BIOSAFETY PRACTICES AND NEEDS IN CLINICAL LABORATORIES SURVEY

SUMMARY DATA REPORT

FEBRUARY 2019

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

Introduction

In June 2018, APHL launched the Biosafety Practices and Needs in Clinical Laboratories Survey to comprehensively assess biosafety practices and needs in sentinel clinical laboratories as well as laboratories in facilities that were identified as Ebola Treatment Centers (ETCs) and Ebola Assessment Hospitals (EAHs) across the United States. Via this survey, APHL collected information from the Clinical Laboratory Improvements Amendments (CLIA) laboratory director on (1) institutional biosafety practices; (2) linkages with public health laboratories and (3) unmet biosafety needs.

Based on information from state and large local public health laboratories, APHL estimates that there are approximately 5,000 laboratories that meet the definition of a sentinel clinical laboratory. Thus the target audience for this survey was approximately 5,000 laboratories. Of this target number, 489 laboratories responded during the data collection period of June 2018 to September 2018.

For questions pertaining to the survey and this summary data report, please contact APHL Public Health Preparedness and Response Staff at biosafety@aphl.org.

Table 1: Survey Completion by State

State	% of Respondents	Number of Respondents (n)
Georgia	11.0%	54
New York	11.0%	54
Texas	8.6%	42
North Carolina	5.9%	29
Massachusetts	4.9%	24
Minnesota	4.9%	24
Tennessee	4.1%	20
Arkansas	3.7%	18
Iowa	3.5%	17
Ohio	3.3%	16
Florida	2.7%	13
Maryland	2.7%	13
Idaho	2.0%	10
Indiana	2.0%	10
New Hampshire	2.0%	10
Oregon	2.0%	10
South Carolina	2.0%	10
California	1.8%	9
Mississippi	1.8%	9
Pennsylvania	1.8%	9
Wisconsin	1.8%	9
Virginia	1.4%	7
Louisiana	1.2%	6
New Jersey	1.2%	6
Rhode Island	1.2%	6
Connecticut	1.0%	5

State	% of Respondents	Number of Respondents (n)
Oklahoma	1.0%	5
South Dakota	1.0%	5
West Virginia	1.0%	5
Guam	1.0%	5
District of Columbia	0.6%	3
Missouri	0.6%	3
Vermont	0.6%	3
Wyoming	0.6%	3
Delaware	0.4%	2
Hawaii	0.4%	2
Illinois	0.4%	2
Montana	0.4%	2
North Dakota	0.4%	2
Alaska	0.2%	1
Alabama	0.2%	1
Colorado	0.2%	1
Kentucky	0.2%	1
Michigan	0.2%	1
Nebraska	0.2%	1
New Mexico	0.2%	1
Total	**100%**	**489**

Demographics

1. Is your laboratory a sentinel clinical laboratory?

Answer	%	n
Yes	76.9%	376
No	23.1%	113

2. Please identify whether your institution is an Ebola Treatment Center or Assessment Hospital. *Please check all that apply*.

Answer	%	n
Neither	67.5%	330
Ebola Assessment Hospital (EAH)	30.1%	147
Ebola Treatment Center (ETC)	4.3%	21

3. How many staff in your facility are currently certified in safe packaging/shipping of International Air Transport Association (IATA) Division 6.2 Category A Infectious Substances?

n	Total	Average	Median	Min	Max
489	2,743	6	4	0	100

Range	%	n
0	9.2%	45
1-9	76.9%	376
10-24	11.2%	55
25-49	1.8%	9
50-74	0.4%	2
75-100	0.4%	2

4. Does your institution have a biosafety plan in place?

Answer	%	n
Yes	91.4%	447
No	8.6%	42

5. Over the last three years (May 2015 to May 2018), did your institution complete risk assessments?

Answer	%	n
Yes, completed at least one risk assessment for an identified infectious agent	37.4%	183
Yes, completed at least two risk assessments for identified infectious agents	19.0%	93
Yes - Other: please specify	10.6%	52
No	32.9%	161

The majority of responses for other risk assessments completed included annual risk assessments and general laboratory risk assessments. Other responses included utilizing risk assessments and evaluating risks when conducting the College of American Pathologists (CAP) Laboratory Preparedness Exercise (LPX). Individual responses are on file with APHL.

