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Assessing the Biological Safety Profession's Evaluation and Control of Risks Associated with the Field Collection of Potentially Infectious Specimens

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Abstract

Because the origins of the biological safety profession are rooted in the control and prevention of laboratory-associated infections, the vocation focuses primarily on the safe handling of specimens within the laboratory. But in many cases, the specimens and samples handled in the lab are originally collected in the field where a broader set of possible exposure considerations may be present, each with varying degrees of controllability. The failure to adequately control the risks associated with collecting biological specimens in the field may result in illness or injury, and could have a direct impact on laboratory safety, if infectious specimens were packaged or transported inappropriately, for example. This study developed a web-based survey distributed to practicing biological safety professionals to determine the prevalence of and extent to which biological safety programs consider and evaluate field collection activities. In cases where such issues were considered, the data collected characterize the types of controls and methods of oversight at the institutional level that are employed. Sixty-one percent (61%) of the survey respondents indicated that research involving the field collection of biological specimens is conducted at their institutions. A majority (79%) of these field collection activities occur at academic institutions. Twenty-seven percent (27%) of respondents indicated that their safety committees do not consider issues related to biological specimens collected in the field, and only 25% with an oversight committee charged to review field collection protocols have generated a field research-specific risk assessment form to facilitate the assembly of pertinent information for a project risk assessment review. The results also indicated that most biosafety professionals (73% overall; 71% from institutions conducting field collection activities) have not been formally trained on the topic, but many (64% overall; 87% from institutions conducting field collection activities) indicated that training on field research safety issues would be helpful, and even more (71% overall; 93% from institutions conducting field collection activities) would consider participation in such a training course. Results obtained from this study can be used to develop a field research safety toolkit and associated training curricula specifically targeted to biological safety professionals.

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Keywords

Biosafety; Field Research Safety; Field Collection; Biological Specimens; and Biological Risk Assessment

Introduction

Conducting work with infectious materials in research laboratories is known to carry inherent occupational exposure risks. Pike and Sulkin (1965) reported about laboratory-acquired infections (LAIs) in a series of papers that identified 4,079 LAI events in the United States between 1930-1978 from this compendium they assembled a list of the most frequently implicated causative agents (Pike, 1951, 1965, 1976, 1978, 1979). Harding and Byers (2000) identified an additional 1,267 overt infections and 22 deaths occurring over the 20 years following the Pike and Sulkin studies (Harding, 2000). Potentially infectious biological specimens are typically handled in the laboratory, using the biological safety (biosafety) containment principles and good microbiologic technique to prevent accidental exposures and infections.

Ideally, the practices, procedures, and containment devices used, along with laboratory facility design, are reviewed by individuals knowledgeable about biosafety and critiqued for alignment with the guidance on biosafety controls set forth in the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) publication *Biosafety in Microbiological and Biomedical Laboratories*, 5th edition (*BMBL*) (U.S. HHS, 2009). Ideally, these safety factors are also reviewed and approved by an Institutional Biosafety Committee (IBC) or another committee charged by the institution to oversee the use of infectious agents according to applicable guidelines (such as the NIH *Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules*) (NIH, 2013), regulations (such as for the use of listed select agents or toxins) (NSAR, 2013), or institutional policy.

As a result of the well documented occurrences of LAIs and recently mandated regulatory compliance (BSAT, 2013) and institutional risk minimization regarding infectious biological agents, the biosafety profession has evolved with a laboratory-centric focus. However, in some cases, biological specimens may be collected in the field for research purposes or during an infectious disease outbreak. These situations may present the investigators with additional, unique, or unknown risks since they outside the controlled laboratory environment with its attendant engineering and administrative controls. Hence, personnel must be adequately trained and controls put into place for field research or disease outbreak assessment activities, especially when infectious organisms may be encountered.

