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Using the Results of Routine Laboratory Workplace Surveillance Activities to Assess Compliance with Recommended Biosafety Guidelines

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Abstract

Safety associated with the handling of potentially infectious agents has historically been achieved through adherence to recommended safety practices rather than through strict compliance with codified regulations. In the absence of a codified regulatory structure, there is also an absence of compliance inspections, so an objective assessment of the level of conformity with recommended biosafety practices is not generally available. In this study, the outcomes of 768 biosafety level 2 (BSL-2) safety surveys were analyzed for commonalities and trends. The data from a subset of 190 BSL-2 laboratories, which were subjected to sequential safety surveys, were examined for temporal changes and trends in compliance levels. The most frequent items of noncompliance encountered during the study time frame were the failure to recertify biosafety cabinetry, followed by ventilation not being negative to the hallway, disorderly general housekeeping, and lack of appropriate hazard communication labeling and postings. Not surprising, the bulk of noncompliance issues encountered were practice-related. Of greater interest was the finding that the five most frequently cited issues represented 68% of the total number of instances of noncompliance recorded during the study period. The findings described in this study are significant because, for the first time, the outcomes of compliance with recommended biosafety practices are characterized and can be used as the basis for focused interventions. Since biosafety is heavily reliant on adherence to specific safety practices, the ability to focus interventions on objectively identified practice-related items of noncompliance can assist in the reduction of worker risk in a field likely to experience tremendous growth in the wake of the 2001 terrorist attacks in the United States.

Introduction

Workplace-acquired infections have been reported in the literature since the early 1900s (CDC, 1999; Collins & Kennedy, 1999; Collins, 2000; Sewell 1995; Sulkin & Pike 1949, 1951). These reports suggested that the prevalence of potential exposure combined with the route of possible transmission were key risk factors in possible contraction of disease. To address the issue of workplace-acquired infections, the Centers for Disease Control (CDC) published the *Classification of Etiologic Agents on the Basis of Hazard* manual, which identified and classified infectious agents into groups based upon their pathogenicity and relative risk of infection in humans, and provided guidance on safe handling and disposal procedures (CDC, 1974).

After the issuance of the 1974 CDC manual, a gradual reduction in laboratory-acquired infections was observed in the United States during the next 10 years (CDC, 1985). Based on this success, the CDC and National Institutes of Health (NIH) collaborated during the 1980s to develop guidelines published as the document *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*) (CDC, 1993). This manual, created to provide recommendations on proper facility controls and safe practices to further decrease the risk of laboratory-acquired infections, has become the consensus standard for biosafety guidance. The *BMBL* quickly became an invaluable guidance document as codified regulations related to biosafety were essentially limited to issues regarding blood-borne pathogens, biological waste management practices, and tuberculosis exposure prevention (OSHA, 1992, 1996). However, this finite set of regulations does not adequately address the myriad of safety issues that are inherent in working with potentially infectious organisms. Only recently have regulations been promulgated regarding the safe handling of unique risks, such as select agents that are required to adhere to the *BMBL* under 42 CFR 73 (HHS, 2002). As this practice of regulation by reference to recommended practice continues, a need for an assessment of compliance becomes significant since these practices were not originally intended nor designed to be regulatory requirements.

To assess compliance with the recommendations of the *BMBL*, the results of an aggressive routine biosafety surveillance program were summarized and analyzed to ascertain if laboratories working with potentially infectious agents exhibited possible trends. The data used in this study stemmed from the routine workplace safety surveillance activities of The University of Texas Health Science Center at Houston (UTHSC-H) Environmental Health & Safety Biosafety Program from the period 1999 to 2000. If commonalities were shown to exist, this information could then be used as the basis for targeted interventions.

Methods

The data used in this study stemmed from the results of 768 laboratory surveys conducted within 578 UTHSC-H laboratories from August 1, 1999 to August 30, 2000, in which UTHSC-H employees or students conducted biomedical research with potentially infectious agents rated as biosafety level 2 (BSL-2). Within the 578 laboratories, a subset of 190 laboratories was surveyed twice in the 1 year period, 6 months apart, to determine workplace violation trends. These 380 laboratory surveys represented the source of sequentially paired data. The remaining 388 surveys stemmed from either newly designated BSL-2 laboratories or laboratories that were originally surveyed but discontinued their BSL-2 status before the next sequential survey was scheduled to occur. Laboratory settings included biomedical research facilities, student teaching laboratories, and clinical/diagnostic laboratories.

