



MEDICAL SURVEILLANCE

1. REGULATORY REQUIREMENTS

The University of Ottawa is obliged under its Human Pathogen and Toxin Licence and the Canadian Biosafety Guideline Version 2 (issued by the Public Health Agency of Canada and the Canadian Food Inspection Agency) to have a medical surveillance program. This is defined as a program which aims to prevent and detect illnesses related to exposure of personnel to pathogens or toxins and to provide a response mechanism through which potential infections and intoxications can be quickly identified and treated before serious injury, disease, or transmission to the public occurs.

It is required that for Risk Group 2 and 3 biological materials and toxins:

- Containment zone personnel to immediately inform appropriate internal personnel or authority of any:
 - Incident that may have resulted in an exposure of an individual to a human pathogen or toxin in a facility; or
 - Disease that may have been caused by an exposure to a human pathogen or toxin in a facility.
- Emergency medical contact card to be issued to containment zone personnel handling non-human primates or a pathogen identified by a local risk assessment (LRA).

Additional Information on PHAC requirements outlined in Appendix A

2. REPORTABLE DISEASES

The Province of Ontario's reportable disease criteria can be used to help identify pathogens and disease that are of concern and may require additional medical surveillance. As this is within the health care professional scope, the determination and assessment is undertaken by:

Employees: Human Resources – Health, Wellness and Leave (HR-HWL)

Students: Personal Physicians

Reportable diseases are classified in four levels:

Level 1: Report Cases Immediately To Public Health Department

Level 2: Report Outbreaks Immediately

Level 3: Sexually Transmitted Diseases

Level 4: No Immediate Action

A complete list of the reportable disease can be found Appendix B.

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3. VACCINATIONS AVAILABLE

Ensuring all individuals working with or potentially exposed to a biological agent should have up-to-date vaccinations. Individuals must review their current status with a health care professional to determine if other vaccinations are available that are not routine but may be recommended based on the exposure risk that exist for them. Health care is a provincial jurisdiction and a complete list of Ontario requirements can be found on the Ontario Ministry of Health and Long Term Care <http://www.health.gov.on.ca/en/pro/programs/immunization/schedule.aspx>

4. PREGANCY

A number of pathogens pose special concern for expecting or lactating mothers, these are outlined by the UK Advisory Committee on Dangerous Pathogens, "Infection Risks To New And Expectant Mothers In The Workplace a Guide For Employers" (Available on the ORM Biosafety Web Page).

The organisms of potential concern are:

- Chlamydia psittaci
- Cytomegalovirus
- Hepatitis A
- Hepatitis B

A more comprehensive list of pathogens of concern was developed by Leyma De Haro, Ph.D and is provided in Appendix C as a resource.

5. RISK ASSESSMENT

Pathogens Safety Data Sheets remain a primary resource of information outlining key issues such as:

- Hazard Identification: Pathogenicity/Toxicity, Epidemiology, Host Range, Infectious Dose, Mode of Transmission, Incubation Period, Communicability
- Dissemination: Reservoir, Zoonosis, Vector
- Stability And Viability: Drug Susceptibility/Resistance, Drug Resistance-susceptibility To Disinfectants, Physical Inactivation, Survival Outside the Host
- First Aid / Medical: Surveillance, First Aid Treatment, Immunization, Prophylaxis
- Laboratory Hazard: Laboratory Acquired Infections, Sources/Specimens, Primary Hazard, Special Hazard

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- Exposure Controls / Personal Protection: Risk Group Classification, Containment Requirements, Protective Clothing, Other Precautions

In addition, a risk assessment must be undertaken to determine if the proposed research or activity presents any additional risk. This risk assessment is considered by PHAC as a local area risk assessment and is outlined in the UO Biorisk Process Guide.

6. IDENTIFICATION AND ASSESSMENT PROCESS

- a. Human Pathogen and Toxin Licences, and Importation Permits:
Both the restrictions associated with the HPT Licence and Import Permits provided boundaries in terms what material can be possessed and use, and hence help to define what material can pose a potential concern which would require medical surveillance.
- b. Biosafety Program:
The structure of the uO Biosafety Program engages both an in-house approval process and the availability of resources to assist in identifying when medical surveillance may be recommended.
- c. Institutional Approval:
To work with regulated biological materials and toxins requires disclosure of regulated biological material prior to possession and use; thus enabling the identification of any inventory that may pose a concern. Similarly each individual user registers and also states what material will be used. (An inventory of material in use is provided to HR-HWL for consideration.)
- d. “Biosafety Health Assessment Survey”:
While completion and submission of the health assessment form cannot be made mandatory, it does provide the user the opportunity to initiate discussion with their health care provider regarding to the advisability of the medical surveillance and immunization. This survey (developed by HR-HWL) is sent by the applicant directly to them for consideration, and is classified as confidential.
- e. Exposure Control Plan
The need to proactively be prepared to mitigate exposure risk, an exposure control plan is prepared when required. A modified version is available for work with animals which may have the added risk of bites, scratches, and exposure to faeces or other exposure routes (ie. Blood).
- f. Post Exposure Prophylaxis Protocol:
HR-HWL also developed and implemented The “Measures to Minimize Exposure to Bloodborne Pathogens and Post-Exposure Prophylaxis Policy” which again assist in reducing exposure risk.

