

NBACC Risk Assessments: Process and Product

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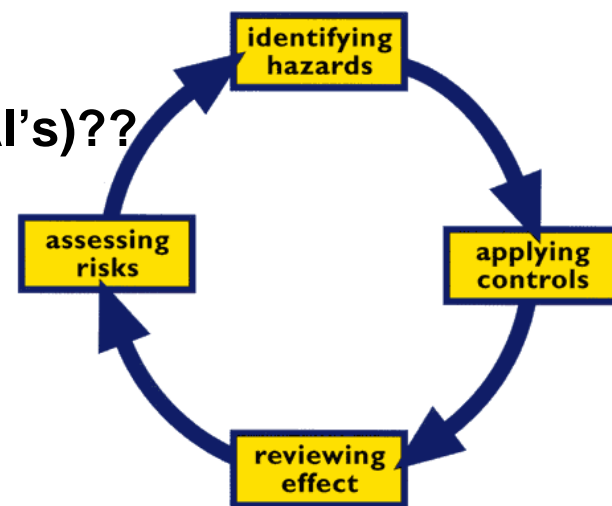
Orlando, FL

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Risk Assessment

- An estimate of the likelihood of adverse effects that may result from exposure to certain health hazards
- Biological risk assessment takes into consideration:
 - Agent characteristics – risk group, infectious dose, severity of disease, route of exposure?
 - Any chemical, radiological or physical hazards?
 - Any hazards associated with the equipment or process?
 - Vaccination and/or prophylaxis? Treatment available?
 - Animal work? Zoonoses?
 - Host status factors?
 - Known Laboratory Acquired Infections (LAI's)??
 - Lots more!!!
- Constant process – re-evaluation, re-assessment, implementation = management and improvement



NBACC – An Introduction



- **National Biodefense Analysis and Countermeasures Center – Ft. Detrick, Frederick, MD**
 - **NBFAC - conducts and facilitates technical forensic analysis and interpretation of material recovered from biocrimes and biological attacks in support of the appropriate lead federal agency**
 - **NBTCC – research to fill in information gaps to better understand current and future biological threats, assess vulnerabilities and conduct risk assessments and determine potential impacts to guide the development of countermeasures such as detectors, drugs, vaccines, and decontamination technologies**

NBACC – An Introduction

- **BSL-4, BSL-3, BSL-2 laboratories (Including ABSL-2, ABSL-3 and ABSL-4)**
- **Employs ~150 employees, about 100 work in laboratories**
- **NBACC Health and Safety Office**
 - Health and Safety Manager/Biosafety Officer
 - Biosafety/Biosecurity Specialist (x2)
 - Biosecurity Manager/Responsible Official



NBACC Risk Assessment Process



- **Has evolved with the organization and its needs**
- **Started as an informal process**
- **As NBACC grew, we learned from previous experiences and improved the quality of the individual Risk Assessments**
- **Quickly realized a standard process and standard product was needed**
 - **Multiple PI's and Project Leads, multiple projects, many employees who needed access to the information contained within a Risk Assessment**
- **Also needed method to track and modify assessments over time**

NBACC Risk Assessment Process



- **Begins with conversation between Project Lead and NBACC Health and Safety**
- **Collaborative**
 - **Multiple disciplines**
 - **Project Leads, Collaborators and SME's, Research Staff, Laboratory Space Manager, Comparative Medicine, Facilities and Maintenance, Health and Safety Office, Biosecurity, Special Immunizations Program Committee, NBACC Safety Committee**
- **Based on the work to be performed in the near term**
- **Time to completion varies**
- **Flexible**
- **Approval signatures required before work can be started**

NBACC Risk Assessment

- **Template was developed**
 - **Simple Microsoft Word document**
 - **Flexible**
 - **Multi-purpose**

NBACC Bio safety and Biosecurity Risk Assessment
24 October 2012
RA# ABSA-001



Project ABSA-001
Genomic Characterization of *N. meningitidis* Clinical Samples
NBACC Rooms 101, 102 and 103
RA# ABSA-001

BACKGROUND INFORMATION

Project ABSA-001 involves the genomic characterization of multiple clinical strains of *Neisseria meningitidis* using various in-house sequencing methods. Multiple platforms will be compared for speed, ease-of-use and accuracy, in an effort to develop methods for the routine genomic typing of clinical sample as a method for approaching diagnosis and treatment.

