Significant Legislative Rules Analysis

Chapter 246-101 WAC
Notifiable Conditions

February 3, 2021

SECTON 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

The purpose of Chapter 246-101 WAC, Notifiable Conditions, is to provide critical information to public health authorities to aid them in protecting and improving public health through prevention and control of infectious and noninfectious conditions as required under RCW 43.20.050, 70.104.055, and 43.70.545. Public health authorities use the information gathered under this chapter to take appropriate action, including, but not limited to, treating ill people; providing preventive therapies for individuals who came into contact with infectious agents; investigating and halting outbreaks; removing harmful health exposures from the environment; assessing broader health-related patterns, including historical trends, geographic clustering, and risk factors; and redirecting program activities and developing policies based on broader health-related patterns. The chapter establishes notification requirements and standards for conditions that pose a threat to public health consistent with this purpose and the authorizing statutes it is adopted under.

The rules require health care providers, health care facilities, laboratories, veterinarians, food service establishments, child care facilities, and schools to notify public health authorities of cases of notifiable conditions identified in chapter 246-101 WAC, cooperate with public health authorities when conducting case investigations, and follow infection control measures when necessary to control the spread of disease.

The rules were last revised in 2011. Since then, there have been a number of advances and developments which can only be addressed in rule. The State Board of Health (Board) and Department of Health (Department), through joint rule making, have proposed changes to chapter 246-101 WAC, Notifiable Conditions, to better protect public health by improving our understanding of emerging conditions, allowing more thorough case investigations, and improving the public health response to infectious and noninfectious conditions. The public health goals for these changes are to reduce the risk of transmission of disease and prevent serious complications and fatalities.

On April 17, 2017, the Department and Board filed a Pre-proposal Statement of Inquiry (CR-101) to begin joint rule making to consider adopting notification requirements for seven new conditions and classes of conditions, and including notification and specimen submission requirements for three conditions identified in the current rules under the definition of “Other Rare Disease of Public Health Significance”. After further review by Department subject matter experts, the Department and Board withdrew the original CR-101 and filed a new Pre-proposal Statement of Inquiry on May 18, 2018 to clarify and expand the scope of rule making. The new CR-101 expanded the list of new conditions and classes of conditions for consideration to 21, and expanded the number of specific conditions identified in the definition of “Other Rare Disease of Public Health Significance” considered for adoption to four.

The new conditions and classes of conditions considered during this rule making are:

- Carbapenem-resistent Enterobacteriaceae (E. coli, Klebsiella species, and Enterobacter species)
- Coccidioidomycosis
- Zika
- MERS and other severe communicable coronavirus infections
- Hantaviral infections (Andes virus, Bayou virus, Black Creek Canal virus, Dobrava-Belgrade virus, Haantan virus, Seoul virus, and Sin Nombre virus)
- Rickettsia prowazekii, Rickettsia typhi (typhus), and other non-spotted fever Rickettsia
- Ehrlichiosis
- B. cereus biovar anthracis
- Candida auris
- Histoplasmosis
- Fungal meningitis
- Amoebic meningitis
- Sleeping sickness
- Baylisascaris infection
- Chagas disease
- Mycobacterium tuberculosis complex
- Typhus
- Echinococcosis (Echinococcus granulosus or E. multilocularis)
- Taeniasis / cysticercosis (Taenia solum)
- Occupational respiratory diseases
- Inpatient hospitalizations associated with a workplace injury

The conditions considered during this rule making identified under the current rules as "Other Rare Diseases of Public Health Significance" are:

- Anaplasmosis
- Babesiosis
- Spotted fever rickettsiosis
- Tick paralysis

Over the course of rule development, the Department and Board consulted with more than 50 subject matter experts and formed a technical advisory committee to gather information in 2018. Members of the technical advisory committee represented a variety of stakeholders including health care providers, health care facilities, laboratories, local health jurisdictions, professional associations, health equity organizations, and state agencies. The draft rules were broadly distributed in May 2019 to gather informal comments from interested parties, further comments were sought in June and July 2019 from local health jurisdictions, and members of the regulated community and the technical advisory committee were asked to complete a cost questionnaire elated to significant changes in the draft rules in November 2019 to complete the proposed rules and required analyses. In addition, Board and Department staff held two information and listening sessions with community and advocacy organizations to help inform newly established reporting categories for patient ethnicity, race, and preferred language data components. The draft rules were broadly distributed again in December 2020 to gather informal comments from interested parties.

If adopted, the proposed rules would significantly amend and clarify notification requirements applicable to health care providers, health care facilities, laboratories, local health jurisdictions, and veterinarians; create notification requirements for the Washington State Department of Agriculture; and clarify requirements for food service establishments, schools, child care facilities, and the general public. Proposed changes to the rules include:

- Adding or revising notification and specimen submission requirements for 74 new or existing conditions;
- Eliminating three categories of conditions ("other rare diseases of public health significance", "emerging conditions with outbreak potential", and "disease of suspected bioterrorism origin");
- Eliminating notification requirements for veterinarians and clarifying requirements for veterinarians to cooperate with public health authorities during case investigations;
- Establishing notification requirements for the Washington State Department of Agriculture;
- Updating local health jurisdiction duties to reflect current technology used for notifying the Department, clarifying existing and establishing new notification timelines, and clarifying notification, investigation report, and outbreak report content requirements;
- Updating reference to the Security and Confidentiality Guidelines developed by the Centers for Disease Control and Prevention (CDC);
- Updating statutory references throughout the chapter; and
- Improving overall clarity and usability of the chapter by merging health care provider and facilities rules, repealing unnecessary rules, clarifying requirements for suspected cases of notifiable conditions, and revising language consistent with clear rule writing standards.

SECTION 2:

Is a Significant Analysis required for this rule?

Yes, the Department and Board determined a significant analysis is required for the proposed chapter and are subject to the requirements of RCW 34.05.328(5). The Board and the Department evaluated the proposed rules and determined several proposed rules are exempt from further analysis under RCW 34.405.328(5)(c). These proposed exempt rules and the corresponding rationale for the exemption are listed in the table below. The Department and Board determined the remaining proposed rules are significant and the section-by-section analysis is included in Section 5 of this analysis.

WAC, Title	Description of Change	Exemption from significant analysis under 34.05.328(5)(b)
REPEAL SECTION 246-101-001, Provisions of general applicability.	Clarifies chapter and improves usability by eliminating unnecessary rule.	(iv) Repealing this section clarifies the chapter without changing its effect

WAC, Title	Description of Change	Exemption from significant analysis under 34.05.328(5)(b)
246-101-005, Purpose of notifiable conditions reporting.	Revises narrative description of purpose and adds scope of chapter for clarity	(iv) Revisions to this section clarify language without changing its effect
246-101-010, Definitions within the notifiable conditions regulations.	Revises, repeals, and adds definitions as necessary for clarity and usability of the chapter. This rule does not set new requirements or standards.	(iv) Revisions to this section clarify language without changing its effect *Definitions are analyzed in context as part of the section-by-section analysis in Section 5.*
246-101-015, Provisional condition notification.	Streamlines and clarifies the process for the State Health Officer to establish provisional conditions request additional information and specimen submission for notifiable conditions	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-120, Handling of case reports and medical information.	Incorporates related health care facilities requirements from repealed section-320, clarifies language, and updates RCW references	(iv) Revisions to this section clarify language without changing its effect
NEW SECTION 246-101-200, Rapid screening testing	Adds new section to clarify that any individual or entity conducting rapid screening testing meets the definition of a laboratory and must comply with sections of the chapter applying to laboratories. Chapter 70.42 RCW already defines "test site" and chapter 246-338 WAC already defines "test site or medical test site" to broadly include individuals or entities that conduct rapid screening tests. The current and proposed rule reference these RCWs and WACs in the definition of laboratory. Proposed WAC 246-101-200 clarifies that these definitions include individuals or entities conducting rapid screening tests.	(iv) Addition of this section clarifies language without changing its effect

WAC, Title	Description of Change	Exemption from significant analysis under 34.05.328(5)(b)
246-101-210, Means of specimen submission – Laboratory directors and laboratories.	Clarifies specimen submission requirements	(iv) Revisions to this section clarify language without changing its effect
246-101-230, Handling of case reports and medical information.	Clarifies requirements for handling confidential information and updates RCW references	(iv) Revisions to this section clarify language without changing its effect
REPEAL SECTION 246-101-301, Notifiable conditions and health care facilities.	Streamlines chapter by merging health care facility requirements with related health care provider requirements in section -101 and repeals section -301.	(iv) Repealing this section clarifies the chapter without changing its effect *Significant changes related to new or revised conditions notifiable by health care facilities are addressed in the analysis of section -201 in Section 5 of this analysis*
REPEAL SECTION 246-101-305, Duties of the health care facility.	Streamlines chapter by merging health care facility requirements with related health care provider requirements in section -105 and repeals section -305.	(iv) Repealing this section clarifies the chapter without changing its effect *Significant changes related to duties of health care facilities are addressed in the analysis of section -205 in Section 5 of this analysis*
REPEAL SECTION 246-101-310, Means of notification.	Streamlines chapter by merging health care facility requirements with related health care provider requirements in section -110 and repeals section -310.	(iv) Repealing this section clarifies the chapter without changing its effect *Significant changes related to means of notification for health care facilities are addressed in the analysis of section -210 in Section 5 of this analysis*
REPEAL SECTION 246-101-315, Content of notifications.	Streamlines chapter by merging health care facility requirements with related health care provider requirements in section -115, and repeals section -315.	(iv) Repealing this section clarifies the chapter without changing its effect *Significant changes related to content of notifications for health care facilities are addressed in the analysis of section -215 in Section 5 of this analysis*

WAC, Title	Description of Change	Exemption from significant analysis under 34.05.328(5)(b)
REPEAL SECTION 246-101-320, Handling of case reports and medical information.	Streamlines chapter by merging health care facility requirements with related health care provider requirements in section -120 and repeals section -320.	(iv) Repealing this section clarifies the chapter without changing its effect
REPEAL SECTION 246-101-401, Notifiable conditions and the responsibilities and duties of others.	Clarifies chapter and improves usability by eliminating unnecessary rule	(iv) Repealing this section clarifies the chapter without changing its effect
NEW SECTION 246-101-408, Content of case reports: Department of Agriculture	Identifies content of case reports submitted by Department of Agriculture	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-410, Responsibilities of food establishments.	Clarifies language and updates WAC reference	(iv) Revisions to this section clarify language without changing its effect
246-101-415, Responsibilities of child day care facilities.	Aligns the definition of child care facility with Department of Children Youth and Family statutes.	(iv) Revisions to this section clarify language without changing its effect
246-101-420, Responsibilities of schools.	Clarifies language only	(iv) Revisions to this section clarify language without changing its effect
246-101-425, Responsibilities of the general public.	Clarifies language only	(iv) Revisions to this section clarify language without changing its effect
REPEAL SECTION 246-101-501, Notifiable conditions and local health departments.	Clarifies chapter and improves usability by eliminating unnecessary rule	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-505, Duties of the local health officer or the local health department.	Clarifies language only	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-510, Means of notification.	Updates local health jurisdiction (LHJ) notification requirements	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party

WAC, Title	Description of Change	Exemption from significant analysis under 34.05.328(5)(b)
NEW SECTION 246-101-513, Content of notifications, case reports, and outbreak reports: Local health officer	Establishes new section and updates content of LHJ notifications, case reports, and outbreak reports from section -510 to new section -513	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-515, Handling of case reports and medical information.	Clarifies language and updates RCW references	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-520, Special conditions—AIDS and HIV.	Clarifies language, repeals outdated language, and updates reference to CDC guidelines	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-525, Special condition—Influenza.	Clarifies language only	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
REPEAL SECTION 246-101-601, Notifiable conditions and the department.	Clarifies chapter and improves usability by eliminating unnecessary rule	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-605, Duties of the department.	Clarifies language, add the Department of Agriculture to the list of entities that the Department must provide technical support to, and specifies that negotiated alternatives must "…provide the same level of public health protection as the reporting requirement for which an alternative is sought."	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-610, Handling of case reports and medical information.	Clarifies language only	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-615, Requirements for data dissemination.	Incorporates requirements from repealed sections -620 and -625 and clarifies language	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party

WAC, Title	Description of Change	Exemption from significant analysis under 34.05.328(5)(b)
REPEAL SECTION 246-101-620, Requirements for notification to the department of labor and industries.	Streamlines chapter by merging notification requirements with related requirements in section -615 and repeals section -620.	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
REPEAL SECTION 246-101-625, Content of notifications to the department of labor and industries.	Streamlines chapter by merging notification requirements with related requirements in section -615 and repeals section -625.	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-630, Special condition—Antibiotic resistant disease.	Clarifies language only	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-635, Special conditions—AIDS and HIV.	Clarifies language, repeals outdated language, and updates reference to CDC guidelines	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-640, Special condition—Birth defects.	Clarifies language only	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
REPEAL SECTION 246-101-701, Notifiable conditions and the department of labor and industries.	Clarifies chapter and improves usability by eliminating unnecessary rule	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-705, Duties of the department of labor and industries.	Clarifies language only	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-710, Handling of case reports and medical information.	Clarifies language only	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-715, Requirements for data dissemination.	Incorporates requirements from repealed sections -720 and -725 and clarifies language	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
REPEAL SECTION 246-101-720, Requirements for notification to local health departments.	Streamlines chapter by merging notification requirements with related requirements in section -715 and repeals section -720.	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party

WAC, Title	Description of Change	Exemption from significant analysis under 34.05.328(5)(b)
REPEAL SECTION 246-101-725, Requirements for notification to the department.	Streamlines chapter by merging notification requirements with related requirements in section -715 and repeals section -725.	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-101-730, Special condition—Hospitalized burns.	Clarifies language only	(ii) Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party

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SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The Board has broad rule-making authority for a range of public health concerns under RCW 43.20.050. The goal and objectives of the statute that chapter 246-101 WAC implements is stated explicitly in RCW 43.20.050(2)(f):

> *In order to protect public health, the state board of health shall adopt rules for the prevention and control of infectious and noninfectious diseases...*

The Board has further rule-making authority granted under RCW 70.104.055:

> *(1) Any attending physician or other health care provider recognized as primarily responsible for the diagnosis and treatment of a patient or, in the absence of a primary health care provider, the health care provider initiating diagnostic testing or therapy for a patient shall report a case or suspected case of pesticide poisoning to the department of health in the manner prescribed by, and within the reasonable time periods established by, rules of the state board of health.*

Rules adopted under this authority recognize and support the Department's responsibility to protect and enhance the public health and welfare as declared in RCW 70.104.010:

> *The department of health has responsibility to protect and enhance the public health and welfare. As a consequence, it must be concerned with both natural and artificial environmental factors which may adversely affect the public health and welfare. Dangers to the public health and welfare related to the use of pesticides require specific legislative recognition of departmental authority and responsibility in this area.*

RCW 43.70.545 further provides rule-making authority to the Department:

> *(1) The Department of Health shall develop, based on recommendations in the public health services improvement plan and in consultation with affected groups or agencies, comprehensive rules for the collection and reporting of data relating to acts of violence, at-risk behaviors, and risk and protective factors. The data collection and reporting rules shall*

be used by any public or private entity that is required to report data relating to these behaviors and conditions.

Rules adopted under this authority recognize and support the Department's primary responsibility to preserve public health as articulated in RCW 43.70.005:

It is the intent of the legislature to form such focus by creating a single department in state government with the primary responsibilities for the preservation of public health, monitoring health care costs, the maintenance of minimal standards for quality in health care delivery, and the general oversight and planning for all the state's activities as they relate to the health of its citizenry.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rule making and the consequences of not adopting the rule.

The proposed rules implement the general goals and specific objectives of RCW 43.20.050, RCW 43.70.545, and RCW 70.104.055 discussed above by establishing a surveillance system that includes notification, investigation, and collection and distribution of data related to infectious and noninfectious conditions. This data is critical to local health jurisdictions, the Department, and other public health authorities tasked with preventing and controlling the spread of disease. Public health authorities also use the data to assess broader patterns, including historical trends and geographic clustering of disease. Based on these assessments, officials are able to take appropriate actions such as conducting outbreak investigations, redirecting program activities, and developing new policies to prevent and control infectious and noninfectious conditions.

While some information can be obtained voluntarily through case investigations and requesting additional information under WAC 246-101-015, Provisional condition notification, it is not a reliable method of data collection. It is critical for the prevention and control infectious and noninfectious conditions for public health authorities to obtain consistent and complete epidemiological data to support prevention and control efforts statewide. This can only be done using the surveillance system established under chapter 246-101 WAC.

The Department and Board assessed the proposed rules and the statutes the rules implement and determined rule making is needed to achieve the stated goals and objectives. The authorizing statutes specifically require the Board and Department to adopt rules for the prevention and control infectious and noninfectious conditions and the protection, preservation, and enhancement of public health. Therefore, the Board and the Department determined there are no feasible alternatives to rule making that meet the general goals and specific objectives of RCWs 43.20.050, 43.70.545, and 70.104.055.

SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

For each separate proposed rule of chapter 246-101 WAC deemed significant under RCW 34.05.328(5), the Department and Board completed the following section-by-section analysis. The analysis includes a description of the proposed changes as well as the associated probable benefits and probable costs of those changes.

To obtain cost estimates for the proposed changes, the Department and Board requested members of the regulated community and technical advisory committee complete cost

questionnaires in 2019 and 2020. The 2019 cost questionnaire was sent to laboratory directors and the regulated health care providers and facilities. The Department received seven completed cost questionnaires in response. In 2020, a supplemental cost questionnaire was sent to laboratory directors and the regulated health care providers intended to capture potential costs associated with additional demographic reporting requirements. The Department received five completed supplemental cost questionnaires in response (one from a respondent who had also completed the survey in 2019), and staff followed up via phone with three of the respondents to clarify the requirements of the rules and the responses. Cost information is summarized in the following section-by-section analysis.

While the rules require notification of named conditions, the rules do not require health care providers or health care facilities to confirm the absence of cases of conditions identified in the rules, nor do they require diagnosis of cases of conditions outside the health care provider's scope or field of practice. The rules also do not require laboratories to test for agents (conditions) or speciate an agent if the laboratory does not perform the test as part of its normal work, or to retain specimens indefinitely in anticipation of a request from a local health jurisdiction or the Department.

Societal Benefits of Notifiable Conditions Surveillance

Public health surveillance plays an essential role in disease prevention and control by providing public health authorities with information and data necessary to take effective public health action. Surveillance provides data and information to assess the burden and distribution of adverse health events, prioritize public health actions, implement disease control measures to reduce the number and severity of cases, monitor the impact of control measures, identify reservoirs or vectors of disease, identify emerging health conditions that may have a significant impact upon population health, and contribute to surveillance activities at the national and international level to implement more effective control measures on a broader scale.[1]

Public health surveillance plays a key role in identifying, controlling, and preventing the spread of zoonotic diseases. Approximately 60% of all known infectious diseases affecting humans are zoonotic. An even larger percentage (70%) of new or emerging infectious diseases of humans have an animal origin.[2,3] Zoonotic diseases are estimated to be responsible for at least 2.5 billion cases of human illness and 2.7 million deaths worldwide annually.[4] Growth of the human population, changes in the environment and agricultural practices, and increases in international travel and trade have all given both recognized and emerging zoonotic diseases new opportunities to spread.

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[1] Groseclose SL , Buckeridge DL. Public health surveillance systems: recent advances in their use and evaluation. Annu Rev Public Health. 2017;38:57–79.

[2] Woolhouse M, Gowtage-Sequeria S. Host range and emerging and reemerging pathogens. Emerg Infect Dis. 2005;11:1842-1847

[3] K, Patel N, Levy M, Storeygard A, Balk D, Gittleman J, et al. Global trends in emerging infectious diseases. Nature. 2008;451:990-993

[4] Gebreyes WA, Dupouy-Camet J, Newport MJ, et al. The global One Health paradigm: challenges and opportunities for tackling infectious diseases at the human, animal, and environment interface in low-resource settings. PLoS Negl Trop Dis. 2014;8:e3257

Public health surveillance can also play a role in promoting equity. Many of the new conditions in the proposed rules disproportionality impact subpopulations who are already experiencing health disparities. For example, anaplasmosis disproportionately impacts immunosuppressed patients or persons with comorbid diseases such as diabetes, person's living and working in tick habitats,[5] and American Indians.[6] Reporting of anaplasmosis and the corresponding public health response enabled by surveillance therefore also has the potential to decrease the disparate impacts of anaplasmosis in Washington's communities. Coccidioidomycosis is another example as this condition has greater impacts (e.g. higher prevalence and more severe outcomes) for people who are living with weakened immune systems, those who are pregnant, African Americans, Filipinos, and Mexican Americans.[7,8, 9,10,] Reporting of these and other conditions with disparate impacts, paired with timely and equity-aware public health responses, can help lessen the impact of these conditions which may benefit communities or populations with the highest burden of disease.

The benefits of establishing a notification requirement for a condition can be demonstrated by the avoided costs associated with the burden on an individual with a case of a condition, the public health system, and the population as a whole.

Avoided costs associated with an individual case can include lost productivity, hospitalization, and the Disability-Adjusted Life Year (DALY), a measure of overall disease burden expressed as the number of years of life lost due to ill health, disability for people living with the health condition or its consequences, or premature death.

Avoided costs for the public health system are related to the resources lost in scaling up the public health response designed to prevent new cases and minimize the disease burden. The heightened public health response can include the costs of providing timely and informed public health interventions including infection control measures such as vaccination, isolation, and quarantine, and contact identification.

Avoided costs for the population as a whole can include lost productivity related to avoiding exposure, receiving prophylaxis to prevent disease, and receiving treatment to decrease severity of acquired cases.

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[5] Symptoms | Anaplasmosis | CDC. http://www.cdc.gov/anaplasmosis/symptoms/.

[6] Folkema AM, Holman RC, Dahlgren FS, Cheek JE, McQuiston JH. Epidemiology of ehrlichiosis and anaplasmosis among American Indians in the United States, 2000-2007. *The American journal of tropical medicine and hygiene*. 2012;87(3):529-537. doi:10.4269/ajtmh.2012.12-0060.

[7] Valley Fever | Coccidioidomycosis | Types of Fungal Diseases | Fungal | CDC. *Cdcgov*. 2016. Available at: http://www.cdc.gov/fungal/diseases/coccidioidomycosis/risk-prevention.html. Accessed December 6, 2016.

[8] Pathogenesis of Coccidioidomycosis with Special Reference to Pulmonary Cavitation. *Annals of Internal Medicine*. 1948;29(4):623. doi:10.7326/0003-4819-29-4-623.

[9] Wright P, Pappagianis D, Wilson M et al. Donor-Related Coccidioidomycosis in Organ Transplant Recipients. *Clinical Infectious Diseases*. 2003;37(9):1265-1269. doi:10.1086/378741.

[10] Ruddy B, Mayer A, Ko M et al. Coccidioidomycosis in African Americans. *Mayo Clinic Proceedings*. 2011;86(1):63-69. doi:10.4065/mcp.2010.0423.

Describe the rule changes that effect state, local, and tribal agencies and how the changes support the goals and objectives of the statute being implemented

While RCW 34.05.328 does not require analysis of proposed "rules relating only to internal governmental operations that are not subject to violation by a nongovernmental party", the Department and Board determined it beneficial to include a description of the substantive rule changes that affect the public health authorities named in the proposed rules, and a description of how these changes support the goals and objectives of the statute being implemented.

The purpose of chapter 246-101 WAC, Notifiable Conditions, and the purpose of the proposed amendments is stated in WAC 246-101-005, Purpose and scope:

(1) The purpose of this chapter is to provide critical information to public health authorities to aid them in protecting and improving the public's health through prevention and control of infectious and noninfectious conditions. Public health authorities use the information gathered under this chapter to take appropriate action, including, but not limited to:
   (a) Treating ill persons;
   (b) Providing preventive therapies for individuals who came into contact with infectious agents;
   (c) Investigating and halting outbreaks;
   (d) Removing harmful health exposures from the environment;
   (e) Assessing broader health-related patterns, including historical trends, geographic clustering, and risk factors; and
   (f) Redirecting program activities and developing policies based on broader health-related patterns.

(2) This chapter establishes notification requirements and standards for conditions that pose a threat to public health consistent with the purpose as established in this section.

In addition to the Department of Health, the chapter is implemented by local health jurisdictions, the Department of Labor and Industries, and the Department of Agriculture. In addition, sovereign tribal nations and tribal epidemiology centers may use these rules as a public health tool. These authorities are critical partners in fulfilling the purpose of the Notifiable Conditions chapter.

By establishing a surveillance system that includes notification, investigation, and collection and distribution of data related to infectious and noninfectious conditions. This data is critical to local health jurisdictions, the Department, and other public health authorities tasked with preventing and controlling the spread of disease. Public health authorities also use the data to assess broader patterns, including historical trends and geographic clustering of disease. Based on these assessments, officials are able to take appropriate actions such as conducting outbreak investigations, redirecting program activities, and developing new policies to prevent and control infectious and noninfectious conditions.

Local Health Jurisdictions

Substantive changes are proposed for WACs 246-101-510 and 246-101-513 and are described below. In addition to these substantive changes, the proposed rules make clarifying changes to all

the sections of Part 5, Notifiable Conditions – Local Health Jurisdictions, which includes WACs 246-101-505, -510, -513, -515, -520, and -525.

WAC 246-101-510, Means of notification: Local Health Officer or Local Health Jurisdiction

Description of substantive proposed rule changes:

- Maintain a 24 hour telephone number to receive confirmation calls for case or laboratory reports submitted for conditions requiring immediate notification and those notifiable within 24 hours.
- Notify the Department of Health using telephone of secure electronic data transmission upon receiving a case or laboratory report for an immediately notifiable condition, excluding Meningococcal disease, invasive (*Neisseria meningitides*), Shiga toxin-producing *E. coli* (STEC) / enterohemorrhagic *E. coli*; and Vaccinia (vaccine-acquired smallpox).
- Notify the Department of Health using the secure electronic disease surveillance system (or WDRS) within three business days of receiving case or laboratory reports for conditions that are not immediately notifiable.
- Close cases using WDRS that do not require investigation within three business days of the decision;
- Immediately reassign cases using WDRS to the Department of Health upon determining a patient who is the subject of a case is a resident of another local health jurisdiction or resides outside Washington state; and
- Submit completed case investigations or notify the Department of Health of incomplete case investigations using WDRS.
- Local Health Officer confirmation that each case submitted is based on clinical criteria, or laboratory criteria, or both prior to submitting the investigation report to the Department of Health.

Description of potential qualitative costs for local health jurisdictions and how these proposed changes support the goals and objectives of the statute being implemented:

Maintain a 24 hour telephone number: This requirement will require local health jurisdictions to ensure they have a staff person on call to respond to 24 hour calls. This could create a burden for local health jurisdictions that do not already have this process in place. This requirement supports health care facilities, health care providers, and laboratories in meeting their requirement to confirm receipt of case or laboratory reports, and ensure all reports can be reviewed and appropriate action initiated in a timely manner by local health jurisdictions.

Notify the Department of Health within three business days for conditions that are not immediately notifiable: Under the current rules, local health jurisdictions can wait to notify the Department of Health up to 21 days until a case investigations are completed for conditions that are not immediately notifiable. Making this a faster reporting timeline does not increase the workload, but it may shift the workload of reporting to Department of Health nearer to the time that the case investigation is being completed, which could tax resources during that window of time for some local health jurisdictions. This delay in notification impedes cross-jurisdiction investigations and public health response, and could delay connection to care and public health prevention measures that could identify community reservoirs of disease. Faster notification can thus decrease the number of community cases identified in the coming months.

Notify the Department of Health of immediately notifiable conditions: While the requirement for local health jurisdictions to notify the Department of Health immediately of named conditions is an existing requirement, the proposed rule expands the list of existing conditions to include all immediately notifiable conditions, excluding meningococcal disease, STEC, and vaccinia, resulting in an increase in the number of conditions that are immediately notifiable by 9 rare conditions. This will create an added burden for local health jurisdictions that will need to use staff time to report these addition conditions immediately.

Immediate notification of cases and immediate reassignment of cases to the Department of Health facilitates rapid identification of cases reported across multiple jurisdictions within Washington State which might necessitate wider coordinated public health action. Given the public health surveillance structure and the fact that the state maintains a global view of cases across jurisdictional lines, the proposed change will help the Department of Health be more able to identify potential cross-jurisdictional linkages for immediately notifiable conditions which may indicate communal spread outside of one region within the state. In order to effectively manage this cross-jurisdictional oversight we need to have accurate and timely information.

Department of Health notification ensures that larger trends or exposures outside of a single jurisdiction are rapidly identified. While some events may be locally based, the transient nature of our communities makes it likely that exposure to these immediately notifiable conditions fall outside of one jurisdiction.

In addition, notification facilitates planning by the Department of Health in order to make resources, such as testing through the Public Health Laboratories, available to local health jurisdictions after hours. The Public Health Laboratories will either need to stand up laboratory staff or enact agreements with other reference laboratories for pass-through of additional testing around these immediately notifiable conditions. Additionally, there will be an assessment of need for resources (guidance and people) to support the communicable disease epidemiology surveillance operations within the Department of Health.

Close cases within three business days that do not require investigation: This may create an extra administrative task for local health jurisdictions. The time frame for closing non-investigated cases is important to having accurate surveillance data for the entire state, for coordinating cross-jurisdictional investigation efforts, and for cost savings for the public health laboratories. If the case is closed after the public health laboratories has determined specimen viability, the cost of performing the test is lost.

Submit completed case investigations or notify of incomplete case investigations using the Washington Disease Reporting System (WDRS): This may create a cost for local health jurisdictions who are not using WDRS. However, all local health jurisdictions have moved to WDRS and can receive technical support from the Department to support the transition to WDRS. Use of a statewide secure electronic disease surveillance system is a key component of the public health surveillance structure that allows the state to maintain the global view of cases across jurisdictional lines that is necessary to identify potential cross-jurisdictional linkages between notifiable conditions. In order to effectively manage this cross-jurisdictional oversight,

the Department of Health must have accurate and timely information, and that is provided by WDRS.

Local Health Officer confirmation that each case submitted is based on clinical criteria, or laboratory criteria, or both: Under the chapter, Local Health Officer means "the legally qualified physician who has been appointed as the health officer for the local health jurisdiction under chapter 70.05 RCW, or their designee". This allows the duties assigned to the Local Health Officer under the chapter to be delegated to an appropriate staff. The requirement to confirm that each case is based on clinical criteria, or laboratory criteria, or both is consistent with the Local Health Officer's responsibility to conduct a case investigation, a part of which is to confirm that a reported case of a condition is accurately identified and in alignment with case standards, such as the CDC, NNDSS, CSTE case definitions.

The draft rules support the Local Health Officer in this duty by:

- Including in the definition of case "… a diagnosis or suspected diagnosis of a condition made by a health care provider, health care facility, or laboratory based on clinical criteria, or laboratory criteria, or both, such as the Centers for Disease Control and Prevention, National Notifiable Diseases Surveillance System, Council of State and Territorial Epidemiologists case definitions."
- Including case and laboratory report content requirements for health care providers and facilities the "diagnosis or suspected diagnosis of the condition", and for laboratories the "test method used" and presumptive and final "test results".

Overall the proposed substantive changes to WAC 246-101-510 improve the identification of cases and helps to ensure connection to care and public health prevention measures that could identify community reservoirs of disease are appropriately implemented, potentially decreasing the number and severity of community cases over time.

WAC 246-101-513, Content of notifications, investigation reports, and outbreak reports
Description of substantive proposed rule changes:
The proposed rule creates a new section and makes the following changes to content requirements for notifications, investigation reports, and outbreak reports submitted to the Department of Health:

- Adds the following content requirements for notifications:
  - Date local health jurisdiction was notified of the case;
  - Condition diagnosis date;
  - Patient date of birth; and
  - Patient sex.
- Adds the following content requirements for investigation reports:
  - Patient ethnicity, patient race, and patient preferred language[11]
  - Pregnancy status (pregnant, not pregnant, or unknown) for patients with hepatitis B infection who are fourteen to fifty years of age;
  - Investigation start date;
  - Investigation completion date;

[11] See Appendix B for ethnicity, race, and preferred language reporting categories.

- Initial notification source;
- Hospitalization status of patient;
- Whether the patient died during the illness;
- Probable geographic region of exposure;
- Whether the patient traveled out of the country (as applicable);
- Whether the case is associated with an ongoing outbreak investigation; and
- Data used to verify the case meets clinical criteria, laboratory criteria, or both.

- Adds the number of people potentially exposed to the content requirements for outbreak reports.

Description of how these proposed changes support the goals and objectives of the statute being implemented:
Notification content: The proposed notification content is necessary to create a unique WDRS record for each unique case of a condition. The potential burdens and benefits of using a singular statewide surveillance system are identified above.

Investigation report content: Not all cases of notifiable conditions are investigated by local health jurisdictions. Local health jurisdictions exercise discretion in which cases pose the greatest risk to public health in any one jurisdiction. The proposed investigation report content applies to only those cases that are investigated by local health jurisdictions and includes information unique to these investigations. All information is necessary to create a complete understanding of the notifiable condition and the circumstances of the event which allows public health, including the Department of Health, to gain the benefits described above.

Outbreak report content: Outbreak reports are rare and are limited to three pieces of information necessary to identify the organism, source, and number of individuals potentially exposed to the organism. As outbreaks typically require rapid public health action to identify all the individuals that may have contracted and prevent the spread of disease, the required report content is limited to only those pieces of information that are absolutely necessary to act.

Department of Agriculture

Description of substantive proposed rule changes:
The proposed rules add two new sections that would establish the following requirements for the Washington State Department of Agriculture (WSDA):

- WAC 246-101-805, Duties, requires:
  - WSDA to submit animal case reports for zoonotic diseases to the Department of Health;
  - WSDA to confirm receipt of animal case reports for specifically named conditions; and
  - Consultation between the Department of Health and WSDA for animal cases submitted to the Department of Health
- WAC 246-101-810, Content of animal case reports, creates requirements for the content of each animal case report submitted to the Department of Health.

Description of how these proposed changes support the goals and objectives of the statute being implemented:

These proposed changes compliment the repeal of requirements for veterinarians in WAC 246-101-405 to submit case reports for suspected human cases of notifiable conditions, under which public health did not receive any case reports. These proposed changes are expected to dramatically improve public health surveillance of zoonotic disease by gathering information about potential exposures prior to suspected human illness. The proposal to require consultation on animal cases is expected to improve investigation outcomes conducted by public health staff with animal owners, including business owners, by cooperatively working with WSDA staff who have carefully worked with their constituents to create productive and trusting relationships.

Department of Labor and Industries

Description of substantive proposed rule changes:
The Washington State Department of Labor and Industries (L&I) requested the Board and Department to require notification by health care providers and health care facilities for five new categorical conditions to promote occupational health and safety. The three agencies worked in close collaboration to assess the feasibility of the changes and to include the requirements in the draft rules. Following this internal work, the agencies shared the requested changes and draft rule requirements with the TAC (on which L&I held a member seat) and worked together to get feedback from other stakeholders. As a result of this collaborative work, the Board and Department included four of the five requested conditions in the proposed rules with some modifications based on feedback from TAC members and other stakeholders.

Description of how these proposed changes support the goals and objectives of the statute being implemented:
The proposed changes improve surveillance of conditions acquired from occupational exposures in work environments and allow L&I to implement public health interventions, including technical assistance and education to improve work environments and prevent further work place exposures to hazardous conditions.

Sovereign Tribal Nations and Tribal Epidemiology Centers

Description of substantive proposed rule changes:
The proposed rule changes the definition of public health authority to include sovereign tribal nations and tribal epidemiology centers. While this change is not substantive as tribal nations and tribal epidemiology centers are already public health authorities and have the authority to conduct surveillance and investigate cases of disease, some who are subject to the requirements of chapter 246-101 WAC did not understand this and pointed to the definition and the absence of tribal nations and tribal epidemiology center as the definitive law.

Description of how these proposed changes support the goals and objectives of the statute being implemented:
The proposed change will improve tribal nations' and tribal epidemiology centers' ability to conduct notifiable conditions surveillance and case investigations by improving cooperation and coordination with health care providers, health care facilities, laboratories, and local health jurisdictions.

WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities

The proposed rule merges the notification requirements for health care facilities included in Table HF-1 of the current rule into Table HC-1 of the proposed rule, and repeals WAC 246-101-301, Notifiable conditions and health care facilities. All conditions requiring notification to public health authorities by health care providers and health care facilities are included in Table HC-1 of WAC 246-101-101 of the proposed rules, which specifies the time frame for notification of each case, who must be notified, and who must provide the notification (health care providers, health care facilities, or both).

Significant changes to the current rule are described below by condition. All other amendments to the proposed rule are editorial only, clarifying the rule without changing its effect, and are not considered significant under RCW 34.05.328.

Most health care providers and health care facilities included in the proposed rules are already required to comply with chapter 246-101 WAC and would only be impacted by changes to the proposed rules. However, the proposed changes to WAC 246-101-010 would expand the definition of "health care facility" to include "enhanced service facility licensed under chapter 70.97 RCW." This change to the definition would require enhanced service facilities (ESF) to report the notifiable conditions listed in the draft section of WAC 246-101-101 for the first time. These facilities were not previously included in the rules because the first ESF opened in 2014,[12] and this is the first broad proposed revision of the notifiable conditions rules since that time. These facilities are included in the proposed rules at the request of the Washington State Department of Social and Health Services. These facilities are congregate care settings and, as in any congregate living setting, early identification of cases of notifiable conditions are essential in reducing transmission within that setting.

These facilities would be required to send case reports and lab requisition forms using the reporting method, data components, and follow-up confirmation protocols required under WAC 246-101-105, WAC 246-101-110, and 246-101-115. The estimated annual costs to ESFs to comply with all four of these sections are discussed here, because the ESF cost questionnaire asked facilities to estimate the costs of complying WAC 246-101-101 **while** considering the reporting methods and data components that would be required with each case report and lab requisition form under WAC 246-101-105, WAC 246-101-110, and 246-101-115. The one-time costs associated with complying with section -105 and section -115 are discussed below with the other costs associated with those sections. There are five ESFs in the state, one of which completed the cost questionnaire. This response indicated that probable costs of complying with the rule would be minimal as a result of only needing to report an estimated two cases per year. The estimated costs to ESFs for reporting all conditions is estimated at about $16 per year[2 cases (~.2 hours X $40 per hour)].

Amoebic meningitis

Description of Proposed Change

[12] https://www.dshs.wa.gov/sites/default/files/ALTSA/rcs/documents/Enhanced%20Services%20Facilities%20Fact%20Sheet.pdf

The proposed rule adds amoebic meningitis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction immediately after diagnosis, without delay, twenty-four hours a day, seven days a week.

Mode of Transmission

Amoebic meningitis is a rare brain infection that is usually fatal and is caused by the free-living amoeba *Naegleria fowleri*. The amoeba lives in:

- Bodies of warm freshwater, such as lakes and rivers
- Geothermal (naturally hot) water, such as hot springs
- Warm water discharge from industrial plants
- Untreated geothermal (naturally hot) drinking water sources
- Swimming pools that are poorly maintained or minimally-chlorinated
- Water heaters
- Soil[13]

Naegleria fowleri destroys brain tissue after entering the body through the nose and moving to the brain. Most infections have been linked to swimming mainly in southern states including Florida and Texas but also in Minnesota, and some very rare cases have been linked to using contaminated tap water to irrigate nasal passages.[14]

Estimated Number of Cases

In the 56 year period from 1962–2018, 145 U.S. infections have been reported to CDC with no more than 8 cases reported each year.[15] Given the mode of transmission and the occurrence of the condition primarily in southern states, the Department assumes no cases of the condition will be reported in Washington State.

Probable Benefits

The following description of the burden of illness on individuals who have contracted amoebic meningitis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of amoebic meningitis as a result of establishing notification requirements for the condition.

Initial symptoms of amoebic meningitis start one to seven days after infection and include headache, fever, nausea, vomiting, and stiff neck. As the disease progresses, symptoms expand to include confusion, lack of attention to people and surroundings, loss of balance, seizures, and hallucinations. After symptoms start, the disease progresses rapidly and usually causes death within one to 12 days.[16]

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[13] https://www.cdc.gov/meningitis/amebic.html Accessed January 14, 2020
[14] https://www.cdc.gov/meningitis/amebic.html Accessed January 14, 2020
[15] https://www.cdc.gov/meningitis/amebic.html Accessed January 14, 2020
[16] https://www.cdc.gov/meningitis/amebic.html Accessed January 14, 2020

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

Though the Department assumes no cases of amoebic meningitis will be submitted to public health authorities, the probable costs for a health care provider or facility to prepare and submit a single case report is estimated at $82.50 (.5 hours X $165 per hour) resulting in an estimated cost range of $0 to $82.50.

Anaplasmosis[17]

Description of Proposed Change

The proposed rule adds anaplasmosis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Some members of the regulated community have been submitting case reports for anaplasmosis as an "other rare disease of public health significance" as defined in the current rules. However, anaplasmosis is not included individually in either Table HC-1 or Table HF-1 of the current rules. The draft rule clearly establishes notification requirements for the condition by naming it specifically in Table HC-1 of the proposed rules rather than as an unnamed condition within a categorical condition.

Mode of Transmission

Anaplasmosis is an emerging tick-borne disease in the United States carried by the Western black-legged tick[18] and caused by various bacteria in the genus *Anaplasma.* In addition to being tick-borne, *Anaplasma phagocytophilum* may occasionally be transmitted in medical procedures involving blood, marrow, or organ transfers.[19] There have also been possible infections through contact with infected deer blood (through cleaning deer carcasses) or perinatal transmission of bacteria or disease during childbirth or potentially breastfeeding.[20,21] More studies need to be conducted to verify these alternative modes of transmission.

Estimated Number of Cases

From 2004 to 2013, four cases of anaplasmosis were reported in Washington State, two with exposure in the Upper Midwest (both in 2013) and two with exposures in the northeastern United

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[17] For more detailed information on this condition, see Appendix A

[18] Ticks : Washington State Department of Health. http://www.doh.wa.gov/CommunityandEnvironment/Pests/Ticks. Accessed December 8, 2016.

[19] Human ehrlichiosis and anaplasmosis - UpToDate. https://www.uptodate.com/contents/human-ehrlichiosis-and-anaplasmosis?source=search_result&search=anaplasmosis&selectedTitle=1~25#H1.Accessed December 8, 2016.

[20] Human ehrlichiosis and anaplasmosis - UpToDate. https://www.uptodate.com/contents/human-ehrlichiosis-and-anaplasmosis?source=search_result&search=anaplasmosis&selectedTitle=1~25#H1. Accessed December 8, 2016.

[21] Horowitz HW, Kilchevsky E, Haber S, et al. Perinatal transmission of the agent of human granulocytic ehrlichiosis. *The New England journal of medicine*. 1998;339(6):375-378. doi:10.1056/NEJM199808063390604.

States (2004, 2007).[22] To date, no locally-exposed Washington cases of anaplasmosis have been reported; however, very low levels of *Anaplasma phagocytophilum* have been found in ticks from Washington State,[23] and multiple cases have been diagnosed in dogs in Washington.[24] Based on this information, the Department estimates zero to five anaplasmosis cases may be submitted to public health authorities annually.

Probable Benefits

The following description of the burden of illness on individuals who have contracted anaplasmosis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of anaplasmosis as a result of establishing notification requirements for the condition.

Anaplasmosis can cause symptoms that range from mild (e.g. headache, muscle pain) to severe (e.g. renal failure, meningoencephalitis, seizures, coma) and in rare cases can result in death.[25, 26]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit zero to five Anaplasmosis case reports is estimated to range from $0 to $412.50 per year [5 cases (.5 hours X $165 per hour)].

Anthrax (*Bacillus anthracis* and confirmed *Bacillus cereus* biovar *anthracis* only –Do not report all *Bacillus cereus*)

Description of Proposed Change

The proposed rule adds confirmed *Bacillus cereus* biovar *anthracis* as a notifiable form of anthrax requiring health care providers and health care facilities to submit case reports to the local health jurisdiction immediately after diagnosis consistent with the current notification requirements of anthrax.

Mode of Transmission

[22] Washington State Department of Health. Washington State Communicable Disease Report 2014. 2015.

[23] ibid.

[24] Zoonotic and vector-borne diseases from A to Z. http://www.kingcounty.gov/healthservices/health/ehs/zoonotics/diseases.aspx. Accessed December 8, 2016.

[25] Biggs HM, Behravesh CB, Bradley KK, et al. Diagnosis and Management of Tickborne Rickettsial Diseases: Rocky Mountain Spotted Fever and Other Spotted Fever Group Rickettsioses, Ehrlichioses, and Anaplasmosis — United States. *MMWR Recommendations and Reports*. 2016;65(2):1-44.

[26] Dahlgren FS, Heitman KN, Drexler NA, Massung RF, Behravesh CB. Human granulocytic anaplasmosis in the United States from 2008 to 2012: a summary of national surveillance data. *Am J Trop Med Hyg*. 2015;93(1):66–72.

While anthrax is currently a notifiable condition, the proposed addition of confirmed *Bacillus cereus* biovar *anthracis* is based on the 2017 CDC, National Notifiable Diseases Surveillance System (NNDSS), Council of State and Territorial Epidemiologists (CSTE) case definition for anthrax. This case definition indicates that *Bacillus cerius* biovar anthracis has emerged as a cause of anthrax-like disease in animals and expresses anthrax toxin genes. The proposed rule adds the condition because it could hypothetically cause anthrax-like disease in humans.

Estimated Number of Cases

The Department assumes no cases of *Bacillus cereus* biovar *anthracis* will be submitted given the emerging nature of the condition.

Probable Benefits

Establishing notification requirements for *Bacillus cereus* biovar *anthracis* supports public health in early identification of a potential emerging zoonotic disease that may have a significant impact on population health, and contributes to surveillance activities at the national and international level to implement control measures on a broader scale if needed.

Probable Costs

Though the Department assumes no cases of *Bacillus cereus* biovar *anthracis* will be submitted to public health authorities, the probable costs for a health care provider or facility to prepare and submit a single case report is estimated at $82.50 (.5 hours X $165 per hour) resulting in an estimated cost range of $0 to $82.50.

Babesiosis[27]

Description of Proposed Change

The proposed rule adds babesiosis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Some members of the regulated community have been submitting case reports for babesiosis as an "other rare disease of public health significance" as defined in the current rules. However, babesiosis is not included individually in either Table HC-1 or Table HF-1 of the current rules. The draft rule clearly establishes notification requirements for the condition by naming it specifically in Table HC-1 of the proposed rules rather than as an unnamed condition within a categorical condition.

Mode of Transmission

Babesiosis is an emerging tick-borne infectious disease in the United States caused by several types of *Babesia*.[28,29] Most recently, human *Babesia duncani* has emerged in the pacific

[27] For more detailed information on this condition, see Appendix A

[28] New York State Department of Health. Babesiosis. https://www.health.ny.gov/diseases/communicable/babesiosis/fact_sheet.htm. Accessed December 1, 2016.

[29] Gelfand JA, Vannier EG. Clinical manifestations, diagnosis, treatment, and prevention of babesiosis. https://www.uptodate.com/contents/clinical-manifestations-diagnosis-treatment-and-prevention-of-babesiosis?source=see_link. Accessed December 1, 2016.

northwest.[30] Infection also occurs via blood donation and transfusion of contaminated blood.[31,32,33] Another rare mode of transmission is congenital transmission (present from birth) from an infected mother to baby during pregnancy or delivery.[34,35]

Estimated Number of Cases

There have been seven cases of human babesiosis in Washington State between 1990 and 2013. Of the seven confirmed cases, three were transfusion-transmitted *Babesia duncani,* one was *Babesia divergens-like,* and three were *Babesia microti*.[36] Due to climate change, ticks have spread to new areas and are emerging in areas previously unaffected. Epidemiological trends in Washington State indicate that, although there remains low incidence of parasitic disease such as babesiosis, the condition is still a concern as rates in endemic states are growing.[37] The Department estimates zero to three cases of babesiosis may be submitted annually to public health authorities in Washington State.

Probable Benefits

The following description of the burden of illness on individuals who have contracted Babesiosis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of Babesiosis as a result of establishing notification requirements for the condition.

Symptoms of Babesiosis range from asymptomatic to severe. Complications resulting from human *Babesia* infection include severe hemolytic anemia, severely low platelet count, low and unstable blood pressure, blood clots and bleeding, malfunction of vital organs (e.g. kidneys, lungs, and liver) and, in rare cases, death.[38,39,40,41]

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[30] ibid.

[31] ibid.

[32] Centers for Disease Control and Prevention. Parasites-Babesiosis. https://www.cdc.gov/parasites/babesiosis/index.html. Accessed December 1, 2016.

[33] New York State Department of Health. Babesiosis. https://www.health.ny.gov/diseases/communicable/babesiosis/fact_sheet.htm. Accessed December 1, 2016.

[34] ibid.

[35] Centers for Disease Control and Prevention. Parasites-Babesiosis. https://www.cdc.gov/parasites/babesiosis/index.html. Accessed December 1, 2016.

[36] Virus WN, Virus M, Virus I. Washington State COMMUNICABLE DISEASE REPORT 2014. 2014.

[37] Trends E. Lyme Disease. 20(6). http://www.doh.wa.gov/Portals/1/Documents/5100/420-002-epitrends2015-06.pdf.

[38] Gelfand JA, Vannier EG. Clinical manifestations, diagnosis, treatment, and prevention of babesiosis. https://www.uptodate.com/contents/clinical-manifestations-diagnosis-treatment-and-prevention-of-babesiosis?source=see_link. Accessed December 1, 2016.

[39] Centers for Disease Control and Prevention. Parasites-Babesiosis. https://www.cdc.gov/parasites/babesiosis/index.html. Accessed December 1, 2016.

[40] New York State Department of Health. Babesiosis. https://www.health.ny.gov/diseases/communicable/babesiosis/fact_sheet.htm. Accessed December 1, 2016.

[41] Boustani MR, Gelfand JA. Babesiosis. *State-Of-The-Art Clin Artic*. 1995:611-615.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit zero to three babesiosis case reports is estimated to range from $0 to $247.50 per year [3 cases (.5 hours X $165 per hour)].

Baylisascariasis

Description of Proposed Change

The proposed rule adds baylisascariasis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within 24 hours of diagnosis.

Mode of Transmission

Baylisascaris infection is caused by a roundworm found in raccoons. *Baylisascaris* can infect people and animals, including dogs, when they accidentally ingest the eggs in soil, water, or on objects contaminated with raccoon feces. When ingested, the eggs hatch into larvae in the intestine and travel throughout the body, affecting organs and muscles. *Baylisascaris* infection can affect the brain and spinal cord, eye, or other organs. Though infectious, *Baylisascaris* infection is not spread from one person to another. [42]

Estimated Number of Cases

As of 2018, 23 cases of *Baylisascaris* disease have been documented in the United States, including in California, Illinois, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, New York, Oregon, Washington, and Pennsylvania. Of these cases, one was identified in Washington State. However, the CDC suspects some cases are incorrectly diagnosed or not diagnosed.[43]

Probable Benefits

The following description of the burden of illness on individuals who have contracted baylisascariasis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of baylisascariasis as a result of establishing notification requirements for the condition.

Symptoms of infection depend on how many *Baylisascaris* eggs are ingested and where in the body the larvae moves. The larger the number of eggs ingested and the location of the infection, the more serious the symptoms. Severe infections result from infection of the eyes, organs, or brain and often lead to death, with six fatalities out of the 23 neurological cases in the United

[42] https://www.cdc.gov/parasites/baylisascaris/index.html Accessed January 14, 2020
[43] https://www.cdc.gov/parasites/baylisascaris/index.html Accessed January 14, 2020

States as of 2018. Symptoms develop over one to two weeks and can include nausea, tiredness, liver enlargement, loss of coordination, lack of attention to people and surroundings, loss of muscle control, blindness, coma, and death.[44]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit zero to one Baylisascariasis case report is estimated at $82.50 per year (.5 hours X $165 per hour).

Campylobacteriosis

Description of Proposed Change

The proposed rule adds campylobacteriosis as a notifiable condition for health care facilities requiring them to submit case reports to the local health jurisdiction within three business days of diagnosis. The proposed change makes notification for this condition consistent with the current notification requirements for health care providers.