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7. RESOURCES AVAILABLE

From the Office of Risk Management:

- The Biorisk Process*
- Exposure Control Plan*
- Clinical and Diagnostic Samples*
- Lyme Disease Risk Mitigation*
- Public Health Agency of Canada – Pathogen Safety Data Sheets *

* available on the UO – Biosafety Web Page.

From Human Resources –Health, Wellness, and Leave:

- “Biosafety Health Assessment Survey”:
- “Measures To Minimize Exposure To Bloodborne Pathogens And Post-Exposure Prophylaxis Policy”

8. PROCESS

a. On-Boarding Process (Biomaterial Use Certificate Applicants and New Users)

Biomaterial Use Certificate Applicants:

The process begins when a principal investigator applies for a Certificate, it is during this process where the proposed work is outlined and discloses the material to be used. A biorisk assessment can provide insight of any practices that may increase the risk. The PI is then provided with an on-boarding reference guide and is recommended to discuss with HR-HWL with regards to Medical Surveillance requirements with HR-HWL.

New Users:

Are assessed and advised based on their proposed work and are strongly advised to complete and submit the Biosafety Health Assessment Form.

b. On-Going Management Strategy

To provide effective review of medical surveillance needs, it is important to review the inventory of biological agents periodically. And to provide the medical professionals with the appropriate information and empower follow-up when required. Two reports are to be prepared:

- A report sorted by inventory
- A report sorted PI, Faculty, Depart, contact email and their inventory.

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* Upon receipt from the HR-HWL a list to agents of concern, these will be flagged within the inventory.

9. ACCIDENT/INCIDENTS

The risk of exposure during an accident or incident must be assessed to determine if exposure was possible and if medical surveillance post-exposure is required. This is undertaken by HR-H.W.L..

To initiate this an accident/incident must be reported following the University form available on line at <https://web30.uottawa.ca/v3/riskmgmtfrm/aioreport.aspx?lang=en> .

In addition reporting to the Public Health Agency of Canada is required and is undertaken by the ORM Biosafety Officer, who also investigates the incident from the biosafety perspective.



APPENDIX A

PUBLIC HEALTH AGENCY OF CANADA MEDICAL SURVEILLANCE PROGRAM

EXPECTATIONS (Handbook) AND REQUIREMENTS (Standard)

Canadian Biosafety Handbook – Second Edition

Chapter 7 - Medical Surveillance Program

The basic purpose of a **medical surveillance program** is to help prevent and detect illnesses related to the **exposure** of personnel to **pathogens** or **toxins**. The focus of this program is primarily preventive, although it also provides a response mechanism through which a potential infection can be identified and treated before serious injury, **disease**, or secondary transmissions occur. The medical surveillance of personnel handling pathogens and toxins can often be integrated into an existing workplace medical surveillance program (e.g., occupational health and safety programs for chemical or radiological hazards).

The requirements for a medical surveillance program are specified in Matrix 4.2 of the *Canadian Biosafety Standard* (CBS), 2nd Edition. [Footnote 1](#) The medical surveillance program is developed and based on an **overarching risk assessment** and **local risk assessments (LRAs)** in order to identify the pathogens and toxins handled, stored, or encountered in the **containment zone** or throughout the organization, and to identify the associated **risks**. A description of the medical surveillance program is included in the containment zone's **Biosafety Manual** so that it is available for reference to all personnel. It is important to update the medical surveillance program accordingly whenever changes are made to a **laboratory** program (e.g., when different pathogens or toxins will be introduced or new procedures or activities will be carried out). It may be appropriate to involve an occupational health professional or a local health care provider (e.g., physician, nurse, local hospital), as well as emergency responders (e.g., local paramedic, fire, and police department personnel), in the process of developing the medical surveillance program, especially with programs involving higher risk pathogens.