The risk of exposure to biological agents in the field has been recognized for some time. For example, basic personal protection measures to prevent exposure to arthropod vectors were recommended in the early 1900s based on Carlos Chagas' investigation of malaria in Brazil (Oda, 2004). Subsequent investigations of arthropod-borne diseases, such as yellow fever and dengue in Brazil have furthered the understanding about necessary health and safety precautions (Oda, 2004). As a result, recommendations for field safety protocols have been

documented, including the use of personal protective equipment and engineering controls (for example, using battery-powered biosafety cabinetry in the field when procedures with infectious materials may generate aerosols), and are available to devise health and safety training programs specifically targeted to field research personnel and public health professionals in Brazil. An important lesson learned from these efforts in Brazil: “The most important but frequently neglected aspect of field work is the minutial planning, from the collection, identification, packing, storing of the material to transport...” (Oda, 2004).

In the late 1970s and early 1980s, McCormick and colleagues described the importance of preparedness training during their field investigations of hemorrhagic fever outbreaks in various African countries (McCormick, 1996). Often working in remote, underdeveloped rural areas, these “virus hunters” were challenged to rapidly develop safety protocols that addressed the many unknowns of the viral pathogens as well as the sub-optimal conditions and the limited availability of resources (McCormick, 1996).

Although researchers typically have options to purchase infectious agent stocks commercially or obtain them collaboratively from other infectious disease-related research laboratories, direct collection of specimens in the field is dictated by the needs of the research or the circumstances of a disease outbreak. While predicting every scenario that may occur in field research is impossible, the field collection of biological specimens generally includes the following: the collection of human, animal, plant, fish, or insect specimens (i.e., field necropsy); the collection of water and wastewater samples; the collection of mold and fungi samples; the collection of food samples for routine sampling and for food-borne outbreak investigations; the collection of archeological samples; quality assurance testing samples; and other scenarios (Table 1). Each of these activities can represent a risk of infection to the researchers, as well as other potential health and safety risks beyond the realm of biosafety depending on the geographic location, environmental conditions, presence of arthropod vectors, and other factors unique to the situation. For example, there may be physical hazards such as slips, trips, falls, extreme heat or cold, high altitude, and others; environmental hazards such as vehicular or other transportation accidents, crime, political or social unrest, and others; endemic infectious diseases; wildlife encounters either voluntarily for the purpose of the study or by circumstance; zoonotic diseases; and so on. Participants in public health response activities, such as the Haiti earthquake in 2010 or the earthquake, tsunami, and subsequent radiation fallout at the Fukushima Nuclear Power Plant in Japan in 2011, including those who may have performed real-time research activities in these “hot zone” settings, were likely to have been presented with a spectrum of such challenges.

Unlike LAIs, the extent of field research-related exposures and illnesses has not been well quantified. No compendia of illnesses or injury events exist similar to the Pike and Sulkin and Harding and Byers publications on LAIs, and only select publications on exposure events as a consequence of field research activities can be found in the literature. An example of a publication that describes exposure to biological specimens in the field is a recent case involving seven Maryland investigators who fell ill with flu-like symptoms after aerosol exposure to surface waters known to have toxigenic blooms of the dinoflagellate *Pfiesteria piscicida* (Haselow, 2001). Other examples include a suspected aerosol exposure

to ebolavirus by an individual performing field necropsy on an infected chimpanzee in the Ivory Coast (Le Guenno, 1999), a Zika virus transmission from exposure while collecting mosquitoes for research purposes in Senegal (Foy, 2011), a hantavirus pulmonary syndrome case following field collection of live small animals in West Virginia (Sinclair, 2007), a doctoral student becoming infected with *Leishmania (Viannia) naiffi* after capturing and handling birds in Brazil (Felinto de Brito, 2012), and a fatal pneumonic plague case from direct blood and aerosol exposure during a mountain lion necropsy (Wong, 2009). Importantly, these publications often lack key words, such as “exposure events” or “illnesses related to field research biological specimen collection,” and thus are not easy to find during a detailed literature search on the subject; if words such as these were used, biosafety professionals could more easily review information critical to their risk assessment process and selection of controls. In addition, many instances of field-acquired infections likely have occurred but have not been reported, published in a peer-reviewed, publically available journal, or recognized as a field research-related event.

