reporting forms for incomplete or missing data;
(ii) making follow-up telephone calls and sending letters to laboratories and physicians for additional information regarding certain lyme cases;
(iii) distributing an issue of "Epidemiology Bulletin" to all physicians and veterinarians summarizing lyme disease surveillance and emphasizing the importance of reporting lyme cases;
(iv) visiting various sites throughout Virginia (e.g., Quantico Marine Base, Prince William Park, University of Virginia Hospital, the Medical College of Virginia, and certain laboratories); and
(v) making presentations to various groups about lyme disease.

Extension Of The CDC Grant Was Not Funded: At the conclusion of the initial 3-year CDC grant, the VDH submitted a proposal to extend the grant for an additional 3-year period. The grant extension was submitted in collaboration with Old Dominion University, North Carolina State University and the North Carolina Department of Environment, Health and Natural Resources. However, while the grant was recommended for approval, funding was not approved. CDC officials interviewed as part of this study indicated that, relative to other states, lyme disease is not as serious an issue in Virginia. The limited amount of CDC funding was provided to other states with more serious lyme disease health problems.

Other Lyme Disease Grant Proposals Have Not Been Funded By CDC

In addition to the VDH grant proposals, at least two other lyme-related grant requests have been submitted to CDC by Virginia organizations. In 1997, Old Dominion University, in collaboration with Johns Hopkins University and the University of Maryland, had proposed to study the reasons why Maryland has such a higher lyme disease rate per 100,000 population than Virginia; however, the proposal was not funded. Also, in 1997, the Department of Fisheries and Wildlife Sciences at Virginia Tech submitted a grant proposal to CDC to produce maps that identify/predict those areas in Virginia where the probability of detecting lyme disease is high. Unfortunately, this proposal also was not funded. In both instances, CDC indicated that funding was approved for other proposals in states that had a more serious lyme disease problem than Virginia.

VDH Has Limited Staff To Conduct More Active Disease Surveillance Activities; Additional Resources May Provide More Accurate Reporting Of Lyme And Other Reportable Diseases

Currently, in addition to the State Epidemiologist and Assistant State Epidemiologist, who provide overall direction and supervision in the office, there are 4 staff persons assigned to the Division of Surveillance and Investigation who have overall responsibility for the reporting and surveillance of the 61 reportable diseases. Staff in VDH's Office of Epidemiology indicate that they would like to conduct more "active" surveillance of lyme and other reportable diseases to increase the level of reporting and to provide greater understanding and education about these diseases. VDH indicated that, due to staff and resource constraints, it must rely more on "passive" surveillance of reportable diseases.

"Passive" surveillance essentially means that reports of the diseases are received, compiled and published, with little follow-up or contact with providers about the reporting process. Passive surveillance also means that VDH epidemiologists have little if any time to do any field work to collect other types of data or information that may shed further light on the degree to which a particular disease may or may not be occurring in a given area.

With respect to lyme disease, "active" surveillance may involve conducting tick surveys in certain endemic areas to determine how many ticks are infected with the *Borrelia burgdorferi* bacteria, or other field work such as serologic (blood) testing of mammals that may be carrying the disease. Other "active" surveillance activities could include follow-up visits with physicians and laboratories regarding lyme reporting.

As previously stated, the number of reported lyme cases was significantly greater during the period 1990-1994 than in prior years or in years since that time. This time period also partially coincided with the CDC grant-funded surveillance activities of VDH. VDH staff commented that the increased reporting of lyme disease during 1990-1994 very likely was caused, at least in part, by the additional surveillance efforts of the department which raised awareness of the disease. VDH staff also indicated that lyme disease was receiving other publicity during this time period as well. Additional resources at VDH to enhance disease surveillance and monitoring activities along with an increased public awareness function could have a similar effect in the future.

IV.
Concerns And Issues Regarding Lyme Disease

In addition to the concern about underreporting of lyme disease, Senate Joint Resolution (SJR) 347 also directed the Joint Commission to examine a number of other issues. Those issues specifically cited in SJR 347 include: (i) what assistance is available from the federal government for prevention, e.g., from the Centers for Disease Control, and for treatment, e.g., through the National Institutes of Health; (ii) the extent to which Virginia is accessing any available federal support for the prevention and treatment of lyme disease; (iii) the most appropriate use of and access to all available support for prevention and treatment of lyme disease in the Commonwealth; and (vii) the most appropriate and expeditious means of publicizing the availability and benefits of the new vaccine.

