Human Pathogens and Toxins Act Implementation at UHN

2016 TORONTO RESEARCH MANAGEMENT SYMPOSIUM, TORONTO

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Employee possibly exposed to Ebola virus at Winnipeg lab

Worker at animal health laboratory is in isolation, and risk to public is considered low, officials say

CBC News  Posted: Nov 08, 2016 12:15 PM ET  |  Last Updated: Nov 08, 2016 5:36 PM ET

An employee at the national animal health lab in Winnipeg was potentially exposed to the Ebola virus yesterday, federal officials say.

The employee of the National Centre for Foreign Animal Disease (NCFAD) was evaluated by an infectious disease specialist and has put himself in isolation for 21 days — the maximum time from Ebola infection to the onset of symptoms, according to the World Health Organization.
Winnipeg researcher charged with smuggling Ebola material into U.S.

A former researcher at the National Microbiology Lab in Winnipeg is facing charges in the United States after allegedly trying to smuggle genetic material from the Ebola virus across the Manitoba-North Dakota border.

U.S. authorities allege Konan Michel Yao had 22 vials of the substance in the trunk of his car when he tried to cross the border on May 5. He is charged with smuggling merchandise, which carries a maximum penalty of 20 years in prison and a fine of $250,000 US.
Human Pathogens and Toxins Act Implementation at UHN (University Health Network)

What we will cover today:

• Who is UHN?
• What is the HPTA/HPTR/CBS?
• Why have legislation?
• Need for HPTA/HPTR/CBS?
• HPTA/HPTR/CBS timeline.
• Specifics of HPTA/HPTR/CBS.
• UHN implementation
University Health Network

Princess Margaret Cancer Centre  Toronto General Hospital  Toronto Western Hospital  Toronto Rehabilitation Institute  Michener Institute

One of Canada’s largest teaching hospitals.

www.uhnresearch.ca
UHN at a Glance

Nearly 18,000 staff, medical staff and students

Nearly 1,200 beds

9 Separate Sites

$1.9B Annual Budget

Laboratory Medicine Program
Research @ UHN

Princess Margaret Cancer Research Institute
TGRI
Toronto General Research Institute
KRI
Krembil Research Institute
TRI
Toronto Rehabilitation Institute

The largest research hospital in Canada
### Research by the numbers at UHN

<table>
<thead>
<tr>
<th>Sq Ft</th>
<th>Publications</th>
<th>Staff</th>
<th>Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>991,894</td>
<td>3,402</td>
<td>4,654</td>
<td>$356,167,153</td>
</tr>
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</table>

*2015 Data*
Laboratory Medicine Program (LMP)

Largest academic laboratory medicine program in Canada

- Over 500 staff including over 65 medical and scientific staff

Complex and routine laboratory medicine services to all UHN programs

- Over 20,000 specimens/day
- Over 22 million tests /yr
UHN Research Biosafety Program

- Biosafety Committee
- Manuals Policy
- Biosafety Certificates
- Medical Surveillance
- Training
- Infrastructure
- Audits and Inspections
- Regulatory Engagement
- Strategic Planning
Oversight by Public Health Agency of Canada

- **Human Pathogens and Toxins Act**: June 23, 2009
- **Human Pathogens and Toxins Regulation**: December 1, 2015
- **Canadian Biosafety Standard (CBS) 2nd Ed.**: December 1, 2015
Why have Laws, regulation & standards for the use of biohazardous materials?

• Health, Safety and Security of People
• Health, Safety and Security of workers
• Health and safety of animals
• Sustain and protect the environment
Why the need for the HPTA?

• “Human pathogens and toxins are inherently dangerous - capable of causing disease and death in humans.”

• 9/11/2001 and international pressure to provide safeguards against bioterrorism (Australia Group)

• Human Pathogens Importation Regulations (HPIR) did not regulate human pathogens or toxins if domestically acquired

• HPIR punishment inconsequential

• Domestically acquired human pathogens and toxins were subject to voluntary guidelines only (Laboratory Biosafety Guidelines-established 1990)
CBS 2nd Ed.-Development

June 1, 2013
CBSG, 1st Ed.

