

# **BIOTERRORISM & EMERGING PATHOGENS UNIT**



## **2010 Annual Report**

NC State Laboratory of Public Health  
NC Regional Response Laboratory - Buncombe County  
NC Regional Response Laboratory – Mecklenburg County  
NC Regional Response Laboratory - Pitt County

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## **Annual Report Purpose Statement**

The purpose of this report is to communicate the major activities of the Bioterrorism & Emerging Pathogens (BTEP) Unit to Laboratory, Epidemiology Section, and Division of Public Health leadership, as well as to key partners and customers for which the information could be beneficial.

## **Organizational Structure**

The BTEP unit was formed as an independent laboratory administrative unit in 2004. Full time staff include six employees located in the NC State Laboratory of Public Health (NCSLPH) in Raleigh including the Business Services Coordinator, Laboratory Improvement Consultant, Laboratory Medical Specialist, Medical Laboratory Supervisor IV, Medical Laboratory Technologist II, and Public Health Scientist. Each of the three NC Regional Response Laboratories (NCRRLs) maintains two full time staff including a Laboratory Medical Specialist, who functions as the laboratory lead, and a Medical Laboratory Technologist II.

## **Strategic Planning**

Two BTEP team meetings were convened in 2010 (Feb & Aug). Both focused extensively on team development and were attended by all BTEP unit staff as well as, NCSLPH and NCRRLs Laboratory Directors. February's meeting initiated the strategic planning process while the August meeting produced a framework for the BTEP Quality Improvement Initiative (QII) to be implemented in 2011.

## **SWOT Analysis**

An internal analysis of the BTEP unit's strengths, weaknesses, opportunities, and threats (SWOT) was conducted in the February team meeting. After the internal analysis was performed, a survey was sent to 35 partners and stakeholders, 29 of whom responded with information to serve as the external SWOT analysis.

## **BTEP Strategic Plan**

The 5 strategic goals were developed at the February BTEP team meeting:

- **Sustain readiness through laboratory operations, emergency drills, and 24/7 capacity**
- **Assure that BTEP has the infrastructure and resources to accomplish its mission**
- **Maintain a technically competent staff through required participation in a structured training program**
- **Meet regulatory compliance by achieving required laboratory certifications**
- **Strengthen the bond between the BTEP Unit and its partners by exercising and improving upon an established outreach program**

These goals and the results of the SWOT analyses served as a foundation for the BTEP Strategic Plan, which can be found in its entirety at:

<http://slph.ncpublichealth.com/bioterrorism/>

## Quality Improvement Initiatives

The August BTEP meeting produced the framework for Quality Improvement Initiatives (QIIs) that support the strategic goals developed in the February Meeting. The QIIs and results will be described in the 2011 Annual Report.

## Laboratory Operations

The BTEP unit runs on a regular 1<sup>st</sup> shift operation. One rotating team member operates and answers the 'Duty Phone' which is maintained 24/7/365. The unit also maintains a call log to document important situations (samples, exercises, critical information) to which we respond. The unit fielded 154 calls or 'situations' necessitating documentation in 2010. The BTEP unit performed 362 assays on 87 ~~429~~ specimens during calendar year 2010. The sample break-down is as follows:

<u>Sample Types:</u>	<u>Totals:</u>
Environmental Threat (White Powder type) Samples:_____	<b>6</b>
<i>Bacillus anthracis</i> :_____	<b>17</b>
<i>Brucella</i> species:_____	<b>13</b> (4 positives)
<i>Francisella tularensis</i> :_____	<b>6</b> (3 positives)
<i>Burkholderia mallei/pseudomallei</i> :_____	<b>5</b>
Influenza (Novel H1N1):_____	<b>33</b>
Vaccinia Virus:_____	<b>7</b> (4 positives)

The year 2010 began with the continuation of the major investigation of a laboratory acquired brucellosis case in the state that was discovered in December 2009. *Brucella* testing requests increased more than 2 fold (6 in 2009 vs. 13 in 2010). Of the 13 clinical specimens analyzed for *Brucella*, 31% were positive. These four isolates caused 39 laboratorians from four different community facilities to be exposed to the *Brucella* bacterium. BTEP, working with the Medical Consultation Unit of the Communicable Disease Branch of the Epidemiology Section, also investigated a *Francisella tularensis* exposure involving four laboratorians in a separate facility.