Since the biosafety profession has traditionally focused on safety issues inside the laboratory, several questions remain unanswered about the extent to which biosafety professionals are involved in the evaluation and control of risks associated with field collection activities involving biological specimens. For example, to what extent does the biosafety profession consider the field collection aspects of research protocols? Are IBCs asked to assess and review these protocols, or do other stand-alone committees exist for this purpose? What controls, if any, are in place in the field to reduce or eliminate the likelihood of exposure to infectious specimens? Whether or not biosafety professionals are being equipped with adequate training and resources to understand and competently address these issues occurring outside the traditional laboratory setting is unknown.

A review of biosafety-related protocol risk assessment forms online, located via a Google® search using the terms “Institutional Biosafety Committee forms” and “IBC forms” (since these forms are not traditionally published anywhere in the literature), suggests that field research issues are not regularly considered because they do not appear on the IBC forms that were examined. A stand-alone field research safety risk assessment form is available only at a few institutions, and it is often unclear which institutional committee, if any, is responsible for the ownership and review of that form.

Equally important is the availability of competent biosafety professionals with knowledge about the risks involved in field activities to identify appropriate controls during the protocol review process. No field research-related courses specifically targeted to biosafety professionals are immediately evident. A review of the American Biological Safety Association (ABSA) annual conference agendas from the past several years found both the pre-conference course offerings and conference platform presentations devoid of this topic (ABSA, 2008, 2009, 2010, 2011, 2012, 2013). The recently released *Guidelines for Biosafety Laboratory Competency* from the CDC and the Association of Public Health Laboratories, which intends to standardize the baseline training competencies of biosafety professionals, does not include safety considerations for field collection of biological specimens (Delany, 2011). However, the *Anthology of Biosafety* series does include manuscripts entitled “Health and Safety During Public Health Responses and International

Travel” (Chosewood, 2008) and “From the Field to the Laboratory in an Animal Disease Outbreak Situation” (Pauli, 2012) that provide some salient guidance for biosafety professionals. Some additional references are available in the literature, such as the recommended guidelines (Kelt, 2010) from the American Society of Mammologists for personnel working with wild rodents potentially infected with hantavirus. However, these are intended to match the level of protection with the level of risk, and therefore are not intended to be applied to infectious disease-related research activities; nevertheless, they present an important caveat which biosafety professionals should understand and consider when conducting risk assessments and prescribing risk controls (Kelt, 2010).

As a result of the author's research into protocols for the control of risks associated with the field collection of potentially infectious specimens, this study developed a web-based survey to verify that, due to the cross-competencies required by their jobs, many biosafety professionals participate in or oversee the field collection of biological specimens, including activities associated with an outbreak investigation. The survey was intended to determine the extent to which institutional oversight committees are considering these protocols, if at all. Additionally, the survey sought to determine if the profession is adequately prepared with the knowledge and resources to develop and review risk assessments and provide recommendations for safety controls for research activities conducted in the field. Since no standard training curriculum for biosafety professionals is mandated (although some training programs now exist such as the National Institutes of Health-sponsored National Biosafety and Biocontainment Training Program (NBBTP, 2013), and degree programs in biosafety are beginning to be available), this study also sought to identify whether biosafety professionals have the opportunity for field research training and if the profession needs training on field research safety.

Research Objectives and Aims

The specific objective of this study was to determine the answers to the following questions about the current state of oversight for field collection activities involving biological specimens:

1. Are biological safety professionals considering and evaluating field collection activities involving biological specimens as part of protocol reviews?
2. If yes, what are the current types of biosafety controls employed in field collection protocols? If no, what are the barriers faced by biosafety professionals or reasons why these activities are not being considered or evaluated?
3. Are Institutional Biosafety Committees (or other safety committees) involved in the review and approval of field collection protocols? If not, are any other committees providing this oversight at the institutional level?
4. Are biosafety professionals currently being afforded the resources necessary to conduct protocol reviews, training for field research personnel, and oversight of biological specimen field collection activities? Do they have access to individuals such as occupational health physicians knowledgeable about field first aid and exposure response protocols, veterinarians familiar with the observation or direct

handling of wild animals, and other expertise required to adequately address issues such as zoonotic disease transmission, physical hazards, hazards associated with encountering wild animals, travel medicine that addresses endemic diseases in the geographic area of study, training for field researchers, and emergency contingency plans? What gaps are typically found at the institutional level?