Personnel, Outreach and Training

6. Does your institution have staff who are responsible for biosafety? *Please select one response*.

Answer	%	n
Yes, at least one full time staff dedicated to biosafety across all institutional laboratories	18.6%	91
Yes, at least one full time staff dedicated to biosafety and multiple staff dedicated to biosafety across all institutional laboratories	10.8%	53
Yes, staff is part time and dedicated to biosafety across all institutional laboratories	5.3%	26
No full time staff dedicated to biosafety but responsibility is allocated to multiple staff across all institutional laboratories	54.4%	266
No	10.8%	53

7. How long has (have) the individual(s) been in this role at your laboratory?

Answer	%	n
Less than 1 year	7.1%	12
1-3 years	28.8%	49
3 to 5 years	15.9%	27
Greater than 5 years	48.2%	82

7a. What is the experience level of of the individual(s)? *Please check all that apply*.

Answer	%	n
Experience working in a clinical laboratory	74.1%	126
Intermediate Biosafety Professional (1 to 5 years working as a Biosafety Officer (BSO) in a laboratory setting)	18.2%	31
Experienced Biosafety Professional (i.e. more than 5 years working as a Biosafety Officer (BSO) in a laboratory setting)	15.9%	27
Other - please specify	9.4%	16
Experience working in a research or academic laboratory	7.1%	12
Biosafety specific education only (no previous experience working in a laboratory)	5.9%	10
Experience working in a public health laboratory performing analytical work	5.3%	9
Currently a Registered Biosafety Professional (RBP)	2.4%	4
Currently a Certified Biosafety Professional (CBSP)	0.6%	1

Other specified responses included working as a registered nurse and as an infection control specialist in hospitals. Other responses were unaware of the individuals experience level. Individual responses are on file with APHL.

8. Have you developed safety-specific competencies for laboratory staff?

Answer	%	n
Yes	84.9%	415
No - Please explain the reasons why you did not develop safety competencies	15.1%	74

The majority of specified responses were institutions incorporating them into their annual general competencies review followed by laboratories currently in the process of incorporating safety specific competencies. Other

responses included laboratories were unaware of safety specific competencies and not being able to develop them due to time constraints. Individual responses are on file with APHL.

8a. Are you aware of the following Competency Guidelines? *Check all that apply*.

Answer	%	n
CDC. Competency Guidelines for Public Health Laboratory Professionals. MMWR 2015; 60 (suppl):1-95	44.4%	217
CDC. Guidelines for Biosafety Laboratory Competency. MMWR 2011; 60(Suppl):1-28	55.2%	270
No	39.7%	194

9. Has your staff received training on the following topics?

Question	Yes		No	
	%	n	%	n
Sharps Hazard	99.6%	487	0.4%	2
Bloodborne Pathogens	99.4%	486	0.6%	3
Personal Protective Equipment (PPE)	99.2%	485	0.8%	4
Spill Prevention, Control, and Countermeasure	97.5%	477	2.5%	12
Chemical Hazards	95.9%	469	4.1%	20
Biological Safety Cabinets (BSCs) and other Engineering Controls	92.6%	453	7.4%	36
BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)	91.6%	448	8.4%	41
Regulated Waste Management	90.8%	444	9.2%	45
Emergency Management and Response	90.2%	441	9.8%	48
Continuous Quality Improvement (review, improvement, and implementation)	90.2%	441	9.8%	48
Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)	89.4%	437	10.6%	52
Decontamination	87.5%	428	12.5%	61
Biological Risk Assessment	69.3%	339	30.7%	150
Select Agent Regulations	67.1%	328	32.9%	161
Biosecurity Plan	64.6%	316	35.4%	173
BSL-3 safety practices	44.4%	217	55.6%	272
Safe Handling and Use of Cryogenic Liquids	30.5%	149	69.5%	340

Question	Additional Training Needed	
	%	n
Biosecurity Plan	16.2%	79
Select Agent Regulations	15.1%	74
Biological Risk Assessment	14.9%	73
Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)	12.9%	63
BSL-3 safety practices	11.7%	57
Continuous Quality Improvement (review, improvement, and implementation)	9.4%	46
BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)	7.8%	38

Question	Additional Training Needed	
	%	n
Emergency Management and Response	7.4&	36
Decontamination	7.2%	35
Regulated Waste Management	5.1%	25
Safe Handling and Use of Cryogenic Liquids	4.1%	20
Chemical Hazards	3.9%	19
Biological Safety Cabinets (BSCs) and other Engineering Controls	3.3%	16
Spill Prevention, Control, and Countermeasure	2.0%	10
Personal Protective Equipment (PPE)	1.0%	5
Sharps Hazard	0.6%	3
Bloodborne Pathogens	0.6%	3

9a. If public health laboratory training was available to you at no cost, would you choose the following areas/ topics?