Testing capacity for H1N1 was removed from regular NCRRL operations on May 1, 2010. This decision was based on the amount of test requests and utilization of laboratory resources required to maintain testing capacity. A total of 33 influenza specimens were tested in BTEP RRLs from January 1 to the conclusion of flu testing in NC RRLs. Currently, all influenza testing is performed in the Virology/Serology section of the NCSLPH.

To ensure the ability to retrieve samples in a public health emergency situation, the BTEP unit maintains accounts with multiple private medical emergency couriers located in the cities of Raleigh, Charlotte, Greenville, and Asheville. Many specimens tested by the BTEP unit are deemed 'non-critical' and can await testing until the next business day. These samples are shipped via FedEx. Also, healthcare maintained (i.e. hospital) couriers are utilized at times by the submitting institution. Special couriers were utilized 19 times in calendar year 2010.

## **24/7/365 Response**

To measure and ultimately improve the initiation of BTEP response, a drill was developed by team members prior to the development of QIIs. The “Duty Phone Drill” consists of calls that are made outside normal business hours with the expectation that >95% are answered within 15 minutes and at least 80% are answered immediately. The 2010 results are as follows:

Total Calls made:	<b>49</b>
Calls Answered immediately:	<b>43 (88%)</b>
Calls Answered within 15 minutes:	<b>47 (96%)</b>
Calls Answered after 15 minutes:	<b>2 (4%)</b>

## **Infrastructure & Resources** **for Mission Success**

### **Funding**

The BTEP unit is funded exclusively through the CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement. Three agreement addenda for the NCRRLs are established to fund the relationship between the state of North Carolina and Buncombe, Mecklenburg and Pitt counties. The grant year covering the majority of calendar year 2010 began August 10, 2009 and ended on August 9, 2010. The remainder of the calendar year was covered by grant year designation EN starting August 10, 2010 and ending on August 9, 2011. The PHEP funds all staff salaries/fringe/overhead, staff travel, supplies (scientific and office), equipment, contracts, and unique items such as telecommunication equipment. The BTEP unit funding totals for the two budget periods represented in calendar year 2010 were similar, as shown below:

### **2009-10 Funding**

**\$1,294,888**

### **2010-2011 Funding**

**\$1,295,456**

### **Staff Stability**

Our overall staffing level for 2010 was 94% which takes into account the time a position is vacant due to vacancy or leave of absence. The unit has been fortunate this year to have no staff turnover (0%). This represents greater stability in the team as the previous rates were higher at 50% in 2008 and 8% in 2009.

## **Staff Training** **&** **Development**

Besides regular technical training given and received in the unit, the major BTEP training events include team members from NCRRL-Mecklenburg and BTEP Raleigh attending separate CDC sponsored 'Conventional Methods' courses for high consequence pathogens. The Laboratory Medical Specialist in Raleigh attended the joint CDC/USAMRIID 'Rapid Methods' course for the same agents.

### **Publications & Abstracts**

2010 represented the BTEP unit's most prolific year for abstract submittals and presentations at national and international meetings.