This chapter presents a number of aspects to be considered in developing a medical surveillance program. The level of detail and the complexity of the program will depend on the nature (i.e., size, structure, complexity) of the organization, the activities carried out involving pathogens and toxins, and the safety-related provisions of applicable legislation. Some components that may be considered when developing a medical surveillance program include a pre-placement medical examination of personnel; serum screening, testing or storage; immunizations; and other tests, as determined by an LRA.

The medical surveillance program complements medical emergency procedures, which form part of a **facility's emergency response plan (ERP)**. ERPs and **incident** investigation and reporting are described further in [Chapter 17](#) and [18](#), respectively.



7.1 Laboratory Exposures and Laboratory Acquired Infections/Intoxications

Individuals who work in areas where **infectious material** or toxins are handled or stored are at risk of exposure to these pathogens and toxins and the adverse consequences of an exposure event (i.e., infection or **intoxication**). The term that is commonly used to describe diseases associated with workplace exposures to infectious material or toxins in a laboratory setting is **laboratory acquired infections/intoxications (LAIs)**; however, the term exposure more accurately includes both infections and intoxications (i.e., resulting from exposure to toxins), whether symptomatic or asymptomatic in nature, as well as those that can be linked to a containment zone but that occur outside of a laboratory environment (e.g., infection of an office worker in a licensed facility by a pathogen handled or stored in that facility).

In addition to the immediate risk to individuals handling infectious materials, exposed persons can pose a risk to the **community** via transmission of infections within or outside the laboratory setting. Although it may be difficult to determine the root cause(s) in all cases, exposures resulting in LAIs are not uncommon. The most recent comprehensive epidemiological review found 5,527 cases and 204 deaths reported worldwide from 1930 to 2004.^{[Footnote 2](#)} While LAIs do still occur and are documented, the incidence of LAIs appears to have declined over the years; this may be attributable to enhanced **biosafety** practices, improved design of **containment facilities** and equipment, or simply due to under-reporting of incidents.^{[Footnote 3](#)[Footnote 4](#)[Footnote 5](#)} Despite this apparent decline, exposures and LAIs continue to occur, and data on these incidents may be used by biosafety professionals to better understand and quantify the risk associated with a given pathogen or a specific laboratory activity. Likewise, the information can be used to improve biosafety and **biocontainment** standards, guidelines, training, equipment and systems, and best practices, as well as medical surveillance programs (e.g., immunization, post-exposure prophylaxis, or treatment recommendations). The Public Health Agency of Canada (PHAC) is currently collecting incident reports documenting LAIs or exposures to human pathogens and toxins to analyze this information and help shape current and future biocontainment and biosafety practices in Canada.

Exposure to an infectious material or toxin is not always immediately followed by symptoms or overt disease. In addition, LAIs themselves can be symptomatic or asymptomatic in nature. Some facilities may employ medical surveillance practices that could identify a **seroconversion**, which may provide an additional source of information for recognition or confirmation of recent or previous infection or disease. Seroconversion can occur following initial infection and clearance of the pathogen, and may indicate a post-infection latency period prior to onset of the disease associated with certain pathogens (e.g., human immunodeficiency virus [HIV], *Mycobacterium tuberculosis*, hepatitis C virus, and **prions**). Sound judgement is needed in evaluating historical LAI data, as the accuracy of statistics may be impacted due to the likelihood of under-reporting of incidents. Under-reporting of exposures and LAIs may be attributed to a variety of factors, including:

- a lack of mechanisms for the reporting and tracking of exposures and LAIs;
- recognition and reporting of only symptomatic or laboratory-confirmed cases of disease;
- limited publication of LAI cases in scientific or medical journals due to factors such as space limitations;
- uncertainty as to whether an illness is due to an exposure that occurred in the laboratory setting or the community;



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- a lack of interest or motivation to report common incidents or incidents involving a commonly used pathogen; and
- fear of reproach or reprisal.

The *Human Pathogens and Toxins Act* (HPTA), [Section 13](#), requires that any exposure to human pathogens or toxins that may cause disease or any disease that may have been caused by an exposure to a human pathogen or toxin in the facility be reported to the PHAC without delay. [Footnote 6](#) This reporting allows the PHAC to assess the severity of the exposure incident and assist the facility in their response, if requested or necessary. The PHAC can also provide expertise and assistance to the facility in developing corrective actions to address the cause of the incident and prevent a recurrence. Information provided in an **exposure notification report** following an exposure incident will allow the PHAC to monitor developing trends, prompt the issuance of biosafety advisories, and amend or update best practices in biosafety practices and training, and at the same time analyze this data at the national level to inform current and future biocontainment and biosafety directions. Local investigation, documentation, and reporting for all types of incidents are intended to capture near misses and LAIs for which no clear exposure event can be identified. Incident reporting and investigation are further discussed in [Chapter 18](#).