Mode of Transmission

Campylobacteriosis is caused by *Campylobacter* bacteria and is the most common bacterial cause of diarrheal illness in the United States. People get *Campylobacter* infection by eating raw or undercooked poultry, or something that touched raw or undercooked poultry; from other foods, including seafood, meat, and produce; by contact with animals; and by drinking untreated water. Very rarely, people have become infected through a transfusion of contaminated blood. *Campylobacter* does not usually spread from one person to another.[45]

Estimated Number of Cases

Data from the Foodborne Diseases Active Surveillance Network (FoodNet) indicate that about 20 cases are diagnosed each year for every 100,000 people. Many more cases go undiagnosed or unreported. CDC estimates *Campylobacter* infection affects 1.5 million U.S. residents every year.[46]

Campylobacteriosis is a notifiable condition for health care providers and laboratories under the current chapter, and the Department receives 1,000 to 1,300 case reports per year. The Department does not expect the number of cases submitted to the Department to increase as a result of the proposed rule.[47]

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[44] https://www.cdc.gov/parasites/baylisascaris/index.html Accessed January 14, 2020
[45] https://www.cdc.gov/campylobacter/faq.html Accessed January 14, 2020
[46] https://www.cdc.gov/campylobacter/faq.html Accessed January 14, 2020
[47] https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/Campylobacteriosis Accessed January 14, 2020

Probable Benefits

The following description of the burden of illness on individuals who have contracted campylobacteriosis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of campylobacteriosis as a result of establishing notification requirements for the condition.

The *Campylobacter* species is the most common notifiable bacterial cause of enteric infection in the United States. People with *Campylobacter* infection usually have diarrhea (often bloody), fever, and stomach cramps. Nausea and vomiting may accompany the diarrhea. These symptoms usually start two to five days after the person ingests *Campylobacter* and last about one week.[48]

Sometimes *Campylobacter* infections cause complications, such as irritable bowel syndrome, temporary paralysis, and arthritis. In people with weakened immune systems, such as those with a blood disorder, AIDS, or receiving chemotherapy, *Campylobacter* occasionally spreads to the bloodstream and causes a life-threatening infection.[49]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

Campylobacteriosis is a notifiable condition for health care providers and laboratories under the current chapter, and the Department receives 1,000 to 1,300 case reports per year.[50] While the rule change clarifies that health care facilities are also subject to the notification requirement for campylobacteriosis, it is considered a significant change under RCW 34.05.328. Even though it is considered significant, the Department does not expect the number of cases submitted to the Department to increase as a result of the proposed rule.

Candida auris **infection or colonization**

Description of Proposed Change

The proposed rule adds *Candida auris* infection or colonization as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within 24 hours of diagnosis.

Mode of Transmission

Candida auris infections are an emerging global public health threat. *Candida auris* is of great concern because it causes serious bloodstream infections that can result in death, antifungal medications are often not effective in treating *Candida auris*, it has spread rapidly to 12 countries

[48] https://www.cdc.gov/campylobacter/faq.html Accessed January 14, 2020
[49] https://www.cdc.gov/campylobacter/faq.html Accessed January 14, 2020
[50] https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/Campylobacteriosis Accessed January 14, 2020

around the globe since it was first discovered in 2009, it is difficult to identify unless specialized laboratory technology is used which increases misidentification of infection leading to inappropriate treatment, and it spreads easily from person to person in hospitals and nursing homes and from contaminated surfaces and equipment.[51]

Those at highest risk of *Candida auris* infection appear to be recent residents of nursing homes who had lines and tubes in their bodies (such as breathing tubes, feeding tubes and central venous catheters), people who have had recent surgery, people with diabetes, and people who have used broad-spectrum antibiotic and antifungal medications. Patients of all ages have acquired *Candida auris* infections, from preterm infants to the elderly.[52]

Estimated Number of Cases

Cases of *Candida auris* infections have been reported in the United States, though none have yet been reported in Washington State. Reporting is expected to increase as laboratories test for the fungus.[53] The Department assumes *Candida auris* infections will begin to emerge in Washington State over the next five years. For the purposes of estimating costs of the proposed rule, the Department assumes the number of cases will be 17, the number of confirmed cases seen in California as of October 31, 2019.[54]

Probable Benefits

The following description of the burden of illness on individuals who have contracted *Candida auris* infections illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of *Candida auris* as a result of establishing notification requirements for the condition.

Because patients with *Candida auris* infection are often patients in a hospital being treated for another serious illness, it can be difficult to identify symptoms of *Candida auris*. Patients with weakened immune systems are more likely to get *Candida auris* infections. Symptoms of the infection are related to the affected part or system of the body, and often manifest as bloodstream infections, wound infections, or ear infections. Invasive *Candida auris* infections can be fatal. Information from a limited number of patients show that 30 to 60% of people with *Candida auris* infections have died. However, many of these people had other serious illnesses that also increased their risk of death.[55]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

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[51] https://www.cdc.gov/fungal/candida-auris/c-auris-drug-resistant.html Accessed January 14, 2020
[52] https://www.cdc.gov/fungal/candida-auris/ Accessed January 14, 2020
[53] https://www.cdc.gov/fungal/candida-auris/tracking-c-auris.html Accessed January 14, 2020
[54] https://www.cdc.gov/fungal/candida-auris/tracking-c-auris.html#states Accessed January 14, 2020
[55] https://www.cdc.gov/fungal/candida-auris/patients-qa.html Accessed January 14, 2020

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit 17 *Candida auris* infection case reports is estimated at $1,402.50 per year [17 cases (.5 hours X $165 per hour)].

Carbapenem-resistant Enterobacteriaceae (CRE) infections limited to: *Klebsiella* species, *E. coli*, *Enterobacter* species[56]

Description of Proposed Changes

The proposed rule adds carbapenem-resistant Enterobacteriaceae (CRE) infections as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Mode of Transmission

CREs are a family of germs that have emerged in the United States during the past decade that are highly resistant to carbapenem antibiotics.[57]

A CRE infection is acquired through exposure to CRE bateria, usually spread from person to person through contact with infected or colonized people, particularly contact with their wounds or stool. CRE often enters the body of an uninfected individual through medical devices like ventilators, intravenous catheters, urinary catheters, or wounds caused by injury or surgery. CRE infections are most commonly seen among people in healthcare settings (e.g. hospitals, long-term care facilities, skilled nursing facilities, and long-term acute care hospitals). In these settings, CRE infections generally occur among sick patients who are receiving treatment for other conditions, patients whose care requires devices like ventilators, urinary catheters, or intravenous catheters, as well as patients on prolonged antibiotic regimens.[58]

Evidence suggests that acknowledging the risk of CRE could help decrease cases. Specifically, failing to "adequately clean and disinfect" surfaces, equipment, and machines for both CRE and non-CRE patients has played a role in the spread of CRE within healthcare facilities.[59] Facilities with strict precautions around patients who have CRE show a decrease in new CRE prevalence (in a 3-year study).[60] Removing the "focus of infection" (e.g. ventilator) is independently associated with surviving CRE. One review suggests that failure to intervene on CRE is because technicians and providers do not recognize it as an "epidemiologically important organism", and a lack of communication.[61]

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[56] For more detailed information on this condition, see Appendix A

[57] Carbapenem-resistant Enterobacteriaceae in Healthcare Settings | HAI | CDC. http://www.cdc.gov/HAI/organisms/cre/. Accessed December 8, 2016.

[58] Carbapenem-resistant Enterobacteriaceae (CRE) Infection: Patient FAQs | HAI | CDC. http://www.cdc.gov/hai/organisms/cre/cre-patientfaq.html. Accessed December 8, 2016.

[59] Chitnis AS, Caruthers PS, Rao AK, et al. Outbreak of Carbapenem-Resistant Enterobacteriaceae at a Long-Term Acute Care Hospital: Sustained Reductions in Transmission through Active Surveillance and Targeted Interventions. *Infect Control Hosp Epidemiol*. 2012;33(10):984-992.

[60] Landman D, Babu E, Shah N, et al. Transmission of carbapenem-resistant pathogens in New York City hospitals: progress and frustration. *J Antimicrob Chemother*. 2012;67(6):1427-1431.

[61] Debby BD, Ganor O, Yasmin M, et al. Epidemiology of carbapenem resistant Klebsiella pneumoniae colonization

Estimated Number of Cases

Washington State has a low CRE prevalence.[62] However, there has been a dramatic increase of CRE infections across the nation in the last decade.[63,64] CRE is of epidemiological importance because of its potential to spread exponentially in health care settings.

In 2014, 97 cases of CRE were submitted to labs in Washington State. Of these cases, 78% met the case surveillance definition when tested, 32% of these samples tested positive for CRE-isolates. These positive results came from 20 different patients; two patients had isolates of more than one CRE.[14] Since 2012, 10-20 cases of CRE were reported each year.[65] These unique characteristics of CRE may contribute to underreporting and opportunities for improvement regarding surveillance.[66] The Department estimates Washington State has 300 cases annually of CRE.

Probable Benefits

The following description of the burden of illness on individuals who have contracted CRE illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of CRE as a result of establishing notification requirements for the condition.

Klebsiella species and *Escherichia coli (E. coli)* are Enterobacteriaceae bacteria that normally live in the human gut that have become CRE.[67] Sometimes *E. coli* and *Klebsiella* can spread outside the gut and cause serious infections, such as urinary tract infections, bloodstream infections, wound infections, and pneumonia. Enterobacteriaceae can cause infections in people in both healthcare and community settings.[68]

Antimicrobial resistance is globally recognized as one of the greatest contemporary threats to public health. The prevalence of CRE infections has increased over the last decade.[69] Some CRE

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in an intensive care unit. *Eur J Clin Microbiol Infect Dis*. 2012;31(8):1811-1817.

[62] State Department of Health - DCHS - Communicable Disease Epidemiology W. CRE Surveillance Update.

[63] Carbapenem-resistant Enterobacteriaceae in Healthcare Settings | HAI | CDC. http://www.cdc.gov/HAI/organisms/cre/. Accessed December 8, 2016.

[64] State Department of Health - DCHS - Communicable Disease Epidemiology W. Washington State Annual Communicable Disease Report 2014.

[65] State Department of Health - DCHS - Communicable Disease Epidemiology W. Carbapenem-Resistant Enterobacteriaceae Reporting and Investigation Guideline.

[66] State Department of Health - DCHS - Communicable Disease Epidemiology W. CRE Surveillance Update.

[67] Carbapenem-resistant Enterobacteriaceae in Healthcare Settings | HAI | CDC. http://www.cdc.gov/HAI/organisms/cre/. Accessed December 8, 2016.

[68] Carbapenem-resistant Enterobacteriaceae (CRE) Infection: Patient FAQs | HAI | CDC. http://www.cdc.gov/hai/organisms/cre/cre-patientfaq.html.

[69] Morrill HJ, Pogue JM, Kaye KS, Laplante KL. Treatment Options for Carbapenem-Resistant Enterobacteriaceae Infections.

bacteria have become resistant to almost all available antibiotics and can be deadly. One report cites they can contribute to death in up to 50% of patients who become infected.[70]

Every year roughly 600 deaths result from CRE infections. The CDC estimates more than 9,000 healthcare-associated infections are caused by the two most common types of CRE, carbapenem-resistant *Klebsiella* species and *Escherichia* species, each year in the United States. CRE infections are a public health concern because CRE mortality rates are high and range from 18% to 48% depending on therapy.[71]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit 300 CRE infection case reports is estimated at $24,750 per year [300 cases (.5 hours X $165 per hour)].

Chagas disease

Description of Proposed Changes

The proposed rule adds Chagas disease as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Mode of Transmission

People can become infected with Chagas disease, which is caused by the parasite *Trypanosoma cruzi*, in a variety of ways. Where Chagas is common (Latin America), people become infected primarily through vector-borne transmission. The vector is the triatomine bug, which is also called the "kissing bug". The bugs can become infected with the parasite *Trypanosoma cruzi* and spread it through defecation. The bugs are nocturnal and tend to bite on the face. The feces can enter the body through the skin at the site of the insect bite or through open membranes such as wounds, eyes, or the mouth. Chagas disease is not communicable person to person.[72]

In the United States, the triatomine bug is less common, but people can also be infected with Chagas disease through congenital transmission (from a pregnant woman to baby), blood

[70] Carbapenem-resistant Enterobacteriaceae in Healthcare Settings | HAI | CDC. http://www.cdc.gov/HAI/organisms/cre/. Accessed December 8, 2016.

[71] Morrill HJ, Pogue JM, Kaye KS, Laplante KL. Treatment Options for Carbapenem-Resistant Enterobacteriaceae Infections.

[72] Centers for Disease Control and Prevention. CDC - Chagas Disease - Detailed Fact Sheet. https://www.cdc.gov/parasites/chagas/gen_info/detailed.html. Published April 16, 2019. Accessed April 25, 2019.

transfusions, organ transplants, consumption of uncooked food, or accidental laboratory exposure.[73]

Estimated Number of Cases

There are currently only estimates of the prevalence of Chagas disease in the United States. Cases of Chagas disease in the United States are rare because most are chronic infections.[74] The estimated prevalence for Chagas disease was 238,091 cases in 2012-2013 nationwide. In 2005 the estimate was 300,167 individuals with Chagas disease in the United States.[75] The incidence of Chagas disease in the United States is unclear in the literature, but incidence from congenital transmission has been documented and is 1-10% in infants born to infected mothers.[76] The majority of Chagas cases in Washington State occur in persons who previously resided in endemic areas. The Department estimates Washington State has between 231 and 2,310 cases annually of Chagas disease, although the majority of these remain undiagnosed and therefore will go unreported. The Department estimates that Washington State will have 10-20 cases reported annually.

Probable Benefits

The following description of the burden of illness on individuals who have contracted Chagas disease illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of Chagas disease as a result of establishing notification requirements for the condition.

"Chagas disease causes the highest burden of any parasitic disease in the Western hemisphere."[77] The severity of the disease depends on factors related to the individual such as age, the way the disease was transmitted, and the strain of the *Trypanosoma cruzi* parasite.[78] The disease can be asymptomatic or life-threatening. In most cases, there are two phases of Chagas disease. Most chronic cases remain asymptomatic, but about 30% of cases develop complications.[79] Acute phase symptoms can range from mild (rash, vomiting, fever, etc.)[80] to severe with young children running the risk of death from inflammation and infection of the heart or inflammation of the

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[73] Centers for Disease Control and Prevention. CDC - Chagas Disease - Detailed Fact Sheet. https://www.cdc.gov/parasites/chagas/gen_info/detailed.html. Published April 16, 2019. Accessed April 25, 2019.
[74] Bennett C, Straily A, Haselow D, et al. Chagas Disease Surveillance Activities — Seven States, 2017. MMWR Morb Mortal Wkly Rep. 2018;67(26):738-741. doi:10.15585/mmwr.mm6726a2
[75] Bern C, Montgomery SP. An Estimate of the Burden of Chagas Disease in the United States. Clin Infect Dis. 2009;49(5):e52-e54. doi:10.1086/605091
[76] Survey of obstetrician-gynecologists in the United States about Chagas disease. - PubMed - NCBI. https://www.ncbi.nlm.nih.gov/pubmed/20889886. Accessed April 25, 2019.
[77] Bern C, Montgomery SP. An Estimate of the Burden of Chagas Disease in the United States. Clin Infect Dis. 2009;49(5):e52-e54. doi:10.1086/605091
[78] Centers for Disease Control and Prevention. CDC - Chagas Disease - Detailed Fact Sheet. https://www.cdc.gov/parasites/chagas/gen_info/detailed.html. Published April 16, 2019. Accessed April 25, 2019.
[79] Bennett C, Straily A, Haselow D, et al. Chagas Disease Surveillance Activities — Seven States, 2017. MMWR Morb Mortal Wkly Rep. 2018;67(26):738-741. doi:10.15585/mmwr.mm6726a2
[80] Chagas Disease. Johns Hopkins Medicine Health Library. https://www.hopkinsmedicine.org/health/conditions-and-diseases/chagas-disease. Accessed April 25, 2019.

brain. The infection can also be severe for people with weakened immune symptoms such as patients undergoing chemotherapy or those with HIV infection.[81]

In the chronic phase, the disease can last for decades or someone's entire life. Most people are asymptomatic, but about 30% of people develop complications.[82,83] Symptoms in the chronic phase include cardiac complications, enlarged heart, heart failure, altered heart rate or rhythm, cardiac arrest, gastrointestinal complications, enlarged esophagus, enlarged colon, difficulties eating, and difficulties passing stool.[84]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit 10 to 20 case reports for Chagas disease is estimated to range from $825.00 to $1,650 per year [10 cases (.5 hours X $165 per hour) and 20 cases (.5 hours X $165 per hour)].

Coccidioidomycosis[85]

Description of Proposed Change

The proposed rule adds coccidioidomycosis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Mode of Transmission

Coccidioidomycosis, also known as Valley Fever, is an emerging fungal disease in Washington caused by *Coccidioides* sp. fungus. Most recently, the fungus has been found in south-central Washington.[86] Most coccidioidomycosis cases are caused by inhalation of airborne spores.[87,88]

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[81] Centers for Disease Control and Prevention. CDC - Chagas Disease - Detailed Fact Sheet. https://www.cdc.gov/parasites/chagas/gen_info/detailed.html. Published April 16, 2019. Accessed April 25, 2019.

[82] Centers for Disease Control and Prevention. CDC - Chagas Disease - Detailed Fact Sheet. https://www.cdc.gov/parasites/chagas/gen_info/detailed.html. Published April 16, 2019. Accessed April 25, 2019.

[83] Chagas Disease. Johns Hopkins Medicine Health Library. https://www.hopkinsmedicine.org/health/conditions-and-diseases/chagas-disease. Accessed April 25, 2019.

[84] Chagas Disease. Johns Hopkins Medicine Health Library. https://www.hopkinsmedicine.org/health/conditions-and-diseases/chagas-disease. Accessed April 25, 2019.

[85] For more detailed information on this condition, see Appendix A

[86] Definition of Valley Fever | Coccidioidomycosis | Types of Fungal Diseases | Fungal | CDC. *Cdcgov*. 2016. Available at: http://www.cdc.gov/fungal/diseases/coccidioidomycosis/definition.html. Accessed December 6, 2016.

[87] Primary coccidioidal infection. *Uptodatecom*. 2016. Available at: http://www.uptodate.com/contents/primary-coccidioidal-infection?source=search_result&search=Coccidioidomycosis&selectedTitle=1~100#H1895492. Accessed December 6, 2016.

[88] Coccidioidomycosis: Background, Pathophysiology, Etiology. *Emedicinemedscapecom*. 2016. Available at: http://emedicine.medscape.com/article/215978-overview. Accessed December 6, 2016.

The most common species that affect humans are *Coccidioides immitis* or *Coccidioides posadasii.*[89]

Estimated Number of Cases

Reported incidence of coccidioidomycosis in Washington State has increased each year. For example, prior to 2014, up to six travel-associated cases were reported each year. Between 2010 and 2014, nine cases with exposure in south-central Washington State were reported, and in 2014 twenty-one cases were reported. Of these, eighteen were travel-related and three were exposed in south-central Washington.[90]

While coccidioidomycosis was not previously considered endemic to Washington State, recent research suggests further investigation is needed to identify cases acquired in eastern Washington. Local environmental conditions in eastern Washington, such as its soil, support the presence of *Coccidioides*.[91] The Department estimates we have 50 to 80 cases of coccidioidomycosis annually in Washington State.

Probable Benefits

The following description of the burden of illness on individuals who have contracted coccidioidomycosis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of coccidioidomycosis as a result of establishing notification requirements for the condition.

Coccidioidomycosis can be mild (asymptomatic or flu-like symptoms that may resolve spontaneously) or can in some cases lead to skin infections, serious or long-term lung problems, or infection of the central nervous system, skin, or bones and joints.[92]

Coccidioidomycosis is nationally notifiable per CDC and CSTE standards.[93] Establishing notification requirements for coccidioidomycosis will contribute to surveillance activities at the national and international level to implement more effective control measures on a broader scale.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes

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[89] Primary coccidioidal infection. *Uptodatecom*. 2016. Available at: http://www.uptodate.com/contents/primary-coccidioidal-infection?source=search_result&search=Coccidioidomycosis&selectedTitle=1~100#H1895492. Accessed December 6, 2016.

[90] *Washington State COMMUNICABLE DISEASE REPORT 2014*. 1st ed. Washington State: Washington State Department of Health; 2016. Available at: http://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReport2014.pdf. Accessed December 6, 2016.

[91] Coccidioidomycosis | Summary | NNDSS. 2016. Available at: https://wwwn.cdc.gov/nndss/conditions/coccidioidomycosis/. Accessed December 6, 2016.

[92] Symptoms of Valley Fever | Coccidioidomycosis | Types of Fungal Diseases | Fungal | CDC. *Cdcgov*. 2016. Available at: http://www.cdc.gov/fungal/diseases/coccidioidomycosis/symptoms.html. Accessed December 6, 2016.

[93] Coccidioidomycosis | Summary | NNDSS. *Wwwncdcgov*. 2016. Available at: https://wwwn.cdc.gov/nndss/conditions/coccidioidomycosis/. Accessed December 6, 2016.

of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit 50 to 80 coccidioidomycosis case reports is estimated to range from $4,125.00 to $6,600.00per year [50 cases (.5 hours X $165 per hour) and 80 cases (.5 hours X $165 per hour)].

Coronavirus: MERS-associated coronavirus

Description of Proposed Change

The proposed rule adds Middle East Respiratory Syndrome (MERS) associated coronavirus (MERS-CoV) as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction immediately after diagnosis, without delay, twenty-four hours a day, seven days a week.

Mode of Transmission

MERS-CoV is caused by a coronavirus that has been linked to travel to, or residence in, countries in and near Arabian Peninsula. MERS-CoV has spread from ill people to others through close contact, such as caring for or living with an infected person. Anyone can get MERS-CoV and patient ages have ranged from younger than 1 year to patients 99 years old. [94]

Estimated Number of Cases

Only two patients in the United States have ever tested positive for MERS-CoV infection, both in May 2014.[95] The Department assumes no cases of MERS-CoV will be submitted to public health authorities.

Probable Benefits

The following description of the burden of illness on individuals who have contracted MERS-CoV illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of MERS-CoV as a result of establishing notification requirements for the condition.

Some people infected with MERS-CoV have no or mild symptoms (such as cold-like symptoms); however, most MERS-CoV patients develop severe respiratory illness with symptoms of fever, cough, and shortness of breath. Others have had diarrhea and nausea or vomiting. For many people with MERS-CoV, more severe complications follow the initial illness, such as pneumonia and kidney failure. Death has occurred in about 3 or 4 out of every 10 cases of reported MERS-CoV. Most of the deaths involved people with a pre-existing medical condition that weakened their immune system, or an unknown underlying medical condition.

[94] https://www.cdc.gov/coronavirus/mers/index.html Accessed on January 14, 2020
[95] https://www.cdc.gov/coronavirus/mers/index.html Accessed on January 14, 2020

Symptoms of MERS start to appear about five or six days after a person is exposed but can range from two to 14 days to appear.[96]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

Though the Department assumes no cases of MERS-CoV will be submitted to public health authorities, the probable costs for a health care provider or facility to prepare and submit a single case report is estimated $82.50 (.5 hours X $165 per hour) resulting in an estimated cost range of $0 to $82.50.

Coronavirus: Novel coronavirus (SARS-CoV-2)

Description of Proposed Change

The proposed rule adds Novel coronavirus (SARS-CoV-2) as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction immediately after diagnosis, without delay, twenty-four hours a day, seven days a week.

Mode of Transmission

There is still much that is unknown about how SARS-CoV-2 (COVID-19), a new coronavirus, spreads. Coronaviruses are a large family of viruses that are common in several species of animals, including camels, cattle, cats, and bats. Animal coronaviruses can infect people and then spread between people. Person-to-person generally happens among close contacts (about 6 feet). Person-to-person spread is thought to occur mainly via respiratory droplets produced when an infected person coughs or sneezes. Evidence suggests that under certain conditions airborne transmission is possible as is transmission from contaminated surfaces. People who are infected but do not show symptoms can also spread the virus to others.[97]

Estimated Number of Cases

This virus has only recently emerged and it is too early to make an informed estimate of the number of cases that may be reported in Washington State in future years. The Department estimates, with the caveat that this estimate is not based on much data and with many unknowns such as rate of vaccine uptake and if this will resurge annually like influenza, that up to 75,000 cases of COVID-19 may be reported in Washington annually in future years.

While this estimate is based on very little data and many unknowns, the estimated annual number of influenza cases in Washington over the past five years provides some indication of where this estimate comes from:

Flu Season	Number of Lab	CDC Estimated	Estimated number of

[96] https://www.cdc.gov/coronavirus/mers/index.html Accessed on January 14, 2020
[97] https://www.cdc.gov/coronavirus/2019-ncov/about/transmission.html. Accessed December 30, 2020.

	Confirmed Influenza-Associated Deaths Reported in Washington State	Influenza Death Rate (percent of **symptomatic** illness resulting in death)	symptomatic influenza cases in Washington State (influenza associated deaths/estimated death rate)
2015-2016	67	0.097%	69,072
2016-2017	278	0.131%	212,214
2017-2018	296	0.136%	217,647
2018-2019	245	0.096%	255,208
2019-2020	114	0.058%	196,551
2015-2020 Average			**190,138**
Adapted from information available from: Influenza-Associated Deaths in Washington[98] and CDC Estimated Death Rates[99]			

Probable Benefits

This is a newly emerging condition with symptoms that range from fever, cough, and shortness of breath to death.[100] Between January 1, 2020 and December 31, 2020 – 237,165 laboratory confirmed COVID-19 cases, 14,748 hospitalizations, and 3,461 deaths had been reported in Washington State.[101] A coordinated public health response that includes notification of suspected and confirmed cases is an essential part of curbing the outbreak, minimizing the number of cases, and reducing stress on the medical system. The ability to identify cases and conduct contract tracing is also an essential component of the state's ability to ease social distancing requirements, which is needed to reduce the mental health impact and economic impacts of the outbreak.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit up to 75,000 COVID-19 case reports is estimated to cost up to $6,187,500.00 per year [75,000 cases (.5 hours X $165 per hour)].

***Cryptococcus gattii* or undifferentiated *Cryptococcus* species (i.e., *Cryptococcus* not identified as *C. neoformans*)[102]**

Description of Proposed Changes

[98] https://www.doh.wa.gov/Portals/1/Documents/5100/420-100-FluUpdateSeason2020.pdf. Accessed January 20, 2021.
[99] https://www.cdc.gov/flu/about/burden/2019-2020.html. Accessed January 20, 2021.
[100] https://www.cdc.gov/coronavirus/2019-ncov/about/symptoms.html. Accessed February 15, 2020.
[101] https://www.doh.wa.gov/Emergencies/COVID19/DataDashboard. Accessed January 4, 2021.
[102] For more detailed information on this condition, see Appendix A.

The proposed rule adds *Cryptococcus gattii* or undifferentiated *Cryptococcus* species as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Mode of Transmission

Cryptococcus gattii is a fungus residing in trees in the Pacific Northwest United States that, when inhaled, can cause mild to severe infection of the lungs and/or central nervous system, meningitis, and death.[103,104] A person exposed to *Cryptococcus gattii* may develop an infection and then show symptoms of the infection anytime from a few weeks after exposure, to six months later, or even years later.[105] Someone with a *Cryptococcus gattii* infection is not contagious at any point and cannot spread the disease to someone else.[106]

Estimated Number of Cases

This condition has emerged in the Pacific Northwest over the past two decades. From 2004 to 2010, health care providers identified 60 cases throughout the United States, of which 15 were in Washington State.[107] From 2012 to 2013, the CDC noted an increase from five to eight cases per year in Washington State.[108] The Department estimates one to ten cases of *Cryptococcus gattii* annually in Washington State.

Probable Benefits

The following description of the burden of illness on individuals who have contracted *Cryptococcus gattii* illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of *Cryptococcus gattii* as a result of establishing notification requirements for the condition.

Cryptococcus gattii exposure can lead to anything from no illness to meningitis and death. The mortality rate from *Cryptococcus gattii* infection ranges from 13 to 33%.[109,110,111]

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[103] Chen S, et al. *Cryptococcus gattii* infection: Clinical features and diagnosis - UpToDate. https://www.uptodate.com/contents/cryptococcus-gattii-infection-clinical-features-and-diagnosis?source=search_result&search=Cryptococcus%20gattii&selectedTitle=1~14. Accessed December 5, 2016.

[104] CDC MMWR. Emergence of Cryptococcus gattii — Pacific Northwest, 2004–2010. *Morb Mortal Wkly Rep*. 2010;59(28):865-868.

[105] CDC. Symptoms of C. gattii Infection | Fungal Disease | CDC. https://www.cdc.gov/fungal/diseases/cryptococcosis-gattii/symptoms.html. Accessed December 5, 2016.

[106] CDC. Sources of C. gattii | Fungal Disease | CDC. https://www.cdc.gov/fungal/diseases/cryptococcosis-gattii/causes.html. Accessed December 5, 2016.

[107] CDC MMWR. Emergence of Cryptococcus gattii — Pacific Northwest, 2004–2010. *Morb Mortal Wkly Rep*. 2010;59(28):865-868.

[108] Espinel-Ingroff A, Kidd SE. Current trends in the prevalence of Cryptococcus gattii in the United States and Canada. *Infect Drug Resist*. 2015;8:89-97. doi:10.2147/IDR.S57686.

[109] Chen S, et al. Cryptococcus gattii infection: Clinical features and diagnosis - UpToDate. https://www.uptodate.com/contents/cryptococcus-gattii-infection-clinical-features-and-diagnosis?source=search_result&search=Cryptococcus%20gattii&selectedTitle=1~14. Accessed December 5, 2016.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit one to ten *Cryptococcus gattii* case reports is estimated to range from $82.50 to $825.00 per year [1 case (.5 hours X $165 per hour) and 10 cases (.5 hours X $165 per hour)].

Cysticercosis

Description of Proposed Changes

The proposed rule adds cysticercosis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Mode of Transmission

Cysticercosis is a parasitic tissue infection caused by larval cysts of the tapeworm *Taenia solium*. These larval cysts infect brain, muscle, or other tissue, and are a major cause of adult onset seizures in most low-income countries. A person gets cysticercosis by swallowing eggs found in the feces of a person who has an intestinal tapeworm. People living in the same household with someone who has a tapeworm have a much higher risk of getting cysticercosis than people who don't.

Cysticercosis occurs globally. The highest rates of infection are found in areas of Latin America, Asia, and Africa that have poor sanitation and free-ranging pigs that have access to human feces. Although uncommon, cysticercosis can occur in people who have never traveled outside of the United States. For example, a person infected with a tapeworm who does not wash his or her hands might accidentally contaminate food with tapeworm eggs while preparing it for others. In the United States, cysticercosis is considered one of the Neglected Parasitic Infections (NPIs), a group of five parasitic diseases that have been targeted by CDC for public health action.

Estimated Number of Cases

Given the rarity of the condition in the United States, the Department assumes zero to two cases of the condition are likely to be reported in Washington State.

Probable Benefits

The following description of the burden of illness on individuals who have contracted cysticercosis illustrates some of the societal benefits of notifiable conditions surveillance

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[110] CDC. Sources of C. gattii | Fungal Disease | CDC. https://www.cdc.gov/fungal/diseases/cryptococcosis-gattii/causes.html. Accessed December 5, 2016.

[111] DC. C. gattii Infection Statistics | Fungal Disease | CDC. http://www.cdc.gov/fungal/diseases/cryptococcosis-gattii/statistics.html. Accessed December 5, 2016.

described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of cysticercosis as a result of establishing notification requirements for the condition.

Symptoms can occur months to years after infection, usually when the cysts start dying. When cysts die, the brain or other tissue around the cyst may swell. The pressure of the swelling is what usually causes the symptoms of the infection. Sometimes symptoms are caused by the pressure of a cyst in a small space.

Cysts, called cysticerci, can develop in the muscles, eyes, brain, or the spinal cord. Symptoms caused by the cysts depend on the location, size, number, and stage of the cysts. Cysts in the muscles generally do not cause symptoms. However, lumps can develop under the skin that can become tender. Cysts in the eyes, although rare, may float in the eye and cause blurry or disturbed vision. Infection in the eyes may also cause swelling or detachment of the retina.

Neurocysticercosis (cysts in the brain, spinal cord) symptoms depend on where and how many cysts are found in the brain. Seizures and headaches are the most common symptoms. However, confusion, lack of attention to people and surroundings, difficulty with balance, excess fluid around the brain (called hydrocephalus) may also occur. The disease can result in death.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit zero to two Cysticercosis case reports is estimated to range from $0 to $165.00 per year [0 case (.5 hours X $165 per hour) and 2 cases (.5 hours X $165 per hour)].

Disease of Suspected Bioterrorism Origin

Description of Proposed Changes

The proposed rule removes notification requirements for the category of condition “disease of suspected bioterrorism origin”. This is one of three categories of conditions (the other two are “other rare disease of public health significance” and “emerging condition with outbreak potential”) removed from the proposed rules.

Probable Benefits

The Department assumes these categories of conditions are best identified by public health authorities through surveillance activities rather than by health care providers, health care facilities, and veterinarians individually. The Department further assume surveillance will be improved by consistently requiring notification for specific conditions in the proposed rules rather than categories of conditions, along with notification required for outbreaks and suspected outbreaks under WAC 246-101-101, voluntary notification of provisional conditions under WAC 246-101-015, voluntary notification of unusual conditions allowed for under WACs 246-101-105

and -205, and emergency rule making to establish notifiable condition requirements pursuant to chapter 34.05 RCW.

Probable Costs

The Department assumes there will be no costs associated with this proposed change.

Echinococcosis

Description of Proposed Changes

The proposed rule adds echinococcosis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Mode of Transmission

Echinococcosis is a parasitic disease caused by infection with tapeworms of the genus *Echinococcus* and is classified as either cystic echinococcosis (CE) or alveolar echinococcosis (AE). [112]

Cystic echinococcosis is caused by infection with the larval stage of *Echinococcus granulosus*, a tapeworm found in dogs, sheep, cattle, goats, and pigs. Dogs acquire the tapeworm when they eat the organs of animals that contain CE cysts. Once the cysts develop into adult tapeworms, infected dogs shed tapeworm eggs in their feces and contaminate the ground. Tapeworm eggs can stay viable for up to a year in the soil. Sheep, cattle, goats, and pigs can eat tapeworm eggs from the contaminated ground which develop into cysts after hatching in the internal organs. The most common mode of CE transmission to humans is by the accidental consumption of soil, water, or food that has been contaminated by the feces of an infected dog.[113]

Alveolar echinococcosis is caused by infection with the larval stage of *Echinococcus multilocularis*, a tapeworm found in foxes, coyotes, dogs, and small rodents. Like CE, AE is transmitted to humans through ingestion of food or water contaminated with tapeworm eggs. [114]

Estimated Number of Cases

Cystic echinococcosis is found in Africa, Europe, Asia, the Middle East, Central and South America, and in rare cases, North America. Alveolar echinococcosis is found across the globe and is prevalent in the northern latitudes of Europe, Asia, and North America. Few human cases of CE and AE have been reported in the United States, with most infections diagnosed in immigrants from counties where CE and AE are endemic.[115]

While both conditions are considered very rare, between 1990 and 2007, 41 echinococcosis-associated deaths occurred in the United States. Populations with the highest mortality rates were

[112] https://www.cdc.gov/parasites/echinococcosis/ Accessed January 14, 2020
[113] https://www.cdc.gov/parasites/echinococcosis/ Accessed January 14, 2020
[114] https://www.cdc.gov/parasites/echinococcosis/ Accessed January 14, 2020
[115] https://www.cdc.gov/parasites/echinococcosis/gen_info/ce-faqs.html Accessed January 15, 2020

males, Native Americans, Asians/Pacific Islanders, Hispanics, and persons 75 years of age and older.[116]

Based on this information, the Department estimates zero cases to one case of echinococcosis will be submitted to public health authorities annually.

Probable Benefits

The following description of the burden of illness on individuals who have echinococcosis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of echinococcosis as a result of establishing notification requirements for the condition.

Cases of CE are asymptomatic until cysts containing the larval parasites grow large enough to cause discomfort, pain, nausea, and vomiting. The cysts grow over the course of several years before reaching maturity and the rate at which symptoms appear typically depends on the location of the cyst. The cysts are mainly found in the liver and lungs, but can also appear in the spleen, kidneys, heart, bone, and central nervous system, including the brain and eyes. Ruptured cysts are most frequently caused by trauma and may cause mild to severe anaphylactic reactions, even death, as a result of the release of cystic fluid.[117]

Alveolar echinococcosis infection causes parasitic tumors in the liver and may spread to other organs including the lungs and brain. In humans, the larval forms of *Echinococcus multilocularis* develop into cyst-like structures that invade and destroy surrounding tissues and cause discomfort or pain, weight loss, and a general feeling of illness. Alveolar echinococcosis can cause liver failure and death because of the spread into nearby tissues and, rarely, the brain. Alveolar echinococcosis has a mortality rate of between 50% and 75%, especially because most affected people live in remote locations and have poor health care.[118]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit zero to one echinococcosis case reports annually ranging from $0 to $82.50 per year [1 case (.5 hours X $165 per hour) and 3 cases (.5 hours X $165 per hour)].

Ehrlichiosis[119]

[116] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3274497/ Accessed January 15, 2020
[117] https://www.cdc.gov/parasites/echinococcosis/disease.html Accessed January 15, 2020
[118] https://www.cdc.gov/parasites/echinococcosis/disease.html Accessed January 15, 2020
[119] For more detailed information on this condition, see Appendix A

Description of Proposed Change

The proposed rule adds ehrlichiosis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Mode of Transmission

Ehrlichiosis is an emerging tick-borne diseases in the United States caused by various bacteria in the genus *Ehrlichia,* including *Ehrlichia chaffeensis, Ehrlichia ewingii,* and E. *muris eauclairensis*. *Ehrlichia chaffeensis* may occasionally be transmitted in medical procedures involving blood, marrow, or organ transfers.[120] There have also been possible infections through contact with infected deer blood (through cleaning deer carcasses) or perinatal transmission of bacteria or disease during childbirth or breastfeeding.[121,122] More studies need to be conducted to verify these alternative modes of transmission.

Estimated Number of Cases

The number of *Ehrlichia chaffeensis* ehrlichiosis cases reported to the CDC has increased steadily in recent years.[123] In 2010, the national incidence rate for *Ehrlichia chaffeensis* ehrlichiosis was 2.5 cases per million persons.[124] In Washington State, one case of ehrlichiosis due to *Ehrlichia chaffeensis* was reported in 2011, and was associated with travel to the southeastern United States[125] Based on this information, the Department estimates zero to two cases annually of ehrlichiosis may be submitted to public health authorities.

Probable Benefits

The following description of the burden of illness on individuals who have contracted ehrlichiosis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of ehrlichiosis as a result of establishing notification requirements for the condition.

Ehrlichiosis can cause symptoms that range from mild (e.g. headache, muscle pain) to severe (e.g. renal failure, meningoencephalitis, seizures, coma) and in rare cases, death.[126,127] The case

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[120] ibid.

[121] ibid.

[122] Horowitz HW, Kilchevsky E, Haber S, et al. Perinatal transmission of the agent of human granulocytic ehrlichiosis. *The New England journal of medicine*. 1998;339(6):375-378.

[123] Dahlgren FS, Mandel EJ, Krebs JW, Massung RF, McQuiston JH. Increasing incidence of Ehrlichia chaffeensis and Anaplasma phagocytophilum in the United States, 2000-2007. *The American journal of tropical medicine and hygiene*. 2011;85(1):124-131.

[124] Symptoms, Diagnosis, and Treatment | Ehrlichiosis | CDC. https://www.cdc.gov/ehrlichiosis/symptoms/index.html. Accessed December 8, 2016.

[125] Washington State Department of Health. Washington State Communicable Disease Report 2014. 2015.

[126] Biggs HM, Behravesh CB, Bradley KK, et al. Diagnosis and Management of Tickborne Rickettsial Diseases: Rocky Mountain Spotted Fever and Other Spotted Fever Group Rickettsioses, Ehrlichioses, and Anaplasmosis — United States. *MMWR Recommendations and Reports*. 2016;65(2):1-44.

fatality rate has been recorded for *Ehrlichia chaffeensis* ehrlichiosis since 2000 and the highest rates were reported in 2001 and 2003 with case fatality rates over 3%. In all other years, the case fatality rate falls between 1-2%. No deaths have been reported specifically for ehrlichiosis caused by *Ehrlichia ewingii*.[128]

Ehrlichiosis is nationally notifiable per CDC and CSTE standards. Making ehrlichiosis a reportable condition will help identify the geographic site of exposure and track the presence of the diseases in this country.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit zero to two case reports annually ranging from $0 to $165.00 per year [0 cases (.5 hours X $165 per hour) and 2 (.5 hours X $165 per hour)].

Emerging Condition with Outbreak Potential

Description of Proposed Change

The proposed rule removes notification requirements for the category of condition "emerging condition with outbreak potential". This is one of three categories of conditions (the other two are "other rare disease of public health significance" and "disease of suspected bioterrorism origin") removed from the proposed rules.

Probable Benefits

The Department assumes these categories of conditions are best identified by public health authorities through surveillance activities rather than by health care providers, health care facilities, and veterinarians individually. The Department and Board further assume surveillance will be improved by consistently requiring notification for specific conditions in the proposed rules rather than categories of conditions, along with notification required for outbreaks and suspected outbreaks under WAC 246-101-101, voluntary notification of provisional conditions under WAC 246-101-015, voluntary notification of unusual conditions allowed for under WACs 246-101-105 and -205, and emergency rule making to establish notifiable condition requirements pursuant to chapter 34.05 RCW.

Probable Costs

The Department assumes there will be no costs associated with this proposed change.

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[127] Human ehrlichiosis and anaplasmosis - UpToDate. https://www.uptodate.com/contents/human-ehrlichiosis-and-anaplasmosis?source=search_result&search=anaplasmosis&selectedTitle=1~25#H1. Accessed December 8, 2016.

[128] ibid.

Hantaviral infection

Description of Proposed Changes

The proposed rule replaces the current notifiable condition of Hantavirus Pulmonary Syndrome with the more inclusive condition of hantaviral infection. This change expands notification for hantavirus-related illness by including milder forms of hantaviral illness including hemorrhagic fever with renal syndrome. The condition remains notifiable by health care providers and health care facilities within 24 hours of being diagnosed.

Mode of Transmission

Hantaviruses are a family of viruses spread mainly by rodents that can cause varied disease syndromes in people worldwide. The most important hantavirus in the United States that can cause hantavirus pulmonary syndrome (HPS) is the Sin Nombre virus, spread by the deer mouse. Each hantavirus serotype has a specific rodent host species and is spread to people via aerosolized virus that is shed in urine, feces, and saliva, or after exposure to dust from their nests, and less frequently by a bite from an infected host animal. Transmission may also occur when infected urine or these other materials are directly introduced into broken skin or onto the mucous membranes of the eyes, nose, or mouth. Transmission from one human to another may occur but is extremely rare.[129]

Estimated Number of Cases

In 2018, there was one case of hantaviral infection in Washington State. This change is not expected to increase the number of cases reported. The Department estimates zero to five cases annually of hantaviral infection may be submitted to public health authorities in Washington State.

Probable Benefits

The following description of the burden of illness on individuals who have contracted hantaviral infection illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of hantaviral infection as a result of establishing notification requirements for the condition.

Infection with any hantavirus can produce hantavirus disease in people. Hantaviruses in the Americas may cause HPS. Other hantaviruses are found mostly in Europe and Asia and may cause hemorrhagic fever with renal syndrome (HFRS).

Hemorrhagic fever with renal syndrome is a group of clinically similar illnesses caused by hantaviruses from the family Bunyaviridae and includes diseases such as Korean hemorrhagic fever, epidemic hemorrhagic fever, and nephropathia epidemica. The viruses that cause HFRS include Hantaan, Dobrava, Saaremaa, Seoul, and Puumala.

[129] https://www.cdc.gov/hantavirus/index.html Accessed January 15, 2020

Symptoms of HFRS usually develop within one to two weeks after exposure, and rarely can take up to eight weeks to develop. Symptoms begin suddenly and include intense headaches, back and abdominal pain, fever, chills, nausea, and blurred vision. Individuals may have flushing of the face, inflammation or redness of the eyes, or a rash. As symptoms progress, they can include low blood pressure, acute shock, vascular leakage, and acute kidney failure, which can cause severe fluid overload. The severity of the disease varies depending upon the virus causing the infection. Hantaan and Dobrava virus infections usually cause severe symptoms, while Seoul, Saaremaa, and Puumala virus infections are usually more moderate. Complete recovery can take weeks or months.

Depending upon which virus is causing the HFRS, death occurs in less than 1% to as many as 15% of patients. Fatality ranges from 5 to 15% for HFRS caused by Hantaan virus, and it is less than 1% for disease caused by Puumala virus.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes there will be no costs associated with this proposed change.

Hepatitis B (chronic infections) and (perinatal)

Description of Proposed Change

The proposed rule changes the notification time frame from monthly to within three business days for cases of hepatitis B (chronic infections)(laboratory confirmed) initial diagnosis and previously unreported prevalent cases.

This change to the notification time frame also applies to hepatitis B (perinatal)(laboratory confirmed) initial diagnosis and previously unreported cases, which was added to Table HC-1 to clearly show that perinatal cases of chronic hepatitis B are notifiable.

Mode of Transmission

Hepatitis B is a liver infection caused by the hepatitis B virus that is transmitted when blood, semen, or other body fluid from an infected person enters the body of an uninfected person. This can happen through sexual contact; sharing needles, syringes, or other drug-injection equipment; or from mother to baby at birth. Hepatitis B can be a short-term illness, or it can become a long-term, or chronic infection. Risk for chronic infection is related to the age of the person when they became infected: approximately 90% of infected infants become chronically infected, compared with 2%–6% of adults. Chronic hepatitis B can lead to serious health issues including cirrhosis (scarring of the liver) and liver cancer. The best way to prevent hepatitis B is by getting vaccinated.[130]

[130] https://www.cdc.gov/hepatitis/hbv/bfaq.htm#bFAQe06 Accessed January 16, 2020

Estimated Number of Cases

Based on Department notifiable conditions data, in 2016, there were 1,512 chronic hepatitis B cases, 45 acute hepatitis B cases, and 1 perinatal hepatitis B case reported.

Probable Benefits

The following description of the benefits of timelier notification of hepatitis B chronic infections illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of Hepatitis B as a result of modifying the notification requirements for the condition.

Most people with chronic hepatitis B are asymptomatic and can remain symptom free for decades. When and if symptoms do appear, they are similar to acute infection symptoms, but can be a sign of advanced liver disease. About 25% of children who become chronically infected and about 15% of those who become chronically infected after childhood will eventually die from serious liver conditions including cirrhosis and liver cancer. While certain blood tests for liver function might begin to show some abnormalities, some people do not show signs of infection even when the liver becomes diseased.[131]

The monthly notification time frame of the current rule can lead to delays in public health action. Shortening the time frame to within three business days will improve the following:

Preventing disease transmission: Contact evaluation is recommended for chronic hepatitis B infection, including vaccination of susceptible contacts to prevent transmission. Delayed contact evaluation as a result of the longer notification time frame can lead to disease transmission.

Health care-associated infection investigations: Prompt reporting is important for identification of health care-associated cases of hepatitis B investigation and work with facilities is required to prevent further transmission,

Blood bank notification: If a person with hepatitis B has donated blood or plasma within six months prior to onset of symptoms, the blood bank should be notified. Delays in reporting can delay both blood bank notification and the recall of any unused products from the infected donor.

Perinatal hepatitis B prevention: Pregnant women should be tested for hepatitis B early in pregnancy. Infants born to mothers with hepatitis B infection should receive Hepatitis B Immunoglobulin (HBIG) within 12 hours of birth along with a first dose of hepatitis B vaccine. If a woman is tested during her third trimester or at delivery, the current monthly notification time frame can lead to the infant not receiving HBIG and possibly even the birth dose of vaccine. This puts the infant at greater risk of contracting hepatitis B infection.

Case follow-up with hard-to-reach populations: The current notification time frame can lead to investigation delays, increasing the likelihood of being unable to follow-up with people with

[131] https://www.cdc.gov/hepatitis/hbv/bfaq.htm#bFAQe06 Accessed January 16, 2020

hepatitis B who frequently move or change their contact information, for example, people experiencing homelessness and people who inject drugs.

Patient education: Delays in notification can lead to delays in patient education about how to prevent disease transmission, harm reduction practices, hepatitis support services, options for health care access, and alcohol or substance use treatment. This can lead to disease transmission and poorer health outcomes for the person infected.

Follow-up testing: Timely notification allows for contact with identified cases and facilitates faster follow-up testing if needed on a specimen. Rapid investigation allows for retrieval of specimens for genetic sequencing before they are discarded in order to determine linkages between cases.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

Based on cost questionnaire responses, the Department assumes this proposed change will not increase notification costs.

Hepatitis C

Description of Proposed Change

The proposed rule changes the notification time frame for cases of:

- Hepatitis C (acute infection) (laboratory confirmed) from within three business days to within 24 hours;
- Hepatitis C (chronic infections)(laboratory confirmed) initial diagnosis previously unreported cases from monthly to within three business days; and
- Hepatitis C (perinatal)(laboratory confirmed) initial diagnosis previously unreported cases from monthly to within 24 hours. In addition to this significant rule change, the proposed rule adds the condition separately to Table HC-1 to clearly show that perinatal cases of chronic hepatitis C are notifiable.

Mode of Transmission

Hepatitis C is a liver infection caused by the bloodborne hepatitis C virus. Most people become infected with the hepatitis C virus by sharing needles or other equipment to inject drugs. For some people, hepatitis C is a short-term illness but for 70%–85% of people who become infected with the hepatitis C virus, it becomes a long-term, chronic infection. Chronic hepatitis C is a serious disease than can result in long-term health problems and even death. Many people are not aware of their infection because they asymptomatic. There is no vaccine for hepatitis C. The best way to prevent hepatitis C is by avoiding behaviors that can spread the disease, especially injecting drugs.[132]

[132] https://www.cdc.gov/hepatitis/hcv/index.htm Accessed January 16, 2020

Estimated Number of Cases

Based Department 2018 notification data, the estimated number of chronic hepatitis C cases in Washington State, including perinatal cases, is 7,625 annually; and the number of acute hepatitis C cases is 87 annually.

Probable Benefits

The following description of the benefits of timelier notification of hepatitis C chronic infections illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of hepatitis C as a result of modifying the notification requirements for the condition.

The monthly notification time frame of the current rule can lead to delays in public health action. Shortening the time frame to within 24 hours will improve the following:

Case follow-up with hard-to-reach populations: The current notification time frame can lead to investigation delays, increasing the likelihood of being unable to follow-up with people with hepatitis C who frequently move or change their contact information, for example, people experiencing homelessness and people who inject drugs.

Patient education: Delays in notification can lead to delays in patient education about how to prevent disease transmission, harm reduction practices, hepatitis support services, options for health care access, and alcohol or substance use treatment. This can lead to disease transmission and poorer health outcomes for the person infected.

Follow-up testing: Timely notification allows for contact with identified cases and facilitates faster follow-up testing if needed on a specimen.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

Based on cost questionnaire responses, the Department assumes these proposed changes will not increase notification costs.

Hepatitis D

Description of Proposed Change

The proposed rule changes the notification time frame from within three business days to within 24 hours for cases of hepatitis D (acute and chronic infections).

Mode of Transmission

Hepatitis D is a liver infection caused by the hepatitis D virus (HDV). Hepatitis D only occurs in people who are infected with the hepatitis B virus because hepatitis D is an incomplete virus that

requires the helper function of hepatitis B to replicate. Hepatitis D is transmitted through percutaneous or mucosal contact with infectious blood.[133]

Estimated Number of Cases

Hepatitis D case reports have historically been rare in Washington. However, in 2019, the Department of Health received 16 hepatitis D lab reports. Fourteen of these individuals met the hepatitis D case definition. The Department estimates that there are 14 cases of hepatitis D in Washington annually.

Probable Benefits

The following description of the benefits of timelier notification of hepatitis D acute and chronic infections illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of Hepatitis D as a result of modifying the notification requirements for the condition.