In addition to the issues contained in SJR 347, lyme disease support groups and patient advocates in Virginia also have raised concerns about certain aspects of the disease. These include: (i) lyme disease underreporting (addressed in previous chapter); (ii) prevention and public education efforts in Virginia; (iii) the availability of well-trained physicians to treat lyme patients; and (iv) insurance coverage for lyme disease patients, particularly for patients with late stage or chronic lyme disease.

Virginia Has Accessed Support From The Centers For Disease Control For Lyme Disease Surveillance; The National Institutes Of Health Currently Is Conducting Research On Lyme Disease Treatment

As reported earlier, the VDH has received CDC funds in the past to support lyme disease research and surveillance efforts. Efforts have been made by VDH as well as other organizations to secure additional funding from CDC; however, these efforts have not been successful. While VDH certainly can and should continue to seek additional CDC funds in the future, based on the most recent responses from CDC, further grant funding for Virginia is at best questionable given CDC's desire to direct such funds to states where lyme disease poses more serious health problems than it currently does in the Commonwealth.

The National Institutes of Health (NIH) funds research focused more directly on the clinical aspects of the disease. Currently, NIH is conducting research on chronic lyme disease patients, with a specific emphasis on the

effectiveness of various doses of antibiotic treatment and varying periods of therapy. This research is being conducted at two locations: the New England Medical Center in Boston and the New York Medical College in Valhalla, New York.

Because NIH grant-supported research appears to be focused more on the clinical aspect of lyme disease, state agencies other than the VDH (e.g., the Commonwealth's three medical schools) likely have a greater chance of receiving NIH funds. However, NIH staff interviewed as part of this study indicated that the research being funded by NIH requires a significant number of lyme patients to complete the clinical trials. Despite the fact that New York and Massachusetts have a much higher rate of lyme disease than Virginia, researchers report difficulty obtaining enough patients to complete the research. NIH staff indicate that while it awards grant funding to various entities doing clinical research, the research has a greater chance of being successfully completed in areas where a larger lyme patient base exists.

A Lyme Vaccine Recently Received Approval From The Federal Food And Drug Administration; Only In The Last Several Months Has The Availability Of The Vaccine Been Publicized

Two lyme disease vaccines have been developed; one by SmithKline Beecham (LYMErix) and one by Pasteur Merieux Connaught (ImuLyme). However, at this writing, only LYMErix has received approval from the Federal Food and Drug Administration (FDA). LYMErix became available to the general public in the last few months.

The vaccine LYMErix, which has been approved for persons aged 15-70 years, is administered in three doses. Following an initial dose, a second dose is administered 1 month later, and a third dose 12 months after the first. Vaccine administration should be timed so the second dose and the third dose are given several weeks before the beginning of the lyme transmission season (usually begins in April). Testing of the vaccine efficacy (i.e., ability to prevent lyme disease) indicated it was 50% effective after the first two doses and 78% effective after the third dose. The duration of immunity following the three-dose vaccination series is unknown and the need for booster doses has not been determined. Because the vaccination is not 100% effective, persons are still encouraged to take all other preventive actions and precautions to avoid infected ticks.

The average wholesale price (AWP) of the vaccine is $61.25 per dose, or a total of $183.75 for the full three-dose vaccination. This price does not include the administration fee that a provider typically would charge to administer the

vaccine. Assuming an administration fee of $50-$75, the total cost of the vaccination series would be approximately $233.75 - $258.75.

The Vaccine Is Indicated Only For Those At Risk: Public health officials, CDC officials, and medical experts all agree that the vaccine is indicated only for those persons at risk for exposure to infected vector ticks. This risk can be assessed by considering the geographical area and the extent to which the person's activities place him or her in contact with ticks.

Insurance Coverage Varies: Because the LYMErix vaccine was just approved by the FDA, some insurers are still reviewing whether to include the vaccination in their benefit packages. Initial indications are that some carriers will include the vaccine and others may not. For those carriers that do include the vaccination, it likely will be covered only for those persons at significant risk for being infected with lyme disease. (This policy would be consistent with the recommendations of medical experts, the vaccine manufacturer, and the CDC.)