7.2 Pre-Placement Medical Evaluation

In some circumstances, it may be beneficial to conduct pre-placement medical evaluations for all personnel. This section describes options when considering the implementation of pre-placement medical evaluations. A pre-placement medical evaluation may be conducted for new personnel or when personnel are given new responsibilities, prior to commencing activities with human pathogens, toxins, or **zoonotic pathogens**. The primary purpose of such an evaluation is to assess the initial health status of the individual and identify if there are any underlying medical conditions that may increase the risk of harm associated with the anticipated job activities. This evaluation may include an interview with the institutional occupational health care provider or completion of a personal medical history questionnaire to document the individual's previous and current medical problems; current medications; known allergies to medications, animals, or environmental allergens; and prior immunizations. Personnel who are immunocompromised or immunosuppressed (e.g., through medical therapy, pregnancy, diabetes, or other conditions) may be particularly susceptible to infection or intoxication, unable to take post-exposure treatment, or experience more severe illness if they develop disease following exposure to a pathogen or toxin. A complete physical examination is rarely necessary as part of this process but may be appropriate.

Before commencing any **controlled activities**, the individual should be informed of the hazards associated with, and the signs and symptoms of disease(s) caused by, the pathogens and toxins to be manipulated, and of all preventive measures available against the pathogens or toxins, such as vaccinations or other treatments, along with the risks and benefits of these vaccinations and treatments. They should also be informed of the steps to follow in the event of potential exposure, including appropriate first aid measures, incident reporting, timely post-exposure prophylaxis and medical treatments. In addition, the early signs and symptoms of a possible infection or intoxication with the pathogen(s) or toxin(s) being handled should be described to personnel, and they should be told what immediate steps to take if they develop these symptoms. In a clinical diagnostic setting, it may not always be possible or practical to advise personnel of all potential pathogens that they may

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encounter; rather, it may be more reasonable to inform personnel of symptoms of key concern in situations when illnesses caused by unusual pathogens have been diagnosed in the laboratory.

Personnel with a considerable risk of exposure to pathogens may be encouraged to provide a blood sample for serum testing and storage prior to the initiation of work with the pathogen(s). Such samples can be stored long-term and later used to determine pre-existing immunity from prior vaccination or infection, and to establish a baseline seroreactivity for comparison with supplementary blood samples collected following a potential exposure.

7.3 Vaccinations

Vaccines are highly regulated and complex biological products designed to induce a protective immune response both effectively and safely. The availability of vaccines or other prophylaxis should be evaluated, and these should be offered to personnel as required prior to commencing work with a pathogen. Periodic testing of antibody titres should be conducted post-vaccination to determine if the required level of protective immunity has been achieved and is being maintained, or if a booster vaccination is necessary. Should an individual decline or not respond immunologically to a vaccination that is deemed a prerequisite for working in a containment zone, a re-evaluation of placement, the implementation of additional environmental controls, or the use of additional **personal protective equipment (PPE)** should be considered.

Further recommendations on vaccines can be obtained from health care professionals specializing in this area or from the National Advisory Committee on Immunization (NACI). The NACI is a national advisory committee of medical and health sciences experts that makes recommendations to the PHAC on the use of vaccines in Canada, including the identification of groups at risk (e.g., occupational groups, age groups) for vaccine-preventable diseases. All NACI recommendations are published in the *Canadian Immunization Guide* with additional statements and updates published in the *Canada Communicable Disease Report (CCDR)*. [Footnote 7](#)[Footnote 8](#)

7.4 Ongoing Medical Surveillance

Ongoing medical surveillance for personnel who are at risk of exposure to pathogens or toxins may provide an indication of occupational exposure. Personnel should be encouraged by the supervisor, without fear of reprisal, to disclose any changes in their health status that could increase their risk of exposure or disease susceptibility. This could include developing an immunodeficiency or a temporary condition, such as the need to take prescribed antibiotics, impaired vision, or even stress. Routine or periodic medical evaluations are generally not necessary; however, such evaluations may be appropriate in the case of personnel with a substantial risk of exposure to pathogens or toxins since they may permit earlier recognition of an infection that may be due to a laboratory exposure. Any clinical tests (e.g., serum testing) requested by a medical advisor or practitioner should be limited to approved, commercially available tests with adequate sensitivity to identify an infection or previous infection (i.e., seroconversion). Serum samples collected during the pre-placement evaluation can be used to establish a baseline or “pre-exposure” reference for any tests to be conducted as part of the medical surveillance program. While medical test results are only reported to the patient, individuals who discover a positive infection or seroconversion that may be associated with a laboratory-related exposure have an

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obligation to inform their supervisor or internal organizational authority (i.e., **biological safety officer [BSO]**, **licence holder**), who, in turn, is legally required to notify the PHAC of the exposure (HPTA 13).