5. Are biosafety professionals, who are typically trained to address biosafety issues occurring within the research laboratory, currently equipped with the knowledge to address biosafety in field collection protocols? Given the current absence of field research safety as a topic in the “typical” training curriculum for biosafety professionals, would the profession benefit from the inclusion of such a training course? What learning venue would be most beneficial for this training? For example, should it be offered as a pre-conference course at the annual national ABSA conference?

Methods

Based on the literature review, personal experiences, and observations from professional practice in the field of biosafety, the authors created a survey tool that was distributed to institutions in the United States and abroad. The survey questions, developed by the authors, were 33 multiple choice questions (inclusive of the informed consent statement and affirmation). A cover letter providing a detailed explanation of the study and the informed consent was included at the beginning of the survey. A request to designate only one biosafety representative per institution to respond was made in the cover letter. The survey was distributed electronically to participants via the Survey Monkey® web tool (www.surveymonkey.com). No paper surveys were distributed. All individuals participated voluntarily and without tangible incentives, only after they had read the study explanation, objectives, and informed consent, and had provided consent. The approximate length of time needed to complete the online survey was 15-20 minutes.

Prior to distribution of the survey, a pilot was developed to ensure adequacy and understanding of the survey questions. Participating members from the Southern Biosafety Association (SBA), an affiliate of ABSA, completed the pilot survey and gave initial feedback. Misleading questions or poor instructions were edited as necessary or deleted based on the findings of the pilot survey. The data analysis procedures were tested and modified during the pilot phase using initial data that determined that a chi square analysis was the most appropriate statistical tool to compare percentages found in the results.

Study Design and Setting

This study represents a cross-sectional survey of the biosafety profession. This study was conducted between July 8, 2013 and July 26, 2013 utilizing an electronic web-based survey distributed to biosafety professionals via the ABSA membership email directory. Permission was sought and obtained from the ABSA Executive Council to use the Association membership email list to distribute the survey.

Study Subjects

All individuals practicing in the biosafety profession, either full- or part-time, who were current members of ABSA with association dues paid in full for 2013 were eligible to participate in this study. Survey questions were specifically targeted to biosafety professionals and were disseminated electronically via the ABSA membership email directory in order to reach the greatest number of biosafety professionals. A challenge of this format was that the study population that received the electronic survey included some non-biosafety-related individuals, since a portion of the ABSA membership includes other professionals who are simply interested in obtaining information about biosafety or networking with the biosafety community (i.e., product vendors, etc.). However, survey distribution through the ABSA membership list was believed to be the most effective way to contact the greatest number of biosafety professionals.

Data Collection

Data for this study compiled the results of the electronic survey returned to the authors by the study participants (biosafety professionals). Vendors and other professionals were not included in the data analysis. The web-based survey was specifically designed to reduce the likelihood of inadmissible responses (i.e., multiple responses to a single question were not possible); however, all survey responses were vetted for consistency and completeness. All survey questions were answered by a majority of respondents; therefore, no survey questions were discarded from the survey results. All data review and coding were conducted by the primary author.

Data Analysis

The survey results were analyzed using descriptive statistics. Quantitative analysis of the results was performed using the numerical data assigned to each nominal and ordinal survey question. Frequency distributions of the responses to each question in the survey were created and displayed both in raw numbers (counts) and percentages. Graphic representation of these data was generated in the form of histograms. Chi-square analysis, using the FREQ procedure of SAS[®] (SAS Institute, Inc., Cary, NC) was used to compare survey response percentages.

Human Subjects and Safety Considerations

The University of Texas Health Science Center at Houston Institutional Review Board reviewed and approved the study protocol (HSC-SPH-13-0290). Informed consent documentation was provided and obtained (through electronic certification by clicking an acceptance box within the Survey Monkey[®] tool) from each participant prior to administration of the survey. All individual results and feedback were kept confidential and reviewed exclusively by the authors (only anonymous survey results were used in the analysis). Participation in the survey was voluntary and no incentives were provided.