A standardized survey form was used to collect health and safety data from the laboratory population. Many of the general safety survey questions have been previously used in a study by Emery et al. to evaluate general safety during a routine radiation safety assessment (Emery et al., 1995). The survey questions for the general laboratory safety assessment were based on the instruments used in the National Occupational Exposure Survey revisited by the National Institute of Occupational Safety and Health (NIOSH) in 1999 (CDC, 1988). The biological safety form, developed by the UTHSC-H Environmental Health and Safety (EHS) department, used the *BMBL* as the basis for the biosafety-related issues. Recommendations from the fourth edition *BMBL* for BSL-2 laboratories were incorporated into the UTHSC-H EHS survey form in the format of "yes," "no," and "not applicable" answers. The survey form addressed all 27 of the recommendations in the *BMBL* for BSL-2 laboratories. Visual inspection of the survey form was performed for evaluation of readability and ease of completion.

The UTHSC-H EHS laboratory survey program is based on a pre-established routine schedule that includes provision for the avoidance of announced inspections. Unannounced inspections reduce the possibility of the laboratory personnel artificially preparing for the inspection, and ensure that routine operating procedures and protocols can be observed. The standardized survey form was used by trained safety specialists using observation techniques in or-

der to complete the items on the survey. Once the inspection was completed, the safety specialist performed error checks by visually inspecting the data forms for completeness.

The survey form consisted of 27 questions that addressed the biological safety environment within the facility. Each laboratory survey was assigned a random identifier number to facilitate data entry. All identifier numbers were kept confidential. The violation response for the surveys was coded to ensure confidentiality and continuity between the first and second survey.

Once data collection and data entry were complete, letters reflecting the results of each laboratory assessment were generated and mailed to the Principle Investigator. These letters were composed of a standard introduction and a list of the safety deficiencies found for each of the laboratories during the site assessment. If a violation was noted in the letter, a follow-up visit was scheduled 1 month later to ensure corrective action had been taken to correct said deficiency.

A number of variables were identified for data analysis. The variable "violation response" was used to categorize the types of violations. One variable assessed was the biosafety level of the violation from the laboratory surveyed. For this categorical variable, biosafety levels were classified into two distinct categories, BSL-1, BSL-2, and violations were analyzed for association according to the biosafety level for which the recommendation was classified. Twenty-two recommendations from the *BMBL* for laboratories classified BSL-1 (15) or BSL-2 (7) were paired with the UTHSC-H survey form questions. Practice-related elements were defined as laboratory work practices that were performed or controlled under the exclusive control of the laboratory worker within UTHSC-H. Facility-related elements were defined as any *BMBL* recommendation that was under the direct control of the UTHSC-H facilities operations component.

Descriptive statistics were used to enumerate the frequencies of recorded violations for all 768-laboratory surveys, and paired *t*-tests were used to compare the differences in observed violations from paired surveys. The number of violations for each individual laboratory was too small to allow for meaningful comparison within each laboratory.

A chi square (McNemar's test) analysis was performed on total aggregate violations, BSL-1/BSL-2 violations, and practice- and facility-related violations to test for association and symmetry with the paired survey sets. Ryan-Joiner normality tests were performed to test for normal distribution of each set of survey violations. Statistical significance was set at the α=0.05 level. All analyses were performed using Minitab, version 13.1.

Results

Of the 578 laboratories surveyed during the study, 428 were found to be in complete compliance with the *BMBL*, a 74% overall compliance rate. Of those noted as exhibiting noncompliance, 135 laboratories received one violation (23%), 14 received two violations (2%), and one laboratory received three violations (0.1%). Overall, 150 violations were recorded during the study period. The most frequent violation cited was the failure to ensure *Biosafety cabinet (BSC) certification within the past year* (31 total violations, 20.6%). A complete summary of the aggregate noncompliance data is shown in Table 1.

Fourteen *BMBL* BSL-1 recommendations were cited in 59 instances, which accounted for 39.3% of all violations. Ninety-one violations (61.7%) were cited under BSL-2 recommendations from the *BMBL* during the specified sampling frame. Overall, 123 (82%) violations were practice-related while 27 (18%) violations were facility-related. Table 2 summarizes the prevalence of practice/facility-related violations categorized according to *BMBL* BSL-1/BSL-2 recommendation.

The first set of paired surveys recorded 47 violations resulting in violations in 24.7% of all laboratories surveyed the first time. The most frequent violations during the first round of surveys were *Ventilation negative to hallway*, [13 (27.7%)]. Thirty violations were recorded during the second set resulting in a 22% decrease in violations from the first set. The most frequent violation recorded during the second set of surveys was *Biosafety cabinet* (BSC) *certification within the past year* [8 (26.7%)]. Table 3 summarizes the first and second set of survey data.

In comparing the paired surveys, some common-

alities were evident in the data. For instance, *Ventilation negative to the hallway* and *Biosafety cabinet (BSC) certification within the past year* were the most frequent violations in both survey sets. Additionally, the top five violations in both sets were identical, indicating recommendations *1) Cultures, stocks, and other regulated waste are disposed of appropriately, 2) General housekeeping orderly, and 3) Appropriate warning signs, names, and emergency numbers posted* accounted for 82.9% and 73.4% of the total violations recorded during the first and second survey set, respectively.