The 3 business day notification time frame of the current rule can lead to delays in public health action. Shortening the time frame to within 24 hours will improve the following:

Preventing disease transmission: Contact evaluation is recommended for hepatitis D cases, including vaccination of susceptible contacts to prevent transmission. Delayed contact evaluation as a result of the longer notification time frame can lead to disease transmission.

Health care-associated infection investigations: Prompt reporting is important for identification of health care-associated cases of hepatitis D investigation and work with facilities is required to prevent further transmission.

Blood bank notification: If a person with hepatitis D has donated blood or plasma within eight weeks prior to onset of symptoms, the blood bank should be notified. Delays in reporting can delay both blood bank notification and the recall of any unused products from the infected donor. Case follow-up with hard to reach populations: The current longer reporting timelines can lead to investigation lags, increasing the likelihood of losing a case to follow-up with cases who frequently move and/or change their contact information (e.g., people experiencing homelessness, people who inject drugs).

Patient education: Delays in notification can lead to delays in patient education about how to prevent disease transmission, harm reduction practices, hepatitis support services, options for health care access, and alcohol or substance use treatment. This can lead to disease transmission and poorer health outcomes for the person infected.

Follow-up testing: Timely notification allows for contact with identified cases and facilitates faster follow-up testing if needed on a specimen. Rapid investigation allows for retrieval of specimens for genetic sequencing before they are discarded in order to determine linkages between cases. To better understand hepatitis D epidemiology in Washington State, the

[133] https://www.cdc.gov/hepatitis/hdv/index.htm. Accessed February 15, 2020.

Department currently sends all HDV specimens for CDC for sequencing. Retrieving specimens for whole genome sequencing also plays an integral role in cluster and healthcare associated infection investigations.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

Based on cost questionnaire responses, the Department assumes this proposed change will not increase notification costs.

Histoplasmosis

Description of Proposed Changes

The proposed rule adds histoplasmosis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Mode of Transmission

Histoplasmosis is an infection caused by a fungus called *Histoplasma.* In the United States, *Histoplasma* mainly lives in soil in the central and eastern states, particularly areas around the Ohio and Mississippi River Valleys,[134] though it likely also lives in other parts of the United States.[135] People can get histoplasmosis after breathing in microscopic fungal spores.

Although most cases of histoplasmosis are not associated with outbreaks, histoplasmosis outbreaks linked to a common source do occasionally occur.[136] These outbreaks often involve activities that disturb soil, especially soil that contains bird or bat droppings. Such activities

[134] Manos NE, Ferebee SH, Kerschbaum WF. Geographic variation in the prevalence of histoplasmin sensitivity. Dis Chest. 1956 Jun;29(6):649-68.
[135] CDC. Histoplasmosis in a state where it is not known to be endemic–Montana, 2012-2013. MMWR. 2013 Oct 25;62(42):834-7.
[136] Benedict K, Mody RK. Epidemiology of Histoplasmosis Outbreaks, United States, 1938-2013. Emerg Infect Dis. 2016 Mar;22(3).

include construction,[137] renovation,[138] exploring caves,[139] tilling soil,[140] and cleaning up bird roosting sites.[141]

Estimated Number of Cases

An estimated 60% to 90% of people living in areas surrounding the Ohio and Mississippi River valleys have been exposed to *Histoplasma* at some point in their lifetime.[142] One study calculated the incidence of histoplasmosis in adults aged 65 years and older in the United States to be 3.4 cases per 100,000 population.[143] Rates were highest in the Midwest, with an estimated 6.1 cases per 100,000 population.[144] Due to the mode of transmission, the Department estimates there will likely be no cases of histoplasmosis in Washington State.

Probable Benefits

The following description of the burden of illness on individuals who have contracted histoplasmosis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of histoplasmosis as a result of establishing notification requirements for the condition.

Most people who are exposed to *Histoplasma* never develop symptoms. Other people may develop flu-like symptoms that usually go away on their own within a few weeks to a month. However, some people have symptoms that last longer, especially if the infection becomes severe. [145] Symptoms of histoplasmosis include fever, cough, fatigue, chills, headache, chest pain, and body aches. Symptoms appear between three and 17 days after breathing in the fungal spores. [146]

In some people, usually those who have weakened immune systems, histoplasmosis can develop into a long-term lung infection, or it can spread from the lungs to other parts of the body, such as

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[137] Wheat LJ, Slama TG, Eitzen HE, Kohler RB, French MLV, Biesecker JL. A Large Urban Outbreak of Histoplasmosis – Clinical-Features. Ann Intern Med. 1981;94(3):331-7.
[138] CDC. Outbreak of histoplasmosis among travelers returning from El Salvador–Pennsylvania and Virginia, 2008. MMWR. 2008 Dec 19;57(50):1349-53.
[139] Lyon GM, Bravo AV, Espino A, Lindsley MD, Gutierrez RE, Rodriguez I, et al. Histoplasmosis associated with exploring a bat-inhabited cave in Costa Rica, 1998-1999. Am J Trop Med Hyg. 2004 Apr;70(4):438-42.
[140] Brodsky AL, Gregg MB, Loewenstein MS, Kaufman L, Mallison GF. Outbreak of histoplasmosis associated with the 1970 Earth Day activities. Am J Med. 1973 Mar;54(3):333-42.
[141] Chamany S, Mirza SA, Fleming JW, Howell JF, Lenhart SW, Mortimer VD, et al. A large histoplasmosis outbreak among high school students in Indiana, 2001. The Pediatric infectious disease journal. 2004 Oct;23(10):909-14.
[142] Manos NE, Ferebee SH, Kerschbaum WF. Geographic variation in the prevalence of histoplasmin sensitivity. Dis chest. 1956 Jun;29(6):649-68.
[143] Baddley JW, Winthrop KL, Patkar NM, Delzell E, Beukelman T, Xie F, et al. Geographic distribution of endemic fungal infections among older persons, United States. Emerg Infect Dis. 2011 Sep;17(9):1664-9.
[144] Baddley JW, Winthrop KL, Patkar NM, Delzell E, Beukelman T, Xie F, et al. Geographic distribution of endemic fungal infections among older persons, United States. Emerg Infect Dis. 2011 Sep;17(9):1664-9.
[145] Wheat LJ, Conces D, Allen SD, Blue-Hnidy D, Loyd J. Pulmonary histoplasmosis syndromes: recognition, diagnosis, and management. Semin Respir Crit Care Med. 2004 Apr;25(2):129-44.
[146] Cano MV, Hajjeh RA. The epidemiology of histoplasmosis: a review. Semin Respir Infect. 2001 Jun;16(2):109-18.

the central nervous system (the brain and spinal cord).[147] One study of patients who were hospitalized for histoplasmosis in the United States estimated the crude mortality rate to be approximately 5% for children and 8% for adults.[148] Another study found a six-month mortality rate of 4% among patients with symptomatic histoplasmosis.[149] The overall mortality rate for histoplasmosis is likely lower than these estimates because these studies did not include patients who had less severe forms of the infection.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

Though the Department assumes no cases of histoplasmosis will be submitted to public health authorities, the probable costs for a health care provider or facility to prepare and submit a single case report is $82.50 (.5 hours X $165 per hour) resulting in an estimated cost range of $0 to $82.50.

Hypersensitivity Pneumonitis (HP), Occupational

Description of Proposed Changes

The proposed rule adds work-related hypersensitivity pneumonitis (HP) as a notifiable condition requiring health care providers and health care facilities to submit case reports to the Safety & Health Assessment & Research for Prevention (SHARP) Program at the Washington State Department of Labor and Industries within 30 days of diagnosis. The cases will be received by SHARP's Occupational Respiratory Disease Surveillance Program.

Work-Related Exposure and Disease

Hypersensitivity pneumonitis, also known as extrinsic allergic alveolitis, is a relatively rare pulmonary disease caused by an abnormal immune response following exposure to an inhaled agent.[150] The initial exposure results in immune sensitization and repeated exposure results in inflammation, which can permanently damage the lung if not ceased. HP is on a continuum of disease sometimes categorized as acute, subacute, and chronic.[151] Chronic HP is a progressive disease with features including weight loss, muscle wasting, and finger clubbing with up to 25% of affected individuals experiencing respiratory failure and death over a 5-year period.[152] Bird fancier's lung and farmer's lung are the most commonly recognized presentations of HP.

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[147] Assi MA, Sandid MS, Baddour LM, Roberts GD, Walker RC. Systemic histoplasmosis: a 15-year retrospective institutional review of 111 patients. Medicine. 2007 May;86(3):162-9.
[148] Chu JH, Feudtner C, Heydon K, Walsh TJ, Zaoutis TE. Hospitalizations for endemic mycoses: a population-based national study. Clin Infect Dis. 2006 Mar 15;42(6):822-5.
[149] Ledtke C, Tomford JW, Jain A, Isada CM, van Duin D. Clinical presentation and management of histoplasmosis in older adults. J Am Geriatr Soc. 2012 Feb;60(2):265-70.
[150] American Thoracic Society, *Breathing in America: Diseases, Progress, and Hope*, Chapter 13. https://www.thoracic.org/patients/patient-resources/breathing-in-america/ Accessed Feb 7, 2020
[151] Ibid.
[152] Feary and Szram (2016) Occupational Hypersensitivity Pneumonitis: *What is the evidence, when to think of it, and what to do*. doi: 10.1097/CPM.0000000000000132.

Broadly, the agents that can cause HP include microbial agents, animal antigens, and chemicals. Exposures can occur in the home, in one's wider geographical environment, can be hobby-related, or can occur in the occupational environment. In the occupational environment, examples of the organic exposures relevant to Washington workers include: moldy hay (farmer's lung), contaminated wood dust (sequoiosis), and green coffee bean (coffee-worker's lung).[1] Examples of non-organic exposures relevant to Washington include isocyanates (manufacturing), heated epoxy resin (aerospace), popcorn flavorings, and metalworking fluids.[153,154]

Confirmed cases of HP are likely to be reported by specialists such as occupational medicine physicians or pulmonary doctors. There is no single 'gold standard' test used to confirm HP. Diagnosis is made based on a combination of occupational and environmental exposure history, clinical history, radiology, and immunology findings.[2] Subacute HP presents with a gradual history of malaise, weight loss, shortness of breath and cough, with repeated acute attacks. Emphysema, tobacco history, and asthma are common conditions that coexist with HP.[155] Because of the diverse clinical presentation and many possible differential diagnoses, it is difficult or unlikely to 'suspect' HP at the time referral to a specialist is made.

Estimated Number of Cases

There is limited data on the epidemiology of all-cause hypersensitivity pneumonitis. A recent U.S. study over a 10-year period between 2004 to 2013 identified 7,498 cases of all-cause HP where the mean age was 52 years and 58% were women.[156] The 1-year prevalence rates for HP ranged from 1.67 to 2.71 per 100,000 persons and 1-year cumulative incidence rates ranged from 1.28 to 1.94 per 100,000 persons. Meanwhile, the American Thoracic Society estimates that the occupational burden of all HP is 19% (range 0% to 81.3%) based on data synthesized from 15 publications regarding HP.[157]

Based on this information and the Washington State 2020 population estimate of 7.8 million,[158] we roughly estimate that between 19 to 29 cases of work-related hypersensitivity pneumonitis will be submitted to the SHARP program annually.

Probable Benefits

The adverse effects of HP range from symptom resolution within several days of exposure (acute) to a significantly reduced quality of life (chronic) and possible respiratory failure. Establishing notification requirements for the reporting of work-related HP could help to prevent the disease in similarly exposed workers.

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[153] American Thoracic Society, *Breathing in America: Diseases, Progress, and Hope*, Chapter 13. https://www.thoracic.org/patients/patient-resources/breathing-in-america/ Accessed Feb 7, 2020

[154] Feary and Szram (2016) Occupational Hypersensitivity Pneumonitis: *What is the evidence, when to think of it, and what to do*. doi: 10.1097/CPM.0000000000000132.

[155] Ibid.

[156] Perez et al. (2017). Epidemiology of hypersensitivity pneumonitis among an insured population in the United States: A claims-based cohort analysis. doi: 10.1513/AnnalsATS.201704-288OC.

[157] Blanc et al. (2019) An official American Thoracic Society and European Respiratory Society Statement, *The Occupational Burden of Nonmalignant Respiratory Disease*. doi: 10.1164/rccm.201904-0717ST.

[158] http://worldpopulationreview.com/states/washington-population/ Accessed Feb 7, 2020

The Washington State Occupational Respiratory Disease Surveillance program will receive the notifiable case reports. Founded in 2002, this program conducts research and prevention efforts for occupational diseases including the currently notifiable conditions of work-related asthma and Coccidioidomycosis. [159] Examples of typical disease prevention efforts include annual surveillance reporting, employer site visits, industry hazard alerts, employer mailings, trade journal articles, peer-reviewed articles, trade and professional presentations, and OSHA referrals to L&I's Division of Occupational Safety and Health.[160]

In the case of occupational HP reporting, the identification of a case within an employer would be enough to warrant a workplace site visit to characterize the causal exposure agent, identify the appropriate industrial hygiene controls, and to facilitate medical monitoring of similarly exposed individuals. Because of our capacity to undertake these kinds of prevention activities, notifiable reporting of work-related HP could facilitate meaningful prevention efforts.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit 19 to 29 HP case reports annually ranging from $1567.50 to $2392.50 per year [19 cases (0.5 hours X $165 per hour) and 29 cases (0.5 hours X $165 per hour)].

Other rare diseases of public health significance

Description of Proposed Change

The proposed rule removes notification requirements for the category of condition "other rare diseases of public health significance". This is one of three categories of conditions (the other two are "disease of suspected bioterrorism origin" and "emerging condition with outbreak potential") removed from the proposed rules.

Probable Benefits

The Department assumes these categories of conditions are best identified by public health authorities through surveillance activities rather than by health care providers, health care facilities, and veterinarians individually. The Department and Board further assume surveillance will be improved by consistently requiring notification for specific conditions in the proposed rules rather than categories of conditions, along with notification required for outbreaks and suspected outbreaks under WAC 246-101-101, voluntary notification of provisional conditions under WAC 246-101-015, voluntary notification of unusual conditions allowed for under WACs 246-101-105 and -205, and emergency rule making to establish notifiable condition requirements pursuant to Chapter 34.05 RCW.

[159] https://lni.wa.gov/safety-health/safety-research/ongoing-projects/occupational-respiratory-disease#prevention-resources Accessed Feb 7, 2020
[160] Ibid.

Probable Costs

The Department assumes there will be no costs associated with this proposed change.

Relapsing fever (borreliosis)

Description of Proposed Change

The proposed rule changes the notification time frame from within 24 hours to within three business days for cases of relapsing fever (borreliosis).

Mode of Transmission

Relapsing fever is caused by *Borrelia* bacteria that can cause recurring bouts of fever, headache, muscle and joint pain, and nausea. There are three types of relapsing fever caused by:

- Tick-borne relapsing fever
- Louse-borne relapsing fever
- *Borrelia miyamotoi* disease (sometimes called hard tick relapsing fever)[161]

Borrelia bacteria are transmitted to humans infected "soft tick" bites of the genus *Ornithodoros*. Humans are typically exposed to soft ticks when they sleep in rodent-infested cabins. The ticks feed briefly while the person is sleeping. Bites are painless and most people are unaware that they have been bitten.[162]

There are several *Borrelia* species that cause relapsing fever that are usually associated with specific species of ticks. For instance, *Borrelia hermsii* is transmitted by *Ornithodoros hermsi* ticks, whose preferred habitat and set of hosts are higher altitudes (1500 to 8000 feet) where it is associated primarily with ground or tree squirrels and chipmunks.[163] *Borrelia miyamotoi* disease occurs in the same places Lyme disease is found and is transmitted by the blacklegged tick.[164]

Tick-borne relapsing fever most commonly occurs during the summer in western states: Arizona, California, Colorado, Idaho, Kansas, Montana, Nevada, New Mexico, Oklahoma, Oregon, Texas, Utah, Washington, and Wyoming.[165]

Louse-borne relapsing fever is caused by a spiral-shaped bacteria, *Borrelia recurrentis*, which is transmitted from human to human by the body louse. Louse-borne relapsing fever outbreaks most commonly occur in conditions of overcrowding and social disruption.[166]

Estimated Number of Cases

There were 483 cases of TBRF reported in the western United States during the years 1990-2011. Most of these cases were transmitted in California, Washington, and Colorado. Assuming

[161] https://www.cdc.gov/relapsing-fever/index.html Accessed January 16, 2020
[162] https://www.cdc.gov/relapsing-fever/transmission/index.html Accessed January 16, 2020
[163] https://www.cdc.gov/relapsing-fever/transmission/index.html Accessed January 16, 2020
[164] https://www.cdc.gov/relapsing-fever/index.html Accessed January 16, 2020
[165] https://www.cdc.gov/relapsing-fever/distribution/index.html Accessed January 16, 2020
[166] https://www.cdc.gov/relapsing-fever/resources/louse.html Accessed January 16, 2020

distribution is equal, and the prevalence remains consistent, the Department estimates five to ten cases of relapsing fever will be identified annually in Washington State.

Today, louse-borne relapsing fever causes sporadic illness and outbreaks in sub-Saharan Africa, particularly in regions affected by war and in refugee camps. Louse-borne relapsing fever is commonly found in Ethiopia, Sudan, Eritrea, and Somalia. Illness can be severe, with mortality of 30 to 70% in outbreaks.[167] However, louse-borne relapsing fever is rare in the United States and the Department estimates there will be no cases identified.

Probable Benefits

The Department assumes changing the notification timeframe from within 24 hours to within 3 business days potentially reduces the burden of notification on health care providers and facilities by allowing more time to submit a case report.

Probable Costs

The Department assumes there are no probable costs associated with this proposed change.

Rickettsia infection[168]

Description of Proposed Changes

The proposed rule adds rickettsia infection as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Some members of the regulated community have been submitting case reports for rickettsia infection as spotted fever rickettsiosis under "other rare disease of public health significance" as defined in the current rules. However, rickettsia infection is not included individually in either Table HC-1 or Table HF-1 of the current rules. The draft rule clearly establishes notification requirements for the condition by naming it specifically in Table HC-1 of the proposed rules rather than as an unnamed condition within a categorical condition.

Mode of Transmission

There are 19 *rickettsia* species that can cause infection in humans. The majority of those species are transmitted through tick, though they can also be transmitted via fleas or the human body louse. In addition, transmission of a few rickettsial diseases have been reported (rarely) from blood transfusions or by organ transplantation. Rocky Mountain spotted fever (*R. rickettsia*) is one of the most commonly acquired rickettsial diseases in the United States. Rocky Mountain spotted fever (RMSF) is discussed in more detail here as an example of rickettsial diseases.[169]

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[167] https://www.cdc.gov/relapsing-fever/resources/louse.html Accessed January 16, 2020

[168] For more detailed information on this condition, see Appendix A

[169] Centers for Disease Control and Prevention. Chapter 4 Travel-Related Infectious Diseases: Rickettsial Diseases. Available from https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/rickettsial-including-spotted-fever-and-typhus-fever-rickettsioses-scrub-typhus-anaplasmosis-and-ehr#table419. Accessed January 18, 2020.

RMSF fever is a tick-borne disease (transmitted by the Rocky Mountain wood tick in Washington State) caused by the bacterium *Rickettsia rickettsii (R. rickettsii)*.[170]

Estimated Number of Cases

On any given year, zero to three cases of RMSF are identified in Washington State. Only some cases are contracted in the state, and some are due to travel outside of the United States.[171] The Department estimates zero to five cases of all rickettsia infection (including RMSF) may be submitted to public health authorities annually.

Probable Benefits

The following description of the burden of illness on individuals who have contracted RMSF illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of cases of the condition as a result of establishing notification requirements for it.

Signs of RMSF include fever, headache, abdominal pain, lack of appetite, rash, vomiting, conjunctival infection (red eyes), and muscle pain. RMSF can be fatal in the first week of symptoms if not treated.[172] RMSF has a case-fatality rate of 25% among untreated individuals.[173] The progression of symptoms varies greatly and while complications are rare patients who have a severe infection may develop long term health issues including amputations.[174]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit zero to five Rickettsia infection case reports estimated at $0 to $412.50 per year [5 cases (.5 hours X $165 per hour)].

Silicosis

[170] Centers for Disease Control and Prevention. Geographic distribution of ticks that bite humans. Ticks | CDC. http://www.cdc.gov/ticks/geographic_distribution.html. Published June 2015. Accessed December 7, 2016.
[171] Washington State Department of Health. Ticks. http://www.doh.wa.gov/CommunityandEnvironment/Pests/Ticks. Accessed December 7, 2016.
[172] Centers for Disease Control and Prevention. Rocky Mountain Spotted Fever (RMSF) | Symptoms, Diagnosis, and Treatment. Available from http://www.cdc.gov/rmsf/symptoms/index.html. Published 2010. Accessed December 7, 2016.
[173] Centers for Disease Control and Prevention. Rocky Mountain Spotted Fever (RMSF) | Statistics and Epidemiology. Available from http://www.cdc.gov/rmsf/stats/index.html. Published September 2013. Accessed December 7, 2016.
[174] Centers for Disease Control and Prevention. Rocky Mountain Spotted Fever (RMSF) | Symptoms, Diagnosis, and Treatment. Available from http://www.cdc.gov/rmsf/symptoms/index.html. Published 2010. Accessed December 7, 2016.

Description of Proposed Changes

The proposed rule adds silicosis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the Safety & Health Assessment & Research for Prevention (SHARP) Program at the Washington State Department of Labor and Industries within 30 days of diagnosis. The cases will be received by SHARP's Occupational Respiratory Disease Surveillance Program.

Work-Related Exposure and Disease

Silica is found naturally in the environment and is divided into two main groups, crystalline and non-crystalline (amorphous) silica.[175] The most common type of crystalline silica is quartz. Workers are exposed to high levels of silica through activities like blasting, cutting, drilling, or grinding materials that contain silica. Jobs with high exposure to silica dust include construction labor, heavy machine operator, abrasive blasting, engineered stone fabrication and handling, mining, stone work, and concrete work.

Silicosis is one of the oldest known occupational diseases, recognized since ancient times. The federal Occupational Safety and Health Administration (OSHA) issued a final rule on Respirable Crystalline Silica with a reduced allowable workplace exposure level to crystalline silica in 2016.[176] The Washington State Department of Labor and Industries adopted a similar Respirable Crystalline Silica Rule in 2018.[177] These rules were created because workers continue to be exposed to hazardous levels of crystalline silica and are at risk for silicosis in modern times.

Silicosis is a progressive, irreversible, fibrotic lung disease resulting from inhalation and pulmonary deposition of respirable dust containing crystalline silica.[178] The causal relationship between inhalation of crystalline silica and the development of silicosis is well-established and not under dispute.[179] Silicosis can be fatal.

There are three classification types of silicosis: acute silicosis (also called silicoproteinosis or alveolar proteinosis), simple silicosis (also called chronic or nodular silicosis), progressive massive fibrosis (PMF, a progression of simple silicosis), and accelerated silicosis (a rapidly progressive form of simple silicosis). Time from first exposure to onset of disease varies with the intensity of exposure and may be as short as a few weeks for acute silicosis to as long as 20 years for simple silicosis and progressive massive fibrosis.[180]

Estimated Number of Cases

The Washington State Occupational Health Indicators report is based on hospitalization data and estimates that the number of hospital discharges with a primary or contributing diagnosis of silicosis for the years 2010 through 2018 ranged from <10 to 12 discharges per year.[181] The rate

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[175] https://www.atsdr.cdc.gov/toxfaqs/TF.asp?id=1492&tid=290 Accessed January 30, 2020

[176] https://www.osha.gov/laws-regs/regulations/standardnumber/1910, 29 Code of Federal Regulations, Section 1910.1053 Respirable crystalline Silica, Accessed Jan 30, 2020
https://apps.leg.wa.gov/WAC/default.aspx?cite=296-840 Washington Administrative Code Chapter 296-840 (Respirable Crystalline Silica) Accessed January 30, 2020

[178] https://www.atsdr.cdc.gov/toxfaqs/TF.asp?id=1492&tid=290 Accessed January 30, 2020

[179] Ibid.

[180] Ibid.

[181] https://lni.wa.gov/dA/a687d98a99/80_15_2020_WA_Indicators_2020Jan.pdf Accessed January 30, 2020

of hospitalizations per million residents is estimated at 1.6 to 2.2 per year.[2] SHARP's occupational respiratory disease surveillance program identified just 1 case of silicosis over the two-year period of 2016-2017 based on workers' compensation data.[182]

Based on this information, the SHARP program estimates one to eight cases of silicosis will be submitted to Labor & Industries annually.

Probable Benefits

The adverse effects of silica are limited to inhalation exposures experienced by workers in occupational settings. Establishing notification requirements for the reporting of silicosis could help to prevent the disease in workers similarly exposed to silica.

The Washington State Occupational Respiratory Disease Surveillance system will receive the notifiable case reports and this system already covers the identification and tracking of silicosis cases using workers' compensation as a data source. Notifiable reporting will improve the current surveillance system because not all eligible persons use the workers' compensation system.

The surveillance program, founded in 2002, is able to conduct research and prevention efforts for occupational diseases including the currently notifiable conditions of work-related asthma and Coccidioidomycosis.[183] Examples of typical disease prevention efforts include annual surveillance reporting, employer site visits, industry hazard alerts, employer mailings, trade journal articles, peer-reviewed articles, trade and professional presentations, and OSHA referrals to L&I's Division of Occupational Safety and Health.[184] One Washington worker is part of a national case series in an emerging (2019) trend for the development of silicosis in young engineered stone fabrication workers.[185] This topic is likely to remain one of our major prevention initiatives for the coming years, and notifiable reporting would support our efforts.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit one to three silicosis case reports annually ranging from $82.50 to $660 per year [1 case (.5 hours X $165 per hour) and 8 cases (.5 hours X $165 per hour)].

Taeniasis

Description of Proposed Changes

The proposed rule adds taeniasis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

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[182] https://lni.wa.gov/dA/57e359945e/64-14-2019_AsthmaTechReport_2016-17v2.pdf Accessed January 30, 2020
[183] https://lni.wa.gov/safety-health/safety-research/ongoing-projects/occupational-respiratory-disease#work-related-asthma Accessed January 30, 2020
[184] https://lni.wa.gov/safety-health/safety-research/ongoing-projects/occupational-respiratory-disease#prevention-resources Accessed January 30, 2020
[185] https://www.cdc.gov/mmwr/volumes/68/wr/mm6838a1.htm Accessed January 30, 2020

Mode of Transmission

Taeniasis is a parasitic infection caused by the tapeworm species *Taenia saginata* (beef tapeworm), *Taenia solium* (pork tapeworm), and *Taenia asiatica* (Asian tapeworm). Humans can become infected by eating raw or undercooked beef or pork.[186]

Taenia eggs can survive in a moist environment and remain infective for days to months. Cows and pigs become infected after feeding in areas that are contaminated with *Taenia* eggs from human feces.[187]

Estimated Number of Cases

Taeniasis usually occurs in the United States among Latin American immigrants.[188] New cases in the United States are likely less than 1,000 per year, though the exact number is unknown.[189] Department assumes zero to five case reports for taeniasis may be submitted annually.

Probable Benefits

The following description of the burden of illness on individuals who have contracted taeniasis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of taeniasis as a result of establishing notification requirements for the condition.

Most people with tapeworm infections have no or mild symptoms. Tapeworms can cause digestive problems including abdominal pain, loss of appetite, weight loss, and upset stomach. The most visible sign of taeniasis is the active passing of tapeworm segments in the feces. In rare cases, tapeworm segments become lodged in the appendix, or the bile and pancreatic ducts.[190]

Infection with *Taenia solium* tapeworms can result in human cysticercosis, which can be a very serious disease that can cause seizures, muscle or eye damage, and even death.[191] (see Cysticercosis above for more information.)

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit zero to five taeniasis case reports is $0 to $412.50 per year [5 cases (.5 hours X $165 per hour)].

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[186] https://www.cdc.gov/parasites/taeniasis/index.html Accessed January 16, 2020
[187] https://www.cdc.gov/parasites/taeniasis/index.html Accessed January 16, 2020
[188] https://www.cdc.gov/parasites/taeniasis/epi.html Accessed January 16, 2020
[189] https://www.cdc.gov/parasites/taeniasis/gen_info/faqs.html Accessed January 16, 2020
[190] https://www.cdc.gov/parasites/taeniasis/disease.html Accessed January 16, 2020
[191] https://www.cdc.gov/parasites/taeniasis/disease.html Accessed January 16, 2020

Tick paralysis

Description of Proposed Change

The proposed rule adds tick paralysis as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Some members of the regulated community have been submitting case reports for tick paralysis as an "other rare disease of public health significance" as defined in the current rules. However, tick paralysis is not included individually in either Table HC-1 or Table HF-1 of the current rules. The draft rule clearly establishes notification requirements for the condition by naming it specifically in Table HC-1 of the proposed rules rather than as an unnamed condition within a categorical condition.

Mode of Transmission

Tick paralysis, also known as tick toxicosis, occurs worldwide and is caused by a neurotoxin secreted in tick saliva during feeding.[192] The neurotoxin is transmitted to humans during attachment of and feeding by the female of several tick species. In North America, tick paralysis occurs most commonly in the Rocky Mountain and northwestern regions of the United States, and in western Canada. [193]

In the United States, this disease is associated with *Dermacentor andersoni* (Rocky Mountain wood tick), *Dermacentor variabilis* (American dog tick), *Amblyomma americanum* (Lone Star tick), *Amblyomma maculatum*, *Ixodes scapularis* (black-legged tick), and *Ixodes pacificus* (western black-legged tick)[194]

Estimated Number of Cases

The Department assumes from zero to two cases of tick paralysis will occur annually in Washington State.

Probable Benefits

The following description of the burden of illness on individuals who have contracted tick paralysis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of tick paralysis as a result of establishing notification requirements for the condition.

Tick paralysis is one of the eight most common tickborne diseases in the United States. Tick paralysis is an acute, ascending, flaccid motor paralysis that can be confused with Guillain-Barre syndrome, botulism, and myasthenia gravis.[195] Symptoms usually start after four to seven days of

[192] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5534a1.htm Accessed January 19, 2020
[193] https://www.cdc.gov/mmwr/preview/mmwrhtml/00040975.htm Accessed January 19, 2020
[194] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5534a1.htm Accessed January 19, 2020
[195] https://www.cdc.gov/mmwr/preview/mmwrhtml/00040975.htm Accessed January 19, 2020

tick feeding, and progressive, beginning with muscle weakness, loss of coordination, numbness, in the legs with difficulty standing or walking; and progressing upward to the abdomen, back, and chest. Symptoms usually disappear within 24 hours of removing the tick. However, if the tick is not removed, paralysis of the chest muscles can lead to respiratory failure and death. The mortality rate for respiratory failure is approximately 10%.[196]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable costs for a health care provider or facility to prepare and submit zero to two tick paralysis case reports ranging from $0.00 to $165.00 per year [2 cases (.5 hours X $165 per hour)].

Tuberculosis disease (confirmed or highly suspicious, i.e., initiation of empiric treatment)

Description of Proposed Change

The proposed rule changes the notification time frame from immediately to within 24 hours for cases of tuberculosis disease (confirmed or highly suspicious).

Mode of Transmission

Tuberculosis (TB) is caused by the bacterium *Mycobacterium tuberculosis*. *Mycobacterium tuberculosis* is spread through the air when a person with TB disease of the lungs or throat coughs, speaks, etc. People nearby may breathe in these bacteria and become infected. The bacteria can settle in the lungs and start to grow. From there, the bacteria can move through the blood to other parts of the body, such as the kidney, spine, and brain. Not everyone infected with TB bacteria becomes sick, therefore two TB-related conditions exist: latent TB infection (LTBI) and TB disease. If not treated, TB disease can be fatal.[197]

Estimated Number of Cases

In 2018 public health authorities statewide identified 188 case of TB in Washington State, with case counts over 200 each year from 2015 to 2017.[198] Based on this information, the Department estimates 225 cases of TB will be submitted to public health authorities annually.

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[196] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5534a1.htm Accessed January 19, 2020
[197] Centers for Disease Control and Prevention. Tuberculosis (TB). Available from https://www.cdc.gov/tb/default.htm. Accessed January 19, 2020.
[198] Washington State Department of Health. Tuberculosis Cases Statewide by Year. Available from https://www.doh.wa.gov/Portals/1/Documents/Pubs/343-113-TBStatewideByYear2018.pdf. Accessed January 20, 2020.

Probable Benefits

The Department assumes changing the notification timeframe from immediately to within 24 hours potentially reduces the burden of notification on health care providers and facilities by allowing more time to submit a case report.

Probable Costs

The Department assumes there are no probable costs associated with this proposed change.

Typhus[199]

Description of Proposed Changes

The proposed rule adds typhus as a notifiable condition requiring health care providers and health care facilities to submit case reports to the local health jurisdiction within three business days of diagnosis.

Mode of Transmission

Typhus, not to be confused with typhoid fever, is a vector-borne disease that is found today primarily in cold, mountainous regions of South America, Africa, and Asia, as well as cities and ports characterized by abundant populations of urban rats. Typhus refers to a group of acute infections caused by the bacteria *Rickettsiae*, which is transmitted to persons by the bite of fleas, lice, and mites. Outbreaks usually occur in crowded or unsanitary environments with limited access to water. Of the several types of infections, the most common forms of typhus to the United States, are typhus fever (epidemic), murine typhus (endemic), and scrub typhus.[200]

Estimated Number of Cases

Murine typhus, though not common in the United States, has been reported in Texas and Southern California. In 2011, Travis County, Texas was determined to be endemic for murine typhus with the appearance of 53 cases.[201] In 2008 there was a reported 33 cases between the months of March and October. These most recent cases have been traced to cats, opossums, and cat fleas.

In Los Angeles County, where some murine typhus cases have been reported, a significant proportion of cats and opossums have been found to be seropositive for *Rickettsiae typhi* (90% and 42%, respectively).[202]

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[199] For more detailed information on this condition, see Appendix A

[200] Centers for Disease Control and Prevention. Typhus Fevers. Available from https://www.cdc.gov/typhus/index.html. Accessed December 29, 2019.

[201] Petri WA. Epidemic Typhus. Merck Manuals Professional Edition. http://www.merckmanuals.com/professional/infectious-diseases/rickettsiae-and-related-organisms/epidemic-typhus. Accessed December 29, 2019.

[202] Civen R, Ngo V. Murine typhus: an unrecognized suburban vectorborne disease. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. 2008;46(6):913-918. doi:10.1086/527443.

More recently, outbreaks have taken place in relief and humanitarian crisis settings, including Burundi, Ethiopia, and Rwanda. The last reported case in Washington State was in 1994 after travel to Asia.

The Department estimates we have zero cases of typhus annually in Washington State.[203]

Probable Benefits

The following description of the burden of illness on individuals who have contracted tick paralysis illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of tick paralysis as a result of establishing notification requirements for the condition.

Typhus can cause symptoms that range from mild (e.g. headache, rash) to severe (e.g. multiple organ dysfunction syndrome with hemorrhaging, coma, and death). During pregnancy, scrub typhus frequently leads to spontaneous abortion.[204]

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

Though the Department assumes no cases of typhus will be submitted to public health authorities, the probable costs for a health care provider or facility to prepare and submit a single case report is $82.50 (.5 hours X $165 per hour).

WAC 246-101-105, Duties: Health care providers and health care facilities

Description of Proposed Change

The draft rule makes the following changes to the data components a health care provider or health care facility must send to a laboratory when submitting a specimen for testing:

- Adds "Patient's ethnicity", "Patient's race", and "Patient's preferred language"[205]
- Adds "For hepatitis B tests only, pregnancy status (pregnant/not pregnant/unknown), for patients fourteen to fifty years of age only"
- Adds "Patient's best contact telephone number"
- Adds "Patient's Medicaid status, for blood lead tests for patients less than 72 months of age only"
- Revises "Name of the principal health care provider" to "Requesting health care provider's name"

[203] Washington State Department of Health. Washington State Communicable Disease Report 2010. 2010.

[204] Centers for Disease Control and Prevention. Typhus Fevers – Information for Health Care Providers. Available at https://www.cdc.gov/typhus/healthcare-providers/index.html. Accessed December 29, 2019.

[205] See Appendix B for ethnicity, race, and preferred language reporting categories.

- Revises “Telephone number of the principal health care provider” to “Requesting health care provider’s phone number”
- Adds “Address where patient received care”
- Revises “Date of ordering specimen collection” to “Specimen collection date”
- Revises “Test type requested” to “Condition being tested for”

Proposed section WAC 246-101-010 would expand the definition of “health care facility” to include “enhanced service facility licensed under chapter 70.97 RCW.” This change to the definition would require ESFs to report notifiable conditions for the first time, and to send the list of information in WAC 246-101-105 to the laboratory with each specimen being tested for a notifiable condition.

All other amendments to the proposed rule are editorial only, clarifying the rule without changing its effect, and are not considered significant under RCW 34.05.328.

Probable Benefits

The probable benefits of expanding the definition of “health care facility” to include “enhanced service facility licensed under chapter 70.97 RCW” are discussed with the benefits of WAC 246-101-101 above.

The probable benefits of changing what health care providers and health care facilities send laboratories when submitting a specimen for testing are primarily gained by adding information necessary to consistently identify potential cases of notifiable conditions across the medical and public health systems, enabling faster identification and follow-up of cases, and implementation of public health interventions to prevent and control notifiable conditions.

The additions of “patient’s race”, “patient’s ethnicity”, and “patient’s preferred language” will help promote equity by identifying populations disproportionality impacted by any condition. This information will allow the public health system to tailor the public health approach to ensure the interventions are linguistically and culturally appropriate and that they are reaching impacted populations The COVID-19 pandemic has highlighted and exacerbated existing inequities in our public health and health care systems. Black, Indigenous and people of color are disproportionality impacted by many chronic and communicable diseases due to systemic racism and barriers to accessing resources that keep people healthy (e.g., medical care, greenspace, healthy food options, etc.). The Department’s data shows disproportionately higher rates of confirmed COVID-19 cases and hospitalizations among Hispanic, Black, Native Hawaiian/Other Pacific Islander, and American Indian/Alaska Native communities.[206] This is true of other notifiable conditions as well, and gathering these demographic data is essential to identifying and addressing these inequities. Some of the specific benefits include:

- Collection of disaggregated data helps reveal inequities across and within groups, which is instrumental for public health efforts in preventing and containing disease and other conditions.

[206] https://www.doh.wa.gov/Emergencies/COVID19/DataDashboard Accessed January 4, 2021

- Collection of disaggregated race and ethnicity data helps us understand in greater detail which communities are impacted by communicable diseases and other conditions. The addition of language reporting can help reveal hidden disparities among aggregated populations groups like "Asian" and can assist in culturally and linguistically appropriate outreach and prevention strategies and ensure that case investigations are conducted in the appropriate language.
- Primary language, combined with disaggregated racial and ethnic identity, can help us better understand families' history of immigration, so we can do more effective and culturally responsive outreach and prevention. Primary language can also serve as a proxy for when race and ethnicity data is missing.
- Understanding which specific subpopulations are being disproportionately impacted helps enable public health to build partnerships with community-based organizations to develop community-led prevention strategies, and to prioritize and allocate public health funding to impacted communities.

In addition, state agencies have been hearing from communities for decades that they feel invisible in datasets. For example, Asian subpopulations (e.g., Southeast Asians) are often invisible in datasets when they are aggregated with into a broad "Asian" category. Often these populations share many of the health inequities experienced by other groups. This harms their ability to apply for and receive grant funding or other resources to address inequities in their communities. Communities have been asking the Board and Department to collect data in a more disaggregated way.

Two additional pieces of patient information are unique: For hepatitis B tests only, pregnancy status (pregnant/not pregnant/unknown), for patients fourteen to fifty years of age only; and patient Medicaid status, for blood lead tests for patients less than 72 months of age only.

Adding pregnancy status for patients fourteen to fifty years of age to requests for hepatitis B laboratory testing is intended to increase identification of hepatitis B in pregnant patients and prevent disease transmission of hepatitis B to infants during delivery.

Infants born to patients with chronic hepatitis B are at high risk of contracting hepatitis B infection. Without treatment, infants infected with the hepatitis B virus have a 90% chance of developing chronic hepatitis B. Up to 25% of infants who acquire chronic hepatitis B infection will die prematurely from related hepatocellular carcinoma or cirrhosis.[207]

When pregnancy status is known to providers, facilities, and public health authorities, infants born to mothers with hepatitis B infection are more likely to receive Hepatitis B Immunoglobulin (HBIG) within 12 hours of birth along with a first dose of hepatitis B vaccine. If the infant does not receive HBIG and the birth dose of vaccine, the infant is at greater risk of contracting hepatitis B infection and experiencing the symptoms and outcomes associated with it. In addition, this information allows public health perinatal hepatitis B prevention coordinators to follow up and ensure appropriate management of infants.[208]

[207] https://www.cdc.gov/hepatitis/hbv/pregstatuslabreporting.htm Accessed January 19, 2020
[208] https://www.cdc.gov/hepatitis/hbv/pregstatuslabreporting.htm Accessed January 19, 2020

Adding Medicaid status for patients less than 72 months of age to requests for blood lead tests is intended to identify lead poisoning among very young children when exposure has the greatest impact on health, and public interventions can be most successful.

The Centers for Disease Control and Prevention (CDC) projects there are about half a million children between the ages of one and five years in the United States who possess blood lead levels greater than 5 micrograms per deciliter (µg/dL), which is the threshold level at which CDC recommends public health actions are taken. All children enrolled in Medicaid are required to receive blood lead screening tests at ages 12 months and 24 months. In addition, any child between 24 and 72 months with no record of a previous blood lead screening test must receive one. [209] Adding Medicaid status for patients less than 72 months of age assists public authorities in identifying new cases lead poisoning, implementing treatment and prevention measures, and reporting information to the Center for Medicare and Medicaid Services and the CDC.

Medicaid status is a valuable data point for the Department Childhood Lead Poisoning Prevention Program. First, Medicaid requires children under 72 months to be tested at 12 and 24 months and at any time before the age of 6 if they have not been previously tested. The Washington State Health Care Authority (HCA) gets lead billing data to track this but the billing data does not have test results. HCA needs the test result to know which children had elevated tests in order to assure proper medical management. The Department cannot reliably give them test results for children enrolled in Medicaid because the billing and surveillance datasets do not share a unique identifier and matching is time consuming and fallible.

The Centers for Medicare and Medicaid Services (CMS) recently issued a memo requiring Medicaid to provide in home case management services to children with elevated blood lead levels. To provide an adequate public health response and comply with this new CMS requirement the Department will need to be able to let HCA know which children enrolled in Medicaid have elevated blood lead levels.

Medicaid status also provides valuable epidemiological information as it is a reliable proxy for income and has been established as a risk factor for lead exposure. This would be a valuable addition to the Department's surveillance dataset.

All other added or revised patient information is needed to accurately identify cases and enable faster public health investigations and response.

Probable Costs

The probable annual costs for ESFs to comply with this section are discussed with the cost of WAC 246-101-101. The Department estimates that the one-time costs for ESFs for complying with this section would be cost neutral based on the cost questionnaire response from one ESF.

[209] https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/lead-screening/index.html Accessed January 19, 2020

Two non-ESF facilities provided estimated costs for these changes. The one-time cost estimates ranged from cost neutral to $15,000 to update the laboratory system to include new fields required by this section. The annual cost estimates ranged from cost neutral to $5,000 per year to update the laboratory system interfaces with each new version of the laboratory system.

WAC 246-101-110, Means of notification: Health care providers and health care facilities

Description of Proposed Change

The draft rule requires all case reports be type written. This change would eliminate hand-written case reports.

All other amendments to the proposed rule are editorial only, clarifying the rule without changing its effect, and are not considered significant under RCW 34.05.328.

Probable Benefits

The proposed change is intended to improve legibility of case reports, reduce errors in transcribing information, reduce the time it takes to identify cases of notifiable conditions, and potentially provide public health interventions sooner as a result of not needing to follow up on case reports when information is illegible. Follow-up is costly not only to the public health system, but to providers and facilities when staff must resubmit information. The delay in receiving complete information also delays the potential public health response to the condition. Improved legibility of case reports provided by type written documents will alleviate these problems.

Probable Costs

The Department assumes that by providing electronic forms on its website, the proposed change is cost neutral for health care providers and facilities.

WAC 246-101-115, Content of case reports: Health care providers and health care facilities

Description of Proposed Change

The draft rule makes the following changes to the content of case reports health care provider or health care facility must submit to the public health authority identified for individual conditions included in Table HC-1:

- Revises "Patient's address" to "Patient physical address including zip code"
- Adds "Patient's ethnicity", "Patient's race", and "Patient's preferred language"[210]
- Adds "For hepatitis B tests only, pregnancy status (pregnant/not pregnant/unknown), for patients fourteen to fifty years of age only"
- Revises "Address of the principal health care provider" to "Address where patient received care"
- Removes "Other information as the department may require on forms generated by the department"

[210] See Appendix B for ethnicity, race, and preferred language reporting categories.

Proposed section WAC 246-101-010 would expand the definition of "health care facility" to include "enhanced service facility licensed under chapter 70.97 RCW." This change to the definition would require ESFs to report notifiable conditions for the first time, and to send the list of information in WAC 246-101-115 to the public health authority with each case report.

All other amendments to the proposed rule are editorial only, clarifying the rule without changing its effect, and are not considered significant under RCW 34.05.328.

Probable Benefits

The Department assumes the probable benefits of these proposed changes are the same as those identified for proposed WAC 246-101-105 as described above.

Probable Costs

The probable annual costs for ESFs to comply with this section are discussed with the cost of WAC 246-101-101. The Department estimates that the one-time costs for ESFs for complying with this section would be cost neutral based on the cost questionnaire response from one ESF.

Two non-ESF facilities provided estimated costs for these changes. The one-time cost estimates ranged from cost neutral to $115,000 for staff time or contract with someone to make system changes such as updating the interface between the registration system and the vendor's system ($75,000) plus the cost of paying vendor to their data system ($40,000).

WAC 246-101-201, Notifiable conditions: Laboratories

All presumptive and final test results requiring notification to public health authorities by laboratories are included in Table Lab-1 of WAC 246-101-201. Table Lab-1 of the proposed rules identifies the notifiable agent (condition), the test results to submit in a laboratory report, time frame for notification, who to notify, what specimens must be submitted, and the time frame for specimen submission.

Significant changes to the current rule are described below by agent. All other amendments to the proposed rule are editorial only, clarifying the rule without changing its effect, and are not considered significant under RCW 34.05.328.

Amoebic meningitis

Description of Proposed Changes

The proposed rule adds amoebic meningitis as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction immediately upon completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive result, if available, must be submitted to the Department of Health within two business days.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes no cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the Laboratory Information Management System (LIMS) and Electronic Laboratory Reporting (ELR) system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR (such as secure file transfer, secure email, secure facsimile), the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to:

- Prepare and submit specimens for this proposed condition ranges from $0.00 to $15.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)]; and

- Call the public health authority to confirm receipt of a laboratory report for this proposed condition ranges from $0.00 to $10.00 per year [0 cases (0.25 hours X $40 per hour) to 1 case (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 for no cases of the condition to $45.00 to submit a laboratory report and specimen, and confirm receipt of the laboratory report.

Anaplasma species (Anaplasmosis)

Description of Proposed Changes

The proposed rule adds *Anaplasma* species (Anaplasmosis) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within two business days of completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive result, if available, must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes zero to five cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $100.00 per year [0 cases (.5 hours X $40.00 per hour) to 5 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $75.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 5 case (0.25 hours X $40 per hour) plus (5 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs are $0.00 to $175.00 to submit laboratory reports and specimens.

Babesia species (Babesiosis)

Description of Proposed Changes

The proposed rule adds *Babesia* species (Babesiosis) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within two business days of completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive result, if available, must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes zero to three cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $60.00 per year [0 cases (.5 hours X $40.00 per hour) to 3 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $45.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 3 case (0.25 hours X $40 per hour) plus (3 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $105.00 to submit laboratory reports and specimens.

Bacillus cereus **(biovar *anthracis* only)**

Description of Proposed Changes

The proposed rule adds *Bacillus cereus* (biovar *anthracis* only) as a notifiable condition requiring laboratories to submit laboratory reports as follows:

- Laboratory reports must be submitted to the local health jurisdiction immediately upon obtaining a confirmed positive result using any test method; and
- Laboratories are prohibited from shipping specimens related to a confirmed positive test result.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes zero cases of this agent will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See “Probable Benefits” for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to:

- Call the public health authority to confirm receipt of a laboratory report for this proposed condition ranges from $0.00 to $10.00 per year [0 cases (0.25 hours X $40 per hour) to 1 case (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 for no cases of the condition to $30.00 to submit a laboratory report and specimen, and confirm receipt of the laboratory report.

Baylisascaris (Baylisascariasis)

Description of Proposed Changes

The proposed rule adds *Baylisascaris* (Baylisascariasis) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within 24 hours of completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive result, if available, must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See “Mode of Transmission” for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes one case of this condition will be reported in Washington State. (For additional information, see “Estimated Number of Cases” for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See “Probable Benefits” for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit a laboratory report using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting one laboratory report for this condition is $20.00 per year [1 case (.5 hours X $40.00 per hour).

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to:

- Prepare and submit specimens for this proposed condition is $15.00 per year [1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)]; and

- Call the public health authority to confirm receipt of a laboratory report for this proposed condition is $10.00 per year [1 case (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 for no cases of the condition to $45.00 to submit a laboratory report and specimen, and confirm receipt of the laboratory report.

Blood lead level

Description of Proposed Changes

The proposed rule changes the notification requirement for adult elevated blood lead level (BLL) results from 10 micrograms per deciliter (≥10µg/dl) to equal to or greater than 5 micrograms per deciliter (≥5µg/dl) for rapid screening tests or venous tests. This proposed change will make the rule consistent with the current case definition used by the CDC Adult Blood Lead Epidemiology and Surveillance (ABLES) program, the National Notifiable Diseases Surveillance System (NNDSS), and the Council for State and Territorial Epidemiologists (CSTE). This proposed change would also align the notifiable conditions requirement with the "advisory level" in the Washington State Department of Labor and Industries (L&I) draft lead rule[211] and the definition used by L&I's state-based ABLES program.[212]

Mode of Transmission

The majority of cases of elevated blood lead among adults are related to work. Nationally, of 11,695 adults with known exposures at BLL≥10 µg/dL in 2016, 90.3% had occupational exposures. The majority of these adults were employed in four main industries: manufacturing, construction, services, and mining.[213]

In addition to posing a risk for workers, lead can inadvertently travel home with a worker where children and other members of their household can be exposed.[214]

Estimated Number of Cases

Between 2013 and 2017 L&I received an average of 252 reports (range 184 to 308 reported case) annually for cases of BLL ≥10µg/dl. Based on this information, the Department estimates 400-500 cases per year of BLLs ≥5 µg/dl but <10µg/dl may be submitted to public health authorities annually.

Probable Benefits

The following description of the burden of illness on individuals with elevate blood lead level between 5 µg/dl and 10µg/dl illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of

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[211] Washington State Department of Labor and Industries. WISHA Lead Rule – Stakeholder Review Draft. Available from https://www.lni.wa.gov/safety-health/safety-rules/rulemaking-stakeholder-information/_leaddocs/LeadRule-WISHADraftLeadRule-June2019.pdf. Accessed January 20, 2020.
[212] https://www.lni.wa.gov/safety-health/safety-research/ongoing-projects/lead-exposure-ables
[213] Centers for Disease Control and Prevention. NIOSH. Adult Blood Lead Epidemiology and Surveillance (ABLES). Available from https://www.cdc.gov/niosh/topics/ables/data.html. Accessed January 20, 2020.
[214] Centers for Disease Control and Prevention. NIOSH. Adult Blood Lead Epidemiology and Surveillance (ABLES) – About ABLES. Available from https://www.cdc.gov/niosh/topics/ables/description.html. Accessed January 20, 2020.

preventing cases of elevated blood lead level or reducing BLLs as a result of modifying the notification requirements for lead.