7.5 Post-Exposure Response Plan

Post-exposure response plans outline the specific procedures to follow and actions to be taken in the event of a known, suspected, or potential exposure to a pathogen or toxin (e.g., reporting, medical testing, and treatment) and could be a component of an overall ERP. For containment zones where pathogens or toxins are handled or stored, a post-exposure response plan may be created in consultation with the occupational health care provider or practitioner, the institutional biosafety committee, the BSO, and the occupational health and safety advisor. Incident reporting and investigation are discussed in further detail in [Chapter 18](#).

7.6 Additional Considerations for High Containment

Any potential occupational exposure that occurs in a **high containment zone** (i.e., **containment level 3 [CL3]**, which includes CL3 **large animal containment zones [LA zone; CL3-Ag]**, or containment level 4 [CL4]) should be promptly evaluated, as infection with a higher risk pathogen may lead to severe illness or death. The pathogens manipulated in CL4 zones are typically exotic and an LAI would represent a serious health concern for the community. Ensuring adherence to all medical surveillance protocols and procedures by all containment zone personnel, including facilities and support personnel, is particularly important in **high containment zones**. It is strongly recommended that an infectious disease specialist be involved in the development of the medical surveillance program, including risk assessment, pre-placement evaluations, and development of a post-exposure response plan. Additionally, it is required (CBS Matrix 4.2) for CL4 zones and strongly recommended for CL3 and CL3 LA zones (CL3-Ag), that the post-exposure response plan be prepared in consultation with local health care facilities, to keep health care providers informed of the pathogens being handled and that the appropriate procedures and treatments are in place. Specific quarantine procedures for potentially infected personnel may need to be established prior to an exposure incident. In CL4 zones, it is also required that the supervisor contact any containment zone personnel with unexpected work absences to determine if the absence is due to an illness that could be related to activities with the pathogens in use (CBS Matrix 4.2).

7.7 Emergency Medical Contact Card

Emergency medical contact cards are issued by the employer to personnel working with non-human primates (NHPs), personnel working with pathogens or toxins that cause diseases unlikely to be recognized by a physician, and all personnel working in CL4 zones to provide a means to facilitate communication with health care providers and other individuals, particularly during emergency situations. The card should summarize important information regarding the pathogen(s) or toxin(s) that are handled by the individual, such as routes of infection or intoxication, transmission, symptoms, and preventive and therapeutic treatments. This measure is also recommended for personnel working in CL3 and CL3 LA zones (i.e., CL3-Ag). In the event of an unexplained illness, this card can be presented to hospital or health care facility staff, or emergency responders. The containment zone supervisor should provide guidance as to when the card should be carried by the personnel (e.g., at all times on the premises except inside the containment zone, or at all times during a period that an active study involving the particular pathogen is being conducted). It is the responsibility of the facility to determine



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when the emergency medical contact card is to be carried by personnel. An example of an emergency medical contact card can be found in [Figure 7-1](#).

Figure 7-1: Example of an Emergency Medical Contact Card

FRONT

EMERGENCY MEDICAL CONTACT CARD	
NAME:	_____
DATE ISSUED:	_____
I WORK WITH:	
<input type="checkbox"/> _____ RISK GROUP 4 PATHOGENS	This card is to be kept in the possession of the laboratory employee and presented to a physician if an illness occurs that may be associated with a pathogen used within the laboratory (see reverse).
<input type="checkbox"/> _____ RISK GROUP 3 PATHOGENS	
<input type="checkbox"/> _____ NON-HUMAN PRIMATES	
<input type="checkbox"/> _____ TOXINS	
<input type="checkbox"/> _____ OTHER	

BACK

TO THE PHYSICIAN This employee works in an environment where pathogenic microorganisms are present. Please contact the individuals listed below for information on the agents to which this individual may have been exposed.	
FACILITY NAME: _____	
ADDRESS: _____ _____	
CONTACT 1:	
NAME	TEL. (Home / Work / Cell)
CONTACT 2:	
NAME	TEL. (Home / Work / Cell)

[Text Equivalent - Figure 7-1](#)