Paired *t*-test analyses demonstrated a significant difference in the number of workplace violations recorded in the paired surveys for both BSL-1 and BSL-2 recommendations. Significant differences in total violations were demonstrated in both facility-related and practice-related violations from first to second survey.

Discussion

Overall, the compliance of all laboratories included in this study was good. With 74% of all laboratories reporting complete compliance, it is evident that the implementation of the *BMBL* as a performance-based document aids compliance. Providing proper training for laboratory personnel and making them aware of recommended practices facilitate adherence to the recommendations. Additionally, the requirements for BSL-2 practices are not too stringent or difficult to adhere to or attain. Considering the violations noted, the finding that more practice-related violations were noted in both the aggregate and paired data is not surprising. The safety profession has recognized for years the importance of placing emphasis on engineering controls (MMWR, 2003). This emphasis stems from the premise that

Table 1

Biosafety Items of Noncompliance Recorded During 768 Laboratory Surveys at the UTHSC-H from August 1999 to August 2000 Using Recommendations from the CDC/NIH *BMBL* as Guidelines.

BMBL Recommendation	Total Number Violations	Violation Percent (of total violations)
Biosafety cabinet (BSC) certification within the past year	31	20.6
Ventilation in laboratory negative to the hallway	25	16.6
General housekeeping orderly	19	12.6
Appropriate warning signs, names, and emergency phone numbers listed	18	12.0
Eating, drinking, and smoking and nonrelated laboratory materials prohibited in laboratory	17	11.3
Cultures, stocks, and other regulated waste are disposed of appropriately	17	11.3
Outside of waste container to be decontaminated before transport	7	4.6
Appropriate decontamination solution, bleach, less than 1 month old	4	2.6
Policies for the safe handling of sharps instituted	3	2.0
Biohazard sign posted at entrance of laboratory displaying infectious agent	2	1.3
Decontamination solution ready for use	2	1.3
Hand washing facilities available and soap is present	2	1.3
Autoclave available for use	1	0.6
Biosafety procedures incorporated into standard operating procedures	1	0.6
Materials to be decontaminated are properly labeled	1	0.6

once installed, the controls are always present and effective. However, procedural controls rely on active worker involvement, which can be subject to variation. Since the profession of biosafety is a combination of facilities and practices, the findings of this study reinforce the notion of the variable implementation of safety practices and thus reiterate the value of retraining workers and conducting routine worksite surveillance.

The findings described in this study are particularly important given the provision in the *BMBL* for work in BSL-2+ situations (CDC, 1993). A study by Emery et al. (1997) examined laboratories nationwide to measure the prevalence of BSL-2+ practices and reported 23% of BSL-3 work in 1997 relied on the BSL-2+ practice. Of the facility-related violations recorded, the most prevalent violation throughout both aggregate and paired survey data was *Ventilation in laboratory negative to the hallway*. Older buildings used for laboratory work, similar to those at UTHSC-H, were not constructed with directional airflow into the laboratory in mind. However, with adequate controls, ventilation patterns can be adjusted to allow adequate exhaust from the laboratory to insure directional airflow. As evidenced by the reduction in *Ventilation in laboratory negative to the hallway* violations from the paired surveys, the need for proper facility monitoring and maintenance is integral to the success of workplace safety for persons operating in biomedical and research laboratories.

It is interesting to note the high number of aggregate violations for biosafety cabinet (BSC) annual certification. The lack of annual certifications could be due to a lack of awareness of the need for annual

Table 2

BMBL BSL-2 Recommendations Categorized by Biosafety Level and Elements of Recommendation Displaying a Breakdown of Workplace Noncompliance Recorded During 768 Laboratory Surveys at the UTHSC-H from August 1999 to August 2000.

	***BMBL* BSL-2 Recommendation Components** *(% violation of all survey violations)*	
	Basic BSL-1 Components	***Additional BSL-2 Components***
Practice-related recommendations	• No food, drink, nonlab materials in laboratory *(11.3%)* • Outside of transport container decontaminated before transport *(4.6%)* • Decontamination solution, in date *(2.6%)* • Appropriate sharps container in use *(2.0%)* • Decontamination solution, ready for use *(1.3%)* • Solid waste labeled correctly and disposed of appropriately *(0.6%)*	• BSC certified annually *(20.6%)* • Written laboratory procedures manual *(0.6%)*
Facility-related recommendations	• Facility constructed so general housekeeping orderly *(12.6%)* • Emergency information posted *(12.0%)* • Hand washing facilities readily available *(1.3%)*	• Ventilation negative to hallway *(16.6%)* • Biohazard/UV posting on door *(1.3%)* • Autoclave available for use *(0.6%)*

certification on the laboratory's behalf, or more commonly, a lack of economic means to recertify a BSC. Of note, a notice of violation for BSC annual certification did not state the BSC was not working, but rather that it was not certified. Future studies could be directed towards determining the correlation between BSC certification and actual proper functioning.