Some Lyme Patients Have Reservations About The Vaccine And Question The Validity Of The Supporting Research

Despite FDA approval of the vaccine and general acceptance of the vaccine by the medical community, some lyme patients have expressed serious reservations about the vaccine and have questioned the validity of the research supporting its efficacy. The Lyme Foundation posted information on its internet site that while it is optimistic about the vaccine, it has the following concerns.

- Is the vaccine safe when administered to persons who already have lyme disease?
- Does the vaccine provide only "partial immunity" which could potentially mask infection?
- Were the clinical trials designed and conducted appropriately?
- Were the researchers predisposed to certain findings?

In addition to the concerns raised by the Lyme Foundation, lyme patients interviewed during the study also expressed several concerns, including: (i) the vaccine takes a full year to become only partially effective; (ii) once given the vaccine, persons will test positive to antibodies in the bloodstream that are produced to fight the infection causing the current tests used to detect the disease useless; and (iii) persons who unknowingly have lyme disease may get sick from the vaccine.

Until there is further information and evaluative data regarding the long-term efficacy of the vaccine, it is difficult to ascertain whether the concerns

voiced by the Lyme Foundation and some lyme patient advocates actually will become problematic.

VDH Should Publish Information Regarding The Lyme Vaccine And Make Such Information Available To Physicians, Local Health Departments And The General Public

Because the LYMErix vaccination was approved in December, 1998, there has been little time for VDH to circulate information about the vaccine. However, VDH should include information about the vaccine in a future issue of "Epidemiology Bulletin" as well as update its brochure on preventing tick-borne diseases in Virginia. In addition, VDH should consider disseminating additional information about the vaccine in those areas of the Commonwealth with the highest level of reported lyme cases, primarily the Northern, Northwest and Eastern regions of the state.

Some Lyme Patient Advocates Cite The Current Level Of Public Education And Surveillance Concerning Lyme Disease As A Serious Concern In Virginia

The degree to which lyme disease information is provided to physicians and the general public is a major concern of some lyme patient advocates. Persons interviewed as part of this study indicated that Virginia should take a more proactive role in providing information regarding lyme disease prevention, diagnosis, and treatment. Lyme patient advocates believe that greater amounts of factual information about the disease to educate both patients and providers would help prevent the disease and dispel some misinformation that many people have about lyme disease. They also assert that such information would educate physicians about how to identify and treat the illness and would help current patients obtain proper treatment.

In addition to more public awareness and education about lyme disease, some patient advocates also argue that the VDH and local health departments should take a more active surveillance role in terms of improving the number of lyme cases being reported by providers.

VDH Distributes A Brochure On Lyme Disease To Local Health Departments And Includes Information About Lyme Disease On The Agency's Web Site

The VDH has published a brochure entitled "Preventing Tick-Borne Diseases in Virginia." This brochure provides general information about lyme disease prevention, symptoms, and treatment, as well as tick removal and other tick-borne diseases (e.g., rocky mountain spotted fever). The brochure is distributed primarily to local health departments for their routine use in public

health activities. In addition, VDH will provide additional copies for special functions or activities.

In addition to printed material, VDH includes information regarding lyme disease on the agency's web site on the Internet. The web site includes a lyme disease fact sheet that includes information on lyme disease prevention, symptoms and treatment. VDH also posts "downloadable" versions of its publication "Epidemiology Bulletin" for persons to read.

Additional Public Awareness About Lyme Disease Would Help Educate Physicians And The General Public About The Disease; VDH Indicates Additional Resources Would Be Needed

One way of enhancing public awareness and education about lyme disease is to increase the number of brochures distributed by VDH and make them available to a broader audience such as doctors' offices, pharmacies, hospitals, public libraries, schools, day care centers, and others. Distribution of the brochure could be statewide with a greater emphasis on those regions of the state with the highest number of reported lyme disease cases. Also, additional information could be distributed during "lyme season" (Spring through Fall) when the risk of infection is greatest.

Another strategy could be to develop more specific educational material tailored to help physicians in the diagnosis and treatment of lyme disease. While the VDH has communicated with physicians about lyme disease through the "Epidemiology Bulletin," more frequent information may enhance physicians' awareness of the disease which could presumably result in better reporting as well as improved education regarding diagnosing and treating the disease.