The U.S. Department of Health and Human Services' (DHHS) National Toxicology Program (NTP) concluded that there is evidence of adverse health effects in adults at blood lead levels <5µg/dl. Adult blood lead, even at low levels, is shown to cause health effects such as adverse cardiovascular and kidney effects, cognitive dysfunction, and adverse reproductive outcomes.[215]

ABLES uses elevated blood lead results to identify and monitor lead exposure trends and intervene with cases and employers to prevent lead exposure. The ability to identify and address worksites with high lead exposure rates will enable L&I to mitigate exposure the workers being exposed currently and those who would have been exposed in the future. The change would also allow ABLES to provide outreach earlier to individual cases at risk of adverse health effects.

For each case of this condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for adult blood lead levels of between ≥5 µg/dl and ≥10 µg/dl and depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $8,000.00 to $10,000.00 per year [400 cases (.5 hours X $40.00 per hour) to 500 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

[215] U.S. Department of Health and Human Services National Toxicology Program. NTP Monograph: Health Effects of Low-Level Lead. 2012. Available from https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf.

The total range of probable yearly costs range from $8,000.00 to $10,000.00 to submit laboratory reports.

Bordetella pertussis (Pertussis)

Description of Proposed Changes

The proposed rule changes notifiable test types from being unspecified to positive results by culture or nucleic acid detection ((nucleic acid testing (NAT) or (nucleic acid amplification testing (NAAT)).

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Borrelia burgdorferi or *Borrelia mayonii* (Lyme disease)

Description of Proposed Changes

The proposed rule adds *Borrelia mayonii* as a notifiable agent associated with Lyme disease.

Mode of Transmission

Borrelia mayonii are a type of bacteria that can cause Lyme disease and are transmitted from the bite of a blacklegged tick. This was recently discovered in North America, and there are still many unknowns about this bacteria. This bacteria is different from the bacteria that currently causes cases of Lyme disease in North America, *Borrelia burgdorferi*, which is already a reportable agent by laboratories in Washington State.[216]

Estimated Number of Cases

Current evidence indicates that within the United States, *B. mayonii* is only found in the Upper Midwest,[217] so the Department estimates zero to one case will be reported annually in Washington State.

Probable Benefits

[216] Centers for Disease Control and Prevention. Lyme Disease: What you need to know about *Borrelia mayonii*. Available from https://www.cdc.gov/lyme/mayonii/index.html. Accessed January 20, 2020.
[217] Centers for Disease Control and Prevention. Lyme Disease: What you need to know about *Borrelia mayonii*. Available from https://www.cdc.gov/lyme/mayonii/index.html. Accessed January 20, 2020.

The following description of the burden of illness on individuals who have been infected with *B. mayonii* illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of Lyme disease from *B. mayonii* as a result of establishing notification requirements for the agent.

There is limited information on *B. mayonii.* Illness caused by this bacteria appears to cause fever, headache, rash, and neck pain in the days after infection and can cause arthritis after a few weeks of illness. These symptoms are similar to those caused by *B. burgdorferi,* however *B. mayonii* can also cause nausea and vomiting; large, widespread rashes; and a higher concentration of bacteria in the blood.[218]

For each case of Lyme disease from *B. mayonii* avoided, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $15.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)].

[218] Centers for Disease Control and Prevention. Lyme Disease: What you need to know about *Borrelia mayonii*. Available from https://www.cdc.gov/lyme/mayonii/index.html. Accessed January 20, 2020.

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $35.00 to submit laboratory reports and specimens.

Borrelia hermsii, miyamotoi, or *recurrentis* (Relapsing fever, tick- or louse-borne)

Description of Proposed Changes

The proposed rule:

- Adds *Borrelia miyamotoi* as an agent associated with relapsing fever, tick- or louse- borne; and
- Changes the time frame for submitting a laboratory report from "within 24 hours" to "within 2 business days".

Mode of Transmission

Like *Borrelia recurrentis, Borrelia miyamotoi* is transmitted by ticks (larval blacklegged ticks).[219]

Estimated Number of Cases

Borrelia miyamotoi disease, (also called hard tick relapsing fever), has been reported as the cause of human infection in the Upper Midwest, the Northeast, and the mid-Atlantic states.[220] Based on this information the Department estimates zero to one case will be reported annually in Washington State.

Probable Benefits

The following description of the burden of illness on individuals who have been infected with *Borrelia miyamotoi* illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases as a result of establishing notification requirements for this agent.

Borrelia miyamotoi disease can cause fever, severe headache, body pain, and in some cases dizziness, confusion, vertigo, rash, shortness of breath, nausea, abdominal pain, diarrhea, and loss of appetite.[221] For each case of *Borrelia miyamotoi* disease avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

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[219] Centers for Disease Control and Prevention. Tickborn Diseases in the United State: *Borrelia miyamotoi* Disease. Available from https://www.cdc.gov/ticks/tickbornediseases/borrelia-miyamotoi.html. Accessed January 20, 2020.
[220] Centers for Disease Control and Prevention. Tickborn Diseases in the United State: *Borrelia miyamotoi* Disease. Available from https://www.cdc.gov/ticks/tickbornediseases/borrelia-miyamotoi.html. Accessed January 20, 2020.
[221] Centers for Disease Control and Prevention. Tickborn Diseases in the United State: *Borrelia miyamotoi* Disease. Available from https://www.cdc.gov/ticks/tickbornediseases/borrelia-miyamotoi.html. Accessed January 20, 2020.

The Department assumes changing the notification timeframe from within 24 hours to within 2 business days potentially reduces the burden of notification on laboratories by allowing more time to submit a laboratory report.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $15.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $35.00 to submit laboratory reports and specimens.

The Department assumes there are no probable costs associated with changing the notification timeframe.

Brucella species (Brucellosis)

Description of Proposed Changes

The proposed rule reduces notifiable test results from all positive results to positive results by any method excluding Immunoglobulin G (IgG).

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Burkholderia mallei (Glanders)

Description of Proposed Changes

The proposed rule changes notifiable test results from all positive results to positive results by any method excluding IgG.

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Burkholderia pseudomallei (Melioidosis)

Description of Proposed Changes

The proposed rule reduces notifiable test results from all positive results to positive results by any method excluding IgG.

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

California serogroup viruses, acute (Arbovirus)

Description of Proposed Changes

The proposed rule separates existing grouped notifiable arboviruses into individual lines in Table Lab-1, including this condition and changes notifiable test results from "IgM positivity, PCR positivity, and viral isolation" to "positive results by any method excluding IgG".

Estimated Number of Cases

Washington State had zero cases of California serogroup viruses between 2002 and 2018.[222] Based on this information the Department estimates that zero to one case will be reported to public health authorities annually. The Department assumes that zero to one reported case may result from one of the test methods newly reportable under the proposed rule.

Potential Benefits

This proposed change updates the list of reportable test results to align with currently available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Potential Costs

While laboratories are already required to report cases of this condition, this proposed change may increase the number of cases laboratories must report (and correspondingly how many specimens they must submit) since the proposed change expands the list of test results that are reportable.

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

[222] Washington State Department of Health. Arboviral Disease Types. Available from: https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=arbo. Accessed January 20, 2020.

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $15.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $35.00 to submit laboratory reports and specimens.

***Campylobacter* species (Campylobacteriosis)**

Description of Proposed Changes

The proposed rule changes notifiable test results from being unspecified to "positive results by culture, nucleic acid detection (NAT or NAAT), or antigen detection".

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Candida auris

Description of Proposed Change

The proposed rule adds *Candida auris* as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within 24 hours of completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive result, if available, must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for *Candida auris* in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes 17 cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for *Candida auris* in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition are $340.00 per year [17 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to:

- Prepare and submit specimens for this proposed condition is $255 per year [17 cases (0.25 hours X $40 per hour) plus (17 case X $5 packaging)]; and

- Call the public health authority to confirm receipt of a laboratory report for this proposed condition is $170 per year [17 cases (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs are $765 to submit 17 laboratory reports and specimens, and confirm receipt of the laboratory reports.

Carbapenem-resistant Enterobacteriaceae (*Klebsiella* species, *E. coli*, and *Enterobacter* species)

Desecription of Proposed Changes

The proposed rule adds Carbapenem-resistant Enterobacteriaceae infections (CRE) as a notifiable condition requiring laboratories to submit laboratory reports and specimens:

- Laboratory reports must be submitted to the local health jurisdiction within two business days of completing a test that results in a positive preliminary or final result for:
  - Known carbapenemase resistance gene (including, but not limited to, KPC, NDM, VIM, IMP, OXA-48) demonstrated by nucleic acid detection (NAT or NAAT), or whole genome sequencing;
  - Phenotypic test for carbapenemase production including, but not limited to, Metallo-B-lactamase test, modified Hodge test (MHT) (for *E. coli* and *Klebsiella* species only), CarbaNP, Carbapenem Inactivation Method (CIM) or modified CIM (mCIM); and
  - Resistance to any carbapenem including, but not limited to, doripenem, ertapenem, imipenem or meropenem.
- Specimens must be submitted as follows:
  - Submit the isolate associated with the positive test result, if available, to the Department within two business days; or
  - If the isolate is not available, submit the specimen associated with the positive result within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes 300 cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable

one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition is $6,000.00 per year [300 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition is $4,500.00 per year [300 cases (0.25 hours X $40 per hour) plus (300 cases X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs is $10,500 to submit laboratory reports and specimens.

Chikungunya virus, (Arbovirus)

Description of Proposed Changes

The proposed rule separates existing grouped notifiable arboviruses into individual lines in Table Lab-1, including this condition, and changes notifiable test results from "IgM positivity, PCR positivity, and viral isolation" to "positive results by any method excluding IgG".

Estimated Number of Cases

Washington State had anywhere from zero to 40 cases of chikungunya virus reported annually between 2002 and 2018.[223] Based on this information the Department estimates that zero to 40 cases will be reported to public health authorities annually. The Department assumes that zero to five of these reported cases may result from one of the test methods newly reportable under the proposed rule.

Potential Benefits

This proposed change updates the list of reportable test results to align with currently available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

[223] Washington State Department of Health. Arboviral Disease Types. Available from: https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=arbo. Accessed January 20, 2020.

Potential Costs

While laboratories are already required to report cases of this condition, this proposed change may increase the number of cases laboratories must report (and correspondingly how many specimens they must submit) since the proposed change expands the list of test results that are reportable.

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $100.00 per year [0 cases (.5 hours X $40.00 per hour) to 5 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $75.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 5 cases (0.25 hours X $40 per hour) plus (5 cases X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $175.00 to submit laboratory reports and specimens.

Chlamydia psittaci (Psittacosis)

Description of Proposed Changes

The proposed rule corrects the name from "*Chlamydophila psittaci*" and changes notifiable test results from being unspecified to "positive results by any method excluding IgG".

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Chlamydia trachomatis

Description of Proposed Changes

The proposed rule changes notifiable test results from being unspecified to "positive and indeterminate results by any method".

(See also "De-identified negative screening results" for additional analysis of significant changes to *Chlamydia trachomatis.*)

Estimated Number of Cases

Each year over 20,000 positive cases of *Chlamydia trachomatis* are reported in Washington State.[224] The Department estimates that 500 new indeterminate cases will be reported as a result of this proposed change.

Probable Benefits

The proposed change to require laboratories to submit indeterminate results in addition to positive results will help ensure that public health authorities are alerted to cases that may be positive so they can initiate a case investigation with follow-up testing and the corresponding public health action if a positive case is identified.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for indeterminate results depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and

[224] Washington State Department of Health. Notifiable Conditions – Chlamydia. Available from: https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/Chlamydia. Accessed January 20, 2020.

submitting laboratory reports for this indeterminate results is $10,000 per year [500 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system. The total probable yearly costs are $10,000 to submit laboratory reports. This condition does not have a specimen submission requirement.

Coccidioides (Coccidioidomycosis)

Description of Proposed Changes

The proposed rule adds *Coccidioides* (Coccidioidomycosis) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within two business days of completing a test that results in a positive preliminary or final result using any test method; and
- Submit the isolate associated with the positive test result, if available, to the Department within two business days; or
- If the isolate is not available, submit the specimen associated with the positive result within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes 50-80 cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable

one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $1,000.00to $1,600 per year [50 cases (.5 hours X $40.00 per hour) to 80 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $750.00 to $1,200.00 per year [50 cases (0.25 hours X $40 per hour) plus (50 cases X $5 packaging) to 80 case (0.25 hours X $40 per hour) plus (80 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $1750.00 to $2,800 to submit laboratory reports and specimens.

Coronavirus: MERS-associated coronavirus

Description of Proposed Change

The proposed rule adds MERS-associated coronavirus as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction immediately upon completing a test that results in a positive preliminary or final result using any test method; and
- Submit the **presumptive** positive isolate, or if the isolate is not available, submit the specimen associated with the **presumptive** positive result within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes two cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition is $40.00 per year [2 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to:

- Prepare and submit specimens for this proposed condition is $50.00 [2 cases (0.25 hours X $40 per hour) plus (2 cases X $15 packaging)]; and
- Call the public health authority to confirm receipt of a laboratory report for this proposed condition is $20.00 per year [2 cases (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs are $110.00 to submit laboratory reports and specimens, and confirm receipt of laboratory reports.

Coronavirus: Novel Coronavirus (SARS-CoV-2)

Description of Proposed Change

The proposed rule adds SARS-CoV-2as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction immediately upon completing a test that results in a positive preliminary or final result using any test method; and
- Submit the **presumptive** positive isolate, or if the isolate is not available, submit the specimen associated with the **presumptive** positive result within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes 75,000 cases of this condition may be reported in Washington State in future years Due to the recent emergence of this condition this estimate is based on very little data. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time cost to include this condition in their LIMS and ELR system is $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition is up to $1,500,000 per year [75,000 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to:

- Prepare and submit specimens for this proposed condition (assuming 10% of specimens are requested), is up to $187,000 [75,000 cases (0.25 hours X $40 per hour) plus (75,000 cases X $15 packaging); and
- Call the public health authority to confirm receipt of a laboratory report for this proposed condition, is up to $750,000 per year [75,000 cases (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs are up to $4,125,000 to submit laboratory reports and specimens, and confirm receipt of laboratory reports.

Corynebacterium diphtheriae (Diphtheria)

Description of Proposed Changes

The proposed rule changes notifiable test results from being unspecified to "positive results by culture, nucleic acid detection (NAT or NAAT)".

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Cryptococcus gattii or undifferentiated *Cryptococcus* species (i.e., *Cryptococcus* not identified as *C. neoformans*)

Description of Proposed Changes

The proposed rule revises the condition name from "*Cryptococcus* non *v. neoformans*" to "*Cryptococcus gattii* or undifferentiated *Cryptococcus* species (i.e, *Cryptococcus* not identified *as C. neoformans*" and adds requirements to submit laboratory reports as follows:

- Notifiable test results of "positive results by any method excluding cryptococcal antigen"; and
- Notification time frame and whom to notify as "within 2 business days to LHJ".

Estimated Number of Cases

The Department assumes one to ten cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

The current rule requires laboratories to submit only specimens. Requiring submission of laboratory reports for all positive results, excluding cryptococcal antigen, within two business days of obtaining the results allows public health to more quickly identify a case of *Cryptococcus gattii* and know to anticipate the specimen's arrival at the public health laboratories.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $20.00 to $200.00 per year [1 case (.5 hours X $40.00 per hour) to 10 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs range from $20.00 to $200.00 to submit laboratory reports.

De-identified negative screening results

Description of Proposed Changes

The proposed rule adds a requirement for laboratories to submit de-identified negative screening results to the Department at least annually for the following agents / conditions:

- *Chlamydia trachomatis*
- Hepatitis C Virus
- Human Immunodeficiency Virus (HIV)
- *Neisseria gonorrhea*
- *Treponema pallidum*

Estimated Numbers of Negative Test Results

The following estimated numbers of negative test results was provided by a single laboratory:

- *Chlamydia trachomatis*: 5,408
- Hepatitis C Virus: 15,953
- Human Immunodeficiency Virus (HIV): 13,998
- *Neisseria gonorrhea*: 3,546
- *Treponema pallidum*: 14,766

Probable Benefits

Requiring submission of de-identified negative screening results that retain demographic and geographic information for HIV, syphilis, chlamydia (CT), gonorrhea (GC), and hepatitis C testing will allow the Department to target, monitor, and evaluate prevention resources and programs more effectively. If only positive results (or negatives results associated with a positive result) are reported, the Department cannot identify groups or areas in need of testing.

Characteristics of Individuals Receiving Screening Tests

Collecting limited demographic information for negative screening results allows the Department to determine if screening is reaching appropriate groups of people or if resources, education, and outreach should be re-directed to groups of people that should be tested and the organizations that serve them.

Geography of Screening

Collecting limited geographic information for negative screening results allows us to determine if screening is reaching populations across the state. This, in conjunction with demographic information, allows for more informed planning, intervention, and follow up to ensure adequate testing.

Changes in Disease Rates

Collecting negative results will allow the Department determine if changes in disease rates are due to actual transmission changes or changes in testing practices. This contributes to planning in the short term (e.g. identifying problems that need immediate response) and long term (e.g. identifying fewer new cases as the pool of previously unidentified cases shrinks). This is particularly helpful for Chlamydia where there are too many cases of the disease for all of them to be investigated, high proportions of which are asymptomatic that carry risks for serious long-term health consequences.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit annual summary reports for de-identified screening results for the five named conditions depends on the form of secure electronic data transmission used by the laboratory.

- The Department assumes laboratories using ELR will need to create a de-identified annual summary report in their LIMS with a probable one-time cost for all five conditions of $40,000 (5 conditions X $800 per condition).

- In the event laboratories are not able to create a de-identified annual summary report from their LIMS, and must submit results individually using a secure electronic data transmission method other than ELR, the Department assumes the probable costs for preparing and submitting the de-identified negatives are:[225]
  - *Chlamydia trachomatis*: $162,240 [5,408 negative test results (.5 hours X $60.00 per hour)]
  - Hepatitis C Virus: $478,590 [15,953 negative test results (.5 hours X $60.00 per hour)]

[225] Estimates created from a cost questionnaire provided by a large laboratory (>,5000 employees).

- HIV: $419,940 [13,998 negative test results (.5 hours X $60.00 hour)]
- *Neisseria gonorrhea*: $106,380 [3,546 negative test results (.5 hours X $60.00 hour)]
- *Treponema pallidum*: $42,980 [14,766 negative test results (.5 hours X $60.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $40,012 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly cost is $1,210,130 for laboratories to submit individual de-identified negative screening results.

Dengue, acute (Arbovirus)

Description of Proposed Changes

The proposed rule separates existing grouped notifiable arboviruses into individual lines in Table Lab-1, including this condition, and changes notifiable test results from "IgM positivity, PCR positivity, and viral isolation" to "positive results by any method excluding IgG".

Estimated Number of Cases

Washington State had anywhere from zero to 23 cases of dengue reported annually between 2002 and 2018.[226] Based on this information the Department estimates that zero to 23 cases will be reported to public health authorities annually. The Department assumes that zero to three of these reported cases may result from one of the test methods newly reportable under the proposed rule.

Potential Benefits

This proposed change updates the list of reportable test results to align with currently available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Potential Costs

While laboratories are already required to report cases of this condition, this proposed change may increase the number of cases laboratories must report (and correspondingly how many specimens they must submit) since the proposed change expands the list of test results that are reportable.

[226] Washington State Department of Health. Arboviral Disease Types. Available from: https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=arbo. Accessed January 20, 2020.

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $60.00 per year [0 cases (.5 hours X $40.00 per hour) to 3 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $45.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 3 cases (0.25 hours X $40 per hour) plus (3 cases X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $105.00 to submit laboratory reports and specimens.

Eastern and western equine encephalitis, acute (Arbovirus)

Description of Proposed Changes

The proposed rule separates existing grouped notifiable arboviruses into individual lines in Table Lab-1, including this condition, and changes notifiable test results from "IgM positivity, PCR positivity, and viral isolation" to "positive results by any method excluding IgG".

Estimated Number of Cases

Washington State had zero reported cases of eastern and western equine encephalitis between 2002 and 2018.[227] Based on this information the Department estimates that zero to one case will be reported to public health authorities annually. The Department assumes that zero to one of

[227] Washington State Department of Health. Arboviral Disease Types. Available from: https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=arbo. Accessed January 20, 2020.

these reported cases may result from one of the test methods newly reportable under the proposed rule.

Potential Benefits

This proposed change updates the list of reportable test results to align with currently available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Potential Costs

While laboratories are already required to report cases of this condition, this proposed change may increase the number of cases laboratories must report (and correspondingly how many specimens they must submit) since the proposed change expands the list of test results that are reportable.

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $15.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $35.00 to submit laboratory reports and specimens.

Echinococcus granulosus **or** ***E. multilocularis*** **(Echinococcosis)**

Description of Proposed Changes

The proposed rule adds *Echinococcus granulosus* or *E. multilocularis* (Echinococcosis) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within two business days of completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive result, if available, must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes zero cases to one case of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $15.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $35.00 to submit laboratory reports and specimens.

Ehrlichia species (Ehrlichiosis)

Description of Proposed Changes

The proposed rule adds *Ehrlichia* species (Ehrlichiosis) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within two business days of completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive result, if available, must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes zero to two cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and

submitting laboratory reports for this condition ranges from $0 to $40.00 per year [0 cases (.5 hours X $40.00 per hour) to 2 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0 to $30.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 2 case (0.25 hours X $40 per hour) plus (2 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0 to $70.00 to submit laboratory reports and specimens.

Haemophilus influenzae (children <5 years of age)

Description of Proposed Changes

The proposed rule changes notifiable test results from being unspecified to “positive result from specimen from a normally sterile site by: culture, nucleic acid detection (NAT or NAAT)”.

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Hantaviral infection

Description of Proposed Changes

The proposed rule changes specimen submission time frame from “on request” to “within 2 business days”.

Estimated Number of Cases

The Department assumes zero to five cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

Though it is unlikely this proposed change to laboratory specimen submittal requirements will change the effect of the existing rule, the Department has estimated the cost of submitting specimens for zero to ten cases of hantaviral infection annually.

The Department assumes laboratories LIMS and ELR systems already include the needed capacity to submit specimens under the current rule. Therefore, the Department assumes the total probable costs associated with this proposed change are:

- One-time cost to update Standard operating procedures of $12.00 (0.2 hours X $60 per hour)]
- Costs for a laboratory to prepare and submit zero to five specimens ranges from $0.00 to $75.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 5 case (0.25 hours X $40 per hour) plus (5 case X $5 packaging)].

Hepatitis A virus

Description of Proposed Changes

The proposed rule adds "nucleic acid detection (NAT or NAAT)" as a notifiable tests result to existing required test results.

Estimated Number of Cases

Washington State had between 21 and 35 cases annually of hepatitis A between 2010 and 2018.[228] Washington is experiencing an outbreak with over 200 cases reported recently. Based on this information the Department estimates that 50 to 100 cases will be reported to public health authorities annually. The Department assumes that two to four of these reported cases may result from one of the test methods newly notifiable under the proposed rule.

Potential Benefits

This proposed change updates the list of reportable test results to align with currently available valid test methods in order to ensure that all cases of this condition are reported. This increases

[228] Washington State Department of Health. Arboviral Disease Types. Available from: https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=arbo. Accessed January 20, 2020.

the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Potential Costs

While laboratories are already required to report cases of this condition, this proposed change may increase the number of cases laboratories must report (and correspondingly how many specimens they must submit) since the proposed change expands the list of test results that are reportable.

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory.

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR (such as secure file transfer, secure email, secure facsimile), the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $40.00 to $80.00 per year [2 cases (.5 hours X $40.00 per hour) to 4 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to:

- Prepare and submit specimens for this proposed condition ranges from $30.00 to $60.00 per year [2 cases (0.25 hours X $40 per hour) plus (2 cases X $5 packaging) to 4 cases (0.25 hours X $40 per hour) plus (4 case X $5 packaging)]; and

- Call the public health authority to confirm receipt of a laboratory report for this proposed condition ranges from $20.00 to $40.00 per year [2 cases (0.25 hours X $40 per hour) to 4 cases (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $90.00 to $180.00 to submit laboratory reports and specimens, and confirm receipt of the laboratory reports since this condition is reportable within 24 hours.

Hepatitis B virus

Description of Proposed Changes

The proposed rule combines 'Hepatitis B virus (acute)' with 'Hepatitis B virus' rows to create a single row, eliminates differentiation between acute and chronic hepatitis B infections, and makes the following significant changes:

- Changes notifiable test results
  - From:
    - IgM positivity
    - HBsAg (surface antigen)
    - HBeAg (E antigen)
    - HBV DNA"
  - To "positive results for:
    - IgM anti-HBc
    - HBsAg
    - HBeAg
    - HBV nucleic acid detection (NAT or NAAT) either qualitative or quantitative e.g., PCR or genotyping"; and
  - To "if associated with a positive result listed above, and available:
    - Hepatocellular enzyme levels;
    - Pregnancy status;
    - Negative IgM anti-HBc result".
- Changes notification of test results from "monthly" for chronic hepatitis B to "within 24 hours".

Estimated Number of Cases

Based on Department 2016 notification data, the estimated number of hepatitis B cases in Washington State, including perinatal cases, is 1,547 annually. Of these cases, 1,521 were chronic.[229]

Potential Benefit

The proposed changes to the reportable test results for this condition will provide public health authorities with the information needed to determine if the case is acute or chronic. This change paired with the proposed change to use a single reporting timeline for laboratories for both acute and chronic hepatitis B shifts the burdens of interpreting laboratory results to determine if a case is acute or chronic from the laboratory to the public health authorities. Public health authorities can then take appropriate action based on the information received. In addition to these benefits see "Potential Benefits" for Hepatitis B (chronic) in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities for additional information

[229] https://www.doh.wa.gov/Portals/1/Documents/5100/420-004CDAnnualReportIncidenceRates.pdf#nameddest=hepb-chronic. Accessed January 20, 2020.

on the benefits of receiving reports of chronic cases within 24 hours rather than monthly and the benefits of requiring laboratories to report pregnancy status associated with a positive test result.

Requiring laboratories to report negative results associated with a previous positive will provide public health authorities with confirmatory test results needed for the full testing algorithm allowing public health authorities to help identify inconclusive results and reduce investigation time (which can reduce burden on public health authorities and laboratories who would be asked to facilitate those investigations in the absence of sufficient reported information). In addition, hepatitis B may lack discrete onset of symptoms, and negative tests can help determine when infection occurred, target acute infection and interrupt transmission.

Potential Costs

The Department assumes that the changes to reportable tests will not impact the number of cases of Hepatitis B virus reported annually or the number or specimens submitted. The Department assumes the probable costs for a laboratory to submit hepatocellular enzyme levels, pregnancy status, and negative IgM anti-HBc results associated with a previous positive result:

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR (such as secure file transfer, secure email, secure facsimile), the Department assumes the probable cost for including these additional data components when submitting laboratory reports for this condition are $15,470 per year [1,547 cases (0.1 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department also assumes laboratories will incur costs related to calling the public health authority to confirm receipt of a laboratory report (a new requirement for chronic cases due to the change from a month to within 24 hour reporting requirement) for this proposed condition ranges is $15,210 per year [1,521 chronic cases (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs are $30,680 to include the proposed additional data components when submitting laboratory reports for this condition and to confirm receipt of laboratory reports via phone for chronic cases.

Hepatitis C virus

Description of Proposed Changes

The proposed rule:

- Changes notifiable test results from being unspecified to:
    - "Positive result by any method";
    - "Positive and nonpositive results for:
        - HVC nucleic acid detection (NAT or NAAT) for qualitative, quantitative, and genotype tests"; and
        - "If associated with a positive result and available:
            - Hepatocellular enzyme levels;
            - Pregnancy status;
            - Negative result for IgM anti-HAV;
            - Negative result for IgM anti-HBc";
- Changes notification of test results from "monthly" to "within 2 business days";
- Changes specimen submission time frame from being unspecified to "within 2 business days of request by local health jurisdiction or Department of Health".

(See also "De-identified negative screening results" for additional analysis of significant changes to Hepatitis C.)

Estimated Number of Cases

Based on Department 2018 notification data, the estimated annual number of chronic, acute, and perinatal hepatitis C cases in Washington State is 7,712. In addition to these cases the Department estimates that laboratories will report 15,000 nonpositive results for nucleic acid detection tests.

Potential Benefit

The proposed changes to the reportable test results for this condition will provide public health authorities with the information needed to determine if the case is acute or chronic. This change paired with the proposed change to use a single reporting timeline for laboratories for both acute and chronic hepatitis C shifts the burdens of interpreting laboratory results to determine if a case is acute or chronic from the laboratory to the public health authorities. Public health authorities can then take appropriate action based on the information received. In addition to these benefits see "Potential Benefits" for Hepatitis C (acute) and (chronic) in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities for additional information on the benefits of receiving reports of chronic cases within 24 hours rather than monthly and the benefits of requiring laboratories to report pregnancy status associated with a positive test result.

Requiring laboratories to report negative results associated with a previous positive as well as non-positive results for select tests will provide public health authorities with confirmatory test results needed for the full testing algorithm allowing public health authorities to help identify inconclusive results and reduce investigation time (which can reduce burden on public health authorities and laboratories who would be asked to facilitate those investigations in the absence of sufficient reported information). In addition, hepatitis C may lack discrete onset of symptoms, and negative tests can help determine when infection occurred, target acute infection and interrupt transmission.

Potential Costs

The Department assumes that the changes to reportable tests will not impact the number of cases of Hepatitis C virus reported annually or the number or specimens submitted other than an increase in reports from HVC nucleic acid detection (NAT or NAAT) for qualitative, quantitative, and genotype tests as a result of the proposed change to require nonpositive in addition to positive results for this test. The Department estimates that laboratories will incur the following costs associated with reporting nonpositive results for nucleic acid detection tests; and submitting hepatocellular enzyme levels, pregnancy status, and negative IgM anti-HBc results associated with a previous positive result:

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR (such as secure file transfer, secure email, secure facsimile), the Department assumes the probable cost for including these additional data components when submitting laboratory reports for this condition are $30,848 per year [7,712cases (0.1 hours X $40.00 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR (such as secure file transfer, secure email, secure facsimile), the Department assumes the probable cost for preparing and submitting laboratory reports for nonpositive nucleic acid detection tests are $300,000.00 per year [15,000 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs are $330,848to include the proposed additional data components when submitting laboratory reports for this condition and for preparing and submitting laboratory reports for nonpositive nucleic acid detection tests.

Hepatitis D virus

Description of Proposed Changes

The proposed rule changes the notification of test results from within 2 business days for hepatitis D to “within 24 hours”.

Estimated Number of Cases

The Department estimates that there are 14 cases of hepatitis D in Washington annually. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefit

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes, for laboratories that submit laboratory reports using Electronic Lab Reporting, one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

The Department assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department also assumes laboratories will incur costs related to calling the public health authority to confirm receipt of a laboratory report (a new requirement due to the change from within 2 business days to within 24 hour reporting requirement) for this proposed condition is $140 per year [14 cases (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs are $140 to confirm receipt of laboratory reports via phone.

Histoplasma capsulatum (Histoplasmosis)

Description of Proposed Changes

The proposed rule adds *Histoplasma capsulatum* (Histoplasmosis) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within two business days of completing a test that results in a positive preliminary or final result using any test method; and
- Submit the isolate associated with the positive test result, if available, to the Department of Health within two business days; or
- If the isolate is not available, submit the specimen associated with the positive result within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes zero to one case of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting a laboratory report for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $25.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $45.00 to submit laboratory reports and specimens.

Human immunodeficiency virus (HIV)

Description of Changes

The proposed rule:

- Consolidates HIV notification into a single row;
- Changes notifiable test results:

    - From examples of "positive Western Blot assays, P24 antigen or viral culture tests"; and "II viral load detection test result – detectable and undetectable"
    - To "positive and indeterminate results and subsequent negative results associated with those positive or indeterminate results for:
        - Antibody detection tests (including RST);
        - Antigen detection tests (including RST);
        - Viral culture;
        - HIV nucleic acid detection (NAT or NAAT) tests:
            - Qualitative and quantitative; and
            - Detectable and undetectable HIV antiviral resistance testing genetic sequences";
- Changes notification of some test results from "monthly" to "within 2 business days";
- Changes the specimen type and time frame from being unspecified to "N/A".

(See also "De-identified negative screening results" for additional analysis of significant changes to HIV.)

Estimated Number of Cases

In 2018, 401 new cases of HIV were reported to public health authorities in Washington State.[230] The Department estimates that laboratories will report an additional 450 negative and indeterminate results as a result of the proposed changes.

Probable Benefits

Requiring laboratories to report indeterminate results as well as negative results associated with a previous positive or indeterminate results will provide public health authorities with confirmatory test results needed for the full testing algorithm allowing public health authorities to help identify inconclusive results and reduce investigation time (which can reduce burden on public health authorities and laboratories who would be asked to facilitate those investigations in the absence of sufficient reported information). In addition, HIV may lack discrete onset of symptoms, and negative tests can help determine when infection occurred, target acute infection and interrupt transmission.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for indeterminate results and to include negative results associated with a previous positive or indeterminate result in laboratory reports depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

[230] https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=hiv. Accessed January 20, 2020.

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for indeterminate results is $4,000 per year [200 cases (.5 hours X $40.00 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR (such as secure file transfer, secure email, secure facsimile), the Department assumes the probable cost for including negative results associated with a previous positive or indeterminate results in laboratory reports for this condition are $2,484 per year [(401 positive cases + 220 indeterminate cases)(0.1 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs are $6,484 for preparing and submitting laboratory reports for indeterminate results and for including negative results associated with a previous positive or indeterminate result in laboratory reports for this condition.

The Department assumes that the change from reporting some test results monthly to within 2 business days will be cost neutral.

Human prion disease

Description of Proposed Change

The proposed rule adds human prion disease as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within 2 business days of completing a test that results in a positive preliminary or final result using any test method excluding TAU protein; and
- Specimens associated with a positive result must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Estimated Number of Cases

During the years 2009-2018, eight to 18 cases of human prion disease were reported each year by providers and facilities in Washington State.[231] Based on this information, the Department

[231] Washington State Department of Health. Notifiable Conditions – Prion Disease. Available from https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/PrionDisease. Accessed January 20, 2020.

estimates 20 cases of human prion disease may be submitted to public health authorities annually.

Probable Benefits

Human prion diseases, including Creuzfelt Jacob disease, are rare conditions. There are forms that are due to new mutations, due to inherited family tendency, or (most rarely) due to medical or other exposures. The frequency of these conditions is being investigated in Washington State. Human prion disease is already notifiable by health care providers and health care facilities under the rule. Having laboratory reports and specimen submissions for human prion disease will help distinguish the forms of the disease, help detect emergence of variant Creutzfeldt-Jakob disease or novel prion diseases in the United States, and inform public health action to prevent the spread of these emergent or novel strains.[232]

For each case of human prion disease avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition are $400.00 per year [20 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition are $500.00 per year [20 cases (0.25 hours X $40 per hour) plus (20 cases X $15 packaging)].

[232] Washington State Department of Health. Notifiable Conditions – Prion Disease. Available from https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/PrionDisease. Accessed January 20, 2020.

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs are $900.00 to submit laboratory reports and specimens.

Japanese encephalitis, acute (Arbovirus)

Description of Proposed Changes

The proposed rule separates existing grouped notifiable arboviruses into individual lines in Table Lab-1, including this condition, and changes notifiable test results from "IgM positivity, PCR positivity, and viral isolation" to "positive results by any method excluding IgG".

Estimated Number of Cases

Washington State had zero reported cases of Japanese encephalitis between 2002 and 2018.[233] Based on this information the Department estimates that zero to one case will be reported to public health authorities annually. The Department assumes that zero to one of these reported case may result from one of the test methods newly reportable under the proposed rule.

Potential Benefits

This proposed change updates the list of reportable test results to align with currently available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Potential Costs

While laboratories are already required to report cases of this condition, this proposed change may increase the number of cases laboratories must report (and correspondingly how many specimens they must submit) since the proposed change expands the list of test results that are reportable.

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and

[233] Washington State Department of Health. Arboviral Disease Types. Available from: https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=arbo. Accessed January 20, 2020.

submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $15.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $35.00 to submit laboratory reports and specimens.

La Crosse encephalitis, acute (Arbovirus)

Description of Proposed Changes

The proposed rule separates existing grouped notifiable arboviruses into individual lines in Table Lab-1, including this condition, and changes notifiable test results from "IgM positivity, PCR positivity, and viral isolation" to "positive results by any method excluding IgG".

Estimated Number of Cases

Washington State had zero reported cases of La Cross encephalitis between 2002 and 2018.[234] Based on this information the Department estimates that zero to one case will be reported to public health authorities annually. The Department assumes that zero to one of these reported case may result from one of the test methods newly reportable under the proposed rule.

Potential Benefits

This proposed change updates the list of reportable test results to align with currently available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Potential Costs

While laboratories are already required to report cases of this condition, this proposed change may increase the number of cases laboratories must report (and correspondingly how many

[234] Washington State Department of Health. Arboviral Disease Types. Available from: https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=arbo. Accessed January 20, 2020.

specimens they must submit) since the proposed change expands the list of test results that are reportable.

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $15.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $35.00 to submit laboratory reports and specimens.

Listeria monocytogenes (Listeriosis)

Description of Proposed Changes

The proposed rule changes notifiable test results from being unspecified to “positive result for specimen from normally sterile site by: culture, nucleic acid detection (NAT or NAAT).”

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Mumps virus

Description of Proposed Changes

The proposed rule changes notifiable test results from "acute: IgM positivity; PCR positivity" to "positive result for: culture; Nucleic acid detection (NAT or NAAT); IgM".

Probable Benefits

This proposed change updates the list of reportable test results to align with currently available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Probable Costs

The Department assumes that this proposed change will be cost neutral.

Mycobacterium tuberculosis complex (Tuberculosis)

Description of Proposed Changes

The proposed rule:

- Consolidates and renames the condition from "*Mycobacterium tuberculosis*" to "*Mycobacterium tuberculosis* complex";
- Changes the notifiable test results from being unspecified and "antibiotic sensitivity for first isolates" to "positive result for: culture; Nucleic acid detection (NAT NAAT); drug susceptibilities (molecular and culture based)".

Mode of Transmission

Mycobacterium tuberculosis complex comprises *M. tuberculosis*, *M. bovis,* and *M. africanum*, among others. The different strains have different modes of transmission. For example *M. bovis* is most commonly transmitted to humans when people eat or drink contaminated, unpasteurized dairy products.[235] *M. tuberculosis is spread from person to person through the air.*[236]

Estimated Number of Cases

In 2018, 189 cases of tuberculosis were reported in Washington State.[237] The Department assumes these proposed changes will reduce the number of positive results and related specimens submitted annually specifically for *M. tuberculosis* as a result of reducing the types of test results

[235] https://www.cdc.gov/tb/publications/factsheets/general/mbovis.htm. Accessed January 20, 2020.
[236] https://www.cdc.gov/tb/topic/basics/howtbspreads.htm. Accessed January 20, 2020.
[237] https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=hepa. Accessed January 20, 2020.

that must be submitted. However, the proposed rule would also add additional Mycobacterium strains to the rule, which could increase the number of overall reports.

Probable Benefits

This proposed change updates the list of reportable test results to align with current available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Including additional strains of *Mycobacterium* as notifiable will help ensure that tuberculosis cases do not go undetected by public health authorities.

Probable Costs

The Department assumes that these proposed changes will be cost neutral with regard to annual costs as a result of decreased reports from reducing the types of test results that must be submitted paired with potential increased reports resulting from adding additional Mycobacterium strains to the rule.

The Department assumes laboratories will incur the following one-time costs:

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- To update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

Neisseria gonorrhoeae **(Gonorrhea)**

Description of Proposed Changes

The proposed rule:

- Changes notifiable test results from being unspecified to “positive and indeterminate result by any method”;
- Changes specimen type and submission time frame from being unspecified to “N/A”; and

(See also “De-identified negative screening results” for additional analysis of significant changes to *Neisseria gonorrhoeae.*)

Estimated Number of Cases

In 2010 2,865 positive cases of *Neisseria gonorrhoeae* were reported in Washington State.[238] The Department estimates that 70 new indeterminate cases will be reported as a result of this proposed change.

Probable Benefits

The proposed change to require laboratories to submit indeterminate results in addition to positive results will help ensure that public health authorities are alerted to cases that may be positive so they can initiate a case investigation with follow-up testing and the corresponding public health action if a positive case is identified.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for indeterminate results depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for these indeterminate results is $1,400 per year [70 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system. The total probable yearly costs are $1,400 to submit laboratory reports. This condition does not have a specimen submission requirement.

Plasmodium species (Malaria)

Description of Proposed Changes

The proposed rule:

- Notifiable test results from being unspecified to "positive results for:
  - Nucleic acid detection (NAT or NAAT);
  - Malaria-specific antigens by rapid diagnostic test;
  - PCR; and

[238] Washington State Department of Health. Notifiable Conditions – Gonorrhea. Available from: https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/Gonorrhea. Accessed January 20, 2020.

Microscopy (thick or thin smear)"

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Powassan virus, acute (Arbovirus)

Description of Proposed Changes

The proposed rule separates existing grouped notifiable arboviruses into individual lines in Table Lab-1, including this condition, and changes notifiable test results from "IgM positivity, PCR positivity, and viral isolation" to "positive results by any method excluding IgG".

Estimated Number of Cases

Washington State had zero reported cases of Powassan virus between 2002 and 2018.[239] Based on this information the Department estimates that zero to one case will be reported to public health authorities annually. The Department assumes that zero to one of these reported case may result from one of the test methods newly reportable under the proposed rule.

Potential Benefits

This proposed change updates the list of reportable test results to align with currently available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Potential Costs

While laboratories are already required to report cases of this condition, this proposed change may increase the number of cases laboratories must report (and correspondingly how many specimens they must submit) since the proposed change expands the list of test results that are reportable.

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory.

[239] Washington State Department of Health. Arboviral Disease Types. Available from: https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=arbo. Accessed January 20, 2020.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $15.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $35.00 to submit laboratory reports and specimens.

***Rickettsia* species, including, but not limited to, *Rickettsia rickettsia, Rickettsia africae, Rickettsia conorii, Rickettsia typhi, Rickettsia parkeri, Rickettsia philipii, Rickettsia prowazekii*.**

Description of Proposed Changes

The proposed rule adds *Rickettsia* species as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within 2 business days of completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive result must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes zero to five cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition range from $0 to $100.00 per year [0 cases (.5 hours X $40.00 per hour) to 5 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0 to $75 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 5 cases (0.25 hours X $40 per hour) plus (5 cases X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly cost ranges from $0 to $175 to submit laboratory reports and specimens.

Rubella virus

Description of Proposed Changes

The proposed rule adds Rubella virus as a notifiable condition for laboratories, requiring submission of laboratory reports and specimens as follows:

- Laboratory report must be submitted to the local health jurisdiction immediately following completion of a test that results is a positive preliminary or final result by culture, IgM, and nucleic acid detection (NAT or NAAT);
- An isolate associated with the positive result, or if no isolate is available, the specimen associated with the positive result must be submitted to the Department of Health within two business days;
- Other specimens must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Estimated Number of Cases

Since year 2000, zero to two cases of acquired rubella have been reported annually.[240] Based on this information, the Department estimates zero to two case of rubella may be submitted to public health authorities annually.

Probable Benefits

Rubella is a rare disease carried by humans that causes congenital birth defects (mostly commonly deafness) as well as fetal death, spontaneous abortion, or premature delivery if acquired during pregnancy. Rubella is nationally notifiable condition. Rubella is already notifiable by health care providers and health care facilities under the rule. Having laboratory reports and specimen submissions for rubella will assist public health authorities in ruling out or confirming the diagnosis in a timely manner to in order to assure prompt treatment and prevent the spread of disease.[241]

For each case of rubella avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

[240] Washington State Department of Health. Notifiable Conditions: Rubella. Available from https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/Rubella. Accessed January 20, 2020.
[241] Washington State Department of Health. Notifiable Conditions: Rubella. Available from https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/Rubella. Accessed January 20, 2020.

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $40.00 per year [0 cases (.5 hours X $40.00 per hour) to 2 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to:

- Prepare and submit specimens for this proposed condition ranges from $0.00 to $30.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 2 cases (0.25 hours X $40 per hour) plus (2 cases X $5 packaging)]; and
- Call the public health authority to confirm receipt of a laboratory report for this proposed condition ranges from $0.00 to $20.00 per year [0 cases (0.25 hours X $40 per hour) to 2 case (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 for no cases of the condition to $90.00 to submit a laboratory report and specimen, and confirm receipt of the laboratory report.

Rubeola (Measles virus)

Description of Proposed Changes

The proposed rule changes:

- Notifiable test results from "IgM positivity; PCR positivity" to "positive result by culture; IgM; Nucleic acid detection (NAT or NAAT)";
- Specimen type and submission time frame from an isolate or clinical specimen associated with the positive result within two business days to:
  - Isolate and specimen associated with positive culture within two business days;
  - Isolate and specimen associated NAT or NAAT result within two business days; and
  - A specimen associated with the positive IgM and other specimen within two business days of request by a local health jurisdiction or the Department of Health.

Probable Benefits

This proposed change updates the list of reportable test results and specimen submission requirements to align with current available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Probable Costs

The Department assumes that this proposed change will be cost neutral.

St. Louis encephalitis, acute (Arbovirus)

Description of Changes

The proposed rule separates existing grouped notifiable arboviruses into individual lines in Table Lab-1, including this condition, and changes notifiable test results from IgM positivity, PCR positivity, and viral isolation to positive results by any method excluding IgG.

Estimated Number of Cases

Washington State had zero reported cases of St. Louis encephalitis between 2002 and 2018.[242] Based on this information the Department estimates that zero to one case will be reported to public health authorities annually. The Department assumes that zero to one of these reported cases may result from one of the test methods newly reportable under the proposed rule.

Potential Benefits

This proposed change updates the list of reportable test results to align with currently available valid test methods in order to ensure that all cases of this condition are reported. This increases the likelihood that public health authorities will be alerted to a case and deploy a timely and appropriate public health response.

Potential Costs

While laboratories are already required to report cases of this condition, this proposed change may increase the number of cases laboratories must report (and correspondingly how many specimens they must submit) since the proposed change expands the list of test results that are reportable.

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $20.00 per year [0 cases (.5 hours X $40.00 per hour) to 1 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

[242] Washington State Department of Health. Arboviral Disease Types. Available from: https://www.doh.wa.gov/Portals/1/Documents/5100/420-004-CDAnnualReportIncidenceRates.pdf#nameddest=arbo. Accessed January 20, 2020.

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $15.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 1 case (0.25 hours X $40 per hour) plus (1 case X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $35.00 to submit laboratory reports and specimens.

Taenia solium (Taeniasis or Cysticercosis))

Description of Proposed Changes

The proposed rule add *Taenia solium* (Taeniasis or Cysticercosis) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within two business days of completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive result must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes 20 cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable

one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable costs for preparing and submitting laboratory reports for this condition are $400.00 per year [20 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable costs for a laboratory to prepare and submit specimens for this proposed condition are $300 per year [20 cases (0.25 hours X $40 per hour) plus (20 cases X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs are $700.00 to submit laboratory reports and specimens.

Treponema pallidum **(Syphilis)**

Description of Proposed Changes

The proposed rule changes notifiable test results from being unspecified to positive and indeterminate result by any method.

(See also "De-identified negative screening results" for additional analysis of significant changes to *Treponema pallidum.*)

Estimated Number of Cases

In year 2010, 261 cases of primary and secondary syphilis were reported in Washington State.[243] The Department estimates that seven new indeterminate cases will be reported as a result of this proposed change.

Probable Benefits

The proposed change to require laboratories to submit indeterminate results in addition to positive results will help ensure that public health authorities are alerted to cases that may be positive so they can initiate a case investigation with follow-up testing and the corresponding public health action if a positive case is identified.

[243] Washington State Department of Health. Notifiable Conditions – Syphilis. Available from: https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/Syphilis. Accessed January 20, 2020.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for indeterminate results depends on the form of secure electronic data transmission used by the laboratory.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for these indeterminate results is $120 per year [6 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system. The total probable yearly costs are $120 to submit laboratory report. This condition does not have a specimen submission requirement for indeterminate results.

Trichinella species (Trichinellosis)

Description of Proposed Changes

The proposed rule changes notifiable test results from being unspecified to positive serologic test for *Trichinella*.

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Trypanosoma cruzi (Chagas disease)

Description of Proposed Changes

The proposed rule adds *Trypanosoma cruzi* (Chagas disease) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within two business days of completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive result, must be submitted to the Department of Health within two business days.

Mode of Transmission

See "Mode of Transmission" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Estimated Number of Cases

The Department assumes 10-20 cases of this condition will be reported in Washington State. (For additional information, see "Estimated Number of Cases" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.)

Probable Benefits

See "Probable Benefits" for this condition in the section analysis of WAC 246-101-101, Notifiable conditions: Health care providers and health care facilities.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $$200 to $ $400per year [10cases (.5 hours X $40.00 per hour) to 20 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $150 to $300 per year [10 cases (0.25 hours X $40 per hour) plus (10 cases X $5 packaging) to 20 cases (0.25 hours X $40 per hour) plus (20 cases X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total probable yearly costs range from $350 to $700 to submit laboratory reports and specimens.

Vaccinia (Vaccine-acquired smallpox)

Description of Proposed Change

The proposed rule adds Vaccinia (Vaccine-acquired smallpox) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction immediately for **any request for testing associated with a suspect case**; and
- Any specimen **collected from a suspect case** must be submitted to the Department of Health immediately.

Estimated Number of Cases

While rare, there are documented cases of transmission of vaccinia in the United States.[244] Based on this information, the Department estimates zero to five vaccinia cases may be submitted to public health authorities annually due to the fact the proposed rule would require a request for testing (rather than a positive test result) to be reported.

Probable Benefits

Vaccinia infection (smallpox vaccine-acquired smallpox) can resemble smallpox. Smallpox (variola infection) is a very serious disease previously carried by humans but now limited to a few laboratories in the world. The virus could be released intentionally so a smallpox case would almost always be part of a bioterrorism attack.[245] Vaccinia is already notifiable by health care providers and health care facilities under the rule.

No laboratories in Washington State outside of the Public Health Laboratories test for vaccinia, so making any request for testing notifiable and requiring any specimen collected from a suspect case to be submitted to the Department will facilitate the flow of information to public health authorities so the State Public Health Laboratories can receive the specimen and conduct the laboratory test. This will assist public health authorities in ruling out or confirming the suspected diagnosis in a timely manner to in order to prevent the spread of disease.

For each case of vaccinia infection avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

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[244] Centers for Disease Control and Prevention. MMWR: Secondary and Tertiary Transmission of Vaccinia Virus After Sexual Contact with a Smallpox Vaccinee – San Dieog, California, 2012.
[245] Washington State Department of Health. Smallpox. Available from: https://www.doh.wa.gov/Emergencies/BePreparedBeSafe/BioterrorismandTerrorism/Smallpox. Accessed January 20, 2020.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $100.00 per year [0 cases (.5 hours X $40.00 per hour) to 5 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to:

- Prepare and submit specimens for this proposed condition ranges from $0.00 to $125.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $15 packaging) to 5 cases (0.25 hours X $40 per hour) plus (5 cases X $15 packaging)]; and

- Call the public health authority to confirm receipt of a laboratory report for this proposed condition ranges from $0.00 to $50.00 per year [0 cases (0.25 hours X $40 per hour) to 5 cases (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 for no cases of the condition to $275.00 to submit a laboratory report and specimen, and confirm receipt of the laboratory report.

Variola virus (Small pox)

Description of Proposed Changes

The proposed rule changes:

- Notifiable test results from being unspecified to **any request for testing associated with a suspect case**;
- Specimen type from isolate or clinical specimen associated with a positive result to specimen **collected from a suspect case**; and

- Specimen submission time frame from two business days to immediately.

Estimated Number of Cases

Smallpox infection was eliminated globally in the 1970s. Because the security of the virus is uncertain, there is a remote risk that smallpox could be used as a weapon.[246] Based on this information, the Department estimates zero to five variola virus case may be submitted to public health authorities annually, due to the fact the proposed rule would require a request for testing (rather than a positive test result) to be reported.