Results

During the 3-week period the survey was available online, 168 survey responses were received. Three respondents declined the informed consent, 9 declared they did not perform

biosafety functions as part of their job responsibilities, and 1 indicated performing biosafety functions but failed to continue the survey after answering the first question. These 13 responses were disqualified, leaving 155 viable survey responses for data analysis. This sample size represents a margin of (sampling) error of 7.44% and a response distribution of 50%. Since differences existed in the number of completed questions, some of the response summaries represent fewer than 155 responses. For example, several questions related to the oversight of field research-related activities did not apply to those who indicated field research is not performed at their institutions, and some respondents simply failed to complete the entire survey.

From the 155 responses, 105 (68%) respondents indicated that more than half of their time was dedicated to biosafety-related job duties. Job position titles for 112 (76%) respondents directly related to biosafety, such as biosafety officers, directors, or support personnel directly assigned to biosafety, including 39 individuals holding certification as a certified biological safety professional (CBSP) and 50 holding registration as a registered biosafety professional (RBP) through ABSA. The remaining respondents' positions were environmental health and safety (EHS) (14%), consultants (7%), or other safety and health-related jobs. The majority of the responses were from individuals in the United States, with only 17 (11%) responses from international ABSA members.

Sixty-one percent (61%) of the survey respondents who completed the survey questions that addressed field collection activities (85 out of 140) indicated that research involving the field collection of biological specimens is conducted at their institutions. A majority (79%) of these field collection activities were conducted at academic research institutions as opposed to non-academic institutions, $\chi^2 (14, N = 140) = 49.26, p = < 0.0001$ (Figure 1). Eighty-five percent (85%) of respondents indicated that up to 25% of all active research protocols at their institutions involved the field collection of biological specimens or other field research-related activities. Only 1 respondent indicated that all (100%) active research protocols at his or her institution involved field collection activities.

Additional responses (N=79) identified that these research activities occurred in the field (e.g., outside the boundaries of a research laboratory) as opposed to collection at a field clinic or hospital (N=67), for example during an infectious disease outbreak event. Respondent descriptions of field collection activities included the collection of wild animals or animal specimens (N=44), human specimens (N=32), water or wastewater samples (N=12), environmental samples such as soil samples (N=12), wild plant specimens (N=11), exo- and endoparasites (N=8), and food samples (N=3).

Regarding institutional oversight, 27% of respondents indicated that their safety committees did not consider issues related to the field collection of biological specimens. Fifty-three percent (53%) indicated that an IBC was responsible for reviewing and approving safety protocols involving the field collection of biological specimens or other field research activities. Other institutions have assigned a Biological Safety Committee (e.g., a committee assigned to review biosafety protocols not involving the use of recombinant or synthetic nucleic acid molecules or not otherwise required to be reviewed by an IBC) to review such protocols. When field research involves animals or human subjects, the safety aspects of the

protocol are reviewed by an Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB), respectively. Only 1 respondent indicated his or her institution has a dedicated Field Research Safety Committee to review such protocols (Figure 2). For submission of information to the institutional oversight committee, only 20 (25%, n=81, since 4 respondents did not complete this portion of the survey) indicated that they had developed a field research-specific risk assessment form for completion by researchers. The remaining 37 (46%) did not have a form; 21 (26%) indicated they obtained information by asking researchers to complete a standard laboratory-based risk assessment form.

Figure 3 displays the specific biosafety aspects considered and evaluated by institutional oversight committees during the initial protocol screening and risk assessment review process. Forty-nine (58%) respondents indicated their committees consider other safety issues besides those typically related to biosafety during the protocol screening and risk assessment review process, such as physical hazards, travel medicine, field first aid, emergency response protocols, and other general safety-related areas. When performing the risk assessment review for field biological specimen collection or field research protocols, 59 (73%) indicated they have access to resources such as individuals knowledgeable in occupational health, travel medicine (including vaccinations), field first aid, and other general safety-related areas who can provide input regarding the risk assessment review, training of field research staff, post-exposure assessment of potentially affected personnel, and other aspects of the institutional oversight program. Similarly, if animals are observed, trapped, or directly handled during field research activities, 61 respondents (75%) indicated they have access to individuals knowledgeable in veterinary medicine and zoonotic disease transmission to provide such input.