#### **Biothreat Agent Workshop, March 2010, Charlotte, NC**

- Bioterrorism and Emerging Pathogens Unit (BTEP) – Service to North Carolina  
-Justin Edwards, poster presentation

#### **International Conference on Emerging Infectious Diseases, July 2010, Atlanta, GA**

- An Investigation of Sequential Exposures to *Brucella* in Three Laboratories and Post Exposure Prophylaxis Failure - Florida and North Carolina, 2009  
-Royden Saah, poster presentation

#### **National Laboratory Response Network Meeting, October 2010, San Diego, CA**

- A Transition from LightCycler 1.2 to ABI 7500 Fast DX for *Francisella tularensis*  
-Jason McMillan, poster presentation
- Tularemia in Eastern North Carolina  
-Barbie Page, poster presentation
- *Brucella* Safety in Sentinel Laboratories: Multi-State Laboratory Exposures and Illness  
- Royden Saah, oral presentation, Best Meeting Abstract
- CAP Laboratory Preparedness Exercise (LPX-A) 2009 Sample Submission to the North Carolina State Laboratory of Public Health Bioterrorism Unit  
-La'Vonda Benbow, poster presentation
- Discussions of What Works and What Doesn't: Select Agent Program Security Drills  
- Royden Saah, oral presentation.

#### **Acknowledgments in Peer Reviewed/Professional Publications**

- Jason McMillan, La'Vonda Benbow and Brenda Mickens were acknowledged:  
"Ocular Vaccinia: A Consequence of Unrecognized Contact Transmission" Military Medicine, 176, 6:699, 2011 for work conducted in 2010.

## **Compliance Activities**

Each of the four BTEP facilities maintains their own CLIA and Select Agent Program certificates. Although no regulatory inspections occurred in 2010, all laboratories contracted independent inspectors to evaluate our biological containment facilities, equipment, procedures and processes.

### **External Proficiency Testing**

BTEP participates in private water, LRN, and CAP proficiency tests (PTs) to maintain EPA/NELAC drinking water certification, LRN membership, and CLIA certifications respectively. With the exception of the extra drinking water certification maintained by the NCRRL-Pitt Co., the BTEP unit maintains the same memberships and certifications. In the case of CLIA, the unit maintains four different certificates. As such, the four BTEP facilities are tested independently in the associated PT programs. These established and regulated proficiency testing programs provide, in part, measureable results of the team's training and capabilities.

The following represents the cumulative proficiency tests and samples sent to the BTEP unit in 2010:

<b>Type of PT</b>	<b># of PTs</b>	<b># Total Samples</b>
<b>CAP Gram Stain</b>	<b>9</b>	<b>45</b>
<b>LRN Environmental</b>	<b>6</b>	<b>30</b>
<b>LRN Clinical</b>	<b>7</b>	<b>35</b>
<b>Drinking Water</b>	<b>2</b>	<b>30</b>

All of the above BTEP proficiency tests were passed with a score of 100% with the exception of one PT being passed at 80% due to a missed gram stain result.

## **Strengthening Partnerships**

### **Outreach**

The BTEP unit conducts formal outreach to 'sentinel' laboratories testing clinical specimens for microbiological organisms. The stated goal of this activity is to promote the ability to recognize, rule-out, and refer suspected biological agents such as *B. anthracis* and *Y. pestis* to an LRN reference laboratory. A major activity in this area includes hands-on workshops for clinical laboratorians held at the NCSLPH. These didactic laboratory workshops teach attendees how to recognize, safely handle, and refer to the NCSLPH any organisms of concern. Two workshops were held in 2010 with a total of 19 participants from 16 facilities. The other major effort of BTEP outreach are staff visits to sentinel laboratories. BTEP staff conducted on-site visits to 43 sentinel laboratories in NC with the intent to assist our partners developing and adhering to an internal bioterrorism plan.

## Partnerships

The NCSLPH strives to maintain strong and collaborative associations with governmental partners as well as client organizations. The BTEP unit assists with this effort by several means, most notably by maintaining the ‘Micronet’ listserv that allows email notifications to be sent to sentinel laboratory partners. The listserv is used for regular updates, such as the weekly NC Influenza Surveillance Update, and emergency notifications when necessary. This mechanism was extensively used in the 2009 Novel Influenza Outbreak.