Probable Benefits

Smallpox (variola infection) is a very serious disease previously carried by humans but now limited to a few laboratories in the world. The virus could be released intentionally so a smallpox case would almost always be part of a bioterrorism attack.[247] No laboratories outside of the Washington State Public Health Laboratories test for variola virus in the state, so making any request for testing notifiable and requiring any specimen collected from a suspect case to be submitted to the Department will facilitate the flow of information to public health authorities so the Public Health Laboratories can receive the specimen and conduct the laboratory test. This will assist public health authorities in ruling out or confirming the suspected diagnosis in a timely manner to in order to prevent the spread of disease. Decreasing the specimen submission time frame from two business days to immediately will also help promote a more rapid confirmation or ruling out of smallpox and the accompanying public health response.

For each case of smallpox avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year.

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition would increase as a result of requiring requests for testing to be reported rather than the status quo of reporting positive test results.

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports for this condition ranges from $0.00 to $100.00 per year [0 cases (.5 hours X $40.00 per hour) to 5 cases (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

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[246] Washington State Department of Health. Smallpox. Available from: https://www.doh.wa.gov/Emergencies/BePreparedBeSafe/BioterrorismandTerrorism/Smallpox. Accessed January 20, 2020.

[247] Washington State Department of Health. Smallpox. Available from: https://www.doh.wa.gov/Emergencies/BePreparedBeSafe/BioterrorismandTerrorism/Smallpox. Accessed January 20, 2020.

The Department assumes the probable cost for a laboratory to:

- Prepare and submit specimens for this condition ranges from $0.00 to $75.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 5 cases (0.25 hours X $40 per hour) plus (5 cases X $5 packaging)]; and
- Call the public health authority to confirm receipt of a laboratory report for this proposed condition ranges from $0.00 to $50.00 per year [0 cases (0.25 hours X $40 per hour) to 5 cases (0.25 hours X $40 per hour)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $225.00 to submit laboratory reports and specimens, and confirm receipt of the laboratory report.

West Nile virus, acute (Arbovirus)

Description of Proposed Changes

The proposed rule separates existing grouped notifiable arboviruses into individual lines in Table Lab-1, including West Nile virus, acute (Arbovirus), and changes notifiable test results from IgM positivity, PCR positivity, and viral isolation to positive results by any method excluding IgG.

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Yellow fever virus (Arbovirus)

Description of Proposed Change

The proposed rule changes notifiable test results from being unspecified to positive results by any method excluding IgG.

Estimated Number of Cases

The Department assumes this proposed change will reduce the number of positive results and related specimens submitted annually.

Probable Benefits

The Department assumes the proposed change may reduce the regulatory burden, including costs, on laboratories by reducing the test results requiring notification and related specimen submittals.

Probable Costs

The Department assumes laboratories would need to update their standard operating procedures for this condition which would result in a one-time cost of $12.00 (0.2 hours X $60 per hour)].

Zika virus, acute (Arbovirus)

Description of Proposed Changes

The proposed rule adds Zika virus, acute (Arbovirus) as a notifiable condition requiring laboratories to submit laboratory reports and specimens as follows:

- Laboratory reports must be submitted to the local health jurisdiction within two business days of completing a test that results in a positive preliminary or final result using any test method; and
- Specimens associated with a positive test result must be submitted within two business days of request by a local health jurisdiction or the Department of Health.

Mode of Transmission

Zika virus is transmitted to humans through the bite of *Aedes* species of mosquito, including *Ae. aegypti* and *Ae. albopictus* in the Americas.[248] *Ae. aegypti* is considered the most significant vector of Zika virus due to its prevalence and role in the transmission of other arboviruses.[249] Horizontal transmission of Zika is possible through congenital and perinatal transmission. Perinatal transmission has been reported, although the incidence of this method of transmission is unknown.[250,251] Zika virus has also been found in breast milk, and it is possible that an individual infected post-partum could then transmit the virus to their breastfeeding infant.[252] There are some reported cases but no confirmed cases of transmission by this route.[253]

Sexual transmission of Zika virus has been confirmed in a handful of cases, and the virus has been isolated in samples of semen from confirmed cases. Finally, horizontal transmission is possible in the case of blood transfusion, organ transfer or laboratory accident.[254]

Estimated Number of Cases

[248] Centers for Disease Control and Prevention. Zika Virus. Available from https://www.cdc.gov/zika/index.html. Accessed April 24, 2019.
[249] Relich R, Loeffholz, M. Zika Virus. Clin Lab Med. 2017; 37:253-267. http://dx.doi.org/10.1016/j.cll.2017.01.002
[250] Centers for Disease Control and Prevention. Zika Virus. Available from https://www.cdc.gov/zika/index.html. Accessed April 24, 2019.
[251] Langerak T, Mumtz N, Tolk V, van Gorp E, Martina B, Rockx B, Koopmans M. The Possible Role of Cross-Reactive Dengue Virus Antibodies in Zika Virus Pathogenesis. *PLoS Pathog* 2019; 15(4):e1007640.
[252] Blohm GM, Lednicky JA, Márquez M, et. al. Evidence for Mother-to-Child Transmission of Zika Virus Through Breast Milk. *Clin Infect Dis*. 2018;55:11201.
[253] Colt S, Garcia-Casal MN, Peña-Rosas JP, et. al. Transmission of Zika virus through breast milk and other breastfeeding-related bodily fluids: A systematic review. *PLOS Negl Trop Dis*. 2017;11: e0005528.
[254] Musso D, Gubler D. Zika Virus. *Clinical Microbiology Reviews.* 2016; 29(3):487-524.

Twenty cases of Zika virus disease were reported to the CDC in the United States in 2019 (no cases reported in Washington State). In 2018, 74 cases were reported nationwide (73 cases from travelers returning from affected areas 1 case acquired through laboratory exposure), with no cases reported in Washington State. In 2017, 452 cases were reported in the United States, with 15 of those cases being in Washington State. The highest number of cases reported in Washington State since 2015 was 69 cases in 2016.[255] Washington State does not have any locally-acquired cases of Zika due to a lack of the *Ae. aegypti* mosquito.[256]

Based on this information, the Department estimates zero to sixty-nine Zika cases may be submitted to public health authorities annually.

Probable Benefits

The following description of the burden of illness on individuals who have contracted Zika illustrates some of the societal benefits of notifiable conditions surveillance described above in the introduction to this section-by-section analysis. This description of symptoms and outcomes serves to qualitatively illustrate the probable benefits of preventing, or reducing the severity of, cases of cases of the condition as a result of establishing notification requirements for it.
Zika virus can be mild (asymptomatic, fever, rash, conjunctivitis),[257,258] but the virus is also linked to more serious outcomes such as Guillain-Barre Syndrome (GBS) in adults .[259] By far the most severe symptoms related to Zika occur in some infants who are infected through in-vitro transmission. Congenital Zika syndrome results in severe fetal brain anomalies related to microcephaly, with long-term effects including blindness, hearing loss, epilepsy, severe neurodevelopmental delay and others.[260]

Probable Costs

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for this condition depends on the form of secure electronic data transmission used by the laboratory, whether specimen submittal is required, and whether the condition is notifiable immediately or within 24 hours.

- For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes one-time costs to update the LIMS and ELR system, the probable one-time costs to include this condition in their LIMS and ELR system are $120.00 [2 systems (1 hour X $60 per hour)].

- For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and

[255] Centers for Disease Control and Prevention. Zika Virus Statistics and Maps. Available at https://www.cdc.gov/zika/reporting/index.html. Accessed January 17, 2020.
[256] Public Health Seattle-King County. Zika Virus Updates. 2019; https://www.kingcounty.gov/depts/health/communicable-diseases/disease-control/zika-virus.aspx Accessed April 24, 2018.
[257] Musso D, Gubler D. Zika Virus. *Clinical Microbiology Reviews.* 2016; 29(3):487-524.
[258] Relich R, Loeffholz, M. Zika Virus. *Clin Lab Med.* 2017; 37:253-267. http://dx.doi.org/10.1016/j.cll.2017.01.002
[259] Baud D, Gubler D, Schaub B, Lanteri M, Musso D. An Update on Zika Virus Infection. *Lancet.* 2017; 390:20199-109. http://dx.doi.org/10.1016/S0140-6736(17)31450-2
[260] Ibid.

submitting laboratory reports for this condition ranges from $0.00 to $1,380.00 per year [0 cases (.5 hours X $40.00 per hour) to 69 case (.5 hours X $40.00 per hour)].

The Department also assumes laboratories would incur a one-time cost to update their standard operating procedures for this condition. The probable cost would be $12.00 (0.2 hours X $60 per hour)].

The Department assumes the probable cost for a laboratory to prepare and submit specimens for this proposed condition ranges from $0.00 to $1,035.00 per year [0 cases (0.25 hours X $40 per hour) plus (0 cases X $5 packaging) to 69 cases (0.25 hours X $40 per hour) plus (69 cases X $5 packaging)].

The total range of probable one-time costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and their LIMS and ELR system.

The total range of probable yearly costs range from $0.00 to $2,070.00 to submit laboratory reports and specimens.

WAC 246-101-205, Duties: Laboratory directors

Description of Proposed Change

The proposed rule requires laboratories to submit presumptive and final test results to the Department of Health for a patient residing outside and visiting Washington State.

The proposed rule also makes the following changes to the data components a Laboratory Director must send to a reference laboratory when referring a specimen to another laboratory for testing:

- Revises patient's address: Removes allowance to use only a zip code and removes language "when available in laboratory database"
- Revises patient's date of birth: Removes allowance to use patient age and removes language "when available in laboratory database"
- Revises patient sex: Removes language "when available in laboratory database"
- Adds "Patient's ethnicity", "Patient's race", and "Patient's preferred language"[261]
- Adds "For hepatitis B tests only, pregnancy status (pregnant/not pregnant/unknown), for patients fourteen to fifty years of age only"
- Adds "Patient's best contact telephone number"
- Adds "Patient's Medicaid status, for blood lead tests for patients less than 72 months of age only"
- Revises "Name of the principal health care provider" to "Requesting health care provider's name"
- Revises "Telephone number of the principal health care provider" to "Requesting health care provider's phone number"

[261] See Appendix B for ethnicity, race, and preferred language reporting categories.

- Revises “Address of principal health care provider” to “Address where patient received care” and removes the language “when available”
- Adds “Name of submitting laboratory”
- Adds “Telephone number of submitting laboratory”
- Adds “Date laboratory received specimen”
- Revises “Test type requested” to “Test method requested”

Note: WAC 246-101-105 of the proposed rule would also require health care providers and health care facilities to submit these data components to laboratories with each notifiable condition test ordered.

All other amendments to the proposed rule are editorial only, clarifying the rule without changing its effect, and are not considered significant under RCW 34.05.328.

Estimated Number of Cases: Case reports for patients visiting Washington State

The Department estimates there are 75 to 100 cases of notifiable conditions identified through laboratory testing each year for patients visiting Washington State.

Probable Benefits: Case reports for patients visiting Washington State

The probable benefits of the proposed requirement for laboratories to submit presumptive and final test results to the Department for a patient who receives care while visiting Washington State, but resides outside the state are all the benefits associated with notifiable conditions. A person visiting Washington State could contract any condition while visiting the state or bring any notifiable condition to the state.

For each case of a notifiable condition avoided, prevented, or treated to reduce the severity of the condition, there are related avoided costs associated with the potential symptoms and outcomes of the condition, for example costs of lost productivity, hospitalization, and the condition specific Disability-Adjusted Life Year (DALY).

Probable Costs: Case reports for patients visiting Washington State

The Department assumes the probable cost for a laboratory to prepare and submit laboratory reports for patients visiting Washington State are included in costs identified in WAC 246-101-201 for updating laboratory LIMS and ELR systems to include all notifiable conditions, update standard operating procedures for each notifiable condition, submit laboratory reports, and confirm receipt for laboratory reports for conditions notifiable immediately or within 24 hours.

For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes the probable cost for preparing and submitting laboratory reports ranges from $1,500 to $2,000 per year [75 cases (.5 hours X $40.00 per hour) to 100 cases (.5 hours X $40.00 per hour)].

The Department assumes the probable cost for a laboratory to call the public health authority to confirm receipt of a laboratory report for patients visiting Washington State ranges from $750 to $1,000 per year [75 cases (0.25 hours X $40 per hour) to 100 cases (0.25 hours X $40 per hour)].

The total probable yearly costs range from $2,250 to $3,000 to submit a laboratory report for patients visiting Washington State and confirm receipt of the laboratory report.

Probable Benefits: Data components when referring a specimen to another laboratory for testing

The probable benefits of changing the content of data components a Laboratory Director must send to a reference laboratory when referring a specimen to another laboratory for testing are primarily gained by adding information necessary to consistently identify potential cases of notifiable conditions across the medical and public health systems, enabling faster identification and follow-up of cases, and implementation of public health interventions to prevent and control notifiable conditions.

The additions of "patient's race", "patient's ethnicity", and "patient's preferred language" will help promote equity by identifying populations disproportionality impacted by any condition. This information will allow the public health system to tailor the public health approach to ensure the interventions are linguistically and culturally appropriate and that they are reaching impacted populations. A more comprehensive analysis of the benefits of collecting these data is provided above under the analysis for WAC 256-101-105.

Two additional pieces of patient information are unique: For hepatitis B tests only, pregnancy status (pregnant/not pregnant/unknown), for patients fourteen to fifty years of age only; and patient Medicaid status, for blood lead tests for patients less than 72 months of age only.

Adding pregnancy status for patients fourteen to fifty years of age to requests for hepatitis B laboratory testing is intended to increase identification of hepatitis B in pregnant patients and prevent disease transmission of hepatitis B to infants during delivery.

Infants born to patients with chronic hepatitis B are at high risk of contracting hepatitis B infection. Without treatment, infants infected with the hepatitis B virus have a 90% chance of developing chronic hepatitis B. Up to 25% of infants who acquire chronic hepatitis B infection will die prematurely from related hepatocellular carcinoma or cirrhosis.[262]

When pregnancy status is known to providers, facilities, and public health authorities, infants born to mothers with hepatitis B infection are more likely to receive Hepatitis B Immunoglobulin (HBIG) within 12 hours of birth along with a first dose of hepatitis B vaccine. If the infant does not receive HBIG and the birth dose of vaccine, the infant is at greater risk of contracting hepatitis B infection and experiencing the symptoms and outcomes associated with it. In addition, this information allows public health perinatal hepatitis B prevention coordinators to follow up and ensure appropriate management of infants.[263]

Adding Medicaid status for patients less than 72 months of age to requests for blood lead tests is intended to identify lead poisoning among very young children when exposure has the greatest impact on health, and public interventions can be most successful.

[262] https://www.cdc.gov/hepatitis/hbv/pregstatuslabreporting.htm Accessed January 19, 2020
[263] https://www.cdc.gov/hepatitis/hbv/pregstatuslabreporting.htm Accessed January 19, 2020

The Centers for Disease Control and Prevention (CDC) projects there are about half a million children between the ages of one and five years in the United States who possess blood lead levels greater than 5 micrograms per deciliter (µg/dL), which is the threshold level at which CDC recommends public health actions are taken. All children enrolled in Medicaid are required to receive blood lead screening tests at ages 12 months and 24 months. In addition, any child between 24 and 72 months with no record of a previous blood lead screening test must receive one. [264] Adding Medicaid status for patients less than 72 months of age assists public authorities in identifying new cases lead poisoning, implementing treatment and prevention measures, and reporting information to the Center for Medicare and Medicaid Services and the CDC.

Medicaid status is a valuable data point for the Department Childhood Lead Poisoning Prevention Program. First, Medicaid requires children under 72 months to be tested at 12 and 24 months and at any time before the age of 6 if they have not been previously tested. The Washington State Health Care Authority (HCA) gets lead billing data to track this but the billing data does not have test results. HCA needs the test result to know which children had elevated tests in order to assure proper medical management. The Department cannot reliably give them test results for children enrolled in Medicaid because the billing and surveillance datasets do not share a unique identifier and matching is time consuming and fallible.

The Centers for Medicare and Medicaid Services (CMS) recently issued a memo requiring Medicaid to provide in home case management services to children with elevated blood lead levels. To provide an adequate public health response and comply with this new CMS requirement the Department will need to be able to let HCA know which children enrolled in Medicaid have elevated blood lead levels.

Medicaid status also provides valuable epidemiological information as it is a reliable proxy for income and has been established as a risk factor for lead exposure. This would be a valuable addition to the Department's surveillance dataset.

All other added or revised patient information is needed to accurately identify cases and enable faster public health investigations and response.

WAC 246-101-105 of the proposed rule would also require health care providers and health care facilities to submit these data components to laboratories with each notifiable condition test ordered.

Probable Costs: Data components when referring a specimen to another laboratory for testing
For laboratories that submit laboratory reports using Electronic Lab Reporting, the Department assumes their LIMS and ELR system will need to be updated to ensure electronic messages include the required data elements that will result in a probable one-time cost $800.

For laboratories that submit laboratory reports using a secure electronic data transmission method other than ELR, the Department assumes some laboratories will create electronic forms

[264] https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/lead-screening/index.html Accessed January 19, 2020

to transmit the newly required data to the reference laboratory, with a probable one-time cost ranging from $20.00 to $2,000 [1 generic form (.5 hours X $40.00 per hour) to 100 unique forms (.5 hours X $40.00 per hour)].

There are also potentially reoccurring costs for a laboratory associated with gathering data for fields that the provider or facility left blank. While WAC 246-101-105, if adopted as proposed, will require providers and facilities to include all of these data components with a specimen when they order a lab test for a notifiable condition, laboratories have expressed concerns that providers/facilities will not consistently provide these data and that the lab will incur the cost of accessing the information from the electronic medical record or from contacting the facility or provider. The costs of gathering these data are discussed below under section WAC 246-101-225 as this information would only need to be gathered once to send the reference lab as required in this section, with the specimen as required under WAC 246-101-215, and to the public health authority with the notification as required under WAC 246-101-225. For this reason, the cost does not need to be repeated in the analysis for each of these sections.

WAC 246-101-215, Content of documentation accompanying specimen submission: Laboratory directors

Description of Proposed Change

The proposed rule makes the following changes to the content of documentation required when submitting specimens:

- Revises patient's address: Removes allowance to use only a zip code and removes language "when available in laboratory database"
- Revises patient's date of birth: Removes allowance to use patient age and removes language "when available in laboratory database"
- Revises patient's sex: Removes language "when available in laboratory database"
- Adds "Patient's ethnicity", "Patient's race", and "Patient's preferred language"[265]
- Adds "For hepatitis B tests only, pregnancy status (pregnant/not pregnant/unknown), for patients fourteen to fifty years of age only"
- Revises patient telephone number: Removes language "when available in laboratory database"
- Revises "Requesting health care providers address" to "Address where patient received care" and removes the language "when available"
- Adds "Date laboratory received specimen"
- Adds "Test method used"
- Removes "other information of epidemiological value, when available"

Note: WAC 246-101-105 of the proposed rule would also require health care providers and health care facilities to submit these data components to laboratories with each notifiable condition test ordered.

All other amendments to the proposed rule are editorial only, clarifying the rule without changing its effect, and are not considered significant under RCW 34.05.328.

[265] See Appendix B for ethnicity, race, and preferred language reporting categories.

Probable Benefits

The Department assumes the probable benefits of these proposed changes are the same as those identified for proposed WAC 246-101-205 as described above.

Probable Costs

The Department assumes the probable costs of these proposed changes are included in the analysis of proposed WAC 246-101-205 above.

WAC 246-101-220, Means of notification: Laboratory directors

Description of Proposed Change

The proposed rule requires all presumptive and final test results be submitted via secure electronic data transmission. This change would eliminate:

- Hand-written presumptive and final test results
- Non-electronic mail submission (e.g. USPS, FedEx, UPS, etc.)

The proposed rule defines "secure electronic data transmission" as electronic communication and accounts developed and maintained to prevent unauthorized access, loss, or compromise of sensitive information, including, but not limited to, secure file transfer, secure email, secure facsimile, the health care authority's health information exchange, and the Department secure electronic disease surveillance system.

The proposed rule defines "secure electronic disease surveillance system" as the secure electronic data transmission system maintained by the Department to submit notifications, case reports, laboratory reports, investigation reports, and outbreak reports under this chapter.

All other amendments to the proposed rule are editorial only, clarifying the rule without changing its effect, and are not considered significant under RCW 34.05.328.

Probable Benefits

The proposed change to eliminate hand-written test results is intended to improve legibility of laboratory reports, reduce errors in transcribing information, reduce the time it takes to identify cases of notifiable conditions, and potentially provide public health interventions sooner as a result of not needing to follow up on laboratory reports when information is illegible. Follow-up is costly not only to the public health system, but to providers and facilities when staff must resubmit information. The delay in receiving complete information also delays the potential public health response to the condition. Improved legibility of laboratory reports provided by type written documents will alleviate these problems.

The proposed change to require secure electronic data submission is intended to reduce the time it takes to identify cases of notifiable conditions, potentially provide public health interventions sooner than would be possible using the postal services, and to protect confidential health information by using electronic communication and accounts developed and maintained to prevent unauthorized access, loss, or compromise of sensitive information.

Probable Costs

The Department assumes that by providing electronic forms on its website, the proposed change to eliminate hand-written test results is cost neutral for health care providers and facilities.

The Department assumes the proposed requirement to use secure electronic data submission of test results is the standard for laboratories to share sensitive data and the probable cost for this change is negligible.

WAC 246-101-225, Content of laboratory reports: Laboratory directors

Description of Proposed Change

The proposed rule makes the following changes to the content of documentation required when submitting specimens:

- Revises patient's address: Removes allowance to use only a zip code and removes language "when available in laboratory database"
- Revises patient's date of birth: Removes allowance to use patient age and removes language "when available in laboratory database"
- Revises patient's sex: Removes language "when available in laboratory database"
- Adds "Patient's ethnicity", "Patient's race", and "Patient's preferred language"[266]
- Adds "For hepatitis B tests only, pregnancy status (pregnant/not pregnant/unknown), for patients fourteen to fifty years of age only"
- Adds patient telephone number
- Adds "Patient Medicaid status, for blood lead tests for patients less than 72 months of age only"
- Revises "Requesting health care providers address" to "Address where patient received care" and removes the language "when available"
- Adds "Test method used"

Note: WAC 246-101-105 of the proposed rule would also require health care providers and health care facilities to submit these data components to laboratories with each notifiable condition test ordered.

All other amendments to the proposed rule are editorial only, clarifying the rule without changing its effect, and are not considered significant under RCW 34.05.328.

Probable Benefits

The Department assumes the probable benefits of these proposed changes are the same as those identified for proposed WAC 246-101-205 as described above.

Probable Costs

The Department assumes the probable one-time costs of these proposed changes are included in the analysis of proposed WAC 246-101-205 above.

In addition to the one-time costs discussed above, there are also potentially reoccurring costs for the laboratory associated with gathering data for fields the provider or facility left blank. While

[266] See Appendix B for ethnicity, race, and preferred language reporting categories.

WAC 246-101-105, if adopted as proposed, will require providers and facilities to include all of these data components with a specimen when they order a lab test for a notifiable condition, laboratories have expressed concerns that providers/facilities will not consistently provide these data and that the lab will incur the cost of accessing the information from the electronic medical record or through contacting the facility or provider. These costs would range from $0 if providers/facilities comply with the requirements of WAC 246-101-105, to $41,795.80. The high end of this range is estimate based on two survey responses from laboratories who assumed they providers/facilities would not consistently provide the required data. One survey estimated $2,500 to $5,000 annual costs and one estimated $41,795.80 annual costs [3,943 cases of all notifiable conditions (0.25 hours X $42.40 per hour)].

WAC 246-101-405, Duties: Veterinarians and the state department of agriculture

Description of Proposed Change

The proposed rule eliminates the requirement for veterinarians to notify the Department of suspected human cases of specifically named zoonotic diseases that poses a high risk of transmission to humans.

All other amendments to the proposed rule are editorial only, clarifying the rule without changing its effect, and are not considered significant under RCW 34.05.328.

Probable Benefits

This proposed rule reduces the potential burden of duplicative reporting for veterinarians as they are required by the Washington State Department of Agriculture to report the animal cases of the conditions identified in the current. Stakeholders expressed that these potentially duplicative reporting requirements created confusion about what information needed to be reported to which agency, and if and when they needed to engage local health jurisdictions for the purposes of case investigations. The Department also received feedback that the requirement for veterinarians to notify public health authorities of suspected human cases could be considered outside the scope of practice for Washington State licensed veterinarians.

The Department assumes public health is not jeopardized by this proposed change as no suspected human cases of the notifiable conditions included in WAC 246-101-405 have been submitted in the nine years the rule has been in effect.

Probable Costs

The Department has historically received no case reports from veterinarians under this requirement and assumes there will be no increased or decreased cost for this proposed change.

Probable Benefit and Cost Conclusion

The Department of Health and State Board of Health evaluated the qualitative and qualitative costs and benefits of the proposed rules, taking into account the general goals and specific objectives of the statute being implemented.

Benefit Summary

The proposed rules implement the general goals and specific objectives of RCW 43.20.050, RCW 43.70.545, and RCW 70.104.055 by establishing a surveillance system that includes notification, investigation, and collection and distribution of data related to infectious and noninfectious conditions. This data is critical to local health jurisdictions, the Department, and other public health authorities tasked with preventing and controlling the spread of disease. Public health authorities also use the data to assess broader patterns, including historical trends and geographic clustering of disease. Based on these assessments, officials are able to take appropriate actions such as conducting outbreak investigations, redirecting program activities, and developing new policies to prevent and control infectious and noninfectious conditions.

Public health surveillance plays an essential role in disease control by providing public health authorities with information and data necessary to take public health action. Surveillance provides data and information to assess the burden and distribution of adverse health events, prioritize public health actions, implement disease control measures to reduce the number and severity of cases, monitor the impact of control measures, identify reservoirs or vectors of disease, identify emerging health conditions that may have a significant impact upon population health, and contribute to surveillance activities at the national and international level to implement more effective control measures on a broader scale.[267]

Public health surveillance plays a key role in identifying, controlling, and preventing the spread of zoonotic disease and can also play a role in promoting equity. Many of the new conditions in the proposed rules disproportionality impact subpopulations who are already experiencing health disparities as documented in this analysis.

The proposed rules establish notification requirements for new conditions and revised notification and specimen submission requirements for some current conditions. These changes help to avoid the costs associated with the burden on an individual with a case of a condition, the public health system, and the population as a whole.

Cost Summary
The proposed rules impose new costs for health care providers, health care facilities, and laboratories for new requirements related to case reports, laboratory reports, and specimens submitted under the proposed rules. Below is a summary of the costs described in the preceding section-by-section analysis.

[267] Groseclose SL , Buckeridge DL. Public health surveillance systems: recent advances in their use and evaluation. Annu Rev Public Health. 2017;38:57–79.

Table 1: Probable Annual per Case Costs

Condition	**Providers / Facilities: Added Cost per Case Report[268]**	**Laboratories: Added Cost per Laboratory Report[269]**	**Laboratories: Added Cost per Specimen Submission[270]**	**Assumed Number of Cases per Year[271]**	**Total Annual Cost per Condition**
Amoebic meningitis	$0 - $82.50	$0 - $30.00	$0 - $15.00	0 - 1	$0 – $127.50
Anaplasmosis	$0 – 412.50	$0 – 100.00	$0 - $75.00	0 - 5	$0 - $587.50
Babesiosis	$0 - $247.50	$0 - $60.00	$0 - $45.00	0 – 3	$0 – $352.50
Bacillus cereus (biovar anthracis only	$0 - $82.50	$0 - $30.00	$0	0 – 1	$0 – $112.50
Baylisascariasis	$0 - $82.50	$30.00	$15.00	1	$0 - $127.50
Blood lead level (adult between 5 µg/dl and 10µg/dl)	N/A	$8,000 - $10,000	N/A	400 – 500	$8,000 - $10,000
Bordetella pertussis	N/A	$0	$0	Fewer notifications	$0
Borrelia burgdorferi or mayonii	N/A	$0 - $20.00	$0 - $15.00	0 – 1	$0 - $35.00
Brucella species	N/A	$0 - $20.00	$0 – $15.00	0 – 1	$0 - $35.00
Burkholderia mallei	N/A	$0	$0	Fewer notifications	$0
Burkholderia pseudomallei	N/A	$0	$0	Fewer notifications	$0
California serogroup viruses	N/A	$0 - $20.00	$0 - $15	0 – 1	$0 - $35.00
Campylobacteriosis	$0[272]	$0	$0	Fewer test results	$0
Candida auris	$1,402.50	$510.00	$255.00	17	$2,167.50
Carbapenem-resistant Enterobacteriaceae: Klebsiella species, E. coli, Enterobacter species	$24,750.00	$6,000.00	$4,500.00	300	$35,250.00

[268] Costs are for staff time to prepare the case report.
[269] Costs are for staff time to prepare the laboratory report.
[270] Costs are for staff time to prepare documentation to accompany specimens and packaging materials.
[271] For rare conditions, such as anthrax, that have not occurred in Washington State, the Department assumed a single case per year to provide a cost estimate in the event a case of the condition ever occurs.
[272] New condition for health care facilities only.

Chagas disease (Trypanosoma cruzi)	$825.00-$1,650.00	$200 - $400	$150 - $300	10-20	$1,175 - $3,525
Chikungunya virus	N/A	$0 - $100	$0 - $75	0 - 5	$0 - $175.00
Chlamydia trachomatis	N/A	$10,000	$0	500	$10,000
Chlamydia trachomatis (De-identified negative results)	N/A	$162,240	$0	5,408	$167,648
Coccidioidomycosis (Coccidioides)	$4,125.00 - $6,600.00	$1,000.00 - $1,600.00	$750.00 – 1,200.00	–50-80	$5,875 - $9,400
Coronavirus: MERS-associated	$82.50	$60.00	$50.00	2	$192.50
Coronavirus: Novel coronavirus (SARS-CoV-2)	Novel coronavirus (SARS-CoV-2) estimated costs are outlined in Table 2.				
Cryptococcus gattii	$82.50 - $825.00	$20.00 - $200.00	$0	1 – 10	$102.50 - $1,025.00
Cysticercosis	$0 – $165.00	N/A	N/A	0 - 2	$0 - $165.00
Dengue viruses	N/A	$0 - $60.00	$0 - $45.00	0 – 3	$0 - $125.00
Diphtheria (Corynebacterium Diphtheria)	N/A	$0	$0	Fewer notifications	$0
Eastern and western equine encephalitis virus	N/A	$0 - $20.00	$0 - $15.00	0 – 1	$0 - $35.00
Echinococcosis (Echinococcus granulosus or multilocularis)	$0 - $82.50	$0.00 - $20.00	$0.00 - $15.00	0-1	$0 - $117.50
Ehrlichiosis (Ehrlichia species)	$0 -165.00	$0 - $40.00	$0 - $30.00	0 – 2	$0 - $235.00
Gonorrhea (Neisseria gonorrhoeae)	$0	$1,400.00	$0	70	$1,400.00
Gonorrhea (Neisseria gonorrhoeae) (De-identified negative results)	N/A	$106,380	$0	3,546	$106,380.00
Haemophilus influenzae (children <5 years of age)	N/A	$0	$0	Fewer notification	$0
Hantaviral	$0	$0	$0 - $75.00	0 – 5	$0 – $75

infections					
Hepatitis A virus	N/A	$60.00 - $120.00	$30.00 - $60.00	2 - 4	$90.00 - $180.00
Hepatitis B (chronic)	$0	N/A	N/A	1,521	$0
Hepatitis B virus	N/A	$30,680	N/A	1,547	$30,680.00
Hepatitis C (acute), (chronic), and (perinatal)	$0	N/A	N/A	N/A	$0
Hepatitis C virus	N/A	$330,848	$0	7,712 positives and 15,000 nonpositive results for nucleic acid detection tests	$330,848
Hepatitis C virus (De-identified negative results)	N/A	$478,590	$0	145,953	$478,590.00
Hepatitis D	$0	$140	$0	14	$140
Histoplasmosis (Histoplasma capsulatum)	$82.50	$0.00 - $20.00	$0 - $25.00	0 – 1	$82.50 - $127.50.00
HIV	N/A	$6,484	$0	851	$6,484
HIV (De-identified negative results)	N/A	$419,940	$0	13,998	$419,940.00
Human prion disease	N/A	$400.00	$500.00	20	$900.00
Hypersensitivity Pneumonitis, Occupational	$1567.50 - $2392.50	N/A	N/A	19 – 29	$1567.50 - $2392.50
Japanese encephalitis virus	N/A	$0 - $20.00	$0 - $15.00	0 – 1	$0 - $35.00
La Crosse encephalitis virus	NA	$0 - $20.00	$0 - $15.00	0 – 1	$0 - $35.00
Listeriosis (Listeria monocytogenes)	N/A	$0	$0	Fewer notifications	$0
Malaria (Plasmodium species)	N/A	$0	$0	Fewer notifications	$0
Mumps virus	N/A	$0	$0	No change in number of	$0

				notifications	
Powassan virus	N/A	$0.00 - $20.00	$0 - $15.00	0 – 1	$0 - $35.00
Psittacosis (Chlamydia psittaci)	N/A	$0	$0	Fewer notifications	$0
Relapsing fever (Borrelia hermsii, miyamotoi, or recurrentis)	$0	$0 - $20.00	$0 - $15.00	0 - 1	$0 - $35.00
Rickettsia infection (Rickettsia species)	$0 - $412.50	$100.00	$75.00	0 – 5	$0 - $587.50
Rubella	N/A	$0 - $60.00	$0 – $30.00	0 – 2	$0 - $90.00
Rubeola (Measles virus)	N/A	$0	$0	No change in number of notifications	$0
Silicosis	$82.50 - $660	N/A	N/A	1 – 8	$82.50 to $660
Smallpox (Variola virus)	N/A	$0.00 - $150.00	$0 - $75.00	0 - 5	$0 - $225.00
St. Louis encephalitis virus	N/A	$0.00 - $20.00	$0 - $15.00	0 - 1	$0 - $35.00
Syphilis (Treponema pallidum)	N/A	$120.00	$0	6	$120.00
Syphilis (Treponema pallidum) (De-identified negatives)	N/A	$42,980	$0	14,766	$42,980.00
Taenia solium	See Cysticercosis and Taeniasis	$400.00	$300.00	20	$700.00
Taeniasis	$0 - $412.50	N/A	N/A	0 - 5	$0 - $412.50
Tick paralysis	$0 - $165.00	N/A	N/A	0 – 2	$0 - $165.00
Trichinellosis (Trichinella species)	N/A	$0	$0	Fewer notifications	$0
Tuberculosis (Mycobacterium tuberculosis complex)	$0	$0	$0	Fewer notifications	$0
Typhus	$82.50	N/A	N/A	1	$82.50
Vaccinia (vaccine-acquired smallpox)	N/A	$0 - $150.00	$0 - $125.00	0 – 5	$0 - $275.00
West Nile virus	N/A	$0	$0	Fewer	$0

				notifications	
Yellow fever virus	N/A	$0	$0	Fewer notifications	$0
Zika virus	N/A	$0 - $1,380.00	$0 – $1,035.00	0 – 69	$0 - $2,415.00
RANGE OF TOTAL PROBABLE COSTS FOR ALL REGULATED ENTITIES IN THE STATE COMBINED					$1,665,227.50 - $1,805,497.50

Table 2: Probable per Case Costs for Novel Coronavirus (SARS-CoV-2)

Condition	**Providers / Facilities: Added Cost per Case Report[273]**	**Laboratories: Added Cost per Laboratory Report[274]**	**Laboratories: Added Cost per Specimen Submission[275]**	**Assumed Number of Cases per Year[276]**	**Total Annual Per-Case Cost**
Coronavirus: Novel coronavirus (SARS-CoV-2)	$6,187,500.00	$2,250,000.00	$187,000	75,000 (estimate based on very limited data)	$8,624,500.00

[273] Costs are for staff time to prepare the case report.
[274] Costs are for staff time to prepare the laboratory report.
[275] Costs are for staff time to prepare documentation to accompany specimens and packaging materials.
[276] For rare conditions, such as anthrax, that have not occurred in Washington State, the Department assumed a single case per year to provide a cost estimate in the event a case of the condition ever occurs.

Table 3: Probable Annual Costs per Entity (costs not captured in Tables 1 and 2)

Cost Description	Health Care Facilities	Laboratories:
Annual updates to the system used to transmit data from the facility to the laboratory with a specimen (regular updates required with each new version of the laboratory system)	$2,500 - $5,000	N/A
Costs associated with contacting the provider or the facility to collect patient information required under WAC 246-101-205, WAC 246-101-215, and WAC 246-101-225.[277]	N/A	$0 - $41,795.80
Total Cost Per Regulated Entity	$2,500 - $5,000	$0 - $41,795.80

Table 4: Probable One-time Costs Per Regulated Entity

Cost Description	Health Care Facilities	Laboratories
Update Standard Operating Procedures	N/A	74 conditions X $12 = $888
Update Laboratory Information Management Systems	N/A	74 conditions X $60 = $4,440
Update Electronic Laboratory Reporting	N/A	74 conditions X $60 = $4,440
Create de-identified annual summary report in LIMS	N/A	5 conditions X $800 = $40,000
Lab reporting updates and information system data components to transmit data to laboratories required in WAC 246-101-105	$15,000	N/A
System updates to report data components required in WAC 246-101-115	$75,000	N/A
Vendor updates to report data components required in WAC 246-101-115	$40,000	N/A
Total Cost Per Regulated Entity	$140,000	$49,768

One-Time Costs Per Entity

The probable one-time costs per entity is $140,000 for facilities and $49,768 for laboratories (Table 4). The estimate for each health care facility or laboratory is likely inflated due to the fact

[277] WAC 246-101-105, if adopted as proposed, will require providers and facilities to include all of these data components with a specimen when they order a lab test for a notifiable condition, but laboratories have expressed concerns that providers/facilities will not consistently provide these data and that the lab will incur the cost of gathering the data.

that some facilities and laboratories do not test for many of the conditions and will not incur the one-time costs of updating their systems. In addition, some one-time costs are specific to laboratories using Electronic Laboratory Reporting (not exclusively, but primarily large labs). Similarly, some facilities indicated that they would incur zero one-time costs. The Department assumes that some laboratories will incur zero one-time costs associated with the proposed amendments, with any one lab incurring no more than $49,768 in one-time costs. Similarly, the Department assumes that some facilities will incur zero one-time costs associated with the proposed amendments, with any one facility incurring no more than $140,000 in one-time costs.

Annual Costs Per Entity
The annual costs by entity are also variable and therefore create a large range (Table 3). For health care facilities the re-occurring costs per entity result from the need to make annual updates to the data system used to transmit data from the facility to the laboratory with a specimen. These regular updates are required with each new version of the laboratory system. This probable annual cost ($2,500 - $5,000) will not impact every facility. Some facilities use paper lab requisition forms for specimen submittals. These paper forms will need to be updated one time when the proposed rules go into effect, but paper forms will not require annual updates .

Annual Costs for All Regulated Entities in Washington State Combined
In addition to these costs per entity, the probable annual costs for all regulated entities in Washington State combined, for all conditions (excluding COVID-19 reporting discussed below) range from $1,665,227.50 - $1,805,497.50 (Table 1). No one entity will absorb all of these costs. As noted above, the Department assumes some regulated entities (e.g. laboratories who do not test for notifiable conditions, or health care providers who do not diagnose notifiable conditions) will incur zero costs. The annual costs of the rules statewide will be distributed among the remaining businesses, with larger entities likely to incur the largest costs due to higher testing volumes. Three healthcare providers/facilities provided annual cost estimates in the cost questionnaires. These estimates were $72.80, $100 (respondent did not indicate number of employees), and $574 annually. One laboratory (>5,000 employees) estimated that the proposed changes would cost them $12,000 - $15,000 in one-time costs and $2,500 - $5,000 in annual costs. Another laboratory estimated the rules would cost them at least $41,795.80 annually—but that was based primarily on the assumption the providers/facilities would not provide all of the required information to the laboratory with each specimen, which would then shift the burden of gathering this information onto the laboratory. Sufficient notification, education, and technical support to ensure providers/facilities come into compliance with the rules should negate that cost.

Annual Costs Associated with Reporting Novel Coronavirus (SARS-CoV-2) for All Regulated Entities in Washington State Combined
In addition to the probable annual costs of reporting all other conditions for all regulated entities in Washington State combined (Table 1), there are additional probable costs associated with reporting COVID-19. If Washington has close to 75,000 COVID-19 cases per year once the rules become effective (an estimate based on very limited data), the estimated annual cost of reporting this condition for all regulated entities in Washington State combined is $8,624,500.00 (Table 2). The cost per case of reporting COVID-19 is presumably accompanied by per-case revenue increases for facilities and laboratories collecting samples and conducting testing. In addition, while the estimated costs of reporting COVID-19 increases as the estimated number of annual

cases increases, the public health need and justification for reporting of these cases also increases.

The Board adopted an emergency rulemaking order in July of 2020 to create WAC 246-101-017, a new section, at a special meeting of the Board on July 30, 2020. The Board adopted a second emergency rule on November 9, 2020 to go into effect upon expiration of the first emergency rule. The emergency rule explicitly designates COVID-19 as a notifiable condition for health care providers, health care facilities, laboratories, and local health jurisdictions. The purpose for drafting the rule was in response to the federal CARES Act and subsequent guidance released by the U.S. Department of Health and Human Services (HHS). While the proposed permanent rules addressed by this significant analysis carry their own cost for COVID-19 reporting since they would replace the emergency rule, it is also important to note that regulated entities have presumably already developed protocols and data system updates to come into compliance with the emergency rule and HHS guidance that will, at least to some extent, minimize the burden on regulated entities to come into compliance with COVID-19 reporting requirements if these proposed rules are adopted.

Evidence of the Benefits of Public Health Surveillance Systems

While the cost-effectiveness of public health surveillance systems and the accompanying public health responses have not been extensively researched, there are a small number of studies which have found that surveillance systems (or improvements to existing surveillance systems) paired with public health action can avert cases of notifiable conditions and, correspondingly, lead to monetary and societal benefits.[278] For example, a 2016 study by Scharff et al. used modeling to estimate the number of cases during outbreaks averted as a result of PulseNet (a foodborne disease surveillance system made up of a network of federal, state, and local public health laboratories). Using data collected from 1994 to 2009 the researchers estimated that nationally, "conservatively, accounting for underreporting and underdiagnosis, 266,522 illnesses from *Salmonella*, 9,489 illnesses from *Escherichia coli* (*E. coli*), and 56 illnesses due to *Listeria monocytogenes* are avoided annually" as a result of PulseNet.[279]

The researchers estimated the costs saved per averted case to be $1,792 (90% CI=$1,461, $2,295) for *Salmonella*, $2,154 (90% CI=$1,464, $3,435) for *E. coli* O157, and $156,019 (90% CI=$81,003, $254,934) for *Listeria* (2010 dollars). These costs include medical costs and productivity losses averted due to reduced illness, but do not account for other societal costs such as welfare losses from premature death and reduced quality of life due to illness. The authors' process change models using reported illnesses estimated that annual median costs averted nationally ranged from $21 to $33 million for these three conditions, depending on the model. When they adjusted for underreporting and underdiagnosis factors, the range became $491–$654

[278] Magid Herida, Benoit Dervaux, Jean-Claude Desenclos, Economic Evaluations of Public Health Surveillance Systems: a Systematic Review, *European Journal of Public Health*, Volume 26, Issue 4, August 2016, Pages 674–680, https://doi.org/10.1093/eurpub/ckv250; Scharff RL , Besser J, Sharp DJ, Jones TF, Peter GS, Hedberg CW. An economic evaluation of PulseNet: a network for foodborne disease surveillance. Am J Prev Med2016; 50:S66–73.
[279] Scharff RL , Besser J, Sharp DJ, Jones TF, Peter GS, Hedberg CW. An economic evaluation of PulseNet: a network for foodborne disease surveillance. Am J Prev Med2016; 50:S66–73.

million. In addition, the direct effect of removing tainted food product from the market (because of faster recalls) added $1–$37 million in cost savings (2010 dollars).[280]

Based on the existing peer-reviewed literature and a history of mobilizing public health action in response to identification of outbreaks and individual cases of notifiable conditions, the Department assumes that the addition of new conditions and modifications to existing notifiable conditions to improve timeliness, accuracy, and comprehensiveness of reporting will result in an improved public health response. This improved public health action is likely to result in averted cases of notifiable conditions. The majority of the conditions added or modified by the proposed rules have severe outcomes up to and including death.

Federal agencies ascribe a monetary value to reducing the risk of a death. This is called the "Value per Statistical Life (VSL)". In 2016 the US Department of Health and Human Services conducted a review of the literature on best practices for calculating the VSL and found that the literature at that time included VSLs ranging from $4.7 million to $15.4 million with a midpoint $10.1 million (adjusted for estimated 2020 dollars and income levels).[281]

Case Study: Carbapenem-resistant Enterobacteriaceae (CRE)
One new notifiable condition for health care providers, health care facilities, and laboratories in the proposed rule is Carbapenem-resistant Enterobacteriaceae (CRE). The estimated probable annual cost for a health care provider or facility of adding CRE to the rules is $24,750.[282] The probable annual costs for a laboratory of adding CRE to the rules is $10,500[283, 284] The total combined probable annual costs for health care providers, health care facilities, and laboratories is $35,250. The total range of probable one-time laboratory costs for adding this condition to the rule are $12.00 to update standard operating procedures to $132.00 to update standard operating procedures and laboratory information management systems and electronic laboratory reporting systems.

According to one CRE clinical and economics outcomes model, the cost-savings for one avoided case of CRE ranges from $22,484 to $66,031 for hospitals and $37,778 to $83,512 for society.[285] According to researchers, the total economic burden may be higher if the societal value of antibiotics is taken into account.[286] In addition, CRE mortality rates range from 18% to 48%

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[280] Scharff RL , Besser J, Sharp DJ, Jones TF, Peter GS, Hedberg CW. An economic evaluation of PulseNet: a network for foodborne disease surveillance. Am J Prev Med2016; 50:S66–73.
[281] Office of the Assistant Secretary for Planning and Evaluation. US Department of Health and Human Services. 2016. Available from https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf. Accessed January 19, 2020.
[282] The Department assumes the probable cost for a health care provider or facility to prepare and submit 300 CRE infection case reports is $24,750 per year [300 cases (.5 hours X $165 per hour)].
[283] The Department assumes the probable cost for a laboratory to prepare and submit 300 CRE infection laboratory reports is $6,000 per year [300 cases (.5 hours X $40 per hour)].
[284] The Department assumes the probable cost for a laboratory to prepare and submit 300 CRE specimens is $6,000 per year [300 cases (.5 hours X $40.00 per hour)].
[285] Bartsch SM, McKinnell JA, Mueller LE, et al. Potential economic burden of carbapenem-resistant Enterobacteriaceae (CRE) in the United States. *Clin Microbiol Infect*. 2016;0(0):165-170. doi:10.1016/j.cmi.2016.09.003.
[286] Gandra S, Barter DM, Laxminarayan R. Economic burden of antibiotic resistance: how much do we really know? *Clin Microbiol Infect*. 2014;20:973-980. doi:10.1111/1469-0691.12798.

depending on therapy.[287] Using the VSL ranges provided by the United States Department of Health and Human Services, one averted death has a benefit of $10.1 million (range $4.7 million to $15.4 million). Therefore, even the most conservative estimate of the benefit of one averted case of CRE is $60,262 ($22,484 for hospitals plus $37,778 for society), roughly 1.7 times the cost for the regulated communities ($35,382) of adding CRE to the rule. Moreover, the benefits of one averted CRE-related death far surpasses the probable statewide costs of the entire rule revision (estimated at: $1,770,352.50 annually for all conditions plus one-time costs of $59,504).

Benefit and Cost Determination
The proposed rules are needed to protect public health by requiring submission of notifiable condition case reports, laboratory reports, and specimens. While health care providers, health care facilities, and laboratories may incur additional costs to comply with the proposed new requirements, the combination of identified quantitative and qualitative benefits translates into increased public health protection with lower societal costs that offset the incremental cost increases for the regulated community.

Based on this analysis, the Department and Board determined that the probable benefits of the proposed changes the Chapter 246-101 WAC, Notifiable Conditions, are greater than the probable costs.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

The Board and the Department considered the following alternatives to the proposed rule.

Electronic Laboratory Reporting
The Department and Board considered many alternative changes to the method of reporting for laboratories as described below. Ultimately the agencies opted to remove postal mail and handwritten laboratory report as options for submitting laboratory reports, but did not mandate Electronic Lab Reporting Using HL7 messaging or remove secure facsimile as reporting option.

Alternative 1: Mandatory Electronic Laboratory Reporting using HL7 Messaging with Mitigating Measures for Small Laboratories
The Board and Department considered mandating laboratory submission of test results using HL7 messaging and including mitigating measures for small laboratories that allow those businesses to submit results using a less costly method. The benefit of this approach is that it

[287] Morrill HJ, Pogue JM, Kaye KS, Laplante KL. Treatment Options for Carbapenem-Resistant Enterobacteriaceae Infections. doi:10.1093/ofid/ofv050.

would move a majority of the reporting to HL7 messaging, which would improve timelines of reporting and reduce the burden on local health jurisdictions and the Department, freeing up limited public health resources to promote public health. This approach would simultaneously mitigate the costs for small laboratories that do not have capacity to acquire and maintain a costly HL7 system.

However, there are also a number of barriers to using this approach. This alternative would require the Board and Department to define a small laboratory based on income or number of employees. This is not necessarily a proxy for the number of notifiable conditions a laboratory reports each year, so this approach could require a laboratory to invest in an expensive ELR system even if they only submit a small number of notifiable conditions each year. In addition, some laboratories are part of hospitals which have a large number of employees, but the Board and Department heard from the Technical Advisory Committee that this does not mean that the laboratory itself has a large staff or operating budget. Using the number of notifiable conditions reported each year as a way to define small laboratories versus large laboratories would be an inaccurate measure of a laboratory's budget and their ability to absorb the costs of mandatory HL7 as a small lab could report a large number of cases each year. Using number of laboratory reports to define laboratory size is not only inaccurate and unenforceable (because the decentralized reporting system in Washington State makes it challenging to track how many cases are submitted by any one laboratory to determine if they meet the definition of a large business), but also creates a potential incentive for labs to underreport in order to stay below the large laboratory threshold. The fact that health care providers and others conducting Rapid Screening Tests are also laboratories under the rule further complicates this alternative.

Alternative 2: Mandatory Electronic Laboratory Reporting with Three Reporting Options
In order to maintain the benefits outlined above while addressing the challenges raised by Alternative 1, the Board and Department considered a second alternative. Rather than using thresholds (e.g. test volume or number of employees) to define "large laboratories" and requiring large laboratories to report using a certain electronic format, this alternative would allow all laboratories (of any size) to choose between the following options for how they would report:

> **Option A:** HL7 according to the most recent HL7 national guidelines for the data content required in the proposed rule (e.g. patient name, provider name, etc.)
> **Option B:** A web-submitter allowing labs to input information on an application built and maintained by the Department that would convert the information into HL7.
> **Option C (for rapid screening tests for blood lead tests only):** A spreadsheet (e.g. Excel document) or similar electronic format allowing rapid screening test results (e.g. point of care lead test results) to be submitted via secure electronic data transmission (e.g., secure facsimile.)

While this alternative would provide a less costly option (the web-submitter) for small laboratories or laboratories who report a small number of cases each year, there was no way to guarantee that the web-submitter would be operational by the time the rule went into effect. Without the web-submitter, this alternative would not have provided adequate mitigation for small businesses. In addition, the Department has not yet on-boarded all the laboratories who are willing to voluntarily move to HL7 messaging. So rather than mandating HL7, the Department

and Board ultimately determined to continue working with laboratories to voluntarily increase enrollment and re-assess the need for a mandatory requirement during the next five-year rule review for the chapter.

Alterative 3: Maintain the Status Quo
The status quo allows laboratories to submit laboratory reports using HL7 or using other formats (e.g. postal service). While this would be the least burdensome alternative for laboratories, this option would not allow the public health benefits outlined above (e.g. increased timeless and accuracy of reporting) and would continue to allow hand-written laboratory reports, which create issues with legibility and increased risk of data entry errors. This alternative does not provided the needed public health benefits.

Alternative 4: Remove Secure Facsimile, Postal Mail, and Handwritten Laboratory Report as Options for Submitting Laboratory Reports, but Do Not Mandate Electronic Lab Reporting Using HL7 Messaging
This option has potential to improve timeliness of notification and data accuracy for laboratory reports, particularly for those submitting Rapid Screening Test results, (e.g., fewer legibility issues and manual data entry errors; more complete information; more usable and consistent information due to the use of Department standardized tools) and to reduce the burden of processing paper reports on local health jurisdictions and the Department, freeing up limited public health resources to promote public health.