The significant difference in total violations recorded from the first to second survey was expected.

Table 3

Biosafety Items of Noncompliance Recorded During the First Set of 190 Paired Laboratory Surveys at the UTHSC-H from August 1999 to August 2000 Using Recommendations from the CDC/NIH *BMBL* as Guidelines.

	1st Survey	1st Survey	2nd Survey	2nd Survey
BMBL Recommendation	**Number of Violations**	**Violation Percent**	**Number of Violations**	**Violation Percent**
Ventilation in laboratory negative to the hallway	13	27.7	5	16.7
Biosafety cabinet (BSC) certification within the past year	10	21.2	8	26.7
Cultures, stocks, regulated waste are disposed of appropriately	6	12.8	4	13.3
General housekeeping orderly	5	10.6	3	10.0
Appropriate warning signs, names, and emergency phone numbers listed	5	10.6	2	6.7
Outside of waste container to be decontaminated before transport	3	6.4	0	0
Eating, drinking, smoking, non-related laboratory materials prohibited in laboratory	1	2.1	0	0
Autoclave available for use	1	2.1	0	0
Biosafety procedures incorporated into standard operating procedures	1	2.1	0	0
Decontamination solution not expired	1	2.1	2	6.7
Solid waste properly labeled	1	2.1	0	0
Materials to be decontaminated are properly labeled	0	0	2	6.7
Biohazard sign posted at entrance of laboratory displaying infectious agent	0	0	1	3.3
Hand washing facilities available and soap is present	0	0	1	3.3
Appropriate decontamination solution, bleach, less than one month old	0	0	1	3.3
Policies for the safe handling are sharps are instituted	0	0	1	3.3
TOTAL	**47**	**100.0**	**30**	**100.0**

The significant reduction between the first and second survey set is due to the fact that a violation noted on the initial survey precipitated subsequent corrective action based on recommended biosafety practices explained in the deficiency letter. Another explanation could be that once a laboratory received a violation, the Principal Investigator required the laboratory staff to participate in additional biological safety training, such as OSHA Blood-borne Pathogen Standard or the Texas Hazard Communication Act.

An unanticipated result was the number of BSL-2 violations compared to BSL-1 violations. The increase in BSL-2 violations could be attributed to more refined, concentrated work being done at the BSL-2 level, which recommends adherence to BSL-1 and increased BSL-2 practices, thereby increasing violation potential. In addition, laboratories surveyed under BSL-2 guidelines may not have had proper facility controls to maintain BSL-2 laboratory work. One example that supports this observation is the frequency of violations for *Ventilation in laboratory negative to the hallway*. It is also possible that BSL-2 violations increased because the blood-borne pathogen standard is applicable and added to BSL-2 recommendations. Future studies could be directed towards examining the relationship between blood-borne pathogen training and the incidence of laboratory-acquired infections.

The findings from this study have numerous implications to both public health and occupational health. The reality of bioterrorism has spurred government support for preparedness and response to threats regarding weapons of mass destruction. With the development of these public health laboratories comes an inherent risk to laboratory workers being exposed to suspected biological agents. With an increased awareness of the most frequent types of laboratory workplace violations described here, extra precautions can be taken for laboratory employees working with potential bioterrorism samples.

Several limitations are inherent to this study. First, only one institution was surveyed, thus the data do not provide a representative sample of national compliance. However, this limitation was minimized by standardizing training of all safety specialists and imposing mandatory peer-reviewed inspections prior to commencement of their own individual inspections. There was also the potential for information bias. Laboratory employees surveyed may have underestimated or exaggerated certain inspection items for fear that the laboratory would be punished or shut down because of a potential workplace violation. However, an attempt was made to minimize this type of bias by performing unannounced inspections.

Despite the acknowledged limitations of this study, the findings provide valuable information to aid the biosafety community. For example, the accumulation of these data lays the groundwork for the creation of a national database regarding workplace violations in the biological safety field. Recently, the creation and publication of a violation database for radiation safety violation incidents by Emery et al. for the state of Texas helped lay the framework for the creation of a national database to track all radiation safety violation incidents (Emery et al., 1997; Emery et al., 2000).

Another possible application of these data is the creation and refinement of training programs for persons working in biomedical laboratories. Accumulating items of noncompliance will allow future studies to analyze the most frequent types of violations and allow researchers to correct or amend training programs as necessary.

In summary, the results from routine workplace surveys in biological safety laboratory settings can serve as a valuable resource for practitioners in biomedical laboratories and public health practice, as well as provide a foundation for improved safety practices and guidelines.

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