Another manner in which the BTEP unit connects with partners is via the NC Laboratory Response Forum. The BTEP unit organized this body in 2006 with a stated goal to “bring together Lab Directors/Public Health Officials concerned with critical emerging issues and problems facing the clinical microbiological laboratory especially as it relates to public health”. Membership is centered on the hospital based Public Health Epidemiology program. The topics and details of the 2010 NC Laboratory Response Forums are as follows:

Date	Topics	Attendees	Survey*
Jan	Tuberculosis, Novel Influenza Testing, Outbreak Updates, Health Care Associated Infections (HAI) Advisory Committee	35	**
Apr	Syphilis/HIV Co-infection & Outbreak Update, Recommendations for Diagnosis of Shiga Toxin Producing <i>E. coli</i> , Outbreak Updates, HAI Advisory Committee Update and Discussion	36	4.7
Sept	Chemical Terrorism, HAI Advisory Committee, Carbapenemase-Producing <i>Enterobacteriaceae</i> , CT/GC Testing of ‘Low Positives’ Using NAATS, <i>Brucella</i> Exposures at the NC State Laboratory of Public Health, BTEP Outreach and CAP LPX, Outbreak Updates, MMWR Recommendations	24	4.6

\*Survey Averages based on the Likert Scale. 5=Strongly Satisfied 1=Strongly Dissatisfied.

\*Ten questions regarding the meetings’ productivity were asked. Facility questions are not represented.

\*\* NC Laboratory Response Forum evaluation surveys began with the April 2010 survey.

Other contributions made toward strong partnerships include BTEP members serving on several extracurricular committees including APHL Emergency Preparedness and Response Committee and the NC State University Institutional Biosafety Committee.

## Goals for 2011

- **January:** Implementation of BTEP developed Quality Improvement Initiatives
- **January:** Introduce the BTEP Unit to the new FBI Weapons of Mass Destruction Coordinator for North Carolina
- **May:** Conduct Homeland Security Exercise and Evaluation Program (HSEEP) functional exercise to test BTEP environmental and clinical surge capacity
- **June to August:** Monitor CDC funding situation and minimize impact to customers of any funding decreases
- **July:** Conduct collaborative CDC study for unification of multiple nucleic acid extraction platforms associated with environmental sample
- **August:** Understand and adhere to the new Public Health Emergency Preparedness Cooperative Agreement and associated performance measures
- **December:** Increase capacity in team for antimicrobial sensitivity analyses
- **December:** Convene 3 in person team meetings for strategic and operational planning purposes
- **December:** Convene 3 Laboratory Response Forum meetings permitting the creation and dissemination of *Brucella* Laboratory Exposure Response Recommendations and Healthcare Acquired Infection planning for clinical laboratories
- **December:** Develop increase performance standards specific to the molecular assays performed in BTEP
- **December:** Maintain the 2010 levels of response for Duty Phone Drills (see p.6)
- **December:** Preparation and completion of 'move plan' for the new NCSLPH with a scheduled completion date of Spring/Summer 2012

## **Abbreviations:**

<b>APHL</b>	Association of Public Health Laboratories
<b>BTEP</b>	Bioterrorism and Emerging Pathogens Unit (NCSLPH)
<b>CAP</b>	College of American Pathologists
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CLIA</b>	Clinical Laboratory Improvement Amendments
<b>EPA/NELAC</b>	US Environmental Protection Agency/National Environmental Laboratory Accreditation Conference
<b>FBI</b>	Federal Bureau of Investigation
<b>HSEEP</b>	Homeland Security Exercise and Evaluation Program
<b>LRN</b>	Laboratory Response Network
<b>NCRRL</b>	NC Regional Response Laboratory (BTEP Unit)
<b>NCSLPH</b>	NC State Laboratory of Public Health
<b>PHEP</b>	Public Health Emergency Preparedness Cooperative Agreement
<b>PT</b>	Proficiency Test
<b>QII</b>	Quality Improvement Initiative
<b>SWOT</b>	Strength, Weakness, Opportunity, and Threat Analysis
<b>USAMRIID</b>	US Army Medical Research Institute of Infectious Diseases