As discussed in the section dealing with underreporting of lyme disease, VDH indicated that it would like to conduct greater surveillance activities on reportable diseases in general, but that additional resources (staff and funding) would be needed. Similarly, VDH staff indicate that additional funding would be needed to expand the types of printed information it distributes and/or increase the number of each item that is printed and distributed.

Some Lyme Patient Advocates Express Concern That Very Few Physicians Are Knowledgeable About Lyme Disease And The Most Effective Means Of Treating Lyme Patients

Lyme patient advocates interviewed as part of this study expressed serious concern that very few physicians in Virginia are adequately trained to diagnose and treat lyme patients, particularly those patients with chronic lyme disease.

Patient advocates assert that the vast majority of physicians are unfamiliar with the appropriate diagnostic methods and treatment protocols for many lyme patients. As a result, patient advocates believe that a significant number of lyme patients are not being diagnosed as having lyme disease, are not receiving the appropriate treatment, and, as a consequence, are having to endure serious health problems.

As discussed later in this section, there is disagreement between some lyme patients and the medical community as to the true prevalence of lyme disease and the appropriate treatment protocols. However, public health officials, as well as the medical community, generally agree that additional training/education for physicians regarding lyme disease would be beneficial in diagnosing and treating the disease. As previously noted, the development and distribution of additional clinical information regarding lyme disease to physicians by VDH could help in this regard. Moreover, the Medical Society of Virginia indicated that it would welcome working with VDH to distribute certain information through its member newsletters or other media to assist in this effort. VDH also could approach the appropriate medical specialty societies and associations to obtain their assistance in communicating with their member physicians.

Insurance Coverage For Lyme Disease Is Identified By Some Lyme Patient Advocates As Another Major Concern

Some lyme support groups/patient advocates complain that insurance companies are not providing adequate coverage for lyme disease, particularly for patients with late stage or chronic lyme disease. The specific concern cited by these groups is that many, if not all, insurers will not provide coverage for lengthy intravenous (IV) antibiotic treatments that they believe some lyme patients require. An associated concern of the lyme support groups/advocates is that some physicians who prescribe lengthy IV treatments are often harassed by the insurer to the point of not wanting to treat lyme patients.

Insurers Argue There Is No Specific Limit On Lyme Disease Benefits; Coverage Depends On The Medical Necessity Of The Prescribed Treatment And Case-By-Case Considerations

Based on the response of various insurers, there does not appear to be any set limit of benefits for lyme disease. For example, insurers indicated that there is no specific limit (e.g., 4 weeks) for coverage of IV antibiotic treatments. Insurers do indicate that, as with all covered services, medical necessity determinations are made for prescribed lyme disease treatments, and, based on the circumstances of each case, the treatment may or may not be covered.

With specific regard to coverage for long-term IV antibiotic treatments, some carriers indicated that there is little or no scientific evidence reported in the medical journals that clearly establishes the efficacy of this particular treatment protocol. Insurers point to the fact that the National Institutes of Health (NIH) is conducting research in this very area (discussed earlier) as support for their position.

Perhaps The Most Critical Issue Regarding Lyme Disease Is That, Currently, There Is No Reliable And Valid Test To Determine With Certainty If Someone Does Or Does Not Have Lyme Disease

As noted in earlier in this report, lyme disease often is difficult to diagnose because many of the symptoms (e.g., headache, fever, chills, fatigue, and muscle soreness) mimic other diseases such as influenza, infectious mononucleosis and types of arthritis. Even the more severe symptoms of lyme disease are similar to those of other illnesses.

The most distinctive symptom or characteristic of lyme disease is the eyrthema migrans rash that typically appears following the bite of an infected tick. However, medical experts agree that the rash does not appear in all lyme patients. In fact, it is estimated that the rash does not appear on 15 to 40 percent of lyme patients. In the absence of the distinctive rash, diagnosis of lyme disease depends on other clinical evidence. While well-trained physicians experienced with lyme patients often are able to diagnose the disease without the appearance of the rash, there are no reliable serologic tests that provide 100% accurate results.