APPENDIX C REPORTABLE DISEASES

LEVEL 1: REPORT CASES IMMEDIATELY TO PUBLIC HEALTH DEPARTMENT

1. Communicable diseases unit
 - Bacterial Meningitis
 - Ebola virus
 - Febrile respiratory illness (FRI) with relevant travel history
 - Lassa fever
 - Marburg virus
 - Severe acute Respiratory Syndrome: (SARS)
 - Streptococcal infections, Group A invasive
2. Enteric, Zoonotic and Vector-Borne Disease Unit
 - Anthrax
 - Botulism
 - Hanta virus
 - Food poisoning, all causes
 - Hepatitis A
 - Paratyphoid fever
 - Plague
 - Shigellosis
 - Typhoid fever
 - Verotoxin-Producing E.coli infections
 - Yellow fever
3. Immunization and Vaccine Preventable Disease Unit
 - Acute Poliomyelitis
 - Diphtheria
 - Haemophilus influenzae
 - Measles
 - Meningococcal disease
 - Smallpox
 - Hepatitis A

LEVEL 2: REPORT OUTBREAKS IMMEDIATELY

4. Communicable diseases unit
 - Encephalitis
 - Legionellosis
 - Psittacosis/Ornithosis
 - Tuberculosis

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Viral meningitis

5. Enteric, Zoonotic and Vector-Borne Disease Unit

Amebiasis

Bites from suspected rabid animals - Rabies

Brucellosis

Campylobacter enteritis

Cholera

Cyclosporiasis

Cryptosporidiosis

Giardiasis; only symptomatic

Listeriosis

Q fever

Salmonellosis

Trichinosis

Tularemia

West Nile Virus

Yersiniosis

6. Immunization and Vaccine Preventable Disease Unit

Mumps

Pertussis

Rubella

Level 3: SEXUALLY TRANSMITTED DISEASES

7. Communicable Disease Unit

Chancroid

Chlamydia

Gonorrhoea

Hepatitis B

Hepatitis C

Ophthalmia neonatorum

Syphilis

Immunization and Vaccine Preventable Disease Unit

Hepatitis B

LEVEL 4: NO IMMEDIATE ACTION

8. Communicable Disease Unit

Congenital Cytomegalovirus infection

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Influenza

Leprosy

Strep. Group B

Transmissible spongiform encephalopathy: Creutzfeldt-Jakob disease, kuru, etc.

9. Enteric, Zoonotic and Vector-Borne Disease Unit

Lyme disease

Malaria

10. Immunization and Vaccine Preventable Disease Unit

Chickenpox (varicella)

Congenital rubella

Tetanus



APPENDIX C BIOLOGICAL AGENTS AND PREGANCY RISK

**General Safety Information for Pregnant Laboratorians working at
[Insert Institution's name here]**

Prepared by: Leyma De Haro, Ph.D.

Prepared on: 09/29/2017

Version 1.0

This document is being provided as a resource.

The actual determination of risk and applicability resides with the Health Care Professionals.

[Insert Institution's name here] strives to create a work environment that recognizes and mitigates risk while providing guidance, structure and education to create a safe workplace for all employees. It is well known that pregnant women are in an immunocompromised state and that the developing fetus possesses no further immunity than that provided by the mother, thus rendering both to a vulnerable state. At [Insert Institution's name here] infectious diseases, chemical hazards, as well as additional general hazards encountered in the laboratory environment and are important considerations regarding the health and wellbeing of both mother and developing child. This document is intended to inform a pregnant laboratorian of the potential safety concerns surrounding her in a laboratory environment at [Insert Institution's name here]. A complete risk assessment specific to the work environment and hazards likely to be encountered by different laboratorians working on different areas should be conducted by their supervisors in consultation with the appropriate safety officers on a case by case basis. Pregnant laboratorians are encouraged to discuss their laboratory work environment with their physician or other medical professional.

This document complies with OSHA 29 CFR 1910.1200 "Right to know", and with BMBL 2009 (page 115-116) guidance stating that when an occupational exposure is substantially more hazardous to identifiable sub-populations (such as pregnant women) "workers should be informed about risks". Self-reporting of pregnant status is entirely at the discretion of the individual and is in no way required by [Insert Institution's name here] in accordance with the US Pregnancy Discrimination Act of 1978. Nor can a change in job duties be imposed upon an individual solely because of self-reporting of pregnant status.

General Safety:

Working in a laboratory creates an environment in which physical hazards, beyond chemical and biological concerns, may also exist. Heavy lifting, excessive noise or vibration, and temperature extremes are among these concerns. Ergonomic issues can be compounded by the challenges associated with the rapid physiological changes occurring during the gestational period. Additionally, exposure to ionizing radiation above background levels should also be avoided. The best way to mitigate factors that may have a negative impact on a pregnant

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laboratorian and her developing child, is communication with supervisors, safety officers, and human resources. An evaluation of assigned duties is necessary to identify relevant hazards.