However, we learned that many laboratories who have not already moved to Electronic Lab Reporting through HL7, including the State Public Health Laboratories and those reporting using Rapid Screening Tests (such as ECEAP programs which submit large volumes of lead tests) still rely heavily on facsimile to submit laboratory reports. The Lead Program at the Department has had great success in helping Laboratories move away from facsimile toward other electronic methods of submission (e.g. secure email using a standardized spreadsheet format provided by the Department) through relationship-building and technical assistance. There are opportunities to work with laboratories to help them voluntarily move away from facsimile, and to continue to pursue a web-submitter resource, before removing this frequently used reporting method through rule. The Board and Department determined that removing the postal mail and handwritten laboratory reports as options at this time, but allowing the continued use of facsimile, was the least burdensome alternative that still created the benefits of increased timeliness and accuracy of reporting.

Negative Screening Results for Select Conditions
Alternative 1: Laboratories submit all Identified Negative Screening Results for Chlamydia Trachomatis, Hepatitis C Virus, Human Immunodeficiency Virus (HIV), Neisseria Gonorrhoeae (Gonorrhea), and Treponema Pallidum (Syphilis) to the Department At Least Annually and the Department Will De-Identify the Results

The Board and the Department considered submission of all negative screening results for *Chlamydia trachomatis,* Hepatitis C virus*,* Human Immunodeficiency Virus (HIV)*, Neisseria gonorrhoeae (Gonorrhea),* and *Treponema pallidum (Syphilis).* The results would be submitted through the mechanism the laboratory was using for the other results for the conditions listed or

through a template provided by the Department. This would decrease the burden on the laboratories by having Department staff do the de-identification.

However, laboratory representatives on the Technical Advisory Committee expressed concern about submitting identifiable negative screening results that were not associated with a previous positive. They were concerned that this could deter screening or that it would create other discomfort among the community. The Technical Advisory Committee recommended that the rules require negative results to be de-identified before being reported.

Modifications to the "Within 24 Hour" Reporting Timeline

Alternative 1: Eliminate the "Within 24 Hour" Reporting Timeline throughout the Rule

The Board and Department considered eliminating the within 24 hour reporting requirement throughout the rule and making all conditions reportable on this timeline either reportable:

- Within 1 business for conditions that will not require a public health response on a weekend or holiday; or
- Immediately for conditions that would require a public health response on a weekend or holiday.

The benefit of this alternative is that it would potentially reduce burden for both the regulated community and public health authorities by eliminating the need for the existing rule language requiring regulated entities to call and confirm receipt of a case or laboratory report for a condition notifiable within 24 hours if that report is submitted outside of normal business hours.

The Board and Department worked closely with subject matter experts at the Department of Health and local health jurisdictions to explore the viability of this option and to determine if each condition currently reportable within 24 hours should be made reportable within 1 business day or immediately. The agencies received several comments from local health jurisdictions either indicating that the rule should not eliminate the 24 hour reporting requirement and replace it with a 1 business day requirement or asking that if it did eliminate the 24 hour option that the Board and Department move many of these conditions to immediately reportable so that they would still be received on a weekend or holiday. This feedback indicated to the Board and Department that the 24 hour reporting option is valuable for local health jurisdictions and should not be replaced with a 1 business day option. Moving a large portion of the conditions reportable within 24 hours to immediately reportable would have increased burden on the regulated community and public health authorities, contrary to the goal of reducing burden.

SECTION 7:

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

SECTION 8:

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

SECTION 9:

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws. There are related regulations and policies, such as the International Health Regulations and the Council of State and Territorial Epidemiologists recommendations for notifiable conditions, which we have coordinated with to the maximum extent possible.

Appendix A: Student and Intern White Papers on Select New Proposed Notifiable Conditions

In 2016 the Board and Department partnered with the University of Washington Masters of Public Health (MPH) Community Oriented Public Health Practice (COPHP) program to prepare for the significant analysis of the proposed changes to chapter 246-101 WAC, Notifiable Conditions. As part of a service-learning project for their policy course, the MPH students developed white papers for nine of the conditions included for consideration as new conditions on the CR-101. The Board and Department did not validate the full papers, edit, or make modifications to the student papers and these are available in full in this appendix. The Board and Department used some content from these papers (once validated) in the writing of the significant analysis for the 2020 update to the Notifiable Conditions chapter. Special thanks to the former COPHP students who completed this important work to support the improvement of the notifiable conditions rules and promote public health.

Conditions

Anaplasmosis and Ehrlichiosis

Babesiosis

Coccioidomycosis

Carbapenem-resistant Enterobacteriacaea (CRE)

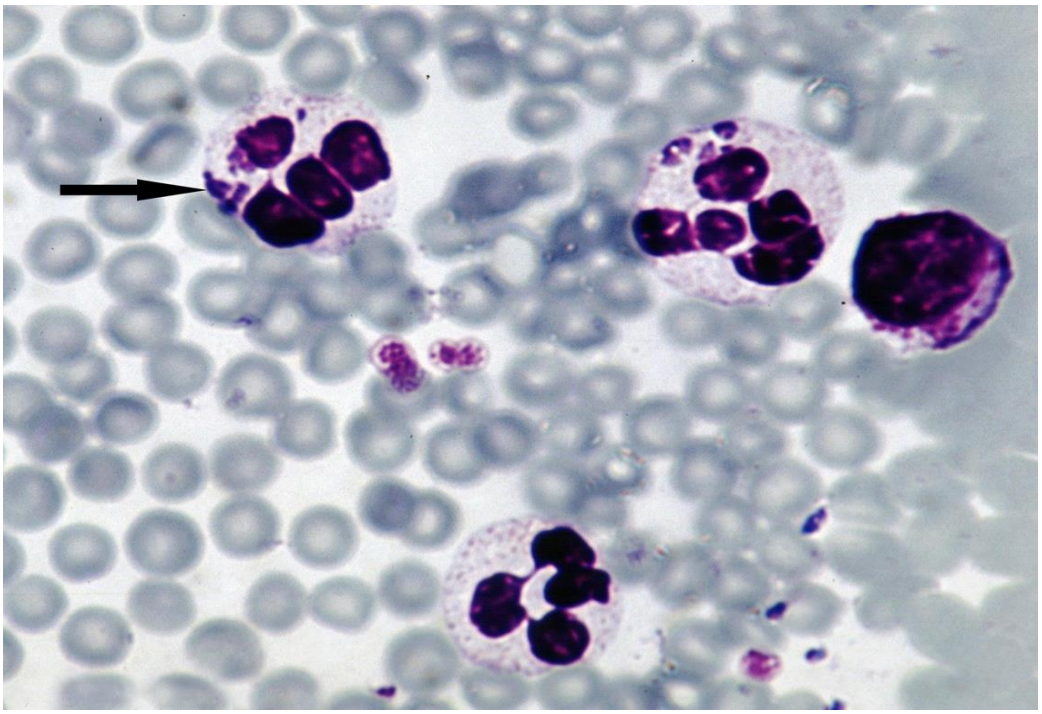
Cryptococcus gattii

Rocky Mountain Spotted Fever

Typhus Fever

Vancomycin Resistant *Staphylococcus aureus*

ANAPLASMOSIS & EHRLICHIOSIS



12/8/16

University of Washington, School of Public Health
Community-Oriented Public Health Practice MPH candidates:
Khanh Ho, Francesca Collins, Celia Goetz, Celina Kareiva, Ada Lin, Chanda Moellenberg, Toni Sarge & Lindsay Scalf

A white paper and disease profile of anaplasmosis/ehrlichiosis to inform the Washington State Board of Health and Department of Health on important policy decisions regarding notifiable conditions in the state.

ABSTRACT

Anaplasmosis and ehrlichiosis are considered "rare diseases of public health significance" by the Washington State Department of Health (DOH).[1] While no human cases of anaplasmosis diseases have been diagnosed in Washington state, multiple cases have been diagnosed in dogs[2]. The tick found in WA that carries *Anaplasma phagocytophilum*, is known as the Western black-legged tick[3]. There have been no reported cases of ehrlichiosis in WA.[4] Due to complicated and continually evolving etiology, and the inaccurate/underreported nature of certain tick-borne illnesses, there is a lack of complete knowledge of anaplasmosis/ehrlichiosis in the literature and clinical world. This may require a more individual look at diseases to understand and track them moving forward. Symptoms of ehrlichiosis and anaplasmosis include fever, headache, muscle pain, and confusion but symptoms vary widely.[5] The gold standard of testing is indirect immunofluorescence assay or IFA, but diagnosis should be made clinically and immediately, later confirmed by laboratory tests. Doxycycline is the drug of choice for treatment of all ehrlichiosis/anaplasmosis illnesses and is most effective early in the disease course.[5]

The addition of anaplasmosis/ehrlichiosis to the WAC 246-101- 101 and WAC 246-101- 301 would require distinct testing to better understand the incidence and prevalence of all diseases in humans and ticks, and would create richer data collection by requiring providers to notify and test patients for anaplasmosis/ehrlichiosis, even after diagnosis and treatment. This increased collection and understanding can also aid WA in reaching populations disproportionately burdened by disease.

BACKGROUND & DISEASE ETIOLOGY

Ehrlichiosis and anaplasmosis are tick-borne diseases caused by various bacteria in the genus *Ehrlichia* and *Anaplasma*, respectively. The three bacteria discussed in this paper are 1) *Ehrlichia chaffeensis* ehrlichiosis, also called human monocytic ehrlichiosis (HME); 2) Other ehrliochiosis, caused by *Ehrlichia ewingii, or human ewingii* ehrlichiosis (HEE); and 3) Anaplasmosis, caused by *Anaplasma phagocytophilum*, also called human granulocytic anaplasmosis (HGA)[5].

These bacteria have caused illness in animals for decades, and was recognized in humans starting in the 1980s. It is important to note that all three tick-borne illnesses are separate disease entities, even though their clinical and laboratory manifestations are similar and often reported in tandem to each other[5]. This paper will refer to the three separate entities when appropriate, grouping HME/HEE together as "ehrlichiosis" and HGA as "anaplasmosis", or will refer to all reported information as "anaplasmosis/ehrlichiosis".

Physiological effects & severity

All species of anaplasmosis/ehrlichiosis have comparable disease manifestations. They are tick borne illness that almost always cause fever (96% of patients) as well as other symptoms including: headache, muscle pain, malaise, chills, nausea, stomach pain, cough and confusion. Rashes are less frequent in ehrlichiosis/anaplasmosis as compared to other tick borne diseases. Severity of HGA and HME/HEE vary widely, with more severe manifestations including: renal failure, disseminated intravascular coagulopathy, meningoencephalitis, severe abdominal pain, seizures, and coma[6]. All of these illness disproportionately affect immunosuppressed patients or persons with comorbid diseases such as diabetes[7].

Some major differences in symptomology between HGA, HME and HEE include:

- HME: Rash is present in approximately one-third of patients, but is more common in children and patients over the age of 60 or who are immunosuppressed experience more severe symptoms.
- HEE: rash and gastrointestinal symptoms are less common
- HGA: Rash is rare. HGA can be a self-limiting illness, meaning it resolves on its own and without long term health effects. Disproportionally affected sub populations may require hospitalization[7].

Symptoms of all ehrlichiosis/anaplasmosis diseases typically begin 1-2 weeks of being bit by an infected tick[4,7].

Mode of Transmission

The bacterial agents responsible for ehrlichiosis/anaplasmosis are primarily transmitted to humans through tick bite. During a tick bite, a tick sucks human blood and this interaction leads to the transfer of bacteria from the tick into a human's white blood cells. The bacterium then replicates and manifests as HGA, HME, or HEE.

Anaplasmosis and ehrlichiosis are more common during high tick season and when people spend time outdoors[8]. In the U.S., most cases of HME are seen April-September, most HGA cases are seen June-August[8].

Ticks carrying *E. chaffeensis, E. ewingii, and A. phagocytophilum* in the U.S. [9]

- ☐ Blacklegged tick (*Ixodes scapularis*)
  - ☐ Transmits: *A. phagocytophilum* and Lyme disease
  - ☐ Northeastern and Upper Midwestern U.S.
- ☐ Lone star tick (*Amblyomma americanum*)
  - ☐ Transmits: *E. chaffeensis* and *E. ewingii*
  - ☐ Southeastern and eastern United S.

Ticks carrying *E. chaffeensis, E. ewingii, and A. phagocytophilum* in Washington State[9]

- ☐ Western blacklegged tick (*Ixodes pacificus*)
  - ☐ Transmits: *A. phagocytophilum* and Lyme disease
  - ☐ Pacific coast of the U.S., northern California, west of Cascades in WA, specifically forested or bushy areas[3]

Other possible modes of transmission

A. phagocytophilum and *E. chaffeensis* may occasionally be transmitted in medical procedures involving blood, marrow or organ transfers[5]. There have also been possible infections through contact with infected deer blood (through cleaning deer carcasses) or perinatal transmission of bacteria or disease during childbirth or potentially breastfeeding[5,10]. Deer are commonly reservoirs of various tick borne diseases, especially HME[6]. More studies need to be conducted to verify these alternative modes of transmission.

Important note: Travelers within and outside of the U.S may be exposed to different ticks during travel that result in illness after returning to WA. For this reason, public health must be aware of different geographic distributions of ticks as well as the pathogens they carry that can cause disease in both humans and animals[6].

EPIDEMIOLOGICAL INFORMATION

Prevalence & Incidence

HME & HEE

The number of HME[1] cases reported to the CDC has increased steadily in recent years[12]. In 2010, the national incidence rate for HME was 2.5 cases per million persons.[13] In WA State, one case of ehrlichiosis due to *E. chaffeensis* was reported in 2011, and was associated with travel to the southeastern U.S.[14]

Case fatality rate has been recorded for HME since 2000 and the highest rates were reported in 2001 and 2003 with case fatality rates over 3%[5]. In all other years, the case fatality rate falls between 1-2%.[5] No deaths have been reported specifically for HEE.[5]

[1] While HME and HEE are both different illnesses, most reported cases are HME, and HEE was not considered a separate entity until 2008. Because of this, national surveillance of ehrlichiosis typically only reports on HME.[11]

HGA

The number of reported HGA cases has also increased since it became reportable to the CDC and in 2010, the incidence rate was 6.1 cases per million persons.[7] From 2004 to 2013, four cases of anaplasmosis were reported in WA state, two with exposure in the Upper Midwest (both in 2013) and two with exposures in the northeastern United States (2004, 2007).[14] To date, no locally-exposed WA cases of anaplasmosis have been reported; however, very low levels of *A. phagocytophilum* have been found in ticks from WA State.[14]

The case fatality rate for HGA has remained low at 1% or less depending on the year.[7]

Surveillance

WA DOH currently offers individuals the option of sending ticks found on humans and animals in for testing.[15] Some states with high prevalence of tick-borne illnesses partner with the CDC's program TickNet for surveillance and research of ticks where the CDC implements a system of classifying reportable cases of anaplasmosis/ehrlichiosis as Suspected, Probable or Confirmed.[16,17] Further surveillance conditions would need to be implemented to have more complete data on all tick-borne illness in WA state, in addition to physician education on all tick-borne illnesses and vectors. North Carolina has a specific algorithm for surveillance of anaplasmosis/ ehrlichiosis and be used for reference.[18]

Estimates of under-reporting in U.S. and in Washington

While no human cases have been diagnosed in WA state, multiple cases have been diagnosed in dogs[2]. *Ixodes pacificus* is found west of the Cascades[2]. As part of a CDC funded grant, the DOH has been mapping ticks and the diseases they carry since 2010 and "in 2011, the state tested 111 ticks...and three ticks tested positive for Anaplasmosis," but in the following two years, no Anaplasmosis was reported.[3]

The non-specific nature of the clinical manifestations of anaplasmosis/ ehrlichiosis and its similarity to other tick-borne illnesses can lead to underreporting nationwide.[19] While the incidence of anaplasmosis/ ehrlichiosis is less than that of Lyme disease[20], there continues to be increasing cases of anaplasmosis/ ehrlichiosis reported since it became notifiable by the CDC, suggesting increased surveillance would find even higher incidence.[21] Until 2008, HME and HEE were documented as one disease which is another source of possible continued misclassification.[13]

Subpopulations affected

Infection with anaplasmosis/ehrlichiosis for individuals with compromised immune systems or other comorbid conditions such as diabetes may be fatal.[13] Additionally, non-treatment or late treatment may worsen effects of these comorbidities, or lead to increased hospitalization. Frequency of reported cases of HME and HGA are highest among males over the age of 40, and person's living and working in tick habitats.[13]

There is insufficient research specifically examining the risk of anaplasmosis/ehrlichiosis among the American Indian (AI) populations in the U.S. While research on other tick-borne illnesses such as Rocky Mountain spotted fever (RMSF) has shown AIs at an increased risk[22], the complex history of the *ehrlichia* and *anaplasma* families of diseases has hindered this more complete picture. One study reviewing nationally reported data and data from Indian Health Service (IHS) inpatient and outpatient visits, found AIs had the highest annual incidence rate of ehrlichiosis and anaplasmosis diseases of any race group at 4 cases per million people.[19]

This study also notes the importance of higher scrutiny and uniformity of surveillance systems, especially related to race. The research noted that in the CDC data used, 35% of cases were missing race data completely. This creates gaps in our understanding of disparate effects on certain groups, which can inhibit our surveillance of geographic, age monitoring and leaving the potential of missing the subtleties among and between different racial groups in the U.S.[19]

TESTING & TREATMENT

The gold standard test for diagnosis of anaplasmosis/ehrlichiosis is the **indirect immunofluorescence assay (IFA**) using the corresponding bacterium antigen[7,13]. This test is quantitative, and gives a specific number of antibody titers. The first test should be done as early as possible, although this round often gives a false negative, or showing no rise in antibodies. A second sample and test should be taken 2-4 weeks later and will show a four-fold increase of antibodies if the disease is present in the bloodstream[7,11]. Specialty and commercial laboratories, and presumably the DOH laboratories, can run these tests, although they are not typical ran in physician offices.[13]

Regarding all ehrlichiosis and anaplasmosis diseases, the CDC clearly states that:

> **"The diagnosis must be made based on clinical signs and symptoms, and can later be confirmed using specialized confirmatory laboratory tests. Treatment should never be delayed pending the receipt of laboratory test results, or be withheld on the basis of an initial negative laboratory result."**[7,13]

Diagnosis of anaplasmosis/ehrlichiosis can be challenging due to the difficulty to distinguish its symptoms from other diseases, though treatments are similarly comparable among diseases, with taking early action as the best option.[7,13]

Doxycycline is the drug of choice for treatment of all ehrlichiosis/anaplasmosis illnesses. It is most effective early in the diseases course.[5] Doxycycline should be taken orally or intravenously at a dose of 100mg twice daily for 10 days, or for 3 to 5 days after patients' fever subsides[7,11]. If the patient is treated within the first 5 days of the disease, fever generally subsides within 24-72 hours. Failure to respond to doxycycline suggests that the patient's condition might not be due to HME or HGA[5].

COST ESTIMATES

Cost of Testing

The specific price of an IFA diagnostic laboratory test was not found in our search. We have assumed that this testing could be done in the DOH Labs. Cost of general, routine blood tests may include a white blood cell count, which health care blue book cites as a $17 test, or other general blood tests between $10 and $20.[23] To a patient, cost of diagnostic testing would depend on individual insurance and whether they have access to health care coverage.

Cost of Treatment

Doxycycline is on the WHO's list of Essential Medicines and is available as a generic medicine and is generally inexpensive $14 for 10-day treatment.[24,25] This is also often covered by insurance depending on the patient.

Cost of Non-Treatment

If left untreated, patients with HGA or HME may suffer from difficulty breathing, hemorrhage, renal failure or neurological problems.[7,13] For individuals with compromised immune systems, these diseases can be fatal. 48% of patients who report a case of HME are hospitalized, while 36% of patients with HGA are hospitalized.[21] Both diseases can have potentially long term-health effects, depending on the severity of the disease course.[6,21]

EQUITY IMPACT OF ADDING THE RULE

In accounting for the limited data on anaplasmosis/ehrlichiosis in WA state, one may pinpoint the overall absence of the pathogen in the Pacific Northwest or the lack of a state-wide system for tracking and reporting specifics of these rare diseases. However, the addition of anaplasmosis/ ehrlichiosis to the Washington Administrative Codes (WAC) WAC 246-101-101 and WAC 246-101-301 would open opportunities for more substantial data collection and confront the current limitations due to the absence of statewide data on these conditions. In doing so, the nuanced and complex etiology of these diseases must not be must be considered to properly categorize them on the codes. Additionally, ignoring the disparate populations affected by all tick-borne diseases when considering the change would hinder goals of the DOH's involvement in government policy and rule making.

CONCLUSION

Anaplasmosis/ehrlichiosis is a serious condition causing a range of symptoms, including nausea, chills, rash, and occasionally confusion, manifestations that are similar across all types of this family of bacteria. Like other tick-borne illnesses, anaplasmosis/ehrlichiosis can be minimized by avoiding tick environments – including wooded and brushy areas – and by regularly examining clothes and skin after exposure to these habitats. Despite relatively low case fatality rates, the limited research on the risks of anaplasmosis/ehrlichiosis among American Indians may necessitate greater research and case tracking. To maintain high quality data reports for diseases, including anaplasmosis/ehrlichiosis, the DOH can follow a system that is modeled by the CDC (Appendix 1) in which, the clinically similar diseases are distinguished through four sub-diseases, making the conditions of HGA, HME and HEE separate notifiable entities since 2008.[17] The WAC outlines that notifiable conditions exist to "improve the understanding of emerging and uncommon diseases in Washington, to assist in the diagnosis and treatment of cases, to identify any potentially exposed persons, [and] to identify sources of transmission and prevent further transmission…".[26] In the case of anaplasmosis/ehrliochiosis, a careful consideration needs to take place distinguishing not only the difference between the two diseases, but within their family of bacteria as well. The addition of anaplasmosis/ehrlichiosis to the WAC 246-101- 101 and WAC 246-101- 301 would require distinct testing to better understand the incidence and prevalence of all diseases in humans and ticks, and would create richer data collection by requiring providers to notify and test patients for anaplasmosis/ehrlichiosis, even after diagnosis and treatment. This increased collection and understanding can also aid WA in reaching populations disproportionately burdened by disease.

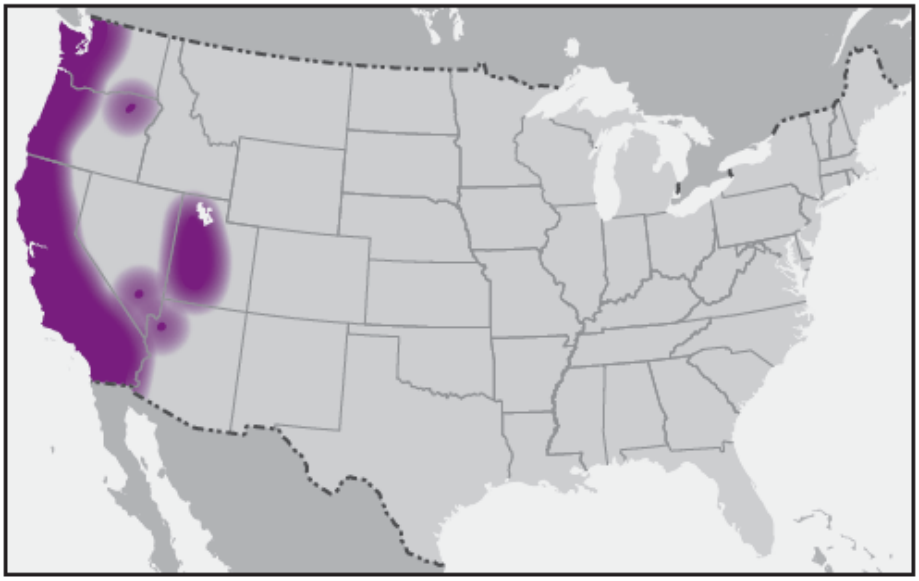
APPENDIX 1: CDC NOTIFIABLE CONDITIONS: EHRLICHIOSIS/ ANAPLASMOSIS

Nationally Notifiable Time Periods

Nationally Notifiable		Condition/Subtype
From Year	To Year	
2008	Current	Ehrlichiosis and anaplasmosis
2008	Current	*Anaplasma phagocytophilum* infection
2008	Current	*Ehrlichia chaffeensis* infection
2008	Current	*Ehrlichia ewingii* infection
2008	Current	Undetermined human ehrlichiosis/anaplasmosis

APPENDIX 2:

FIGURE 18. Approximate U.S. distribution of *Ixodes pacificus* (western blacklegged tick)



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Babesiosis

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December 2016

Summary and Purpose

Babesiosis, a tickborne parasitic infectious disease, and is endemic in the upper Midwest and Northeastern regions of the United States. *Babesia* infection is rare in Washington state; however, it poses a high health risk to vulnerable persons including individuals who are of advanced age, immunocompromised or asplenic.[1–3] The Centers for Disease Control and Prevention (CDC) consider babesiosis to be a nationally notifiable condition and are particularly concerned with the increasing prevalence of Transfusion-Transmitted Babesiosis (TTB), though this designation is non-judicial and the condition is not currently considered to be notifiable by Washington state executive agencies.[4] This disease is listed as a "Rare Disease of Public Health Significance" by the Washington State Department of Health (DOH) and, as a result, is a condition that medical providers must report to their local health jurisdiction within 24 hours of diagnosis pursuant to WAC, 246-101- 101. Concerning "Rare Diseases," no reporting requirements for laboratories exist. However, per WAC 246-101-301, institutions are required to notify public health authorities about "Rare Diseases" within 24 hours of detection.[5]

Though the designation of babesiosis as a "Rare Disease" makes it "of general or international public health concern," it has not yet been classified as a notifiable condition via the state Board of Health's rulemaking process.[6] The Washington State Board of Health (BOH) is currently considering whether babesiosis should be moved from its current "Rare Disease" classification to designation as a "Notifiable Condition" so that it may be explicitly listed in WAC 246-101-101; 201; and 301. In relation to 246-101-201, the BOH is exploring the following language for type and timing of specimen submission to the DOH: "Lab report positive test result and provide specimen upon request."[7]

Making babesiosis a notifiable condition would allow the DOH and BOH to create reporting standards for providers, labs, and institutions that are unique to the disease as opposed to adhering to the more general reporting requirements for "Rare Diseases of Public Health Significance." Transparency is an additional benefit of doing so, as it would become easier for stakeholders to understand the current level of public health interest in the condition.

Washington State Board of Health and Washington State Department of Health teams would benefit from consulting with stakeholders such as medical providers, laboratories, and former patients, to evaluate if this shift would have any drawbacks or increased costs.[8] By understanding

the disease, epidemiology, costs, and equity impacts of babesiosis as well as hosting future discussions with key stakeholders, the Washington State Board of Health and Washington State Department of Health can make an informed decision about whether to make babesiosis a "Notifiable Condition" through the rulemaking process.

Disease background and etiology

Babesiosis, a tick-borne infectious disease, is caused by several types of *Babesia*.[1–3] *Babesia*, a red blood cell infecting piroplasm or protozoan parasite, is most commonly seen in wild or domestic animals. There are over 100 *Babesia* species, few documented as human infection cases.[1–3] The *Babesia* species generally reported globally are *B. microti, B. divergens, B. duncani*, *MO1.*[1] The most common species of human infection in the United States is *B. microti*; widely reported in the upper Midwest and Northeast regions including New England, New York state, New Jersey, Wisconsin and Minnesota.[1,2,8,9] While *B. divergens* has been reported in Europe, a *B. divergens*-like species (*MO1*) have been found in the Midwest and pacific northwest region of the United States[1,3,8]. Most recently, human *B. duncani* has emerged in the pacific northwest.[1]

History of the condition

Medical experts track the first reported epidemic of babesiosis to biblical references as an infectious disease ("plague or divine murrain")[10] infecting cattle.[10] Between 1888 and 1893 babesiosis was recognized as a bacteria and eventually linked to tickborne widespread cattle fever in Texas (Texas fever).[10,13,14] In 1957, a Yugoslavian asplenic farmer became the first case of zoonotic babesiosis.[10] Bovine babesiosis became widely known as an illness among cattle as mammalian intraerythrocytic parasites are very common in nature and human infections were rarely being reported in mainly in Europe among asplenic patients.[10,14] The first human babesiosis infection reported of a patient with an "intact spleen"[10] came from Nantucket Island, Massachusetts and identified as *B. microti.*[10] In 2010, the Council of State and Territorial Epidemiologists (CSTE) recommended, at their Annual Meeting, that babesiosis be added to the national notifiable conditions surveillance system.[4] On January 1, 2011, babesiosis was officially recognized as a nationally notifiable condition strongly recommending states and territories across the nation share reported cases with the Centers for Disease Control and Prevention (CDC); the CDC being the entity responsible for collecting and publishing nationally notifiable disease data.[15]

Physiological effects and severity

The symptoms of human *Babesia* infections develop over a 1-4 week incubation period following a tick bite, or 6- 9 weeks following a blood transfusion transmission; symptoms range from asymptomatic (no symptoms) to severe and may result in death.[1,3,8,10] The severity of the symptoms could last weeks dependent on the the *Babesia* species along with the immune health or condition of the host and do not correlate with the level of parasitemia.[1,8,10] As Babesia is a parasitic disease resulting in the destruction of red blood cells, it can cause hemolytic anemia.[1,8] Hemolytic anemia occurs when bone marrow production of red blood cells cannot compensate for the rate of lost red blood cells.[11,12] Babesiosis can be severe and life-threatening for individuals who are of advanced age, immunocompromised, asplenic (low or abnormal spleen function) or have had their spleen removed.[3] Complications resulting from human Babesia infection include severe hemolytic anemia, severely low platelet count, low and unstable blood pressure, blood clots and bleeding, malfunction of vital organs (e.g. kidneys, lungs, and liver) and, in rare cases, death.[1–3,10] Reports of human *B. microti* infection identify non-specific flu-like symptoms associated with the disease such as fever, chills, sweats, headache, body aches, nausea, or fatigue.[1,2]

Mode of transmission[*]

The primary mode of human *Babesia* infection is tickborne through microscopic parasites transmitted by an infected tick bite[2,8]. The Ixodes scapularis tick (Black legged or Deer tick) is the main species responsible for human infection in the United States, *B. microti*. Peak infection rates occur during the warm months in the upper Midwest and Northeast regions; most recently emerging in the pacific northwest.[2] Infection also occurs via blood donation and transfusion of contaminated blood.[1–3] Another rare mode of transmission, is congenital transmission (present from birth) from an infected mother to baby during pregnancy or delivery.[2,3,8]

Testing protocol[*]

Contingent upon the mode of transmission, the diagnosis of babesiosis can be completed through blood collection by fingerstick or venipuncture and confirmed by laboratory processing.[1,16]

[*] *See* ***Appendix I***

[*] *See* ***Appendix II***

Generally, laboratories follow American Medical Association (AMA) and Clinical Laboratory Standards Institute (CLSI) guidelines and depend upon physician discretion regarding test selection, interpretation, diagnosis and patent management.[17] Laboratory guidelines suggest individuals suitable for testing are "symptomatic individuals with a history of exposure to a tick-endemic area."[18] A clinician may suspect babesiosis in a patient that presents with unexplained flu-like symptoms (e.g., febrile illness), has lived or traveled in high risk, endemic *Babesia* regions and when the patient has a history of a tick bite during peak infection months (i.e., spring or summer).[1,3,9,10] Laboratory testing available for diagnosing *Babesia* are manual microscopy, serology and molecular DNA diagnostic testing.[10,16,18,19]

Testing

Identification of *B.microti* can be made through microscopy detection with a Giemsa-stained blood smear (2 thick 2 thin) and confirmed via laboratory diagnosis.[10,16] Specialists handling specimen for the Giemsa procedure follow CLSI protocol in CLSI document M29-A3, *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition.*[20] Giemsa stains may be rapid (4 step, 6 minutes) or standard (6 step, 67 minutes) procedures involving deionized water, Giemsa solution and methanol, air drying and evaluation.[21] This particular test may return false-negative results upon low parasitemia and if unstained vacuoles are present and repeated smears may be necessary.[10,16,22] Indirect immunofluorescent antibody assay (IFA) is considered a useful antibody detection test for patients with low parasitemia.[22,23] This test has high specificity and determines the presence of antibodies against a certain antigen in a serum with fluorescent dye using *B. microti* parasites as antigen and detects antibodies in 88-96% of patients with a *B. microti* infection.[22,24,25] IFA takes approximately 4 steps:

i. An antigen or microorganism is incubated with the patient's serum,
ii. excess serum is washed away,
iii. the sample is incubated with antibodies labeledge with fluorescent dye (specific for human antibodies), and
iv. sample viewed with fluorescence viewer.[24]

An IFA assay can also diagnose after a therapy cleared infection and distinguish between *Plasmodiu falciparum* (the parasite that causes malaria) and *Babesia* infection.[22] The IFA method is generally necessary when a blood smear is returned as inconclusive and when an patient's travel history "cannot exclude either parasite."[22] Immunofluorescence (IF) is cell imaging utilizing fluorescent dye (fluorophores or fluorochromes).[23] A molecular diagnosis can be made using

Polymerase Chain Reaction (PCR) assays for *B.microti* during the acute febrile phase.[10,16,26] PCR is highly sensitive and specific.[27] The detection of *B.microti* using the PCR method can be done by extracting *Babesia* genomic DNA.[28]

Transfusion-Transmitted Babesiosis (TTB) protocol

In 2014, the leading reported cause of red blood cell (RBC) transfusion-transmitted infection in the United States was *B.microti.*[26] There is no licensed blood donor screening for *Babesia* approved by the Food and Drug Administration (FDA).[26,29] The established tool used for screening for rare blood abnormalities is a self-reported history, *Uniform Donor Health History Questionnaire* (UDHQ).[26] The *Babesia* parasite has the ability to withstand blood preparation and holding conditions and therefore proves to be a dangerous infectious risk to transfusion patients; in particular high risk (immunocompromised, elderly) patients.[26,29] Thus, due to inaccurate donor report, units of blood may transmit *Babesia.*[3,9,30] In order to accurately detect this occurrence, units of blood would need to be screened to prevent TTB.[26,29,31] Donor screening assays are currently in development.[26] Therefore, post-transfusion patients presenting with unexplained symptoms such as hemolytic anemia or fever should be tested for infection.[26,29,32] Medical and laboratory personnel follow rigorous codes and regulations regarding blood specimen handling and shipping protocol.[33] Depending on the requested panel of testing, general lab results turnaround upon receipt 24-48 hours and the receipt of lab results vary depending on the method of communication to provider or institution.[27,34,35]

Epidemiological Information

Prevalence and incidence

Nationally, in 2013 alone, 1,762 cases of babesiosis were reported to the CDC; all of which came from 22 states.[36] From 1979 through 2014, over 160 cases of TTB have been reported (at least 12 deaths).[29] There have been seven cases of human *Babesia* infection in Washington state between 1990-2013. Of the seven confirmed cases, three were TTB *B.duncani,* one case of *B. divergens-like,* and three *B. microti* likely acquired during travel-high risk endemic areas in upper Midwest or northeastern United States and recorded as likely/confirmed.[37]

Estimates of under-reporting in Washington

In 2013, babesiosis surveillance efforts involved 27 states. These states required reporting of babesiosis; among these states the CDC was notified of 1,762 cases of babesiosis in 22 of the 27 states (5 states did not report any cases).[36] Most of the cases were reported by 7 states (95%):

Connecticut, Massachusetts, Minnesota, New Jersey, New York, Rhode Island, and Wisconsin.[36] The findings of this surveillance were not surprising as these states already have well established tickborne transmission of *babesia* parasites.[36] The median age of the cases reported was 62, also aligning with the known risk factors of babesiosis.[36] However, due to climate change, ticks have spread to new areas and are emerging in areas previously unaffected; thus prevention and education should be prioritized.[38] Epidemiological trends in Washington state indicate that although there remains low incidence of parasitic disease such as babesiosis, the condition is still a concern as rates in endemic states are growing.[38] Such a low incidence in Washington may indicate health care providers are unfamiliar with babesiosis detection, delaying treatment and reporting.[3,19]

Subpopulations affected

While healthy individuals rarely contract or are severely affected by a *Babesia* infection, it is most severe and potentially fatal in the elderly or immunocompromised individuals.[3] Further, the most common transmission is by tick bites, so travelers around the upper Midwest or Northeastern regions during endemic or peak seasons are at higher risk.[2,3] High risk transfusion patients are also of greater threat to a babesiosis post-transfusion of contaminated blood.[26,29] Stress induced cardiomyopathy (diseases of the heart muscles[39]) can complicate babesiosis, therefore, individuals experiencing high levels of stress are at risk for recovery complications thereby disproportionately affecting vulnerable or populations of low socioeconomic status.[40]

Retrospective study

From 2006-2013 Menis M, Forshee RA, Kumar S, et al. completed a retrospective study reporting that cases of babesiosis among the elderly in the United States are increasing.[41] They found a statistically significantly higher incidence in males than females (5.57/100,000 vs. 4.48/100,00) the researchers suggested this could be “associated with greater outdoor activity in males” than that of females.[41] Avoiding endemic regions (in particular during peak months) is one of the most effective preventative measures against *Babesia* exposure.[2,3] Immediately removing ticks and seeking advice from a healthcare expert is the recommendation upon exposure.[1,10] As treatment for severe *Babesia* infection requires patients to stay in care, adherence to tailored recovery plans crucial for recovery is necessary. Recovery may vary with regards to socioeconomic class, the patient’s personal work schedule, family and financial commitments.[9,41,42]

Cost Estimates

Babesiosis is particularly rare in non-endemic regions, thus the cost of recovery can be difficult to estimate in these areas.[26,29] In addition, the cost estimate of a patient who experienced a tick bite *babesia* infection compared to TTB may vary greatly. Therefore, the cost of treatment can be loosely estimated* per patient and costs incurred per increased incidence and prevalence in endemic regions referenced.[26,31,37] Cost* can vary depending on the patient history such as comorbidities, previous exposures to *Babesia*, and socioeconomic status.[26,29,34,43–45] Coupled with a competitive price market, healthcare is structured differently among various divisions and can change depending on the market (supply and demand) and competition.[34,43,45] The following cost considerations separate "walk in" patient diagnosis in a clinic setting and additional cost incurred regarding TTB.

Walk in : In Washington state, the cost of recovery for a tick bite patient can range including costs incurred from the facility, provider, payment method, treatment and other social and personal factors. Specifically, there may be fees for building use (facility fee) for every procedure as well. Cost of testing for babesiosis can range between $400-$4000.* The variance in facility and clinic building costs depend on services offered, contracted partners such as internal and external laboratory services, staffing and system management.[34,45–47]

TTB: Due to the nature of a TTB occurrence, the risk of TTB is neither seasonal or geographic; the risk is due to the travel of donors, storage and transport of blood.[29,32] The overall cost associated with TTB can be grouped into three buckets: donation testing, hospitalization, and treatment.[26,29,48] The average estimated cost of screening for *B.microti* is $6.37-$27.[29] The average cost of a discarded unit of contaminated whole blood is assumed at $427.[29] The estimated mean daily inpatient charge incurred ranges from $4101-$5215 depending on the severity of disease code.* The financial burden of TTB on hospitals (and the US blood supply) can be costly.[26,29] The price to test per unit of blood is expensive and may mean an associated social cost with regards to loss of employment, resources and affect the availability of essential

* *See* ***Appendix III***
* *See* ***Appendix III***
* *See* ***Appendix IV***
* *See* ***Appendix V***

blood for transfusions.[26,29,32] These expenditures are initially absorbed by the hospitals.[29] The hospital mean cost nationally per unit of blood ranges between $200-250 and this has been constant between 2008-present, however, adding new panel requirements or screening to donor blood will increase costs and continue to trickle down to a final payer (e.g., transfusion patient and healthcare plan).[26,29,32,48]

Rhode Island 2016

One example is Rhode Island, an area within an endemic region. The Rhode Island Blood Center (RIBC), in 2010, was the first lab-based blood donor screening program for *Babesia* (*B.microti*) using PCR screening assays and other assays in development.[19,26,31] In 2015 the RIBC estimated they would need to put forth $1.5 to $2 million dollars a year to test the blood for babesiosis beginning in 2016; therefore, the RIBC cut staff to make up cost for babesiosis testing.[31,49] The RIBC and national cost-effectiveness studies performed to date acknowledge the adverse effect of increased cost for laboratory donor screening directly affects the price of blood per unit for hospitals and patients.[29,31,36] As of a January 2016 there has been no forecast to the potential price increase of blood per unit, the RIBC citing there was no established standard to identify this future cost movement.[19,31]

Cost of treatment[*]

As most asymptomatic (healthy) individuals do not need treatment and make a full recovery, the cost of treatment varies among the vulnerable and high risk patients.[26,29,48] Babesiosis, in severely ill patients, usually takes a treatment lasting at least 7-10 days with a combination of two prescription medications.[2,3] These medication combinations are atovaquone and azithromycin; or clindamycin and quinine.[8] Treatment regimens are tailored to the patient and created with consideration to patient history, age and health status. Therefore, the following cost-of-treatment breakdown were gathered as an estimate based on current market prices and the information confirmed by a pharmaceutical laboratory technician:

Treatment 1

- Atovaquone: $200 per 100 tablets (62.5mg per 25mg atovaquone/proguanil) or $50 per 7 250mg-100mg[43,50]
- Azithromycin: $14 per 6 tablets (250mg) or $33 per 3 (500mg)[43,51]

[*] *See* ***Appendix VI***

Treatment 2 (for patients more severely ill)

- Clindamycin: $104 per 200 capsules (75mg), $7 per 4 (150mg) or $23 per 6 (300mg)[43,52]
- Quinine: $50-200 (200mg or 300mg)[43,53]

For patients who are of advanced age, immunocompromised, or asplenic, treatment consists of a combination treatment regimen of intravenous (IV) clindamycin and oral quinine or IV atovaquone and IV azithromycin.[1,10] Adhering to a combination treatment therapy of clindamycin and quinine or atovaquone and azithromycin is cited as more effective than either atovaquone or azithromycin alone.[8] Pricing for IV therapy and combination treatment can be time intensive and requires the CPT coding per patient status.[34,45,46,54] If treated, babesiosis symptoms may continue for two months and patients may make a full recovery.[30]

Cost of non-treatment

B. microti has a 5-10% fatality rate while *B. divergens* have a fatality rate of 42%.[1] For vulnerable individuals, if left untreated, *Bibesia* infections can develop into a very severe infection and may result in death.[1] Other costs of undiagnosed (and untreated) babesiosis can be social and monetary costs resulting from multiple doctor visits, being mis-diagnosed and trying several different types of medication that could cause side effects worse than Babesiosis and years of discomfort.[42]

Potential equity impacts of adding the condition to rule

Babesiosis is already a nationally notifiable condition and there have been 7 cases thus far in Washington state.[37] Due to the asymptomatic nature of the disease and the presence of "non-specific" febrile and flu-like symptoms, if babesiosis were updated to a stand alone condition, this change could be interpreted in various ways by acting physicians. Therefore, there could be a disproportionate burden on local and regional laboratory testing and costs incurred due to a potential increase in panel requests. However, an increase in cost may occur when reporting the condition and consequent confirmatory blood panels (personnel, equipment, facility). As there have only been 7 cases, keeping this as a rare status and notifiable is incredibly important due to the potential non-treatment health costs (sever illness, death) and the infectious disease risk to the US blood supply. There appears to be minimal equity issues around disclosure with the condition. Adding babesiosis to the rule, can allow the State Board of Health authority over

creating laboratory reporting standards and requirements for *Babsia*, alert authorities and the public of the risk of babesiosis in the area and provide an opportunity for education around tick safety.

Conclusion

As *Babesia* is most commonly contracted through tick bite, most people affected are travelling, living, or working in endemic regions.[2,3] However, the public health concern of the infectious risk of TTB further highlight the importance of babesiosis being a nationally notifiable condition.[6] Washington state residents and visitors are all at risk for a tick bite if traveling to these regions and participating in high exposure risk activities; in particular, vulnerable individuals are at higher risk for severe illness or death due to a tick bite or TTB. Perhaps future tracking via electronic system will contribute to a more rapid treatment response for healthcare providers and patients. If there is a change to the rule giving more authority to the board regarding standards and regulation, this may lead to increased attention to TTB and risks associated with TTB. In turn, these efforts could further support an understanding of the importance of donor blood screening for babesiosis and working towards an equitable screening mechanism for Washington state.

Appendix

Appendix I.

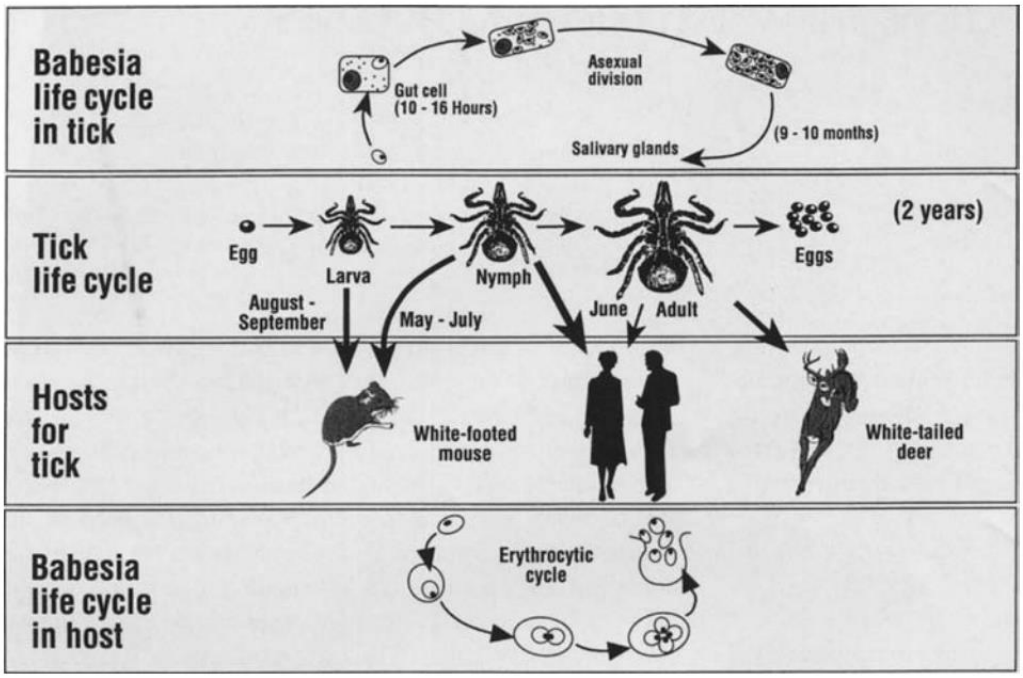

Figure 1. Life Cycle of *B. microti*

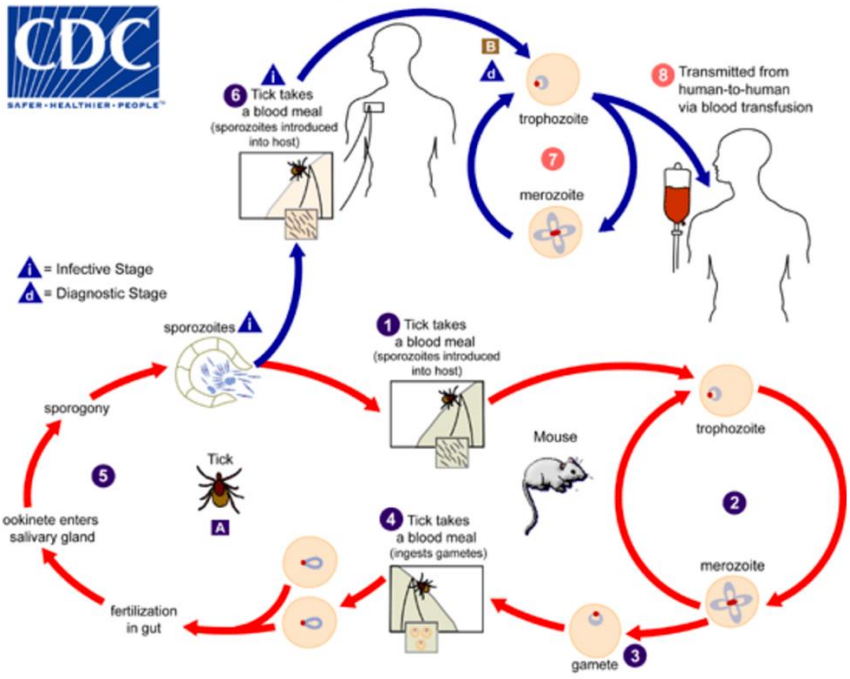

Figure 2. Parasites - Babesiosis Life Cycle[55]

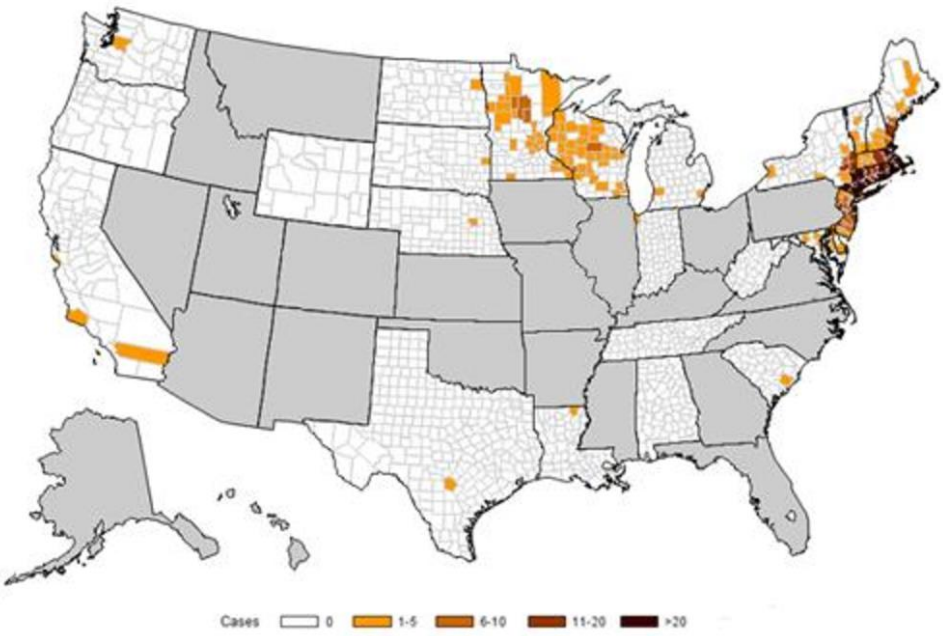

Figure 3. Regions of tick-borne transmission of *Babesia* parasites [56]

Appendix II.