Dec 1, 2015
CBS 2nd Ed.
Timelines for the HPTA/HPTR/CBS?

Bill C-54 introduced for HPTA
Bill C-54 reintroduced as Bill C-11
HPTA Receives Royal Accent
End HPTA Phase 2 & CBSG Consult
CBSG replaces previous guidelines
End HPTA Phase 3-4 Consult
HPTR & CBS published
HPTR & CBS come into force

April 2008
May 2009
June 23, 2009
November 2012
July 2013
June 2014
March 2015
December 1, 2015
Applicable Federal Legislation

Health Canada
- *Hazardous Products Act (WHMIS/GHS)*

Public Health Agency of Canada
- *Human Pathogens and Toxins Act*
- *Human Pathogens and Toxins Regulations*
- *Canadian Biosafety Standard, 2nd Ed (includes terrestrial animal pathogens)*
- Biosafety Directives, Advisories and Notifications
Applicable Federal Legislation

Canadian Food Inspection Agency
◦ *Health of Animals Act (HAA)*
◦ *Import Program* (*pathogens causing foreign animal and emerging animal diseases*)

Environment Canada
◦ *Canadian Environmental Protection Act (CEPA)*
◦ New Substances Notification Regulations (Organisms)

Transport Canada
◦ Transportation of Dangerous Goods Act & Regulations
Applicable Provincial Legislation

**Ministry of Labour**
- *Occupational Health and Safety Act*
- *O.Reg. 67/93 Health Care and Residential Facilities*
- *O.Reg 833 Control of Exposure to Biological or Chemical Agents*
- *O.Reg 851 Industrial Establishments*

**Ontario Ministry of the Environment**
- *Environmental Protection Act*
- *Guideline C-4 Management of Biomedical Waste*
Other:

- International Law
  - USA Select Agent Law
  - Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH)

- National Institute of Health (NIH)
  - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
HPTA

“An Act to promote safety and security with respect to human pathogens and toxins.”

• Human pathogen means a micro-organism, nucleic acid or protein (including synthetic form) that is listed in schedules 2-4 or falls into Risk Group 2, 3 or 4;

• Toxin means a substance (including synthetic form) that is listed in Schedule 1 or in Part 1 of Schedule 5
### HPTA-Prohibitions

No persons shall conduct the following "controlled activities" (CA) with human pathogens or toxins without a licence:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Prohibited Activity</th>
</tr>
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<tbody>
<tr>
<td>Possession</td>
<td>Production</td>
</tr>
<tr>
<td>Storage</td>
<td>Permitting access to</td>
</tr>
<tr>
<td>Importing</td>
<td>Exporting</td>
</tr>
<tr>
<td>Release or abandonment</td>
<td>Disposal</td>
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HPTA-Does Not Apply to:

A human pathogen or toxin that is in an environment in which it naturally occurs if it has not been cultivated or intentionally collected or extracted, including a human pathogen or toxin that:

<table>
<thead>
<tr>
<th>Is in or on a human suffering from a disease</th>
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<tbody>
<tr>
<td>Has been expelled by a human suffering from a disease</td>
</tr>
<tr>
<td>Is in or on a cadaver, a body part or other human remains</td>
</tr>
</tbody>
</table>

A drug in dosage form whose sale is permitted or otherwise authorized under the *Food and Drugs Act* or a human pathogen or toxin contained in such a drug.
HPTA

• Licences:
  • *All persons* shall comply with the licence conditions.

• Security Clearances

• **Biological Safety Officer** (BSO) qualifications, obligations, power, functions

• Administration and Enforcement
  • Offences and Punishment
*Every person who contravenes this Act or the regulations is guilty of an offence and liable, on summary conviction,
  • ...in the case of a contravention with respect to a human pathogen that falls into Risk Group 2 (ii) for a subsequent offence, to a fine of not more than $500,000 or to imprisonment for a term of not more than six months, or to both.