Biosafety:

Any severe infection may be detrimental to the health of the mother and child during pregnancy, after birth, and during the lactation period. Here we present organisms that have been highlighted by CDC, FDA, and internationally of special concern for expectant mothers and developing fetus/neonates. We have separated the organisms into three categories: *Table 1*. Select Agents (not complete). *Table 2*. Organisms of highest concern. *Table 3*. Organisms of concern. Laboratorians may work with or test for these organisms after a specific risk assessment has been performed and recommendations for increased PPE and/or changes in practices are implemented (if recommended by the risk assessment).

Table 1*. Review of seven select agents and their known maternal and fetal effects. We recommend performing a risk assessment and consulting with a physician before working with these agents while pregnant, trying to become pregnant, or lactating.

Organism	Risk	Transmission route from mother to child
<i>Bacillus anthracis</i> (anthrax)	Limited evidence suggests that pregnant women are not at increased risk for anthrax infection compared to the general population, infants not at an increased risk for birth defects	Unknown
<i>Burkholderia mallei</i> (glanders)	No case has been reported in the literature, unknown effects	Unknown
<i>Burkholderia pseudomallei</i> (melioidosis)	Only two cases reported in the literature: 1. Pregnant woman presented with cystitis and later had a stillborn 2. Pregnant woman presented with placenta previa and severe vaginal bleeding, had emergency C-section, infant born with sepsis and respiratory distress (survived with treatment)	Unknown 1. <i>Burkholderia pseudomallei</i> cultured from urine 2. <i>Burkholderia pseudomallei</i> identified in blood and tracheal aspirate from infant
<i>Clostridium botulinum</i> toxin (botulism)	Little is known about the effects of botulism in pregnant women. Due to potential routes of exposure (ingestion or inhalation) it is not expected that pregnant women would be at increased risk for infection. It is not known if infants are more likely to experience adverse effects.	Unknown
<i>Francisella tularensis</i> (tularemia)	It is not known if pregnant women and fetuses are at increased risk from infection. Eight recorded cases of tularemia during pregnancy (two in the 1930s, and 6 between 2008-2012 in Turkey).	Unknown

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	-2 fetal deaths (both untreated) -6 delivered healthy infants (1 untreated and 5 treated successfully) *Due to such a small amount of cases, birth defects cannot be excluded.	
<i>Rickettsia prowazekii</i> (typhus)	No case has been reported in the literature, unknown effects	Unknown
variola virus (smallpox)	Mother and fetus: high morbidity and mortality	Unknown (but likely)
fetal vaccinia	Fetus: death, slight increase in risk for birth defects	
<i>Yersinia pestis</i> (plague)	It is not known if pregnant women and fetuses are at increased risk from infection. One case of intrauterine infection reported Pregnant women diagnosed with plague have experienced spontaneous abortion, fetal tachycardia, and fetal distress.	Unknown (possible intrauterine infection)

*Watson. Birth Defects Research (2017).

Table 2. The following organisms are known to pose a serious risk to fetus/neonate and/or mother. We recommend performing a risk assessment and consulting with a physician before beginning to work with these agents while pregnant, trying to become pregnant, or lactating.

Organism	Risk	Transmission route from mother to child
<i>Brucella spp.</i>	Spontaneous abortion, preterm delivery, chorioamnionitis (intra amniotic infection-IAI), and fetal death	Placenta
Chikungunya virus	Miscarriage, fetal death, harmful fever, neurodevelopmental disorders	Not clear
<i>Chlamydia psittaci</i>	Death of unborn child, premature delivery	Placenta
Coccidioides (Valley fever)	Mothers: coccidioimycosis, severe respiratory disease, meningitis Fetus: coccidioimycosis, severe respiratory disease, death	Delivery (aspiration of amniotic fluid or vaginal secretions)
<i>Coxiella burnetii</i> (Q fever)	Miscarriage, preterm delivery, infant small for gestational age, oligohydramnios (deficiency in amniotic fluids), fetal growth restriction, or perinatal death	Placenta
Cytomegalovirus	Long term complications include damage to the central nervous system, learning disabilities, deafness	Placenta
Ebola virus	100% fetal death rate, fatal to mother	placenta
<i>Listeria monocytogenes</i>	Fetal septicemia or meningitis (death rate 50-100%), miscarriage, premature birth. Long term effects in many organs including the eyes, airways, and central nervous system	Placenta, delivery