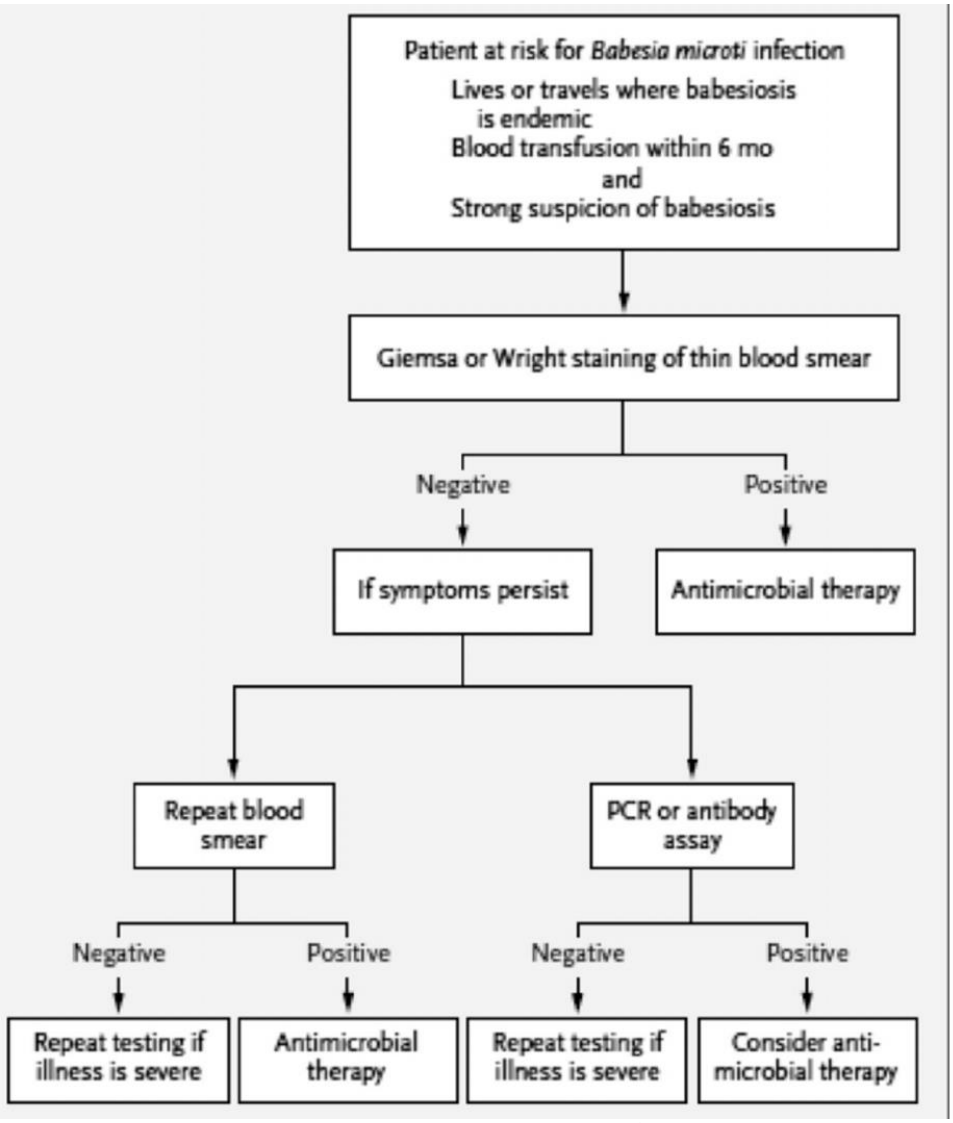

Figure 1. Testing Protocol[56]

Appendix III.

Cost estimates and projections:

To get more precise cost estimate, a list of the possible CPT codes can be acquired, though time intensive, for the exact item, procedure, laboratory request and call each location of choice to acquire location-specific billing estimate. For example, regional public health labs (such as PACLAB Network Laboratory) is more cost effective that private labs and serve the greater western Washington region[34,44]. Exact Current Procedural Terminology (CPT) medical code is needed to calculate and asses and project patient cost[34,43–46,54]. The CPT list for patient healthcare is divided into 6 sections with corresponding numeric and alphanumeric coding[34,43–46,54]:

- Evaluation and Management: 99201 – 99499
- Anesthesia: 00100 – 01999; 99100 – 99140
- Surgery: 10021 – 69990
- Radiology: 70010 – 79999
- Pathology and Laboratory: 80047 – 89398
- Medicine: 90281 – 99199; 99500 – 99607[54]

Each field has numerous subfields associated with the various patient-healthcare process and subsequent outcome[54].

Appendix IV.

The following should be considered in any cost estimates and were acquired through in-person and telephone interviews around Washington state:

- Provider visit (facility fee): Cost can range from a new patient out-of pocket fee of approximately $150 to a more expensive facility charge of $400[45,57].
- Blood draw (procedure): Cost can range from $200 to $3,000 procedure (and facility fee)
- Laboratory testing: Cost can average between $190-250 if the panels are sent to PACLAB Network Laboratories (PACLAB)[34]. PACLAB is Washington state's regional public health lab, serves the greater western Washington region and is more cost effective than private labs[34,44]. Patients and institutions will pay more for private or hospital based labwork[34].
    - extra shipping charges (e.g., $50 PACLAB[34]) varies depending on the healthcare location and contracted services[34,45].
- Provider fee: These cost vary and are a charge for the physician. These charges are on top of all other charges[34,45,46].
- Any additional facility fees: On top of all base costs (the facility where you visit, your tests visit, etc..)[34,43,45,46].
- Any follow ups: depending on the patient status (e.g., comorbidities such as Lyme disease) [10,26,29].
- Treatment cost: Varies (expanded in next section below)[34].
- Social and personal cost: Socioeconomic hardships, time off work, family and financial burden[10,26,29].

Appendix V.

National Mean Cost Estimates

- Total cost (reagents, labor, overhead): *B.microti* manual IFA cost per sample is approximately $21 (range $15-$27)[29].
- Estimated costs of screening *B.microti* using enzyme-linked immunosorbent assay (ELISA) $8.83 ($6.37-$12.29) per donation and $22.50 ($20-$25) for PCR[29].
- Discarded unit of whole blood (consequences of false-positive screening result) assumed $427 ($213-853)[29].
- Estimated mean charge incurred daily inpatient charge hospitalization for a moderate disease code $4101 (parasitic and/or infectious disease patients with out complications and/or comorbidities) [29,58].
- Estimated mean charge incurred daily inpatient charge hospitalization for a severe disease code $5212 (parasitic and/or infectious disease patients with out complications and/or comorbidities)[29,58].

Appendix VI.

Drug	Adult dosage (usually treat for at least 7-10 days)
Atovaquone	750 mg orally twice a day
along with	
Azithromycin	On the first day, give a total dose in the range of 500-1000 mg orally; on subsequent days, give a total daily dose in the range of 250-1000 mg
or	
Clindamycin	600 mg orally 3 times a day **or** 300-600 mg intravenously 4 times a day
along with	
Quinine	650 mg orally 3 times a day

Figure 1. Pharmaceutical Treatment Regimen[8]

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Coccioidomycosis

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December 2016

Summary and Purpose

Coccidioidomycosis, also known as Valley Fever, is an infection caused by the *Coccidioides* fungus that can cause pneumonia-like symptoms and even death.[1-4] This disease is listed as a "Rare Disease of Public Health Significance" by the Washington State Department of Health (DOH) and, as a result, is a condition that medical providers must report to their local health jurisdiction within 24 hours of diagnosis (per a regulation in the Washington Administrative Code, WAC, 246-101- 101).[11]

Though the designation of Coccidioidomycosis as a "Rare Disease" makes it "of general or international public health concern," it has not yet been classified as a notifiable condition via the state Board of Health's rulemaking process.[11] The Washington State Board of Health (BOH) is currently considering whether Coccidioidomycosis should be moved from its current "Rare Disease" classification to designation as a "Notifiable Condition" so that it may be explicitly listed in WAC 246-101-101; 201; and 301. In relation to 246-101-201, the BOH is exploring the following language for type and timing of specimen submission to the DOH: "isolate or clinical specimen excluding serum associated with positive result if no isolate is available."[27]

Making Coccioidomycosis a "Notifiable Condition" would allow the DOH and BOH to create reporting standards for providers, labs, and institutions that are unique to the disease as opposed to adhering to the more general reporting requirements for "Rare Diseases of Public Health Significance." Transparency is an additional benefit of doing so, as it would become easier for stakeholders to understand the current level of public health interest in the condition.

Washington State Board of Health and Washington State Department of Health teams would benefit from consulting with stakeholders such as medical providers, laboratories, and former patients, to evaluate if this shift would have any drawbacks or increased costs.[8] By understanding the disease, epidemiology, costs, and equity impacts of Coccioidomycosis as well as hosting future discussions with key stakeholders, the Washington State Board of Health and Washington State Department of Health can make an informed decision about whether to make Coccioidomycosis a "Notifiable Condition" through the rulemaking process.

Disease Background and Etiology

History of the Condition

Coccidioidomycosis, also known as Valley Fever, is an infection caused by the *Coccidioides* fungus.[1] The fungus is known to live in the soil in the southwestern United States and parts of Mexico and Central and South America.[1] Specific areas where *Coccidioides* is known to live include Arizona, California, Nevada, New Mexico, Texas and Utah.[2] Most recently, the fungus has also been found in south-central Washington.[1]

Coccidioidomycosis was first discovered by a medical student, Alejandro Posadas, in Buenos Aires, Argentina in 1892.[8] In 1896, scientists identified and reported a few cases from previous infected tissue and found that the material resembled a protozoan organism named *Coccidia* and named this new protozoan-like organism *Coccidioides immitis*.[8] However, by 1905 *C. immitis* was found to be a fungus, and not a protozoa.[8]

Coccidioidomycosis disease was considered rare and fatal until 1929 when a Stanford Medical Student, Harold Chope, accidentally inhaled a culture of *Coccidioides* and developed non-fatal pulmonary illness.[7] This case sparked interested and led researchers to uncover the association between *C. immitis* and the clinical condition known as San Joaquin Valley fever Reseachers also developed a coccidioidin skin test and serologic testing for Coccidioidomycosis.[7]

Coccidioidomycosis received increased attention in the 1930s and 1940s, when there was an increase of immigrants from the Midwest to California (specifically the San Joaquin Valley) who were escaping the drought and seeking agricultural employment.[7] Late in 1957, the first effective therapy for Coccidioidomycosis was introduced and by the 1980s, various oral antifungal agents have been introduced as further advances in treatment of Coccidioidomycosis.[7]

Due to a severe outbreak between 1991 and 1994, Coccidioidomycosis was identified as a nationally notifiable condition in 1995 through 2009 and again from 2011 to current time.[9]

Physiological Effects & Severity

Generally, most people exposed to *Coccidioides* never have symptoms. However, if people do experience symptoms they are likely to feel flu-like symptoms that may resolve spontaneously within weeks and/or months.[3] Other symptoms unique to Coccidioidomycosis include: fatigue, fever, shortness of breath, cough, headache, night sweats, body aches, and/or rash on upper

body or legs.[3] Rare cases of Coccidioidomycosis involve fungal spores entering the skin through a cut, wound, or splinter – which then lead to skin infections.[3]

Symptoms may appear between one to three weeks after a person breathes in the fungal spores.[3] Roughly five to ten percent of people who get Valley fever will develop serious or long-term problems in their lungs.[3] In roughly one percent of people, the infection spreads from the lungs to other parts of the body, such as the central nervous system, skin, or bones and joints.[3]

Mode of Transmission

Most Coccidioidomycosis infections are caused by inhalation of airborne spores of the fungi genus *Coccidioides*.[4,5] The most common species that affect humans are *C. immitis* or *C. posadasii.*[6] Coccidioidomycosis is most commonly acquired in the summer or the late fall during outdoor activities.[7] Microscopic *Coccidioides* spores circulate in the air after contaminated soil and dust are disturbed by humans, animals, or weather.[2]

Testing Protocol

While someone with Coccidioidomycosis may have abnormal blood and imaging test results, these results are nonspecific and may point to a number of different possible illnesses.[2] As a result, clinicians need to identify antibodies reacting to *Coccidioides* fungus in the patient's blood or other body fluids.[2]

Laboratories may offer several other suitable blood tests and the medical provider will decide which test to pursue.[11] However, clinicians recommend serologic testing, testing blood, or other bodily fluids to look for antibodies, and prefer "enzyme-linked immunoassays for IgM and IgG," if this specific serologic test is available from the medical facility's laboratory.[2] Patients can expect to receive serologic testing results in a few days.[11]

For patients who are very ill or hospitalized, clinicians may also consider examining patients' specimens and identifying *Coccidioides* directly from a specimen or through a fungal culture.[2] Clinicians must be cautious, however, as the CDC lists *Coccidioides* as a potential tool for bioterrorism and has strict security procedures for how clinicians and laboratories must handle these fungi.[2] One of the disadvantages of this procedure is that patients may have to wait a few days or a few weeks to receive test results from their specimens.[12]

Some medical providers recommend testing skin cells of all patients living in areas where *Coccidioides* thrives on a routine basis, so providers can compare these baseline results with test results they observe when a patient feels ill.[2] Most importantly, medical providers and laboratory specialists are required by the Washington State Department of Health to report cases of Coccidioidomycosis to their local health jurisdiction within 24 hours of diagnosis and to send any specimens within two days.[21]

Epidemiological Information

There is a low prevalence of Coccidioidomycosis in WA.[14] As mentioned above, the vast majority of *Coccidioides* infections occur in the endemic zones, such as California, Arizona, Mexico, and Central America.[1]

Coccidioidomycosis was made reportable as a rare disease of public health significance in 2014 because incidents have increased each year.[14] For example, prior to 2014, up to six travel-associated cases were reported each year. Between 2010 and 2014, nine cases with exposure in south-central Washington State were reported and in 2014 twenty-one cases were reported. Of these, eighteen were travel-related and three were exposed in southcentral Washington.[14]

Estimates of Under-Reporting in Washington

Local health jurisdictions must improve surveillance efforts to better understand Coccidioidomycosis.[15] To do this, the Washington State Department of Health is working with local public health partners, healthcare providers, and veterinarians to raise awareness that Coccidioidomycosis can be acquired in Washington. Medical professionals are required to report any suspected cases to public health officials. Reporting cases helps public health officials identify and investigate where the fungus lives and keep track of the number of cases over time.[15]

While Coccidioidomycosis was not previously considered endemic to Washington State, recent research suggests further investigation is needed to identify cases acquired in Eastern Washington. Between 2010 to 2011 there were three cases of Coccidioidomycosis in Eastern Washington. Local environmental conditions in Eastern Washington, such as its soil, support the presence of *Coccidioides*.[9]

Subpopulations Affected

Anyone who lives in or travels to the southwestern United States (Arizona, California, Nevada, New Mexico, Texas, or Utah), or parts of Mexico or Central or South America can get Coccidioidomycosis. However, certain groups of people may be at higher risk for developing the severe forms of Coccidioidomycosis.[16] More specifically, people who have weakened immune systems are especially at-risk.[16] For example, Coccidioidomycosis is most common in adults aged 60 and older because their immune system is increasingly compromised.

People who are living with weakened immune systems, like people living with HIV/AIDS, diabetics, organ transplants recipients, or people who are taking medications such as corticosteroids or TNF-inhibitors, have a higher risk of Coccidioidomycosis spreading to multiple body systems.[16] For example, an incidence as high as 5% has been reported among transplant receivers in areas where *Coccidioides* is endemic, and the rate of mortality associated with Coccidioidomycosis disease in multiple body systems has been reported to be up to 72% among these patients. Delay in the diagnosis of Coccidioidomycosis in donors has had significant implications, including death.[18]

Similarly, a retrospective study of 52 diabetic patients who had undergone surgery for pulmonary Coccidioidomycosis found that the incidence of more severe, progressive disease was four times higher in patients who had insulin-dependent diabetes than in those who had non-insulin-dependent diabetes.

Pregnancy is also an established risk factor for the development of severe and widespread Coccidioidomycosis, particularly when infection is acquired during the later stages of gestation.[19]

Coccidioidomycosis in multiple body systems is also more likely to occur among certain ethnic groups, especially among persons of Asian or African descent.[18] It's important to note that with the same level of exposure, persons of any race are not more likely or less likely to inhale airborne spores than persons of another race. Therefore, there is no known difference in the racial susceptibility to primary Coccidioidomycosis.[20] However, numerous retrospective studies have suggested that African Americans have an increased risk of severe or widespread *Coccidioidal* infections.[20]

The earliest epidemiological studies in California raised concern of the effect of race in Coccidioidomycosis because extra pulmonary infection was fourteen times more likely to develop in African Americans than in whites. Other groups at risk included Filipinos (the disease was 175 times more likely to spread to multiple body systems) and Mexican Americans (three times more likely).[20]

It is possible that occupational exposure placed these patients at higher risk of acquiring the infection. For example, populations with exposure to airborne *Coccidioides* spores working in agriculture and construction have a higher risk of developing Coccidioidomycosis in multiple body systems.[20]

Outbreaks have also been linked to earthquakes, windstorms and military training exercises where the ground is disturbed. Historically, an infection is more likely to occur in males than females—this could be due to a person's occupation rather than their gender.[20]

Cost Estimates

Cost of Testing

The cost of testing for Coccidioidomycosis depends on the type of test ordered and/or done by the medical provider, the laboratory completing the test, and the patient's insurance. A laboratory may charge just over $300 for a serologic test.[22] Medicaid, Medicare, and other government insurances cover the cost of testing and treatment for patients, so some of the financial burden of detecting and supporting patients with Coccidioidomycosis falls on taxpayers.[22]

Cost of Treatment

Similarly, the costs of treating Coccidioidomycosis depend on the patient's condition, the medical facility, and the patient's insurance. Most patients suffering from Coccidioidomycosis require rest, fluids, and check-ins with their medical provider for a few weeks—a generally low-cost treatment plan for patients if the patient has access to a restful environment, hours without work, clean water, and medical care.[23] Medical providers may encourage patients with more severe *Coccidioides* infections or symptoms, or with compromised immune systems, to take antifungal medication—also a generally low-cost treatment plan for patients and taxpayers if the patient has access to free or low-cost pharmaceuticals in addition to the items previously mentioned as helpful for treatment and recovery.[23] Some patients may experience side effects

from antifungals, which would require additional treatment and increase their overall treatment cost.[23]

Medical providers may recommend patients with severe cases of Coccidioidomycosis enter a hospital, where the costs of treatment can increase dramatically for both patients and taxpayers; this high-cost treatment plan may also have negative economic consequences for businesses who lose productive work time when their employee is hospitalized.[24] The costs of hospitalization can be astronomical, with one source listing the average cost at over $100,000.[24]

The cost to medical providers to provide diagnosis and treatment services will depend on the provider's licensure, facility, medical coding, reimbursement understanding with a patient's insurance, and time spent working with the patient, among other factors. The cost of antifungal therapy is high, from $5,000 to $20,000 per year. These costs increase for critical patients in need of intensive care. Arizona spent an average of $33,762 per patient with Coccidioidomycosis between 1998 and 2001.[23]

Cost of Non-treatment

Three quarters of people with Coccidioidomycosis miss an average of two weeks of work or school. More than 40% of Valley Fever victims are hospitalized, but an estimated 150,000 more cases go undiagnosed every year.[23] More alarmingly is the cost of not treating Coccidioidomycosis: almost 100% mortality rate.[23] Other costs of undiagnosed (and untreated) Coccidioidomycosis can be social and financial costs resulting from multiple doctor visits and being misdiagnosed.

Potential Equity Impacts of Adding the Condition to Rule

Making Coccidioidomycosis a notifiable condition, can alert authorities and the public of the risk of Coccidioidomycosis in the area. Because populations at risk for contracting Coccidioidomycosis are already vulnerable populations (HIV/AIDs, pregnant, diabetics, and organ transplant receivers), notification helps authorities manage the condition and can possibly warn communities of a potential outbreak.[17-19]

Because recommended antifungal therapy can be costly and can take several months to a year for people with weakened immune systems, it is important that reporting is bolstered with adequate access to health care services, such as treatment.

Some medical providers recommend routine serologic testing for all people with weakened immune systems to prevent potential outbreaks.[19] A positive test result would suggest active disease and would warrant further clinical evaluation and consequential reporting.[19]

Conclusion

Coccidioidomycosis has not yet been classified as a notifiable condition via the state Board of Health's rulemaking process.[11] Due to its potential impact on vulnerable subpopulations, such as those living with weakened immune systems,[17-19] and potential for increased cost associated with non-treatment we recommend that Coccidioidomycosis be moved from its current "Rare Disease" classification to designation as a "Notifiable Condition" so that it may be explicitly listed in WAC 246-101-101; 201; and 301.

Making Coccioidomycosis a "Notifiable Condition" would allow the DOH and BOH to create reporting standards for providers, labs, and institutions that are unique to the disease as opposed to adhering to the more general reporting requirements for "Rare Diseases of Public Health Significance." Transparency is an additional benefit of doing so, as it would become easier for stakeholders to understand the current level of public health interest in the condition.

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Carbapenem-resistant Enterobacteriacaea (CRE)

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December 2016

Summary and Purpose

Carbapenem-resistant Enterobacteriaceae, or CRE, are a family of highly antibiotic-resistant germs that emerged in the U.S. during the past decade. This disease is considered a "Rare Disease of Public Health Significance" by the Washington State Department of Health (DOH) and, as a result, is a condition that medical providers must report to their local health jurisdiction within 24 hours of diagnosis pursuant to WAC 246-101- 101. Concerning rare diseases, no reporting requirements for labs exist. However, pursuant to WAC 246-101-301, institutions are required to notify public health authorities about rare diseases within 24 hours of detection.[1]

Though CRE's designation as a "Rare Disease" makes it "of general or international public health concern," it has not yet been classified as a notifiable condition via the state Board of Health's rulemaking process.[2] The Washington State Board of Health (BOH) is currently considering whether CRE should be moved from its current "Rare Disease" classification to designation as a "Notifiable Condition" so that it may be explicitly listed in WAC 246-101-101; 201; and 301. In relation to 246-101-201, the BOH is exploring the following language for type and timing of specimen submission to the DOH: "Isolate or clinical specimen associated with positive result if no isolate is available."[3]

Making CRE a "Notifiable Condition" would allow the DOH and BOH to create reporting standards for providers, labs, and institutions that are unique to the disease as opposed to adhering to the more general reporting requirements for "Rare Diseases of Public Health Significance." Transparency is an additional benefit of doing so, as it would become easier for stakeholders to understand the current level of public health interest in the condition.

Washington State Board of Health and Washington State Department of Health teams would benefit from consulting with stakeholders such as medical providers, laboratories, and former patients, to evaluate if this shift would have any drawbacks or increased costs.[8] By understanding the disease, epidemiology, costs, and equity impacts of CRE as well as hosting future discussions with key stakeholders, the Washington State Board of Health and Washington State Department of Health can make an informed decision about whether to make CRE a "Notifiable Condition" through the rulemaking process.

Physiological Effects/Severity

CRE are a family of germs that are highly resistant to carbapenem antibiotics.[4]

Carbapenems have historically been used to treat infections comprised of gram-negative bacteria (Enterobacteriaceae).[5] Carbapenem is a β-Lactam antibiotic used to fight against gram-negative bacteria[6,7] *Klebsiella* species and *Escherichia coli (E. coli)* are examples of Enterobacteriaceae, and exist as a normal bacteria that lives in the human gut, and have become carbapenem-resistant.[4] Sometimes *E. coli* and *Klebsiella* can spread outside the gut and cause serious infections, such as urinary tract infections, bloodstream infections, wound infections, and pneumonia.[8] Enterobacteriaceae can cause infections in people in both healthcare and community settings.[8] For many years carbapenems have been used to treat infections due to resistant Enterobacteriaceae, such as *Escherichia coli* and *Klebsiella pneumoniae*.[5]

Concerning the severity of CRE, antimicrobial resistance is globally recognized as one of the greatest contemporary threats to public health.[5] The prevalence of CRE infections has increased over the last decade.[5] Some CRE bacteria have become resistant to almost all available antibiotics and can be deadly. One report cites they can contribute to death in up to 50% of patients who become infected.[4] Every year roughly 600 deaths result from CRE infections.[5] The Centers for Disease Control and Prevention (CDC) estimates more than 9,000 healthcare-associated infections are caused by the 2 most common type of CRE, carbapenem-resistant *Klebsiella* species and *Escherichia* species, each year in the United States.[5] CRE infections are a public health concern because CRE mortality rates are high and range from 18% to 48% depending on therapy.[5] Currently there are a limited selection of treatment options for CRE infections.[5]

Mode of Transmission

A CRE infection is acquired through exposure of CRE germs.[8] CRE germs are usually spread person to person through contact with infected or colonized people, particularly contact with their wounds or stool.[8] CRE often enters the body of an uninfected individual through medical devices like ventilators, intravenous catheters, urinary catheters, or wounds caused by injury or surgery.[8] CRE infections are most commonly seen among people in healthcare settings (e.g. hospitals, long-term care facilities, skilled nursing facilities, and long-term acute care hospitals).[8] In these settings, CRE infections occur among sick patients who are receiving treatment for other conditions, patients whose care requires devices like ventilators, urinary catheters, or intravenous catheters as well as patients on prolonged antibiotic regimens are among those at risk for CRE infections.[8]

Specifically, failing to “adequately clean and disinfect” surfaces, equipment, and machines for both CRE and non-CRE patients has played a role in the spread of CRE within healthcare facilities.[17] Facilities with strict precautions around patients who have CRE show a decrease in new CRE prevalence (in a 3-year study). [21] Removing the “focus of infection” (e.g. ventilator) is independently associated with surviving CRE. [18] One review suggests that failure to intervene on CRE is because technicians and providers do not recognize it as an “epidemiologically important organism”, and a lack of communication.[18]

History of the Condition

Historically, carbapenems have been used as the “last-line” treatment for infections caused by resistant Enterobacteriaceae.[5] In December 1985, Merck & Co. launched imipenem, an antibiotic treatment for bacteria, in the United States.[6] Two decades of research led to the release of imipenem. Research was prompted by the emergence of β – lactamase producing bacteria and the threat of penicillin resistance.[6] Similar to penicillin, carbapenems have a β – lactam ring, yet carbapenems have shown greater stability against β – lactamases.[6]

Thienamycin was the first carbapenem that proved to have a wide range of antibiotic activity however it was chemically unstable.[6] Imipenem proved to be more satisfactory β – lactam antibiotic in the 1980s.[6] In 1986, research was introduced about meropenem.[6] Meropenem was launched in the mid-90s in Europe and has shown clinical advantages over imipenem and has been the most widely used carbapenem in the UK.[6] By 2000, carbapenems were widely used for *Pseudomonas* and *Acientobacter* infections because species’ growing resistance to other antibiotics.[6] Carbapenems were also used against the increasing numbers of infections due to Enterobacteriaceae.[6]

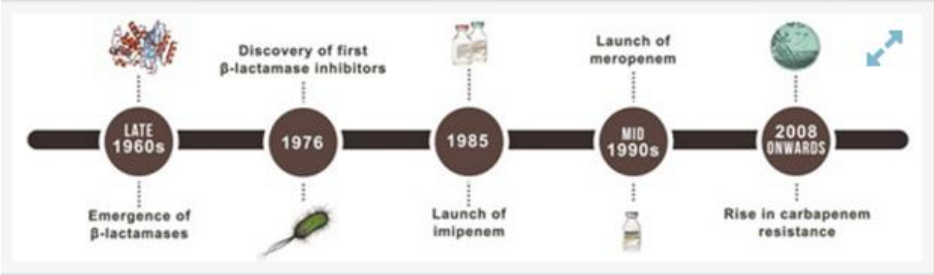

Figure 1. A timeline of the emergence of carbapenem resistance.[6]

Recently, Enterobacteriaceae-producing carbapenemases (another name for CRE) have emerged and present a broad resistance to most ß-lactam antibiotics.[5] Enterobacteriaceae that produce carbapenemases are enzymes that deactivate carbapenems and most other ß-lactam antibiotics; this causes infections due to carbapenem-resistant Enterobacteriaceae (CRE).[5]

Testing Protocol

The most common way to diagnose CRE is by bacterial isolation with antibiotic susceptibility testing.[9] A test and method are chosen based on Clinical Laboratory Standards Institute (CLSI) guidelines. Antibiotics are then chosen to test for resistance. The results are confirmed with Public Health Laboratory and the Office of Communicable Disease Epidemiology.

Laboratory testing is mostly automated for this culture. Methods for determining resistance have included broth dilution, disk diffusion or E test. The most up to date resistance breakpoints (the accepted concentration of an antibiotic that determines if a bacterium is resistant or susceptible to that antibiotic) from CLSI should be used to determine resistance. The Office of Communicable Disease Epidemiology should be contacted if there are questions about how to determine if a case meets the definition for CRE.[9, 10]

The only test for carbapenemase production that is currently used widely in laboratories in the United States is the Modified Hodge Test (MHT).[11,12] However, MHT has limitations and may be less informative than other tests.[9, 10] The MHT test requires 5ml Mueller Hinton broth or 0.85% physiological saline, Mueller Hinton agar, ertapenem susceptibility disk along with sterile cotton-tipped swabs, 1ml sterile pipette, sterile loop, a Turbidity meter and an ambient air incubator. The specimen should be incubated for 16-24 hours. If a clover leaf-like growth forms then it is positive for resistance; if no growth has occurred the specimen is CRE-negative.[12]

Another test that can be used to determine if a patient is colonized with carbapenem-resistant or carbapenamase-producing Enterobacteriaceae in the intestinal tract. This tests requires an ambient air incubator and Vortex. This process takes four days to complete. One limitation of this test is that it may not identify CRE if the concentration of colonization is too low for this test to detect.[13]

CDC protocol may require more than one test when CRE is suspected.[11] Hospitals and long term care settings are encouraged by the CDC to complete routine facility evaluations in order to identify patients growing colonized CRE.[11]

Prevalence

Washington State has a low CRE prevalence.[15] The Washington State Department of Health (DOH) did not begin tracking CRE until 2012. However, there has been a dramatic increase of CRE across the nation in the last decade.[4,14] CRE is of epidemiological importance because of its potential to spread exponentially in health care settings.

Incidence

In 2014, 97 cases of CRE were submitted to labs in Washington State. Of these cases, 78% met case surveillance definition when tested, 32% of these samples tested positive for CRE-isolates. These positive results came from 20 different patients; two patients had isolates of more than one CRE.[14] Of the 20 patients, 40% were female (8) and the median age was 62 (ranging from 31 to 91). One of the patients engaged in illicit intravenous drug use, one had household contact with a chronically ill person and the rest (18) had chronic illnesses.[14]

Within Washington State, *Klebsiella* pneumoniae (KPC) is the most prevalent CRE genus as indicated by the table below.[14]

Genus and species: **Carbapenemase**	*Enterobacter cloacae* (*n*=1)	*Escherichia coli* (*n*=3)	*Klebsiella pneumoniae* (*n*=16)
KPC only	1 (100%)	0	14 (88%)
NDM only	0	2 (67%)	0
OXA-48 only	0	1 (33%)	0
NDM and OXA-48	0	0	2 (12%)

Figure 2. Carbapenemase-producing CRE isolates identified by Notifiable Condition reporting, by species and carbapenemase type, Washington 2014.[14]

Since 2012, 10-20 cases of CP-CRE are reported each year.[9] Mortality for CRE is as high as 40-50% of cases.[16]

Estimates of Under-reporting in Washington

Although Washington State has been tracking CRE, there are many limitations to the surveillance system. Some potential reporters may not know of or comply with reporting standards. Not all laboratories use the most up-to-date CLSI breaking points for carbapenems

when they test for resistance, leading them to miss cases. These factors likely contribute to an underreporting of CRE in Washington.[15]

Some indications of underreporting of CRE in Washington include a case that had no out-of-state medical care which suggests transmission occurred in Washington. Another case had an unusual cephalosporin susceptibility pattern that may be overlooked under current screening practices. One case had no recent hospitalizations or medical care, indicating an alternate mode of transmission.[15] These unique characteristics of CRE may contribute to underreporting and areas of improvement regarding surveillance.[15]

Public health agencies can play a pivotal role in reporting and transmission through a national, voluntary program called Detect and Protect. Funding for Detect and Protect comes from the CDC as part of their efforts to identify and prevent the spread of germs that cause healthcare-associated infections (HAI). Strategies include "tracking CRE, including use of the National Healthcare Safety Network (NHSN), and Prevention activities, such as those found in CDC guidelines and HAI prevention toolkits."[4]

Subpopulations Affected

There are several risk factors for CRE infections:

- Patients who use devices like ventilators, urinary catheters, intravenous catheters.[4,17,18,19]
- Patients who are taking long courses of antibiotics.[19]
- Patients who participate in organ/stem cell transplantation.[18, 19]
- Elderly patients and patients with compromised immune systems.[20]

Females are at higher risk for CRE than males.[17] In addition, there is an association between CRE infection and length of stay in healthcare facility, meaning that both patients and staff at healthcare facilities are at increased risk of contracting CRE.[18, 19,21]

Cost of Testing

There are many types of tests for antibiotic resistance, each having its own positive and negative attributes. Factors that should be considered when an institution is selecting what test they will use are organism type, prevalence mechanism of resistance, test performance, result time laboratory capabilities and cost.[22]

Costs for the tests mentioned in the testing protocol section vary somewhat. The cost for prepared panels for the broth dilution test range from $10 to $22 each. E-test strips cost $2 to $3 each, but can become expensive if more than a few drugs are tested. The disk diffusion test is the least costly at $2.50 to $5 per test for materials. This test has the advantages of not requiring special equipment, it offers flexibility in selecting disks for testing and the results are easily interpreted. The disadvantage is that this test is not automated.[23]

One study performed a cost projection analysis using 2012 screening results for three protocols and took turnaround and personnel time into account. They found that the CDC and CA-modified protocols had a turnaround time of 3 days. The cost of the CDC protocol was $22,818 and 482 hours. This protocol has a lower sensitivity and may require extra labor for added work-ups of non-CPE isolates. The cost of the CA-modified protocol was $37,411 and 376 hours. Molecular testing had a turnaround of only 1 day but cost $224,596 and 343 hours. [24]

Cost of Treatment

Currently, optimal treatment for CRE infections remain undefined. One reason for this is that most reports are retrospective, small single-center studies. Also, it is hard for to distinguish between infection and colonization, especial in retrospective studies, when CRE isolates are obtained from non-sterile sites like wounds or urine. A final complicating factor is that it is common to have co-infection or co-colonization with other pathogens.[25]

The options of antibiotics for treating CRE are very limited. The only antibiotics that are used to treat CRE are polymyxins, aminoglycosides, tigecycline, fosfomycin and temocillin.[26] Costs for these medications are hard to estimate due to varying treatments and combinations of drugs used for each CRE infection. These treatment options are often associated with adverse reactions. Because of this, infectious disease consultation is recommended.[9]

A single case of CRE, specifically, has a median cost of $22,484 to $66,031 for hospitals and $37,778 to $83,512 for society according to one CRE clinical and economics outcomes model.[27] According to researchers, the total economic burden may be higher if the societal value of antibiotics is taking into account.[28]

In the United States, annual costs associated with resistant organisms are estimated to be $21 billion to $34 billion more than those of susceptible organisms.[29] In cases of CRE, national

recommendations are to place the patient on “Contact Precautions” or isolation. This may increase costs due to the additional equipment, space and personnel as well as intensified sanitization protocol.[30,31,32] Finally, antibiotic resistant organisms may lead to the long-term unavailability of effective antibiotics.[33]

Cost of Non-treatment

Antibiotic resistant infections are linked with hospital stays that are on average 6.4-12.7 days longer per patient. They also include more doctor visits and higher rates of long-term disability. Medical costs for an extended hospital stay range from $18,588 to $29,069 per patient.[34]

A significant cost of not treating CRE is the cost of life. CRE infections have high mortality rates of up to 58%.[35] Many other considerations include years of potential life lost (YPLL), lost wages, and decreased government revenue from taxes. Little information on these factors in relation to CRE could be found during the preparation of this white paper.

Potential Equity Impacts of Adding the Condition in Rule

The CDC currently recommends regular surveillance within healthcare facilities to determine if CRE is present, and to identify and intervene upon the cause.[36] CRE can spread from healthcare facilities to the larger community, so some researchers suggest adding it to the notifiable conditions list (as some other states have); this could lead to a decrease in the incidence.[18,37]

Medicare and Medicaid will not cover any extra days spent in a hospital due to a hospital acquired infection.[38,39] This may put an added economic burden on those already dealing with complicated health issues and with limited financial resources. It is also important to consider factors that may contribute to some hospitals having CRE infections while others do not. If some hospitals are underfunded or understaffed, this could lead to unsterile machines, surfaces or equipment. An increase in identifying CRE in hospitals that are already underfunded may have a harmful impact on those hospitals due to Medicare and Medicaid refusing to pay for hospital acquired infections. This in turn may have negative ramifications for the communities that these hospitals serve. It may be helpful to consider ways of supporting these hospitals beyond adding CRE to the WAC.[17]

Alternatively, adding CRE to the list of notifiable conditions might begin to hold health care facilities accountable for conditions that are conducive to patients acquiring the condition. It might encourage healthcare facilities to include more thorough “respiratory isolation and environmental cleaning” practices and take CRE seriously. This will benefit the least healthy patients in the facility. [21]

Conclusion

Through CRE incidence and prevalence remain low in Washington state, the disease may warrant individualized reporting requirements due to its global significance as an antibiotic resistant condition. As previously stated, antimicrobial resistance is one of the greatest contemporary threats to public health on a global scale, leading the CDC to monitor CRE trends on a national level. The condition’s unusually high mortality rate and resource-intensive treatment protocol are also something for the Board of Health to consider as it deliberates about whether CRE should be made into a Notifiable Condition.

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Cryptococcus gattii Cryptococcosis

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December 2016

Status of *Cryptococcus gattii* in the Washington Administrative Code

Cryptococcus gattii cryptococcosis (also referred to by the organism's name: *Cryptococcus gattii or C. gattii)* is a fungal infection that can cause pneumonia-like symptoms, meningitis, and death.[1] This disease is listed as a "Rare Disease of Public Health Significance" by the Washington State Department of Health and, as a result, is a notifiable condition that medical providers must report to a local health jurisdiction within 24 hours of diagnosis (per a regulation in the Washington Administrative Code, WAC, 246-101-101).[2–5] Laboratories in Washington State must send cultures of any strain of *Cryptococcus* that is not *Cryptococcus v. neoformans*—a much less virulent strain than *Cryptococcus gattii* and other *Cryptococcus* strains—to a local health jurisdiction within two business days (per WAC 246-101-201).[6,7] While the Washington State Department of Health states *Cryptococcus gattii* is a condition "endemic to the state" and "recently identified in a Washington State resident," the disease is not yet classified on its own as a notifiable condition whose status is protected by its direct incorporation into the WAC.[2]

Officials and employees of the Washington State Board of Health and Washington State Department of Health are considering whether *Cryptococcus gattii* should be moved from the "Rare Disease" classification to being named explicitly as a notifiable condition in the WAC (for example, in WAC 246-101-101 and WAC 246-101-301).[4,8–10] Listing *Cryptococcus gattii* directly would make the disease more difficult to remove from the notifiable condition list than in its previous "Rare Disease" status and would allow Washington State Board of Health and Washington State Department of Health teams to discuss if they would like to adjust the standards for how it is reported to health jurisdictions.[10] Washington State Board of Health and Washington State Department of Health teams must consult with stakeholders, such as medical providers, laboratories, and former patients, to evaluate if this shift would have any drawbacks or increased costs.[10] By understanding the disease, epidemiology, costs, and equity impacts of *Cryptococcus gattii*, as well as hosting future discussions with key stakeholders, the Washington State Board of Health and Washington State Department of Health can make an informed decision about whether to change the status of *Cryptococcus gattii* to an explicitly listed notifiable condition.

Abstract

Cryptococcus gattii is a fungus residing in trees in the Pacific Northwest United States and when inhaled by humans can cause mild to severe infection of the lungs and/or central nervous system.[11] While less than 10 people develop *Cryptococcus gattii* infections in Washington State each year, some of these individuals have died from the *Cryptococcus gattii* infection and researchers are unsure if the number of cases per year is on the rise.[11] While diagnosing *Cryptococcus gattii* infection requires medical providers to order and review several tests, some of which are costly, untreated *Cryptococcus gattii* infection can lead to hospitalization, surgery, and death and the cost of any of these outcomes far exceeds that of diagnostic testing.[1] Individuals who develop *Cryptococcus gattii* infection in their lungs may be more likely to be given a nonstandard or less-effective treatment protocol.[12] Listing *Cryptococcus gattii* explicitly in the WAC may aid to alert local health jurisdictions, medical providers, and laboratories to improve their awareness, diagnosis, and treatment of *Cryptococcus gattii* infection—especially when the infection is pulmonary.[12]

Overview, History, and Diagnosis of *Cryptococcus gattii* Infection

Cryptococcus gattii is a fungus, found in the Pacific Northwest, that can cause a lethal infection in humans.[13] While there are over 30 species of *Cryptococcus* fungi, *Cryptococcus gattii* and *Cryptococcus neoformans* are the two species that most frequently cause disease in humans and other animals.[14] *Cryptococcus gattii* infection has much worse potential health consequences for humans than infections with *Cryptococcus neoformans* or other strains of *Cryptococcus*.[7] *Cryptococcus gattii* is found in soil and trees in Washington State, Oregon, Vancouver Island and mainland British Columbia, and in other areas of the world.[13]

Anyone exposed to *Cryptococcus gattii* can develop an infection and has the potential to suffer mild to fatal health consequences.[1] A person encounters *Cryptococcus gattii* when they inhale spores of the dried fungus from the environment.[7] The fungus then settles into the person's lungs and can travel, through the bloodstream, to other parts of the person's body—like the brain and other organs of the central nervous system (see Figure 1).[7]

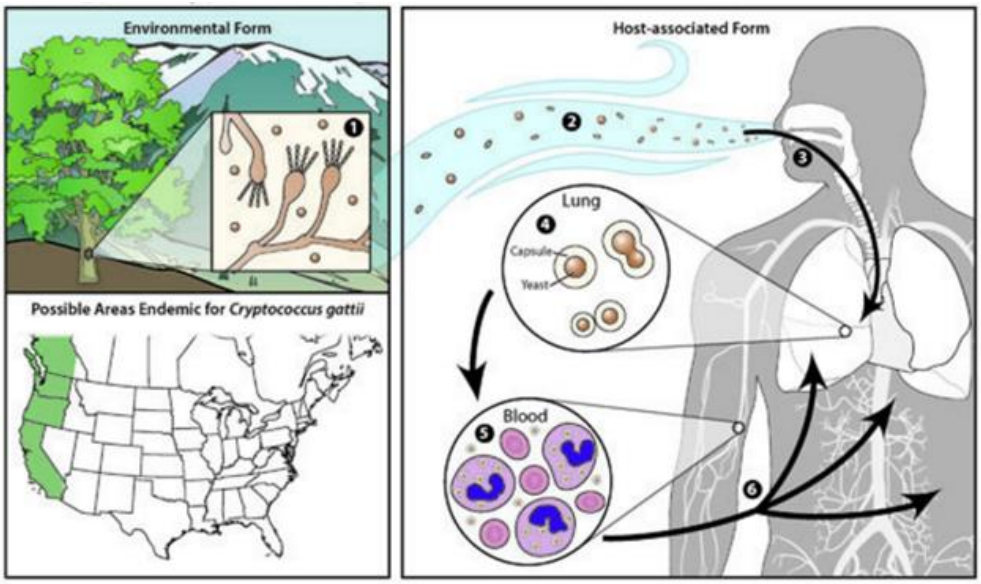

Figure 1. CDC Diagram of *Cryptococcus gattii* exposure[7]

Some people who are exposed to *Cryptococcus gattii* develop an infection, while others remain healthy because their immune systems contain the fungus and keep it from spreading.[1,7] Individuals with both compromised and competent immune systems can develop infections from *Cryptococcus gattii*; scientists don't know why some people get sick when others don't.[1] Some researchers think a person's use of steroids prior to *Cryptococcus gattii* exposure, their work habits, or co-existing conditions may make them more susceptible to develop *Cryptococcus gattii* infection.[12]

A person exposed to *Cryptococcus gattii* may develop an infection and then show symptoms of this infection anytime from a few weeks after their exposure, to six months later, or even one year later.[15] Most people with infections develop symptoms six to seven months after exposure.[15] An infected person may develop the infection in their lungs and show symptoms like pneumonia, such as cough, chest pain, fever, and shortness of breath.[15] The infection can spread to the person's brain, causing meningitis, and the person will experience more severe symptoms: nausea, vomiting, neck pain, sensitivity to light, fever, confusion, and changes in behavior.[15] Someone with a *Cryptococcus gattii* infection is not contagious at any point and cannot spread the disease to someone else.[7]

Medical providers identified the first case of *Cryptococcus gattii* infection in the Pacific Northwest in 1999 on Vancouver Island.[16] From 1999-2004, medical providers diagnosed over 100 people with *Cryptococcus gattii* infection and all the infected individuals lived in or visited a specific area of Vancouver Island.[16] From 2004-2010, medical providers identified 60 cases throughout the U.S.—15 in Washington State.[11]

To diagnose a patient with *Cryptococcus gattii* infection, medical providers urge one another to complete several different tests:

- Complete a "funduscopic examination" to check for swelling of the optic nerve (papilledema);
- Examine blood or cerebrospinal fluid for *Cryptococcus* antibodies;
- Further evaluate cerebrospinal fluid in general and measure intracranial pressure;
- Use blood or cerebrospinal fluid to conduct an India Ink Stain;
- Send a tissue specimen from the patient to a laboratory for a fungal culture to confirm if it is *Cryptococcus gattii* or another strain of *Cryptococcus*;
- Conduct lung imaging, including an x-ray and possibly a CT scan;
- Consider sending a specimen of bronchoalveolar lavage fluid for a stain and fungal culture; and
- Test for HIV or another underlying condition which may increase the patient's susceptibility to infection.[1]

Medical providers and patients may receive some test results instantly (e.g. the funduscopic exam), while others may take a few minutes, hours, days, or weeks to conduct.[1] Medical providers and laboratory specialists are required by the Washington State Department of Health to report cases of *C. gattii* infections to their local health jurisdiction within 24 hours of diagnosis and to send any specimens within two days (per WAC 246-101-101 and WAC 246-101-201).[4,6] Because some patients develop symptoms one year after exposure, medical providers may potentially misdiagnose a patient's *Cryptococcus gattii*, leading to underreporting of *Cryptococcus gattii* cases.[15]

Epidemiology

Cryptococcus gattii infection in humans is rare and, in the United States, mostly affects individuals residing in the Pacific Northwest. Of the 60 human cases between 2004-2010, 43 were from Oregon, 15 from Washington, one from California, and one from Idaho.[11] The

mortality rate from *Cryptococcus gattii* infection ranges from 13-33%.[17] From 2012-2013, the Centers for Disease Control and Prevention (CDC) noted an increase in the number of cases per year in Washington State, from five to eight cases.[18] The case fatality rate is 14% and one person in Washington State died from *Cryptococcus gattii* infection in 2014.[19]

Outside of the human host, *Cryptococcus gattii* infection occurs in animals as well.[19] Since 2005, however, 59 animal cases have been identified in Washington State. Epidemiological investigators have also identified *Cryptococcus gattii* on their shoes, vehicles, and in a parking lot in counties in the Northwest part of Washington State.[19]

Cost of Testing and Treating *Cryptococcus gattii* Infection

While some tests to diagnosis *Cryptococcus gattii* infection are expensive, a delayed diagnosis or misdiagnosis could result in the spread of the infection—eventually causing extremely high-cost hospital stays, surgeries, loss of productive work time, long-time disability or injury, or death for the patient.[1,12,20] The cost of testing for a *C. gattii* infection depends on the type of test ordered and/or done by the medical provider, the laboratory completing the test, and the patient's insurance. The price of each test varies widely, from a few hundred dollars for a visit with a medical provider or for a blood serum test, to hundreds and sometimes thousands of dollars for a CT scan.[21–23]

Similarly, the costs of treating a *C. gattii* infection depend on the patient's condition, the medical facility, and the patient's insurance. Medical providers recommend treating *C. gattii* infections with antifungal medication, and the course of treatment and cost of pharmaceuticals depend on the patient's condition and insurance.[1,23,24] Patients often take antifungals for a minimum of 6 months, sometimes continue for a year, and other times maintain treatment beyond a year.[23] Depending on the patient's condition, medical providers may recommend shunting to relieve intracranial pressure, use of steroids, surgery, hospitalization, and careful monitoring for some time.[1] Medical procedures, surgeries, and hospitalizations may cost patients, taxpayers, medical facilities, and others hundreds of thousands of dollars per procedure, surgery, or hospital stay.[25] Some researchers calculate that when a working individual is sick, every dollar they spend on medical costs is associated with a $.40 loss in work productivity.[20] A working individual hospitalized for *Cryptococcus gattii* infection might incur $100,000 dollars or more in medical costs; the person's employer might pay $40,000 dollars or more for their loss of work time.[20]

If untreated, *Cryptococcus gattii* infection can cause brain damage, coma, hearing loss, hydrocephalus ("water on the brain"), meningoencephalitis and eventual death.[26] Someone with HIV who develops meningitis from *Cryptococcus* has a 10-30% chance of dying from the infection.[27] If left untreated, meningitis from *Cryptococcus* is fatal: people with healthy immune systems can survive for years while people who are immunocompromised survive for only a few weeks.[27]

Equity Impact of Listing *Cryptococcus gattii* Explicitly as a Notifiable Condition

By giving *Cryptococcus gattii* its own explicit designation as a notifiable condition, the Washington State Board of Health and Washington State Department of Health may motivate local public health officials, medical providers, and laboratories to be more vigilant of *Cryptococcus gattii* infection and more diligent in their treatment of this condition. Some researchers believe patients with pulmonary *Cryptococcus gattii* infections are more likely to receive insufficient treatment because their providers are less familiar with infectious disease treatment and fail to recognize the distinct treatment protocols for *Cryptococcus gattii* infections of the pulmonary system and infections of the central nervous system.[12] Labeling *Cryptococcus gattii* infection explicitly as a notifiable condition might aid local health jurisdictions and medical providers in following up with experts if they have insufficient knowledge and ensuring a more robust treatment for patients with pulmonary *Cryptococcus gattii* infection. Furthermore, some researchers call for more examination of data about the treatment of *Cryptococcus gattii* infection and designating *Cryptococcus gattii* infection as a distinct notifiable condition may improve monitoring of this condition and researchers' ability to analyze collected data about cases and outcomes.[12]

Conclusion

Cryptococcus gattii infection is a rare but potentially fatal condition that is emerging in the Pacific Northwest. The Washington State Board of Health and Washington State Department of Health, as leaders of public health policy in Washington State, must improve awareness, diagnosis, and treatment of *Cryptococcus gattii* infection and, thus, are accountable to the public to consider in earnest listing *Cryptococcus gattii* explicitly in the WAC as a notifiable condition. Whether teams from The Washington State Board of Health and Washington State Department of Health decide to pursue a new classification for *Cryptococcus gattii*, these leaders must acknowledge the potential severity of *Cryptococcus gattii* infection and take steps to prevent the

public from acquiring this infection and providing residents of Washington State with expert diagnosis and treatment if they suffer from *Cryptococcus gattii* infection.

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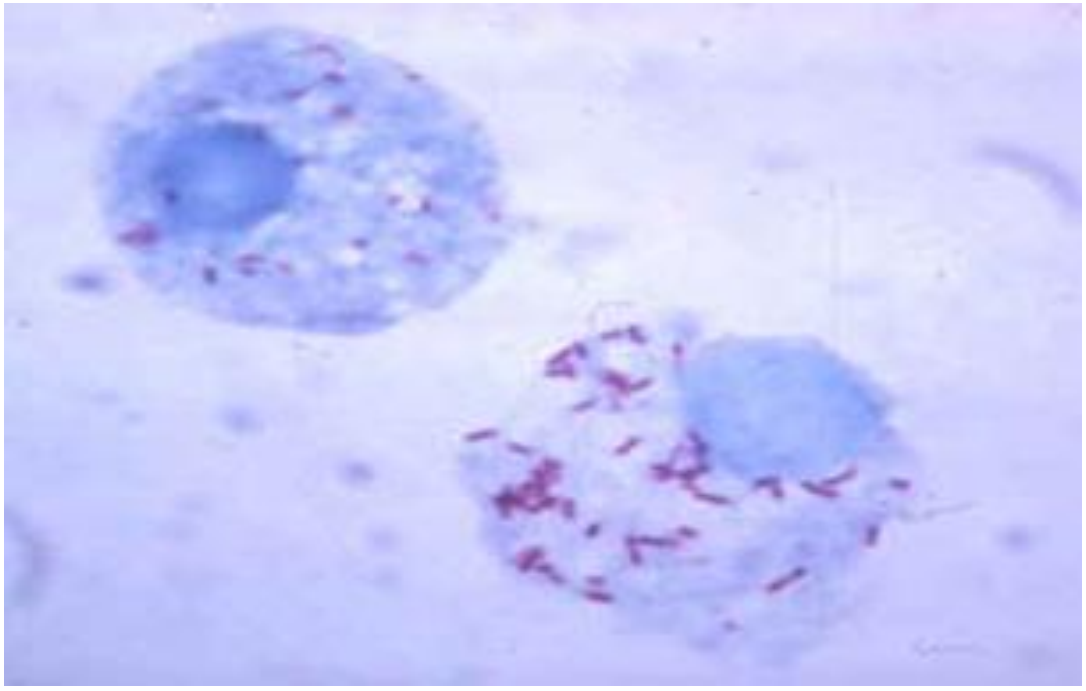
ROCKY MOUNTAIN SPOTTED FEVER



12/8/16

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A white paper and disease profile of Rocky Mountain spotted fever to inform the Washington State Board of Health and Department of Health on important policy decisions regarding notifiable conditions in the state.