• ...creates a risk to the health or safety of the public is guilty of an indictable offence and liable to imprisonment for a term of not more than five years.
• Licence Details
  • Duration related to Risk Group Licence conditions related to controlled activities and
    • Persons must inform BSO
  • Biosafety Officer qualifications, Functions, Powers
  • Security Sensitive Biological Toxins Table 1 (Sec 10 (2))
  • Security Clearance Process/Requirement details
HPTTR – Biological Safety Officer (BSO)

Qualifications: Knowledge of:

• Microbiology/risks,
• Act, Regulations and other Federal/Provincial legislation,
• Applicable biosafety and biosecurity practices

Functions:

• Communicate with Minister
• Report to Minister: (exposures, inadvertent possession, etc.)
• Conduct inspections/audits
• Develop biosafety manual

Power:

• To Obtain records to support functions
27 (1) A person who carries out laboratory analyses or diagnostic testing with a human pathogen that is neither a prion nor a prescribed human pathogen is exempt from the application of section 7 of the Act on condition that

(a) they do not cultivate or otherwise produce a human pathogen;
Licence

• Administered by PHAC via Biosecurity portal (web-based)
• Includes HPTA, HPTR and sections under HAA (terrestrial animal pathogens)
• Required for all parties conducting controlled activities
• Party must identify a “Licence Holder” and the “Biological Safety Officer (BSO)”
• Only Licence Holder and BSO can access Biosecurity portal.
• Plan for Administrative Oversight (POA) for Pathogens and Toxins in a Research Setting is required for scientific research
Plan for Administrative Oversight (POA) for Pathogens and Toxins in a Research Setting:

1. Management Commitment
2. Roles and Responsibilities
3. Key Contact
4. Identification of Biosafety and Biosecurity Risk
5. Assessment of Biosafety and Biosecurity Risk
6. Management & Control of Biosafety and Biosecurity Risk
7. Description of Work Areas Covered by Plan
8. Description of Individuals Covered by Plan
9. Summary of Communication Plan
10. Plan Review and Monitoring
UHN Involvement HPTA/HPTR/CBS

- UHN submitted commentary to PHAC/OUBSO
  - UHN Asked to develop a design cost report for CL1 to CL2 lab
- Participated in PHAC forums
- Sept 2013 UHN invited to PHAC to discuss impact of HPTA/R on Biomedical labs/LMP CBS Draft review
- Discuss with PHAC re SSBA trigger qty RG reduction Beta test licence portal
- Draft review: CBH C1 guidelines
### Implementation of HPTA at UHN?

#### Communication:

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
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</table>
| UHN Intranet            | • Policies, UHN Research Biosafety Manual, general program information, SOP’s, templates, guidance documents, etc.  
                          | • Special news stories                                                                                                                      |
| Email Program Updates   | • Broadcast emails  
                          | • Directed emails to PI’s, supervisors, personnel, etc.                                                                                     |
| Mandatory Training      | Mandatory orientation, eLearning and in-class Wet-Laboratory Safety Training                                                                 |
| In-Lab Orientation      | PI’s are responsible for ensuring new personnel are provided in-lab orientation/training on laboratory-specific procedures/SOP’s and emergency procedures. |
### Implementation of HPTA at UHN?

**Communication (continued):**

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator (PI) Onboarding</td>
<td>All new PI’s assigned a RFPS Safety Coordinator to assist one-on-one with laboratory start-up and biosafety and biosecurity program compliance,</td>
</tr>
<tr>
<td>Special Information Sessions</td>
<td>UHN conducted multiple information sessions</td>
</tr>
</tbody>
</table>
| Inspection & Audit             | UHN Inspectors (Safety Coordinators/BSO):  
  - Provide literature information  
  - Provide direct feedback on reports |
| Committee Reports/Debriefs     | RFPS/BSO provided ongoing updates senior management, council, committees and departments                                                  |
Key Highlights of HPTA and HPTR

- Governance
- Legislation Alignment
- Reporting Requirements
- Security Sensitive Biological Agents (SSBAs)
- Biosecurity
- Medical Surveillance
- Training
Governance

- Laboratory Medicine Program exempt as it does not cultivate/produce Human pathogen
- Licence administered under UHN Research Safety program
- Licence Holder-Ian McDermott
- Biological Safety Officer (BSO)-John Shannon
  - Previously 3 BSO’s: Principle Investigators representing 3 institutes
  - Change to Biosafety Committee
  - Forming Clinical Research Biosafety Committee
Implementation of HPTA at UHN?