Current Serologic Tests Identify Antibodies In The Blood, But Not The Bacteria Itself: Unfortunately, the lyme disease microbe itself is difficult to isolate or culture from body tissues or fluids. As such, the blood tests used today to help in the diagnosis of lyme disease actually test for the presence of antibodies in the bloodstream that act as the body's defense against the *Borrelia burgdorferi* bacteria, and not the bacteria itself. Because the antibodies that fight the lyme disease bacteria are similar to those that defend against other strains of bacterial infection, some tests cannot distinguish lyme disease antibodies from antibodies to similar organisms. This means that the serologic tests often produce "false positives" (i.e., the patient tests positive for lyme disease but does not actually have lyme disease).

Several physicians interviewed during this study, as well as some of the medical literature, indicate that there is a significant number of "false positive" test results. Physicians also indicate that a sizable number of patients who believe they have lyme disease, in fact, do not. Conversely, some lyme support

groups and patient advocates contend that there are many lyme patients who are not properly diagnosed by physicians.

Another shortcoming of the current serologic tests is that the antibodies may take up to 2 to 6 weeks after infection to appear in the blood. If the blood test is given during this period, "false negatives" (i.e., the person does not test positively for lyme disease, but does, in fact, have the disease) can result. Moreover, antibiotics given to a person early during infection may also prevent antibodies from reaching detectable levels, even though the lyme disease bacteria is the cause of the patient's symptoms. This situation also can lead to "false negative" test results.

Just as these serologic tests cannot reliably determine if a person is infected with the lyme disease bacteria, the tests also cannot reliably determine when a patient becomes bacteria-free following treatment.

The Absence Of A Reliable Test For Positively Determining Whether Someone Has Lyme Disease Poses Serious Problems For Patients, Physicians, And Public Health Officials

Without a reliable test to determine whether or not someone has lyme disease, patients, physicians, and public health officials face a number of serious problems. Often, patients who suffer with symptoms typically associated with lyme disease believe strongly that they have the disease, and want to be treated accordingly. However, without a reliable means of testing for lyme disease, some physicians are reluctant to treat a condition that they cannot positively diagnose. Such a situation can seriously strain patient-provider relations, cause some patients to question the physician's willingness to treat the patient, or cause the physician to decide not to treat the patient anymore.

Conversely, the lack of a definitive test may result in patients being treated for lyme disease, when, in fact, some other medical condition exists that goes untreated. Inadequate testing also causes problems in determining whether certain treatment protocols are effective. If there is no reliable means of determining whether the disease exists, there likely will continue to be questions as to whether certain treatments are working or not.

Lastly, the absence of a reliable lyme test seems to have contributed to the existence of two schools of thought regarding the prevalence and severity of lyme disease in Virginia and throughout the nation. One school of thought, held by some lyme support groups and patient advocates, is that there is a significant number of patients with lyme disease who are not being treated appropriately by the medical community, and who are not having their medical expenses covered

by insurance. The other school of thought is that there is an overdiagnosis of lyme disease and that many of the patients who believe they have lyme disease actually have some other medical condition. Until such time as a reliable test is developed to diagnose lyme disease, there likely will continue to be an ongoing debate on this subject.

The National Institutes Of Health Is Conducting Research On Developing More Reliable Lyme Disease Tests

Physicians, public health officials, and lyme disease researchers all agree that the most important advancement needed in dealing with lyme disease is the development of more reliable diagnostic tests. The National Institutes of Health (NIH) currently is conducting research on this topic. Hopefully, NIH's efforts will prove successful in the near future.

V.
Policy Options

The following Policy Options are offered for consideration by the Joint Commission on Health Care. They do not represent the entire range of actions that the Joint Commission may wish to pursue.

Option I	**Take no action**
Option II	**Introduce A Budget Amendment Providing Additional Staff And Funding To The Virginia Department Of Health To Conduct Additional Ongoing Disease Surveillance And Monitoring Activities And To Reduce The Amount Of Underreporting Of Lyme Disease And Other Reportable Diseases**
Option III	**Introduce A Budget Amendment Providing Funds To The Virginia Department Of Health To Develop Additional Lyme Disease Educational Materials And To Distribute These Materials To A Broader Audience Of Persons And Health-Related Organizations**
Option IV	**Introduce A Joint Resolution Requesting The Commonwealth's Three Academic Health Centers To Seek Grant Funding, Either Individually Or Collaboratively, From The National Institutes Of Health Or Other Appropriate Funding Sources To Conduct Research On Improving The Accuracy And Utility Of Serologic Tests For Diagnosing Lyme Disease**

APPENDIX A

SENATE JOINT RESOLUTION NO. 347

Requesting the Joint Commission on Health Care, in cooperation with the Virginia Department of Health, to examine issues relating to the incidence, reporting, treatment, and prevention of Lyme disease in the Commonwealth.