ABSTRACT

Common name: Rocky Mountain Spotted Fever (RMSF), sometimes called “blue disease” (1)

Bacterium name: *Rickettsia Rickettsii*

Rocky Mountain spotted fever (RMSF) is a tick-borne disease caused by the bacterium *Rickettsia rickettsia (R. rickettsia)*.[1] It is currently considered a notifiable condition in Washington state (WA) as part of the “other rare diseases of public health significance” as it is not commonly found in WA but would be of serious concern if detected because it would signal that a vector tick in WA is carrying that bacteria.[2] The tick found in WA which carries *R. rickettsia* is known as the Rocky Mountain Wood Tick (*Dermacentor andersoni*).[3] On any given year, 0-3 cases of RMSF are identified in WA, but only some are contracted in the state, and some are due to traveling.[4] RMSF is found throughout the U.S. and in other parts of the American continents.[1] Typical symptoms include: fever, headache, stomach pain and rash.[5] The gold standard test for RMSF is indirect immunofluorescence assay (IFA) but standard practice is diagnosis should be made clinically and immediately, later confirmed by laboratory tests.[5] Doxycycline is the first line of treatment and is most effective if started early on.[5]

The addition of RMSF to the Washington Administrative Codes (WAC) 246-101- 101 and WAC 246-101- 301 would open opportunities for more substantial data collection by requiring providers to notify and test patients for RMSF, even after diagnosis and treatment. This increased collection and understanding can also aid WA in reaching populations disproportionately burdened by RMSF, including American Indian populations and children.

BACKGROUND & DISEASE ETIOLOGY

Over a century has elapsed since the first clinical description of Rocky Mountain Spotted Fever (RMSF) yet the disease remains among the most severe vector-borne diseases recognized to date.[6] From 1906- 1910, Howard Ricketts isolated the pathogen and showed that it circulated among ticks and mammals in the wild.[7] In 1919, Burt Wolbach published an extensive study on the agent of RMSF, confirming that ticks carried the bacterium and naming the agent *Rickettsia rickettsii* in honor of Howard T. Ricketts.[1]

Physiological effects/severity

The first symptoms of RMSF typically begin 2-14 days after the bite of an infected tick.[1] (2) Symptoms may be nonspecific; and therefore physicians may not always properly diagnose RMSF correctly or immediately.[5] Signs of RMSF include **fever, headache, abdominal pain, lack of appetite, rash, vomiting, conjunctival infection (red eyes), and muscle pain**.[5]

Of those likely infected, **90% will develop a rash 2-5 days after the bite**.[5] The rash is usually small, flat, pink, non-itchy spots (macules) on the wrists, forearms, and ankles and spreads to include the trunk and sometimes the palms and soles.[5] A red to purple, spotted (petechial) rash is usually not seen until the sixth day or later after onset of symptoms and occurs in 35-60% of patients with the infection.[5] This is a sign of progression to severe disease, and every attempt should be made to begin treatment before petechiae develop.[5]

RMSF can be fatal in the first week of symptoms if not treated.[5]The progression of symptoms varies greatly and while complications are rare patients who have a severe infection may develop long term health issues.[5] Because *R. rickettsia* infects the endothelial cells that line the blood vessels, some patients may suffer damages to these cells, or "vasculitis" which may result in loss of circulation to the extremities leading to amputation.[5] Patients may also be left with profound neurological deficits or damage to internal organs.

Mode of transmission

RMSF is transmitted to humans by the bite of infected tick species.[1]

While cases of RMSF have been reported in every month of the year, most cases take place during June and July, although different regions see different seasonal trends.[8]

Ticks that transmit Rocky Mountain spotted fever in the U.S.[3]

- American dog tick (*Dermacentor variabilis*)
  - Widely distributed east of the Rocky Mountains and limited areas on the Pacific Coast
- Brown dog tick (*Rhipicephalus sanguineus*)
  - Found throughout U.S. but transmits RMSF in southwestern U.S. only

Ticks that transmit Rocky Mountain spotted fever in Washington State [3]

- Rocky Mountain wood tick (*Dermacentor andersoni*)

Important note: Travelers within and outside of the U.S may be exposed to different ticks during travel that result in illness after returning to WA. For this reason, public health must be aware of different geographic distributions of ticks as well as the pathogens they carry that can cause disease in both humans and animals.[8]

EPIDEMIOLOGICAL INFORMATION

Prevalence & Incidence

RMSF has been a nationally notifiable disease by the CDC since as early as the 1920's.[9] States report their number of annual cases to the CDC who tracks the national prevalence and case fatality.[2]

- RMSF remains the **most lethal tick-vectored disease in the U.S.**[8]
- On average, 0-3 cases of RMSF are reported in WA each year [10]
- The last reported case of RMSF in Seattle, King County occurred in 2008 [10]
- In 2010, the incidence was 6 cases per one million people [8]
- Trends of increased incidence come and go in periods with an all-time high of 8 cases per one million people in 2008 [8]
- RMSF has a case-fatality rate of 25% among untreated individuals [8]

The name "Rocky Mountain" spotted fever is misleading, as the illness is present in all US states except for Maine and Vermont[1] (2). The southern states comprise much of cases, with 60% of reported cases occurring in North Carolina, Oklahoma, Arkansas, Tennessee and Missouri.[10]

Surveillance

RMSF, while rare in Washington State, can be very serious if undiagnosed and due to the very low number of cases in Washington State, many healthcare providers do not have experience diagnosing RMSF and differentiating it between other tick-borne diseases. **Surveillance systems are critical for studying the changing epidemiology of *R. rickettsii* and for developing effective prevention strategies and public health outreach activities.** Data collection on tick-borne illnesses are useful for guiding public health on emerging trends, but further surveillance conditions would need to be implemented to have more complete data on all tick-borne illness in WA state, in addition to physician education on all tick-borne illnesses and vectors. The CDC uses this case report form for tracking RMSF, as well as other tick-borne diseases.

Estimates of under-reporting in U.S. and in Washington

The last recorded case of spotted fever in the state was in 2008, in an individual who had recently traveled through Eastern Washington and Yellowstone, so it remains unclear where the illness was contracted.[11] Between 2004-2013, **eight cases of RMSF** were reported, and half of these cases were likely contracted in Washington, in the eastern and central counties.[11] The remainder of cases were likely acquired from travel outside the state.

Important data regarding underreporting because of misclassification of race for American Indians (AIs) is also an issue of disease knowledge in WA and throughout the U.S.[12] Additionally, many physicians do not immediately recognize symptoms as trademark signs of RMSF because it is rarely seen in WA, and may be misdiagnosed as Lyme disease, or possibly another tick-borne illness.

Subpopulations affected

Underreporting issues aside, research shows that the incidence of RMSF is extremely high among American Indian (AI) males and all adults over the age of 40.[1] The average annual incidence among AIs was **16.8 per one million people** compared to **6 cases per one million people on average** reported in the U.S.[12] Research examining CDC surveillance trends found that RMSF has disproportionate effects on the health and lives of AIs and concluded additional educational and preventative measures should be implemented, especially in the states with the highest risk.[12] Additionally, RMSF has a higher case fatality rate amongst the AI population, at 7% compared to the 1% average in the U.S.[13]

The population with the highest case fatality rate of RMSF is children under 10 years-old and individuals with compromised immune systems.[8] Special attention should also be paid to individuals and communities who live or work in wooded or grassy areas in WA and throughout the U.S.[1]

TESTING & TREATMENT

Diagnostic tests for this disease will frequently appear negative in the first 7-10 days of illness. After a preliminary diagnosis is made on clinical suspicion and treatment has begun, specialized laboratory testing should be used to confirm the diagnosis of RMSF.[5]

The gold standard test for diagnosis of RMSF is the indirect immunofluorescence assay (IFA) using the *R. rickettsii* antigen.[5] This test is quantitative, and gives a specific number of antibody titers. The first test should be done as early as possible, although this test often gives a false negative, or showing no rise in antibodies. However, a positive result can be helpful.[5] A second sample and test should be taken 2-4 weeks later and will show a four-fold increase of antibodies if the disease is present in a person's blood streams.[5]

If the patient has a rash, PCR or immunohistochemical (IHC), "staining" can be performed on a skin biopsy taken from the rash site to guide treatment decisions.[5]

The CDC clearly states regarding RMSF:

> **"The diagnosis of RMSF must be made based on clinical signs and symptoms, and can later be confirmed using specialized confirmatory laboratory tests. Treatment should never be delayed pending the receipt of laboratory test results, or be withheld on the basis of an initial negative finding for R. rickettsii."[1]**

Treatment

Due to the complexities of this disease and the limitations of currently available diagnostic tests, there is no test current test that provides a conclusive result in time to make important decisions about treatment. Physicians must use their judgment to treat patients based on clinical suspicion alone, and can use important information in the patient's history as well as simple blood tests to decide about treatment.[1]

Doxycycline is the drug of choice for treatment of RMSF and should begin within the first 5 days of symptoms.[5] Doxycycline should be taken orally or intravenously at a dose of 100mg twice daily for 7-14 days.[5] If the patient is treated properly, fever generally subsides within 24-72 hours. Failure to respond to doxycycline suggests that the patient's condition might not be due to RMSF.[5]

COST ESTIMATES

Cost of Testing

Test	Cost
Antibody titer by complement fixation or immunofluorescence	For uninsured patients, a typical lab fee for antibody screening is $25 -$100. The Healthcare Blue Book estimates the fair cost of a direct antiglobulin test at $25 -$49[14]
Partial thromboplastin time (PTT)	Healthcare Blue Book estimates the fair cost of a PTT to be $16, but states that this price can be 3 to 5 times as expensive depending on lab and location[14]
Skin biopsy taken from the rash to check for R. rickettsii	Healthcare Blue Book estimates the fair cost of a skin biopsy to be $249[14]

Cost of Treatment

Rapid treatment of suspected cases with doxycycline should begin immediately even before lab confirmation of the diagnosis to improve patient outcomes and minimize tissue and organ damage. It is both an effective therapy and a cost-effective treatment. A course of doxycycline for RMSF would cost as low as $15 without insurance, and the generic version is often covered by Medicare and most insurance plans.[15] Treatment for RMSF is fairly accessible, yet if the cases go undiagnosed and progress to organ damage or even failure, the cost is much higher and may require extended hospital stays, time in the intensive care unit, or potential long-term care management.[1]

Cost of Non-Treatment

Costs of non-treatment for RMSF were calculated for two American Indian Reservations in Arizona (population estimated at 20,000) between 2002 and 2011.[16] Acute medical costs totaled more than $1.3 million.[16] The study estimated $181,100 in acute productivity lost due to illness, and $11.6 million in lifetime productivity lost from premature death, totaling an aggregate cost of RMSF cases from 2002–2011 of $13.2 million.[16] Researchers stated it most likely underestimated the cost of non-treatment because long-term losses from disability and expensive medical procedures are not included.[16] If we were to conduct a cost analysis of treatment versus non-treatment, we could extrapolate from the Arizona study to show $13.2 million/9 years/20,000 people to establish a cost per person of non-treatment per year, which equals about $74. This cost analysis does not consider the value of quality or length of life affected by contracting the disease.

EQUITY IMPACT OF ADDING THE RULE

Although most cases of RMSF are reported in the South Atlantic region of the United States, the WA DOH should consider that WA is home to many outdoor enthusiasts that may be visiting or living in tick habitats such as wooded and dense brush areas, meadows, and areas with weeds and tall grass. The addition of RMSF to the Washington Administrative Codes (WAC) WAC 246-101- 101 and WAC 246-101- 301 would open opportunities for more substantial data collection. Notification of a higher-than-normal number of RMSF cases in one region may alert health officials to notify the public of the risk of working or recreating in wooded areas, prompting them to check for ticks and notify a provider if they have symptoms of RMSF. Additionally, providers would be encouraged to begin treatment early for suspected cases, reducing poor outcomes from delayed or non-treatment with further knowledge surrounding RMSF.

While adding the RMSF to the rule would increase data collection and general education, ignoring the disparate populations affected by all tick-borne diseases when considering the change would hinder goals of the DOH's involvement in government policy and rule making.

CONCLUSION

Though uncommon in WA, RMSF's high fatality rate, especially among high risk populations, such as children and the American Indian population urges a policy change for RMSF to be individually notable, and separated from other tick-borne illnesses and rare diseases of public health significance in terms of reporting. The scarcity of RMSF in WA leads to lack of experience and understanding among physicians and lack of complete knowledge by public health. This leads to a continuation of incorrect reporting or diagnosis of an extremely dangerous disease. Like other tick-borne illnesses, RMSF can be minimized by checking persons and their pets regularly for ticks. Long pants and sleeves are also advised if individuals plan to visit known tick habitats. The CDC tracks RMSF in a similar fashion to other *Rickettsia* and tick-borne diseases. Tracking RMSF will allow health professionals to identify trends and policy makers to act quickly when decisions need to be made regarding an outbreak or notification of health facilities. Tracking RMSF will also help improve understanding of its disproportionate impact on American Indian populations, and children.

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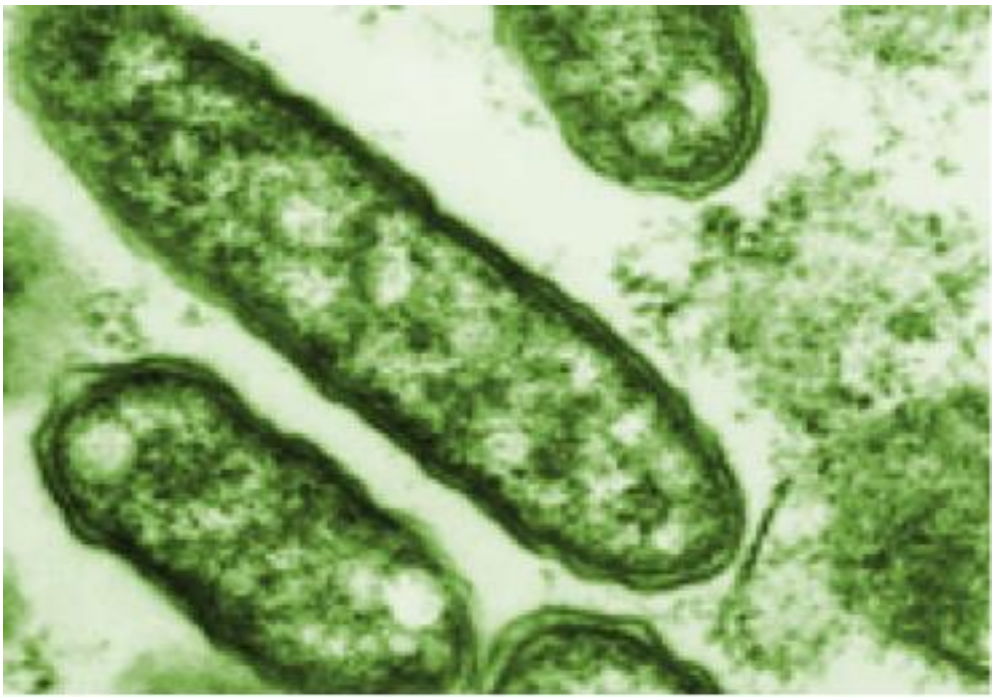
TYPHUS FEVER



12/8/16

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A white paper and disease profile of Typhus Fever to inform the Washington State Board of Health and Department of Health on important policy decisions regarding notifiable conditions in the state.

ABSTRACT

Typhus fever, not to be confused with typhoid fever,[1] is a flea-borne disease that is found today primarily in cold, mountainous regions of South America, Africa, and Asia, as well as cities and ports characterized by abundant populations of urban rats. Typhus refers to a group of acute infections caused by the bacteria Rickettsiae, which is transmitted to persons by the bite of fleas, lice, and mites. Outbreaks usually occur in crowded or unsanitary environments with limited access to water. Of the several types of infections, the most common forms of typhus to the United States, are:

Typhus Fever (Epidemic): Caused by a human body louse known as *Rickettsia priwazekii*. In the U.S. humans have been known to contract epidemic typhus after having been in contact with flying squirrels[1].

Murine Typhus (Endemic): Caused by *Rickettsia typhi*, which is carried by fleas commonly found on cats and rats. It can be found around the globe and is typically most common in crowded or overpopulated settings, where people may be in close proximity to rats. In the United States, cases of murine typhus have been contained mostly to suburban areas of California and Texas, where opossums and rats are the most common reservoirs of infection.

Scub Typhus: Caused by *Orientia tsutsugamushi*, scub typhus commonly presents in parts of Asia, Australia, and Papua New Guinea, as well as the Pacific Islands.

Symptoms typically include sudden onset of rash, fever, and chills. More serious cases may be characterized by vomiting, confusion, and hypotension, with a fever lasting between one to two weeks. The gold standard for diagnosis is serological testing. Doxycycline is the antibiotic of choice for treatment, and may help shorten the course of illness. Typhus fever as a rare disease lacks an individualized surveillance and reporting protocol and is yet a specified notifiable conditions under the Washington Administrative Code (WAC) 246-101-101 and WAC 246-101-301. Further research must be conducted on the communities that are disproportionately affected by this disease including homeless and medically underserved populations to fully warrant adding typhus fever as a notifiable condition.

BACKGROUND & DISEASE ETIOLOGY

Written descriptions of typhus date as far back as 1489, when the death of 17,000 Spanish troops during the siege of Granada was attributed to a likely infection of epidemic typhus. Throughout history, typhus has also been called gaol or jail fever. Typhus, formally identified in 1760, is named after the Greek word for “smoke” or “stupor” because of the symptoms of delirium that sometimes accompany infection[2]. Outbreaks have also been recorded in the 1800s in Philadelphia, Baltimore, Concord, and Washington, D.C. An estimated 2-3 million people died from typhus during World War I. Hundreds of thousands of prisoners also died in Nazi concentration camps from typhus as hygiene conditions deteriorated.

The introduction of a vaccine and the use of dichloro-diphenyl-trichloroethane (DDT) [2], to kill lice at the end of WWII, is thought to have dramatically curbed typhus. As the number of cases dropped in the United States, the vaccine was phased out, and manufacturing ground to a halt. And yet, cases of typhus continue to be reported sporadically across the U.S.

Murine Typhus, though not common in the U.S. has been reported in Texas and Southern California. In 2011, Travis County, Texas was determined to be endemic for murine typhus with the appearance of 53 cases[1]. In 2008 there was a reported 33 cases between the months of March and October. These most recent cases have been traced to cats, opossums, and cat fleas. In Los Angeles County, where some murine typhus cases have been reported, a significant proportion of cats and opossums have been found to be seropositive

[1] Despite their similar names and physiological effects, typhus and typhoid fever have very different modes of transmission.

[2] A pesticide used widely through the 1970s.

for *R. typhi* (90% and 42%, respectively)[3]. More recently, outbreaks have taken place in relief and humanitarian crisis settings, including Burundi, Ethiopia, and Rwanda.

Today travelers and humanitarian relief workers are most at risk of infection because of their likely exposure in refugee camps and overcrowded settings[4].

Physiological effects/severity

Symptoms depend on the exact type of typhus, but generally involve a headache, rash, fever, and chills. Symptoms of epidemic typhus manifest rapidly, and generally include a fever of above 104 degrees, a severe headache, a rash extending across the trunk of the patient (across their back and chest), disorientation, and low blood pressure. Though not present in all diagnoses, 61% of cases have reported the presence of a rash. Patients have also reported sensitivity to bright lights, severe muscle pains, and losing touch with reality (see Appendix 1). Flea bites are also occasionally found on patients, and may help with diagnosis. Endemic typhus can last between ten days to two weeks, presenting a similar set of symptoms though less severe than is found in patients of epidemic typhus. Symptoms include nausea, vomiting, and diarrhea. Scrub typhus results in extreme fatigue, swollen lymph nodes, red lesions or sores surrounding the site of the bite, rashes, and a cough. If left untreated, typhus can result in gastrointestinal hemorrhaging, hepatitis, and a condition known as hypovolemia, or a decrease in blood volume.

Some infections such as those caused by *R. prowazekii*, can remain latent, appearing years later in the form of Brill–Zinsser disease. This form of typhus is usually mild, with a fever lasting between seven to ten days.[5]

Mode of transmission

Typhus is caused by an infection by the bacterium known as Rickettsia, most often transmitted through fleas, mites, lice, or ticks, typically distributed by rodents, cats, and opossums. *R. typhi* multiplies in the epithelial cells of the flea or related arthropod. When the arthropod bites its unsuspecting hosts, the infected invertebrate excretes rickettsia onto the skin. When their host scratches the bites vectors leave behind, they often break the skin, leaving bacteria, which then enters the bloodstream, reproduces, and grows. Because typhus is spread by lice and similar arthropods, prevention can be challenging, and typically involves a combination of insecticides, insect repellents and proper hygiene. Controlling the rodent population has also been known to have an impact on typhus cases.

EPIDEMIOLOGICAL INFORMATION

Prevalence and Incidence

Data regarding prevalence of epidemic and endemic fever are limited because neither epidemic typhus or murine typhus are nationally reportable conditions. Further, due to the nature of the condition, the climate of the majority of the United States does not support rapid spread of either type of typhus[6]. In Washington State, typhus was last mentioned in the Department of Health's (DOH) Communicable Disease report in 2010. The entry described the etiology of endemic and epidemic typhus, and stated, "the last reported case was in 1994 after travel to Asia". While Typhus is included in the WAC case definition for rare diseases of public health significance, it is still considerably rare and has not been included in any of the DOH Communicable Disease reports since 2010[7].

Estimates of under-reporting in Washington

Typhus is generally believed to be underreported because of its similarities to typhoid fever. Furthermore, physicians lack awareness of this infection because it so rarely presents in the United States. While the most recent cases of typhus have been reported in very specific areas of the United States, it is not

inconceivable that new cases may appear in similar localities across the country. The ubiquity of *R. typhi* vectors and their urban and suburban dwellings would suggest that typhus may appear elsewhere in the U.S.

Subpopulations affected

Though travelers and humanitarian relief workers are believed to be most at risk for infection, clinical severity of typhus may be greater for male patients, those of African origin, individuals who have glucose 6-phosphate dehydrogenase deficiency, are older, or may have received a delayed diagnosis. Those with hepatic and renal dysfunction, CNS abnormalities, and pulmonary complications may also be at greater risk of clinically severe typhus fever[3]. In recent outbreaks of murine typhus in the U.S. in the 1980s, the majority of cases (69%) took place during the spring and summer months (between April through August).[8] During a similar outbreak in 2008 in Austin and Travis County, Texas, the onset of illness was also traced to the spring and summer months, in this case, April through July.[9]

TESTING & TREATMENT

Typhus fever can be difficult to diagnose because it is often confused with typhoid fever, particularly in tropical countries. And yet accurate diagnosis is critical for proper treatment. Confirmation of both endemic (Murine) typhus and epidemic typhus is performed through serological testing[10,6]. There are a few types of serological tests, with the gold standard test being the Immunofluorescence (IFA) test which confirms the condition by detecting antibodies. However, a diagnosis of typhus is most often based on clinical suspicion. In suspected cases of typhus fever, a titer that presents rising rates of OXK, OX2, and OX19 antigens may support the diagnosis, but can't alone provide confirmation[11]. More often, diagnosis is made based on eliciting the patient's travel history, exposure to cold weather, and a crowded environment, as well as their spectrum of symptoms. Many providers doubt the usefulness of laboratory tests, except to assess the severity of infection and to exclude other ailments[12]. If a diagnosis of typhus fever is suspected, patients should be started on a treatment regimen of doxycycline immediately, even before laboratory confirmation[3].

COST ESTIMATES

Cost of Testing

Serological tests range in cost from $80-$200[13]. Further testing for typhus includes a complete blood count test that looks for a low white blood cell count, anemia, and low platelets to confirm the diagnosis[1]. However, due to the urgency of treating typhus (particularly epidemic typhus) clinicians are more likely to forgo testing and immediately start the patient on a course of antibiotics. As a result, cases of typhus are not often confirmed through a test, rather confirmed through observation of symptoms[14].

Cost of Treatment

Treatment for both types of typhus include antibiotics such as doxycycline, tetracycline, and chloramphenicol. Doxycycline is the primary recommended treatment, and has been found to result in a mean duration of three days of epidemic typhus. It is both an effective therapy and a cost effective treatment. The advised dose is 200 mg per day for 7 days, reducing to 100 mg per day if there are signs of treatment until the end of the treatment period[1]. A course of doxycycline for typhus would cost as low as $15 without insurance, and the generic version is often covered by Medicare and most insurance plans[15].

Table 1. Cost Estimates for Typhus Fever

Testing or Treatment Item	Cost
Serological test	$80-200
Complete blood count	Healthcare Blue Book estimates the fair cost of a CBC with differential to be $21, which does not include the price of the physician's visit.[16]
Doxycycline	$15

Cost of Non-Treatment

As the prevalence is so low, data regarding health productivity loss for epidemic or endemic typhus is not available for the United States. The case-fatality rate increases with age and varies from 10% to 40% in the absence of specific treatment. The mortality rate for murine typhus is relatively low if patients are promptly treated with antibiotics (1%). Even without treatment, mortality rates sit at just 4%[3]

EQUITY IMPACT OF ADDING THE RULE

The most recent cases of typhus in the United States have been murine typhus, a milder form of the disease, transmitted by fleas. Given its preferred vector, those who are homeless, transient or living in poverty may be at greater risk of infection. Not only does this present surveillance challenges, but typhus may require some degree of isolation because of the ease with which mites, lice, and fleas spread from host to host. Finding appropriate accommodations for homeless individuals may be difficult and a potential breach of their privacy. The provision of uninterrupted treatment can also be difficult for homeless or transient communities who may find it difficult to acquire or steadily abide by a full course of doxycycline.

CONCLUSION

Though few cases have been presented in the United States, typhus fever can cause pain and suffering if not treated, with symptoms ranging from a high fever to nausea, a cough, and body pain. The absence of definitive signs and symptoms poses challenges to diagnosing typhus. To prevent future outbreaks of typhus individuals should minimize their exposure to its primary vectors, such as fleas, lice, and mites, by practicing basic hygiene and using insect repellant if fleas and lice are common to the local environment. While there are no current examples of surveillance systems for typhus fever in place in the United States, the WHO has previously issued recommendations for scrub typhus, involving immediate case-based reporting of all suspected cases. The WHO also recommends a parallel laboratory surveillance system to confirm suspected cases. This may be used to detect outbreaks, monitor trends in endemic disease, and to monitor changes and new epidemiological patterns presenting for typhus fever.[17] However, given the limited amount of the data on typhus, before considering an individualized surveillance system for this rare disease, the DOH should advocate for greater research on the communities and individuals disproportionately affected by this condition, particularly medically underserved communities and those experiencing a shortage of health care professionals.

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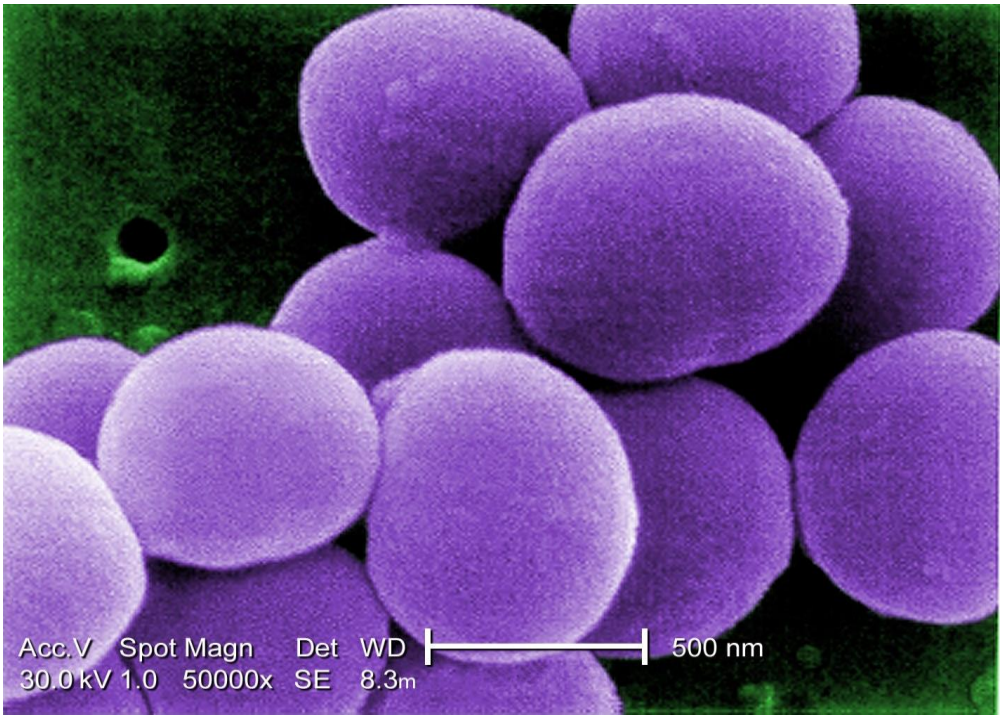
APPENDIX 1. CLINICAL SYMPTOMS ASSOCIATED WITH MURINE TYPHUS

Symptom	Range of occurrence (%)
Fever	98-100
Headache	41-90
Rash	20-80
Arthralgia	40-77
Hepatomegaly	24-29
Cough	15-40
Diarrhea	5-40
Splenomegaly	5-24
Insect bite	0-39
Nausea and/or vomiting	3-48
Abdominal pain	11-60
Confusion	2-13

VANCOMYCIN-RESISTANT STAPHYLOCOCCUS AUREUS



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A white paper and disease profile of Vancomycin-resistant Staphylococcus aureus to inform the Washington State Board of Health and Department of Health on important policy decisions regarding notifiable conditions in the state.

ABSTRACT

Staphylococcus aureus is a bacterium that can cause skin infections such as blisters, abscesses, and redness and swelling in the infected area. According to the Centers for Disease Control & Prevention (CDC), it is common and normal for about one-third of the world's population to have staphylococcus bacteria on their skin or in their nose without having an infection, and about 2% of the world's population can be carriers of this bacteria without ever showing symptoms or needing treatment. Staph infections are best known for occurring in a hospital setting, however, infection can also be common among community members that have direct skin-to-skin contact with one another. Although Staphylococcus bacteria has become a common medical problem, its history, evolution, and disparate effect on some subpopulations is very serious. Due to its severity, efforts to increase surveillance of VRSA, including updating its reporting status in the Washington Administrative Code (WAC) 246-101-201, will only provide more data on its effect on vulnerable populations and efficacy of its treatment.

BACKGROUND & DISEASE ETIOLOGY

The earliest origin of *S. aureus* can be traced to mid-1800s when medical providers were working to reduce the onset of post-operation infection.[1] Although scientists were able to identify and assign nomenclature to this microorganism, a viable treatment progressed slowly causing mortality rates to rise from infections during the early 1900s.[1] In the 1940s, a surgical patient was cured for their "staph" infection with penicillin. Since then, penicillin-like medications have been used to treat staph infections. As staph became more resistant to penicillin, methicillin was developed to combat *S. aureus*. However, methicillin had a short lifespan for curing this infectious disease and the bacteria evolved to resist treatment. This strain would be later referred to as methicillin-resistant *Staphylococcus aureus* (MRSA), and remains the most common drug resistant bacterial infection. MRSA is still a widespread concern around the world because of its ease of transmission and difficulty to cure.[2,3]

One of the newest drugs to succumb to the ever-smart *S. aureus* is vancomycin. While vancomycin was successful in treating S. aureus for some time, the bacterium eventually evolved to become Vancomycin-resistant (VRSA) and now has the potential to spread. The CDC states that "appropriate identification of the organism and implementation of infection control precautions" are needed to combat the emergence of VRSA.[4,5]

Not every isolate of *staph* with reduced susceptibility to vancomycin is VRSA – that is, "resistant." The Clinical and Laboratory Institute (CLSI) and the US FDA have established vancomycin minimum inhibitory concentration (MIC) interpretive criteria for staph (modified in 2006).[6] MIC refers to the lowest concentration of an antibiotic that prevents visible growth of a bacterium.[7]

- Vancomycin susceptible: <= 2 mcg/mL
- Vancomycin intermediate (VISA): 4 – 8 mcg/mL
- Vancomycin resistant (VRSA): >= 16mcg/mL
- hVISA refers to heterogeneous VISA, where VISA strains are mixed with vancomycin susceptible strains such that the MIC is still less than 2 mcg/mL (the cutoff for susceptibility).

The mechanisms for VISA and VRSA are different. VISA is caused by an unusually thickened cell wall, while VRSA is due to a plasmid-mediated transfer of the *vanA* gene cluster from enterococci with vancomycin resistance (VRE).[6,8] To date, all VRSA strains have arisen from MRSA.

Physiological effects & severity

The most common physical sign of VRSA are skin abscesses and cellulitis. Additional signs include redness, swelling, and pain at the site of the wound or open skin.[9] Incision and drainage of the infected site may be necessary for both abscesses and cellulitis. Some people can be colonized with *S. aureus* and never get an infection, however for those who do get an infection, it may take days to years after exposure for the disease to develop. Yet, *S. aureus* can cause serious health complications such as pneumonia or bacteremia typically requiring hospitalization and treatment with intravenous antibiotics.[10]

Mode of Transmission

S. aureus bacteria are usually transmitted by having direct contact with an infected person or by using a contaminated object. Since the transfer of this bacterium is so common, *S. aureus* can be found on items like gym equipment, telephones, door knobs, elevator buttons, and drug paraphernalia. It is also possible to become infected with *S. aureus* when the bacteria penetrate a mucus membrane or broken skin after inhaling infected mucus or sputum dispersed by sneezing or coughing within close-range of the infected person. Carriers of the infection, who may not typically show signs and symptoms of the infection or need to be treated, can develop infection if they have surgery, are treated with hemodialysis or chronic ambulatory peritoneal dialysis, or have HIV/AIDS. The efficacy of the bacteria to yield infection, even in small amounts and its versatility make it the number one cause of hospital-acquired infections. [11]

EPIDEMIOLOGICAL INFORMATION

Prevalence & Incidence

At least 14 cases of VRSA isolates have been identified in the United States, with the first reported case in 2002. Although no cases have been reported in Washington state[6,12], 8 cases have occurred in Michigan[8,13]. The 13th VRSA isolate in the U.S. was the first and only community associated transmission.[13] All U.S. cases of VRSA arose in settings of polymicrobial infections where MRSA and vancomycin-resistant enterococci (VRE) were present.[8] The patients were all treated for their infections with antibiotics, meaning the known prevalence of VRSA in the U.S. is 0 cases[13].

Surveillance

In 2002, the Council of State and Territorial Epidemiologists (CSTE) added VRSA to the national reportable disease list and placed them under surveillance through the National Notifiable Diseases Surveillance System (NNDDSS).[4] "Most state and territorial jurisdictions in the U.S. have laws or regulations requiring standard reporting of *S. aureus* resistant to vancomycin to public health authorities."[14] In each of the 14 cases of VRSA reported in the U.S., spread of VRSA to other patients and healthcare workers were probably prevented by prompt identification and implementation of recommended infection control practices such as an outbreak investigation[4,13]. The CSTE published a position that "population-based surveillance will help identify incidence cases, characterize the individuals at highest risk, and develop appropriate prevention and control measures"[4].

Estimates of under-reporting in U.S. and in Washington

VRSA reporting depends on providers noticing that patients with staph infections are not responding to vancomycin as expected in a sterile environment. Additionally, when a laboratory test is done, VRSA categorization is due to an arbitrary MIC value. For these reasons, several articles suggest that VRSA is under-reported.[15,16] Without a standardized and broad-reaching surveillance system, the true prevalence and incidence of VRSA infections in the US are unknown[4].

Although there are no specific predictions for how rapidly VRSA will spread, researchers might make a reasonable estimate using a parallel case. One example is the evolution of vancomycin-resistant enterococci (VRE), which has passed resistance to create VRSA, indicating the close relationship between the two bacteria.[17] Until the late 1980s, most enterococci were susceptible to vancomycin; the first case of VRE was reported in 1986, the next in 1988.[18] Between 1989 and 1993, the number of VRE cases in hospital patients increased 20-fold and 61 percent of hospitals nationwide had reported cases of VRE by 1994.[18]

Subpopulations affected

Two factors associated with VRSA is a history of recurrent MRSA and the use of vancomycin in the prior month[4,19]. Persons that are most likely to become infected with staph are hospitalized patients. Infections may be more severe and increase burden of disease in hospitalized patients with weakened immune systems such as infants; the elderly; patients with Diabetes; persons on dialysis or receiving medication, nourishment, or life assistance with medical tube equipment; or those living with a chronic condition such as AIDS.[9] Persons who are recovering from surgery or have open wounds or skin infections are also likely to be susceptible to *S. aureus*.[9]

Outside of hospital walls, staph infections have also been associated with people that have close, frequent, and direct skin contact with others such as athletes, inmates, soldiers, and child care workers. Another subpopulation disproportionately affected by *S. aureus* are person who inject drugs (PWID). Because PWID puncture their skin often and may have the bacteria on their skin, it is easy for the bacteria to enter a deeper layer of the skin or their bloodstream, which would cause infection. Improving the preparatory stages of injecting drugs or wound care post-injection could significantly decrease abscesses, however, proper treatment of infection can be difficulty for this subgroup to obtain.[9]

TESTING & TREATMENT

Testing

If patients are receiving seemingly appropriate therapy for longer than seven days in normally sterile sites and still have repeated isolates of *S. aureus*, susceptibility testing is warranted. [6] The CSTE and the CDC recommend that any suspicion of reduced susceptibility to VRSA should trigger isolates to be sent to the state public health lab or the CDC for a confirmatory evaluation[6,20,21]. Although there have been previous recommendations to the contrary, the CDC wrote in its 2015 guide to the investigation and control of VRSA that all automated minimum inhibitory concentration (MIC) susceptibility testing systems "currently approved for use in the U.S. can reliably detect VRSA."[20] In addition, manual minimum inhibitory concentration (MIC) methods such as broth microdilution, agar dilution, or agar-gradient diffusion (Etest), can also be used for detection of *S. aureus* with reduced susceptibility to vancomycin. Vancomycin screen agar plates can also be used, although ones that are commercially prepared are preferred; in studies conducted at CDC, some screen plates prepared in-house were less specific than plates prepared commercially. Of note is the fact that the disk diffusion method is still considered insufficient.[6] For all methods, a full 24-hour incubation period should be used.[6,20] A confirmatory MIC test should be performed for *S. aureus* when the vancomycin MIC is $\geq$ 2 mcg/mL.[6]

Treatment

The optimal antimicrobial regimen for VRSA is uncertain[6]. Therefore, an appropriate approach would be treatment with at least one antimicrobial to which the organism is susceptible to, particularly for isolates with a vancomycin MIC greater than 2 mcg/mL. Often these antimicrobials are daptomycin, linezolid, telavancin, ceftaroline, minocycline, or quinupristin-dalfopristin; medication like chloramphenicol, rifampin, and trimethoprim-sulfamethoxazole are also suitable.

There have been several reports of reduced susceptibility to vancomycin also having reduced susceptibility to daptomycin, although the clinical relevance is uncertain[6]. Using vancomycin in combination with a second antibiotic may also not improve its therapeutic efficiency[6]. Otherwise, treatment with high-dose daptomycin in combination with another agent, such as gentamicin intravenously [IV] every eight hours, rifampin by mouth (PO)/IV daily, linezolid 600 mg PO/IV twice daily, or trimethoprim-sulfamethoxazole IV twice daily, may be considered[6].

Prevention measures from spreading VRSA should also be considered including restricted admissions and more frequent environmental cleanings during outbreaks in hospitals.

COST ESTIMATES

Cost of Testing

It was difficult to find the cost to run automated susceptibility tests. With regards to methods such as Etest or broth dilution, the test materials themselves are inexpensive: $2.75/strip for E test and between $10-22 a test panel for broth dilution in 2009 dollars.[22] Other costs that might be considered include the costs for lab materials, such as test plates, as well as labor.[22]

Cost of Treatment

As reported in the above, the optimal regimen for a patient with VRSA is still unknown. However, usual practice is to combine several antimicrobials, primarily daptomycin with another drug, such as gentamycin. The amount of each drug prescribed varies by the patient's weight, as well as the length of time described. In 2009, daptomycin costed $0.37/mg; gentamycin was $0.12/mg.[23] If we take the described dosages previously described, using the average weight of a person in North America (80 kg), as well as assume average course of treatment to be 28 days, the course of treatment would be approximately $8,300 (2009 US). [23,24] This estimate is comparable to the costs calculated to treat MRSA in a 2009 study. The study also calculated two additional cost strata: 1a.) "the cost of therapy for treatment failures and adverse events, therapeutic drug monitoring and preparation and administration of all medications", and 1b.) the previous stratum plus hospital bed costs. For MRSA patients, 1a.) was an additional several hundred dollars, while for 1b.) the costs were several times larger. These cost estimates also fall in line with a 2009 study of antibiotic-resistant infections in general, which found that the medical costs attributed to these infections in a Chicago hospital ranged from $18, 588 - $29,069 per patient, when considering all costs.[14,23]

Cost of Non-Treatment

While presence of *S. aureus* colonies on the body may not always result in infection and some skin infections may heal without treatment, other staph infections may be more serious. If untreated, severe staph infections may become life threatening and lead to pneumonia (infection of the lungs) or bloodstream infections. Although none of the VRSA isolates found in the U.S. had been transmitted beyond the original patient, and none have definitively contributed to patient morbidity and mortality[13,25].

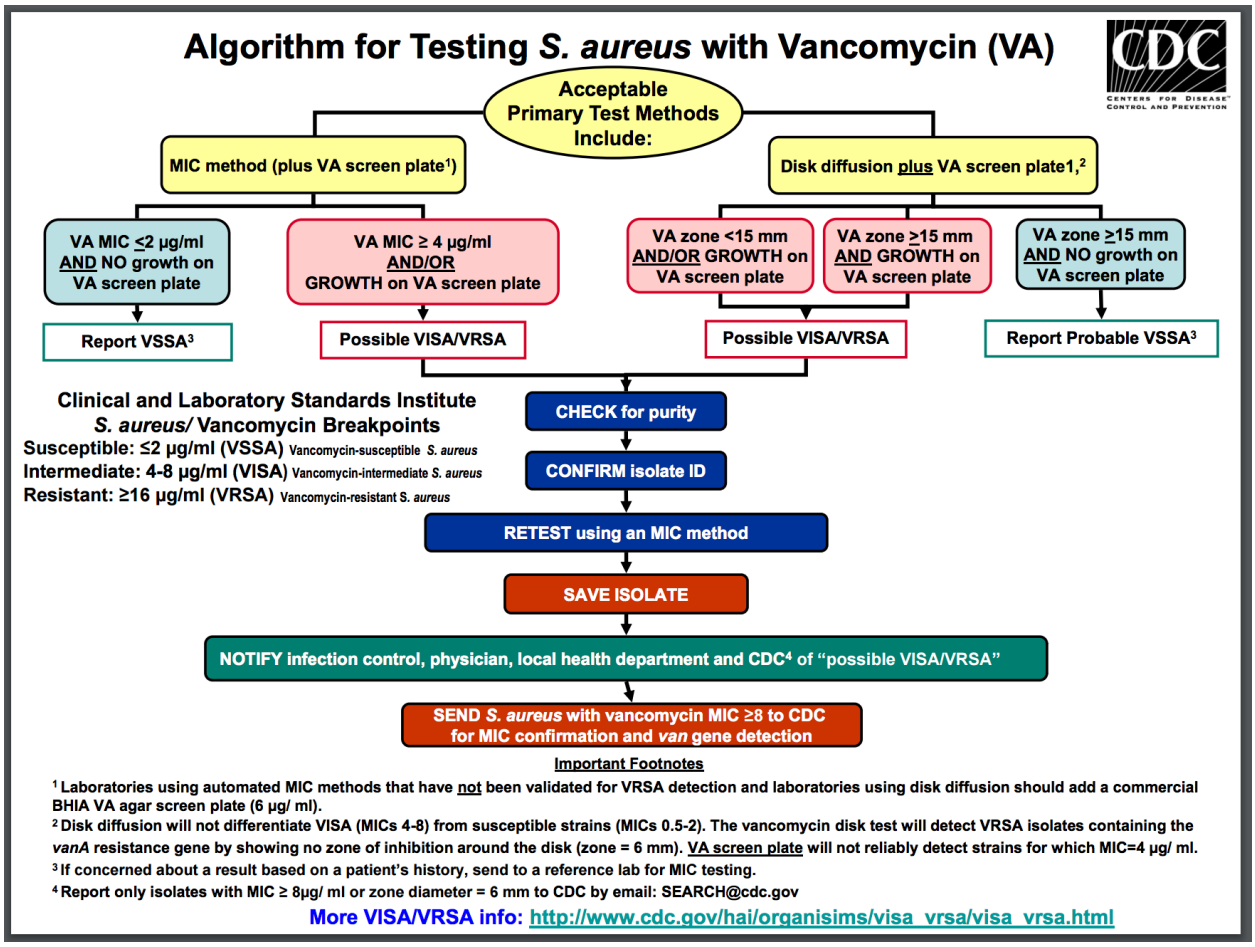
EQUITY IMPACT OF ADDING THE RULE

Potential equity impacts of adding this condition in the rule could mean that persons who might prefer not to be identified on a list or contacted by a public health system, including people who inject drugs or persons living with HIV/AIDS, would not have that option. Another potential equity impact is related to the homeless population, individuals in this population may not be able to provide the hospital with contact information for future follow-up (if they could access hospital care). Subgroups that might benefit from this condition being added to the list, especially for follow-up, might be childcare workers and those caring for the elderly or with weakened immune system because one could advise them to stop providing care and prevent mass transmission of disease.

CONCLUSION

While common, *S. aureus* has the potential to cause pain, suffering, and even loss of life and thus should be treated seriously. To address current cases, medical providers should test for VRSA and treat with a combination of medications that will effectively cure the patient of bacterial infection without perpetuating antibiotic resistance. Further, medical providers should be aware of how skin contact and infected medical equipment could increase the transmission of VRSA amongst hospitalized patients. Proper protective equipment and universal precautions for hand washing and sanitization should be followed to prevent further nosocomial infections. Additionally, surveillance efforts for VRSA should be increased in order to monitor and accurately report the potential of Vancomycin-resistance for *S. aureus*. Cases should be followed closely to observe efficacy of treatment. Adopting the change to require reporting of positive lab results of VRSA to WAC 246-101-201 may be a step the BOH can take towards increased surveillance efforts of this serious disease. Furthermore, as the CSTE recommends, "population-based surveillance will help identify incidence cases, characterize the individuals at highest risk, and develop appropriate prevention and control measures". Special populations and their needs should be explored prior to executing formal, mandatory registry and follow-up for VRSA patients to be considerate of their personal lives and environment in case they cannot or do not wish to be reached.

APPENDIX 1


Algorithm for Testing S. aureus with Vancomycin (VA)
CDC
Centers for Disease Control and Prevention
Acceptable Primary Test Methods Include:
MIC method (plus VA screen plate[1])
Disk diffusion plus VA screen plate1,[2]
VA MIC ≤2 µg/ml AND NO growth on VA screen plate
VA MIC ≥ 4 µg/ml AND/OR GROWTH on VA screen plate
VA zone <15 mm AND/OR GROWTH on VA screen plate
VA zone ≥15 mm AND GROWTH on VA screen plate
VA zone ≥15 mm AND NO growth on VA screen plate
Report VSSA[3]
Possible VISA/VRSA
Possible VISA/VRSA
Report Probable VSSA[3]
Clinical and Laboratory Standards Institute
S. aureus/ Vancomycin Breakpoints
Susceptible: ≤2 µg/ml (VSSA) Vancomycin-susceptible S. aureus
Intermediate: 4-8 µg/ml (VISA) Vancomycin-intermediate S. aureus
Resistant: ≥16 µg/ml (VRSA) Vancomycin-resistant S. aureus
CHECK for purity
CONFIRM isolate ID
RETEST using an MIC method
SAVE ISOLATE
NOTIFY infection control, physician, local health department and CDC[4] of "possible VISA/VRSA"
SEND S. aureus with vancomycin MIC ≥8 to CDC for MIC confirmation and van gene detection
Important Footnotes
[1] Laboratories using automated MIC methods that have not been validated for VRSA detection and laboratories using disk diffusion should add a commercial BHIA VA agar screen plate (6 µg/ ml).
[2] Disk diffusion will not differentiate VISA (MICs 4-8) from susceptible strains (MICs 0.5-2). The vancomycin disk test will detect VRSA isolates containing the vanA resistance gene by showing no zone of inhibition around the disk (zone = 6 mm). VA screen plate will not reliably detect strains for which MIC=4 µg/ ml.
[3] If concerned about a result based on a patient's history, send to a reference lab for MIC testing.
[4] Report only isolates with MIC ≥ 8µg/ ml or zone diameter = 6 mm to CDC by email: SEARCH@cdc.gov
More VISA/VRSA info: http://www.cdc.gov/hai/organisims/visa_vrsa/visa_vrsa.html

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Appendix B: Proposed Patient Ethnicity, Race, and Preferred Language Reporting Categories for All Notifiable Conditions

The draft rule adds patient's ethnicity, patient's race, and patient's preferred language to the list of reportable data components in the following sections:

- WAC 246-101-105: Duties—Health care providers and health care facilities.
- WAC 246-101-115: Content of case reports – Health care providers and health care facilities.
- WAC 246-101-205: Duties—Laboratory directors.
- WAC 246-101-215: Content of documentation accompanying specimen submission—Laboratory directors.
- WAC 246-101-225: Content of laboratory reports—Laboratory directors.
- WAC 246-101-513: Content of notifications, investigation reports, and outbreak reports—Local health officer.

Patient's **ethnicity** shall be identified by the patient and reported using one or more of the following categories:

- Hispanic, Latino/a, Latinx
- Non-Hispanic, Latino/a, Latinx
- Patient declined to respond
- Unknown

Patient's **race** shall be identified by the patient and reported using one or more of the following categories:

- Afghan
- Afro-Caribbean
- Alaska Native
- American Indian
- Arab
- Asian
- Asian Indian
- Bamar/Burman/Burmese
- Bangladeshi
- Bhutanese
- Black or African American
- Central American
- Cham
- Chicano/a or Chicanx
- Chinese
- Congolese
- Cuban
- Dominican
- Egyptian
- Eritrean
- Ethiopian
- Fijian
- Filipino
- First Nations
- Guamanian or Chamorro
- Hmong/Mong
- Indigenous-Latino/a or Indigenous-Latinx
- Indonesian
- Iranian
- Iraqi
- Japanese
- Jordanian
- Karen
- Kenyan
- Khmer/Cambodian
- Korean
- Kuwaiti
- Lao
- Lebanese
- Malaysian
- Marshallese
- Mestizo
- Mexican/Mexican American
- Middle Eastern
- Mien
- Moroccan
- Native Hawaiian
- Nepalese
- North African
- Oromo
- Pacific Islander
- Pakistani
- Puerto Rican
- Romanian/Rumanian
- Russian
- Samoan
- Saudi Arabian
- Somali
- South African
- South American

- Syrian
- Taiwanese
- Thai
- Tongan
- Ugandan
- Ukrainian
- Vietnamese
- White
- Yemeni
- Other Race
- Patient declined to respond
- Unknown

Patient's **preferred language** shall be identified by the patient and reported using one of the following categories:

- Amharic
- Arabic
- Balochi/Baluchi
- Burmese
- Cantonese
- Chinese (unspecified)
- Chamorro
- Chuukese
- Dari
- English
- Farsi/Persian
- Fijian
- Filipino/Pilipino
- French
- German
- Hindi
- Hmong
- Japanese
- Karen
- Khmer/Cambodian
- Kinyarwanda
- Korean
- Kosraean
- Lao
- Mandarin
- Marshallese
- Mixteco
- Nepali
- Oromo
- Panjabi/Punjabi
- Pashto
- Portuguese
- Romanian/Rumanian
- Russian
- Samoan
- Sign Languages
- Somali
- Spanish/Castilian
- Swahili/Kiswahili
- Tagalog
- Tamil
- Telugu
- Thai
- Tigrinya
- Ukrainian
- Urdu
- Vietnamese
- Other language
- Patient declined to respond
- Unknown