• REPORTING STRUCTURE:

CEO

EVP
Research

Licence Holder

Biosafety Committee

BSO
HPTA only regulates RG2 and greater human pathogens and toxins
Biomedical laboratories (basic and clinical) conduct research with human blood/tissues
UHN’s biosafety program treats human tissue as RG2
Personnel health and safety under OHSA

HPTA only regulates microbiological toxins yet non-microbiological toxins (i.e., ricin from castor bean, tetrodotoxin from puffer fish) have health, safety and security implications and are regulated under USA Select agent law.
Continued:

- NIH has regulatory guidelines for use of recombinant DNA/synthetic DNA research-impacts to Clinical trials (HPTA exempts drug form)

- Terminology: human pathogens and toxins vs biological agents
New Requirements to REPORT TO PHAC:

- Exposure reporting
  - Requirement to report all incidents to BSO without delay
  - Existing requirement to report to OHS, OHS also notifies BSO
- Inadvertent acquisition
- Accidental Release
Reporting Requirements

Continued:

New Requirements to REPORT TO BSO/Licence Holder:

• Importing or Exporting
• Receiving
• Transferring (i.e. Core facilities)
• Increasing pathogenicity, toxicity, communicability, etc.

Must be included on UHN Biosafety Certificate, transfer forms, notification requirements in policy/UHN Research Biosafety Manual Agreements with 3rd party importers (i.e. Cedarlane, Sigma)
Security Sensitive Biological Agents (SSBAs)

Control of Trigger Quantities

- Audit of inventories and actual storage quantities
- Accurate central inventory
- Managed parts of a facility via notification and biosafety certificate program and space information to stay below trigger quantities
- Biosafety certificate special conditions
- HR and security clearance HR, job description etc.

<table>
<thead>
<tr>
<th>Toxin</th>
<th>Trigger Quantity (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha toxin</td>
<td>5</td>
</tr>
<tr>
<td>Botulinum neurotoxin</td>
<td>0.5</td>
</tr>
<tr>
<td>Cholera toxin</td>
<td>20</td>
</tr>
<tr>
<td><em>Clostridium botulinum</em> C2 and C3 toxins</td>
<td>5</td>
</tr>
<tr>
<td><em>Clostridium perfringens</em> Epsilon toxin</td>
<td>5</td>
</tr>
<tr>
<td>Hemolysin</td>
<td>10</td>
</tr>
<tr>
<td>Shiga-like toxin (verotoxin)</td>
<td>1</td>
</tr>
<tr>
<td>Shigatoxin</td>
<td>1</td>
</tr>
<tr>
<td>Staphylococcal enterotoxins, Type B (SEB)</td>
<td>1</td>
</tr>
<tr>
<td>Staphylococcal enterotoxins, types other than Type B</td>
<td>10</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em> Toxic shock syndrome toxin</td>
<td>5</td>
</tr>
</tbody>
</table>
Biosecurity

- New term!
- Overarching risk assessment
- Reassessment of large open concept labs and containment zones
- Locking closing doors – blitz campaign
- Change in behavior

Medical Surveillance

- As determined by risk assessment and as may be required by UHN Research Biosafety Certificate
- OH&S provides medical expertise
- Update to OHS onboarding
- OHS resource issue
Training

Canadian Biosafety Standard Training Requirements:

- Biosafety Manual
- Standard Operating Procedures
- Demonstrate knowledge and proficiency*
- Hazards-symptoms of disease/precautions
- Containment zone/systems*
- Use and operation of primary containment devices
Canadian Biosafety Standard Training Requirements: 
*Continued:*

- Use of restraints for animal work
- Visitors, maintenance, janitorial staff, contractors
- Refresher Training-annual for emergency response*
  - Labs to review internal ERP, new eLearning launched
UHN Program Active Elements

1. Management Commitment
2. Identification of Biosafety and Biosecurity Risk
3. Assessment of Biosafety and Biosecurity Risk
4. Management & Control of Biosafety and Biosecurity Risk
5. Communication Plan
6. Plan Review and Monitoring
Questions?