When asked to envision an ideal field research safety oversight program, respondents indicated the key resources they would implement to perform risk assessments, provide consultation and advice on the risk assessment and subsequent safety recommendations, provide training for field researchers, and provide assessment of potentially affected personnel. These included an occupational health physician, a veterinarian, designated field research safety personnel, designated field research safety training providers, and individuals knowledgeable in diving safety.

Overall, 72 (57%) respondents indicated they feel adequately prepared to review field research protocols involving biological specimens; of these, 21 are CBSPs (66% of CBSP responses), 19 are RBPs (58% of RBP responses), and 32 are without certification or registration (52% of non-certified or non-registered responses). From these 72 respondents, only 34 (27%) have received training on field research safety oversight, risk assessment, or other considerations related to health and safety in the field (31% of CBSPs, 22% of RBPs, and 28% of those without certification or registration have been trained). Specifically for institutions conducting field collection activities, 62 (79%) indicated they felt adequately prepared to review protocols involving the collection of biological specimens, although only 18 (29%) have actually received any training on the topic (Figure 4).

Descriptions of previous training classes completed by these individuals can be found in Table 2. The topic areas respondents considered critical for training can be found in Table 3.

Overall, 80 (64%) respondents indicated additional training on field research safety would be helpful to them and their biosafety program, and if offered, 87 (71%) would consider attending such a training class. Specifically for institutions conducting field collection, 59 (87%) indicated that additional training on field research safety would be helpful and 55 (93%) would consider attending such a training class (Figure 5).

Of significance were responses from CBSPs indicating the ideal setting for this training would be either a pre-conference course offered at a future ABSA conference or an online class; non-certified individuals preferred a stand-alone class format, $\chi^2 (4, N = 192) = 9.27$, $p = 0.05$. A statistically significant proportion of non-certified individuals (37%) are uncertain as to whether making field research safety a topic or mandatory competency on the CBSP certification examination would be worthwhile, whereas a majority of CBSPs (56%) rejected the notion that the topic be included, $\chi^2 (4, N = 123) = 9.64$, $p = 0.04$.

Of the 85 individuals indicating field collection activities occur at their institutions, 23 are CBSPs (5 of whom are co-registered as RBPs), 22 are registered (exclusively) as RBPs, and the remaining 40 are not certified or registered. No statistical significance was found when comparing the oversight of field collection activities by CBSPs versus non-certified respondents, $\chi^2 (4, N = 140) = 1.58$, $p = 0.81$.

Discussion

The biosafety profession has traditionally focused on the control and prevention of LAIs through the safe handling of biological specimens within the laboratory setting; however, the results of this survey suggest that many biosafety professionals (61%), especially those employed at academic research institutions, were extending their evaluations to consider the risks associated with the collection of biological specimens in the field. Eighty-five percent (85%) of respondents stated that up to 25% of the total active research volume at their institutions involved field collection of biological specimens. Currently, no standardized risk assessment form or mechanism for evaluating and controlling risks in a systematic manner exists for such field research protocols. This highlights the need for biosafety professionals working at institutions performing such research to be equipped with the knowledge and tools to perform risk assessments and provide recommendations for appropriate controls when collecting and handling potentially infectious specimens in the field, prior to their arrival in the laboratory.