AGENTS USED

Neisseria meningitidis, often referred to as meningococcus, is a bacterium that can cause meningitis and other forms of meningococcal disease such as meningococemia, a life threatening sepsis. *N. meningitidis* is a major cause of morbidity and mortality during childhood in industrialized countries and has been responsible for epidemics in Africa and in Asia. Upon approximately 2500 to 3500 cases of *N. meningitidis* infection occur annually in the United States, with a case rate of about 1 in 100,000. Children younger than 5 years are at greatest risk, followed by teenagers of high school age. Rates in sub-Saharan Africa can be as high as 1 in 1000 to 1 in 100 (1).

Persons with confirmed *N. meningitidis* infection should be hospitalized immediately for treatment with antibiotics. Third-generation cephalosporin antibiotics (i.e. cefotaxime, ceftriaxone) should be used to treat a suspected or culture-proven meningococcal infection before antibiotic susceptibility results are available.

LABORATORY ACQUIRED INFECTIONS

Laboratory acquired infections caused by *N. meningitidis* including recent fatalities (2000, 2012), have been well reported in the literature (2). Prompt reporting of any illness is imperative for any researcher working with this agent, as early medical intervention is critical to survival and recovery.


VACCINES

On October 27, 2010, the Advisory Committee on Immunization Practices (ACIP) approved updated recommendations for the use of quadrivalent (serogroups A, C, Y, and W-135) meningococcal conjugate vaccines (Menveo, Novartis; and Menactra, Sanofi Pasteur) in adolescents and persons at high risk for meningococcal disease. Information about who should receive the meningococcal vaccine is available from the Centers for Disease Control and Prevention (CDC).

- **Standard Sections**
 - **Title**
 - **Unique Identifier**
 - **Research Project Number**
 - **Location of Work**
 - **Introduction and/or Background Information**
 - **Agents Used**
 - **LAI's**
 - **Vaccination Information**
 - **SOP's**
 - **Disinfection/Decontamination**
 - **PPE Requirements**
 - **BSAT Considerations**
 - **Recommended Engineering and Administrative Controls**
 - **Residual Risk**
 - **References**
 - **Signature Block**

Standard Sections in Template

NBACC Biosafety and Biosecurity Risk Assessment
24 October 2012
RA# ABSA-001



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NBACC Rooms 101, 102 and 103
RA# ABSA-001

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Standard Sections in Template

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Based on the available information, the NBACC Special Immunizations Program Committee has recommended meningococcal vaccination for all individuals at NBACC routinely working with *N. meningitidis* (3).

Standard Sections in Template

RESEARCH SPECIFIC STANDARD OPERATING PROCEDURES

NOTE: All applicable Biosafety and Biosecurity SOP's shall be followed.

- SOP-020 Pipetting Devices: Operation and Maintenance
- SOP-021 NBACC Centrifuge Operation and Maintenance
- SOP-030 Genome Sequencer: Operation and Maintenance
- SOP-032 Nanodrop Operation and Maintenance
- SOP-044 DNA Sequence Analysis

DISINFECTION/DECONTAMINATION

Chemical Inactivation

- Chemical disinfection of laboratory waste materials (i.e. media waste) will be accomplished with a 1:10 dilution of bleach per NBACC **SOP-010, Disinfectants and Decontamination**.
- Laboratory surfaces such as bench tops and equipment surfaces will be cleaned with an appropriate disinfectant (i.e. 1:10 dilution of bleach, Bleach-Rite, Hype-Wipes, followed by 70% isopropanol).

Physical Inactivation

- Inactivation by autoclaving at 121°C for 30 minutes, per NBACC **SOP-011, Autoclave Operation and Maintenance**.

Standard Sections in Template

RESEARCH DESIGN AND RECOMMENDED ENGINEERING AND ADMINISTRATIVE CONTROLS

BMBL 5th Edition Recommendations

BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment (4).

NBACC Recommendations

Samples from Risk Group 2 agents or those originating from other BSL-2 laboratories manipulated on this project are not required to be sterility tested or inactivated by a NBACC verified method. As such, they cannot be expected to be free from all infectious agents. Standard BSL-2 practices and containment are recommended.