Question	Yes		No	
	%	n	%	n
Biological Risk Assessment	89.8%	439	10.2%	50
Biosecurity Plan	87.1%	426	12.9%	63
Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)	84.9%	415	15.1%	74
BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)	80.8%	395	19.2%	94
Continuous Quality Improvement (review, improvement, and implementation)	76.5%	374	23.5%	115
Select Agent Regulations	76.3%	373	23.7%	116
Emergency Management and Response	75.3%	368	24.7%	121
Decontamination	67.5%	330	32.5%	159
BSL-3 safety practices	64.4%	315	35.6%	174
Biological Safety Cabinets (BSCs) and other Engineering Controls	63.8%	312	36.2%	177
Chemical Hazards	61.8%	302	38.2%	187
Regulated Waste Management	58.9%	288	41.1%	201
Spill Prevention, Control, and Countermeasure	57.5%	281	42.5%	208
Bloodborne Pathogens	57.3%	280	42.7%	209
Personal Protective Equipment (PPE)	50.5%	247	49.5%	242
Sharps Hazard	45.0%	220	55.0%	269
Safe Handling and Use of Cryogenic Liquids	36.2%	177	63.8%	312

9b. What training format(s) do you prefer?

Question	Online/Live Webinar		Online/Archived Webinar		Virtual Course		In-Person Classroom		Telephone (no web component)		Total
	%	n	%	n	%	n	%	n	%	n	
Biological Risk Assessment	41.5%	182	68.8%	302	37.4%	164	21.4%	94	0.7%	3	439
Biosecurity Plan	38.7%	165	66.0%	281	35.2%	150	23.5%	100	0.2%	1	426
Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)	33.7%	140	59.5%	247	33.0%	137	38.1%	158	0.2%	1	415
BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)	39.5%	156	71.1%	281	36.5%	144	21.5%	85	0.5%	2	395
Continuous Quality Improvement (review, improvement, and implementation)	39.0%	146	68.4%	256	34.8%	130	21.7%	81	0.8%	3	374
Select Agent Regulations	39.9%	149	70.5%	263	33.5%	125	20.4%	76	0.5%	2	373
Emergency Management and Response	41.8%	154	68.8%	253	32.6%	120	22.0%	81	0.8%	3	368
Decontamination	36.7%	121	68.8%	227	34.8%	115	18.2%	60	0.9%	3	330
BSL-3 safety practices	41.0%	129	66.0%	208	34.0%	107	23.5%	74	0.6%	2	315
Biological Safety Cabinets (BSCs) and other Engineering Controls	38.8%	121	71.5%	223	34.0%	106	14.4%	45	0.6%	2	312
Chemical Hazards	38.4%	116	70.2%	212	33.1%	100	14.2%	43	1.0%	3	302
Regulated Waste Management	38.2%	110	69.8%	201	35.1%	101	15.3%	44	0.7%	2	288
Spill Prevention, Control, and Countermeasure	36.7%	103	67.6%	190	37.4%	105	18.1%	51	0.7%	2	281
Bloodborne Pathogens	39.3%	110	71.4%	200	35.7%	100	17.5%	49	0.7%	2	280
Personal Protective Equipment (PPE)	36.4%	90	67.2%	166	36.0%	89	19.8%	49	0.4%	1	247
Sharps Hazard	36.4%	80	70.0%	154	35.5%	78	15.0%	33	1.4%	3	220
Safe Handling and Use of Cryogenic Liquids	37.3%	66	68.9%	122	32.8%	58	13.0%	23	1.7%	3	177

10. Based on the training and knowledge of your laboratory staff, do you believe they are prepared to respond to an emerging threat comparable to Ebola Virus Disease?

Answer	%	n
Yes	60.5%	296
No - Please provide a brief explanation as to why staff are not prepared to respond to an emerging threat	39.5%	193

Explanations included lack of specific knowledge and training on how to respond to an emerging threat, institutions not having the proper resources including facilities, equipment and staff necessary, and lack of documented laboratory procedures. Individual responses are on file with APHL.

11. What training materials do you use? *Please check all that apply*.

Answer	%	n
Public Health Laboratory provided	67.7%	331
Self-developed	63.0%	308
Purchased	32.5%	159
Other - please specify	16.6%	81

Other training materials described were CDC and CAP developed training materials and trainings offered through hospital and health care systems. Individual responses are on file with APHL.

12. What training mechanism(s) do you currently use? *Please check all that apply*.

Answer	%	n
In-Person/Classroom	65.6%	321
Online/Archived Webinar	58.1%	284
Online/Live Webinar	47.6%	233
Virtual Course	32.3%	158
Other - please specify	10.8%	53
Telephone (no web component)	4.5%	22

Other specified responses included hands-on drills, tabletop exercises and written procedures. Individual responses are on file with APHL.