Agreed to by the Senate, February 18, 1999
Agreed to by the House of Delegates, February 16, 1999

WHEREAS, Lyme disease is considered the most prevalent vector-borne disease in the United States; and

WHEREAS, Lyme disease is transmitted through the bite of an infected tick; and

WHEREAS, Lyme disease is caused by a spirochete which can be detected through testing of the tick if the tick has been removed and stored for testing; and

WHEREAS, without the results of such tests many physicians are reluctant to treat for Lyme disease, and others may prescribe antibiotics; and

WHEREAS, the indiscriminate use of antibiotics can result and has resulted in the development of resistant organisms; and

WHEREAS, Lyme disease is alleged to be underreported and under-treated; and

WHEREAS, Lyme disease is a devastating illness which can lead to disability and personal loss of health and income; and

WHEREAS, in December of 1998, the federal Food and Drug Administration approved a license for a new vaccine against Lyme disease; and

WHEREAS, physicians and the public may not yet be aware of this new vaccine and its potential to prevent the pain and disability of Lyme disease; and

WHEREAS, although Lyme disease is a reportable disease in Virginia, the Commonwealth does not have a systematic approach at the state level to evaluate the incidence, treatment patterns, validity of the reporting, and viable approaches to prevention and treatment of this disease; now, therefore, be it

RESOLVED by the Senate, the House of Delegates concurring, That the Joint Commission on Health Care requested, in cooperation with the Virginia Department of Health, examine issues relating to the incidence, reporting, treatment, and prevention of Lyme disease in the Commonwealth. The study shall examine but not be limited to, (i) the incidence of Lyme disease in Virginia; (ii) whether Lyme disease is underreported in Virginia; (iii) if Lyme disease appears to be underreported in Virginia, why, and what steps can be taken to ensure the accurate reporting of Lyme disease; (iv) what assistance is available from the federal government for prevention, e.g., from the Centers for Disease Control, and for treatment, e.g., through the National Institutes of

Health; (v) the extent to which Virginia is accessing any available federal support for the prevention and treatment of Lyme disease; (vi) the most appropriate use of and access to all available support for prevention and treatment of Lyme disease in this Commonwealth; and (vii) the most appropriate and expeditious means of publicizing the availability and benefits of the new vaccine.

All agencies of the Commonwealth shall provide assistance to the Joint Commission, upon request.

The Joint Commission shall complete its work in time to submit its findings and recommendations to the Governor and the 2000 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for processing legislative documents.

APPENDIX B

JOINT COMMISSION ON HEALTH CARE

SUMMARY OF PUBLIC COMMENTS: LYME DISEASE STUDY (SJR 347)

Individuals/Organizations Submitting Comments

A total of four individuals and organizations submitted comments in response to the SJR 347 report on Lyme Disease.

- Virginia Pharmacists Association
- Joan McCallum (Lyme Information Center of Virginia)
- Debbie Hays
- Rebecca H. Day

Policy Options Included in the SJR 347 Issue Brief

Option I **Take no action**

Option II **Introduce A Budget Amendment Providing Additional Staff And Funding To The Virginia Department Of Health To Conduct Additional Ongoing Disease Surveillance And Monitoring Activities And To Reduce The Amount Of Underreporting Of Lyme Disease And Other Reportable Diseases**

Option III **Introduce A Budget Amendment Providing Funds To The Virginia Department Of Health To Develop Additional Lyme Disease Educational Materials And To Distribute These Materials To A Broader Audience Of Persons And Health-Related Organizations**

Option IV **Introduce A Joint Resolution Requesting The Commonwealth's Three Academic Health Centers To Seek Grant Funding, Either Individually Or Collaboratively, From The National Institutes Of Health Or Other Appropriate Funding Sources To Conduct Research On Improving The Accuracy And Utility Of Serologic Tests For Diagnosing Lyme Disease**

Overall Summary of Comments

The three private citizens who submitted comments offered additional information regarding the incidence, symptoms and treatment of lyme disease. All four commenters indicated support for Options II and III, with two of the three private citizens noting that if any additional funding is provided to the Health Department for further disease surveillance and monitoring activities, a certain amount should be designated specifically for lyme disease. None of the commenters indicated support for Option IV; the Virginia Pharmacists Association commented that the research on serologic tests for lyme disease contemplated in Option IV already is being conducted by other organizations.