Additional Comments:

- 1) Access to the laboratory is restricted to authorized personnel only. The laboratory door shall be posted with a placard specifying the entry requirements and the agents handled in the laboratory.
- 2) Use of secondary containment (unbreakable biological transport carrier) shall be used when transporting infectious materials (i.e. preps/cultures) within the laboratory.
- 3) No intentional aerosols shall be generated; no animal work will be conducted.

Standard Sections in Template

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Work in Rooms 101, 102 and 103 will require:

- 1) Disposable Lab Coat
- 2) Safety glasses
- 3) Gloves (latex, nitrile)

BSAT

Not applicable. No genomic materials categorized as subject to the BSAT regulations will be utilized on this project (5).

REFERENCE LIST

- (1) Chapter 8: Meningococcal Disease. Manual for the Surveillance of Vaccine-Preventable Diseases. 5th ed. 2011.
- (2) Laboratory-Acquired Meningococcal Disease --- United States, 2000. MMWR. 51(07);141-42012.
- (3) NBACC Memorandum for the Record, 20 July 2012. Vaccination Risk Assessment for Project ABSA-001.
- (4) Biosafety in Microbiological and Biomedical Laboratories (BMBL), CDC/NIH Fifth Edition, Feb 2009. <http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>
- (5) National Select Agent Registry. Applicability of the Select Agent Regulations to Issues of Synthetic Genomics. <http://www.selectagents.gov/SyntheticGenomics.html>.

Standard Sections in Template

Summary Hazard Assessment

This project may require the execution of tasks with potential for CRITICAL injury or illness. Molecular extractions from clinical samples are utilized in this research, but sterility testing will not be a requirement for acceptance of materials into this laboratory. Still, the probability of live agent being present and an exposure event occurring is considered to be UNLIKELY. The likelihood of any injury is reduced due to training and enhanced practices and procedures (sharps reduction, proper waste disposal, etc), adherence to SOP's, and proper PPE usage. Therefore, the work proposed for this research is considered a LOW risk after mitigating measures are applied.

Risk Assessment Matrix					
Probability of the Event Occurring					
Severity of the Outcome	Frequent	Likely	Occasional	Seldom	Unlikely
Catastrophic	Extremely High	Extremely High	High	High	Moderate
Critical	Extremely High	High	High	Moderate	Low
Marginal	High	Moderate	Moderate	Low	Low
Negligible	Moderate	Low	Low	Low	Low

Standard Sections in Template

- **Signature Page**

As the Project Lead for this project, I assure the information contained in this risk assessment is accurate to the best of my knowledge, and understand my responsibilities regarding notifying NBACC Health and Safety Office of any modifications or additions to the scope of this project prior to initiation. I also assume responsibility for the adequate training of all personnel associated with this project, and will ensure that all personnel assigned to this project have read and understand this risk assessment before starting work.

NBACC Project Lead

Date

- **Additional signatures of approval**
- **Can be signed digitally**

Risk Assessment Management



- **Modifications to Approved Risk Assessment**
 - Change in process, location and/or agent
 - Memorandum for the Record with signatures
 - May require full review by immunizations committee
 - Occasional email approval (mostly for very minor changes or clarifications), with email becoming part of the Risk Assessment file

- **Post-Approval Monitoring**
 - Health and Safety team member observes laboratory staff performing work, and cross-checks with approved agents and activities in approved assessments
 - Interviews with staff:
 - “Have you read the RA for this project?”
 - “Which SOP are you following?”
 - “Do you have any concerns? Is anything missing from the RA?”

Risk Assessment Management



- **Review of Approved Risk Assessments**
 - Annually, as the next year's projects are planned and implemented
 - Following any accident or incident

- **Retire RA's No Longer Needed**

- **Continuous Process of Improvement**
 - Respond to feedback from PI's, laboratory staff and inspectors
 - Streamline the process from inception to product
 - Merge information gained through risk assessment process with project management



This Document was prepared for the Department of Homeland Security (DHS) by the Battelle National Biodefense Institute, LLC (BNBI) as part of contract HSHQDC-07-C-00020 to manage and operate the National Biodefense Analysis and Countermeasures Center (NBACC), a Federally Funded Research and Development Center. In no event shall the DHS, BNBI or NBACC have any responsibility or liability for any use, misuse, inability to use, or reliance upon the information contained herein. **In addition, no warranty of fitness for a particular purpose, merchantability, accuracy or adequacy is provided regarding the contents of this document.**