13. How do you identify biosafety training needs? *Please check all that apply*.

Answer	%	n
Accreditation/Certification checklist	71.6%	350
Gap risk assessment	41.1%	201
None, do not evaluate	11.5%	56
Other - please specify	11.2%	55

Other specified responses included individual staff competency assessments, review of public health laboratory resources, institutional safety inspections and site visits by consultants and public health laboratory staff, and mock drills and exercises. Individual responses are on file with APHL.

14. Are you aware that there is a biosafety officer/resources available through your public health laboratory?

Answer	%	n
Yes	61.1%	299
No	38.9%	190

15. How does the public health laboratory biosafety officer or other staff interact with your institution? *Please check all that apply*.

Answer	%	n
Provides training on packaging and shipping of infectious substances (e.g. IATA Division 6.2 Category A Infectious Substances)	62.2%	186
Provides guidance on developing biosafety plans	48.2%	144
Provides guidance on completing institutional risk assessments	43.5%	130
Provides biosafety tools and other resources via email or other electronic platform	43.5%	130
Provides challenge sets to assess competency of clinical laboratories to rule out and/or refer biological threats [this can encompass the public health lab providing the challenge set or purchasing the challenge set for your institution (e.g. APHL, CDC and College of American Pathologists Laboratory Preparedness Exercise)]	34.1%	102
Provides guidance on biosafety practices, such as engineering controls (e.g. use of BSCs)	33.8%	101
Provides guidance on completing agent specific risk assessments	33.8%	101
Reviews and provides guidance on broad safety practices such as use of personal protective equipment, decontamination and disinfection practices, waste management and sharps hazards	31.1%	93
Provides guidance on developing biosecurity plans	30.8%	92
Conducts in-person site visits at least once per year	30.4%	91
Provides guidance on completing equipment based risk assessments	26.1%	78
Inspects the facility per state regulations	21.4%	64
Convenes meetings of sentinel and other clinical laboratories	16.7%	50
Convenes meetings of sentinel clinical laboratories	16.4%	49
Other - please specify	14.0%	42
Conducts in-person site visits more than once per year	3.0%	9

Other specified responses included routine communications via email, phone and/or newsletters along with providing other useful biosafety related resources. Some respondents noted that they were not sure how the public health laboratory staff interact with their institutions. Individual responses are on file with APHL.

16. How satisfied are you with the services and support provided by your public health laboratory biosafety officer?

Answer	%	n
Very satisfied	30.4%	91
Satisfied	50.2%	150
Somewhat satisfied	17.4%	52
Unsatisfied	1.3%	4
Very unsatisfied	0.7%	2

16a. Briefly describe your rating of the public health laboratory biosafety officer.

The majority rated their public health laboratory biosafety officer very highly, stating that these staff are very knowledgeable and communicate regularly, sending pertinent information on available trainings and available at all times for questions. Respondents saw the site visits provided by the biosafety officers as very useful. Some respondents stated that they have not directly interacted with their public health laboratory biosafety officer as of yet and would like more involvement and information from their biosafety officers. Individual responses are on file with APHL.

17. What are your needs of a public health laboratory biosafety officer?

Respondents noted that more guidance and communication around laboratory biosafety was needed, specifically relevant information and trainings. Some respondents stated that more in-person communications and visits across the laboratory would be helpful. Individual responses are on file with APHL.

18. Please briefly describe biosafety training needs for your facility and your plans to address those needs.

The majority of responses included training in the areas of packaging and shipping, risk assessments and proper personal protective equipment usage. Other responses included training needs in biosafety plans, biosafety competencies and regulatory requirements. Responses to address these needs included online and in-person courses available through public health laboratories, CDC and consultants. Individual responses are on file with APHL.

19. Does your institution support continuing education in biosafety? *Please check all that apply*.

Answer	%	n
Yes, provides funding for continuing education courses	29.7%	142
Yes, shares information on conferences and other continuing education courses	45.4%	217
Yes, provides onsite annual training in biosafety	37.9%	181
Yes, provides onsite biannual (every two years) training in biosafety	6.9%	33
No	16.1%	77

20. What top three conferences would you or your colleagues attend to strengthen your biosafety knowledge, skills and abilities?

The majority of responses included the American Society for Microbiology (ASM) Microbe, CDC International Biosafety Symposium and the American Biological Safety Association Annual Biosafety and Biosecurity Conference. Individual responses are on file with APHL.

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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