Summary of Individual Comments

Virginia Pharmacists Association

Rebecca P. Snead, Executive Director of the Virginia Pharmacists Association, commented in support of Options II and III. She also commented that while Option IV is an admiral goal, research is already being conducted in this area and that further research would be duplicative. Ms. Snead also noted that lyme disease is an ideal candidate for prevention and that pharmacists can play a major role in the prevention and identification of the disease. She also commented that pharmacists also can recognize and triage patients to ensure that they receive appropriate medical care.

Joan McCallum, Lyme Information Center of Virginia

Joan McCallum of the Lyme Information Center of Virginia did not indicate support for any specific Policy Option; however, she did comment that a specific amount of funding should be designated for lyme disease surveillance and monitoring by the Virginia Department of Health (VDH). Ms. McCallum also provided additional information regarding various issues covered in the report including the diagnosis, treatment, and incidence of lyme disease. She also commented that, overall, VDH is not very concerned about lyme disease. She suggested that VDH send additional information to physicians about lyme disease and the new LYMErix vaccine. Ms. McCallum also suggested that patients ought to be able to obtain disease-reporting forms from their local health department or VDH to take to their doctors to ensure that lyme disease diagnoses are reported to VDH. She also commented that VDH and the local health departments need to work together more closely. Lastly, she commented that Virginia should have a laboratory at which patients could have ticks tested locally to determine if they are infected with the lyme bacteria.

Debbie Hays

Debbie Hays, a lyme disease patient, provided additional information regarding several aspects of lyme disease. She commented in favor of designated funding for the Virginia Department of Health (VDH) to conduct additional lyme disease surveillance and monitoring. Ms. Hays also recommended having at least one laboratory in Virginia capable of conducting tick testing and that information about the laboratory be included in any lyme disease fact sheets or brochures. Lastly, she recommended that all Virginia schools be supplied with lyme disease brochures and fact sheets for distribution to the children.

Rebecca H. Day

Rebecca H. Day, a lyme patient, did not submit formal comments regarding the study. However, she had written a letter to the Department of Health Professions during the comment period in which she expressed several concerns regarding lyme disease.

Inasmuch as her letter focused on a number of issues included in the report, her letter was included in the public comments.

Ms. Day's letter primarily focused on what she believes to be a serious lack of knowledge about lyme disease in the Tidewater area. She noted that she consulted with over 30 physicians and was diagnosed with 12 separate illnesses prior to being diagnosed with lyme disease. Ms. Day identified the following shortcomings: (i) insufficient information about lyme disease; (ii) unreliable testing; (iii) lack of information regarding lyme disease in the medical community; and (iv) underreporting of lyme disease. She recommended taking action to raise the general public's awareness of the disease and to highlight the difficulties in receiving appropriate treatment.

JOINT COMMISSION ON HEALTH CARE

Executive Director

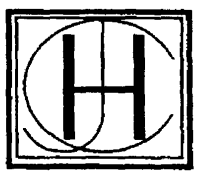
Patrick W. Finnerty

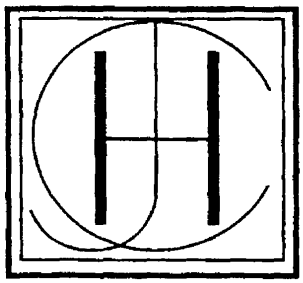
Senior Health Policy Analysts

Joseph J. Hilbert
William L. Murray, Ph.D.
E. Kim Snead

Office Manager

Mamie V. White





Joint Commission on Health Care
Old City Hall
1001 East Broad Street
Suite 115
Richmond, Virginia 23219

(804) 786-5445
(804) 786-5538 (FAX)

E-Mail: jchc@leg.state.va.us

Internet Address:

http://legis.state.va.us/jchc/jchchome.htm