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Lymphocytic choriomeningitis virus (LCM)	Injury of brain and retina leads to permanent dysfunction (microcephaly, periventricular calcifications, and hydrocephalus)	Not known
Malaria	Miscarriage, premature delivery, low birth weight, congenital infection, perinatal death	Placenta
Measles (unvaccinated)	Miscarriage, stillbirth, premature delivery	Not known
<i>Mycobacterium tuberculosis</i> (TB)	Low birthweight, child born with TB	Not known, but placenta suspected
Parvovirus B19	Fetal death, miscarriage	Placenta
Rubella virus	Wide range of birth defects including deafness, cataracts, microcephaly, heart defects, and learning disabilities.	Placenta
<i>Toxoplasma gondii</i>	Long term eye damage, hydrocephaly, inflammation of the eyes, various non-specific signs	Placenta
<i>Varicella-zoster</i> (chickenpox)	Skin scarring, brain damage resulting in learning disability, limb abnormalities	Placenta
Zika virus	Miscarriage, microcephaly, deafness, other long term conditions	Placenta

Table 3. The following organisms may pose a risk to fetus/neonate and/or mother occasionally. We recommend performing a risk assessment and consulting with a physician before beginning or continuing to work with these agents while pregnant, trying to become pregnant, or lactating.

Organism	Risk	Transmission route from mother to child
<i>Borrelia burgdorferi</i> (Lyme disease)	Stillbirth, premature birth, and other complications	Not known
<i>Campylobacter spp.</i>	Neonatal sepsis and death (if infected during 3 rd trimester), severe enteritis, meningitis, fetal wastage, spontaneous abortion, premature labor, stillbirth, neonatal diarrhea, neonatal bacteremia, death of mother	Placenta
<i>Clostridium perfringens</i>	Sepsis and death	Not known
group B <i>Streptococcus</i> (GBS)	Maternal colonization with GBS in the genitourinary or gastrointestinal tracts is the primary risk factor for disease	Not known
<i>Haemophilus influenzae</i>	Miscarriage, chorioamnionitis (intra amniotic infection-IAI)	Placenta
Hepatitis A (unvaccinated)	Transmission from mother to child	Mother to child transmission
Hepatitis B (unvaccinated)	Severe fulminant hepatitis after birth	Delivery and exposure to mother's blood
Hepatitis C	Gestational cholestasis (jaundice), low birth weight, small for gestational age, more likely to be admitted to NICU and require assisted ventilation, long term effects lead to chronic hepatitis	Placenta, delivery (contact through the birth canal)
Hepatitis E	Mother: fulminant hepatic failure and death, acute hepatitis	Not known

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HIV	AIDS and other diseases	Placenta, delivery, breastfeeding
Herpes virus	Miscarriages, serious birth defects	Placenta
Influenza virus	Premature labor and delivery, severe birth defects, flu related complications for mother and child	Placenta
Measles (vaccinated)	Miscarriage, stillbirth, premature delivery	Not known
<i>Salmonella spp.</i> (enteritidis and typhimurium)	Sepsis, miscarriage, chorioamnionitis (intra amniotic infection-IAI)	Placenta
<i>Treponema pallidum</i> (syphilis)	Fetal death, congenital syphilis	Placenta
Pathogenic <i>Escherichia coli</i> (<i>E. coli</i>)	STEC: infection experiments in rats have shown pre-term labor, fetal death, and stillbirth	Placenta (Hypothesized)
<i>Shigella spp.</i>	Chorioamnionitis (intra amniotic infection-IAI) leading to premature rupture of membranes leading to preterm labor and pre-term delivery	Placenta
<i>Staphylococcus aureus</i> Staph enterotoxin B (SEB) Staph enterotoxin C (SEC) toxic shock syndrome toxin-1 (TSST-1)	Child born colonized (especially MRSA)	Umbilical cord
<i>West Nile virus</i>	Congenital malformations (risk is minor)	Not known
<i>Vibrio cholerae</i> <i>Vibrio parahaemolyticus</i> <i>Vibrio vulnificus</i>	Mother can experience extreme diarrhea, vomiting, fever, low blood pressure leading to Intrauterine fetal death, neonatal death	Not known, effects to fetus due to extreme dehydration and low blood pressure
<i>Yersinia enterocolitica</i>	Fetal growth retardation (leading to death), hypoalbuminemia, preeclampsia	Placenta

Pregnant laboratorians should consult with their physician regarding further questions and consult about other possible complicating factors (such as having gestational diabetes, pre-eclampsia, asthma, autoimmune disorders, etc.) that could further compromise their immune system and make them vulnerable to infections by other organisms not mentioned here. Additionally, this list does not include antibiotic resistant or multidrug resistant organisms that could further complicate treatment in the case of a pregnant woman.

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FDA 14 foodborne pathogens of concern for mothers-to-be: <https://www.fda.gov/food/resourcesforyou/healtheducators/ucm091681.htm>

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