The data collected suggests that many institutions have taken proactive steps to address the oversight of field collection protocols. For example, most respondents (73%) indicated they had an oversight committee (either an Institutional Biosafety Committee, Biological Safety Committee, or in one case, a Field Research Safety Committee) in place to perform risk assessments and provide recommendations for appropriate safety controls when conducting field collection activities. Although these committees, in most cases, were not specifically dedicated to the oversight of field research protocols, knowing that oversight mechanisms

are in place for such protocols is reassuring. However, 27% of institutions do not have an oversight committee in place. An unanticipated finding from this survey was the number of institutions indicating that an IACUC (15%) or IRB (8%) committee was involved in the review of safety aspects for field research protocols involving animals or human subjects, respectively. The previous assumption was that the safety aspects, if considered, were under the purview of an institutional safety committee, not these other oversight committees since occupational health and safety are not their primary charge. Unfortunately, based on the design of the survey questions, the survey results were unable to quantify how many IACUC or IRB committees review such safety issues exclusively compared to how many serve as a secondary checkpoint or redundancy measure for the institution to ensure health and safety issues are addressed and controls are in place for field research activities. To paraphrase a survey response, “Our field safety issues apply to protocols reviewed by the IACUC and IBC...our IBC does occasionally review protocols involving the field collection of biological specimens but not every IACUC protocol involving field collection activities has a corresponding IBC protocol...therefore the IACUC considers zoonotic disease issues as well as our IBC.”

Perhaps this is a potential gap if field collection protocols occur without being identified and channeled to the appropriate committee assigned to perform a safety review. How many biosafety professionals serve as members or participants on IACUC and IRB committees that provide input during the risk assessment process is unknown, as well as what specific safety-related information is requested and reviewed by these committees, or to what level of rigor the safety review is held. Future research on the participation of IACUCs and IRBs in the oversight of field collection protocols could determine this information; thus, future surveys on the topic should include questions regarding participation and level of involvement by IACUCs and IRBs. In the meantime, some guidance is available for IACUCs on this topic, including *Field Studies and the IACUC: Protocol Review, Oversight, and Occupational Health and Safety Considerations* (Laber, 2007).

Interestingly, slightly less than half of the institutional oversight committees (46%) did not have a field research-specific form for researchers to complete when submitting their research protocol risk assessment; 26% required researchers to complete a laboratory-based risk assessment form. The relevance of the laboratory-based forms was not assessed in this study, but presumably these could vary depending on the elements of field research included within the form, if any. Absence of a dedicated form for field research could lead to consternation among field researchers attempting to complete the risk assessment if they are asked to answer irrelevant laboratory-related questions such as biosafety levels, use of recombinant or synthetic nucleic acid technology, the use of laboratory-based equipment, or other laboratory-related concerns. For institutions that have not developed a dedicated form, this could be a consideration for oversight improvement—add specific risk assessment questions regarding the particular aspects that field researchers should be submitting for evaluation and documentation. Institutions might consider including input from field research staff in the development of a field research-specific form; this may help to maximize the document's relevance and effectiveness. Additionally, several examples of publicly available field research-specific risk assessment forms exist that could serve as templates for institutions desiring to create such a form. These include the University of

California—Berkeley (UC—Berkeley, 2012), the University of California—San Diego (UC—San Diego, 2012), and Duke University (Duke, 2012). These forms address field research-specific issues spanning biosafety, physical safety, communication (e.g., with local contacts, the parent institution, and local hospitals and clinics in case of emergency), travel medicine, field first aid, and emergency response training.

The biosafety aspects evaluated during the initial protocol screening and risk assessment reviewed by the institutional oversight committee for field collection protocols were similar to the laboratory-based criteria found in the *BMBL* (U.S. HHS, 2009). For example, the most frequently evaluated biosafety aspects included those that were both intuitive for field collection activities and also typically included in a laboratory-based risk assessment review, such as risk identification (risk level of specific infectious agents to be encountered, collected, and handled in the field), use of personal protective equipment in the field, disinfection, decontamination and sterilization, hand washing and infection control, and safe specimen transport. However, survey respondents also provided several unanticipated yet critically important elements in their text responses. For example, several indicated their institutions' requirements for field researchers to implement mechanisms for reporting field incidents to the host institution, to develop protocols for handling and storage of potentially contaminated field research equipment (e.g., animal traps), and to consider permitting field research activities in certain areas or jurisdictions. If applicable to the types of field collection activities conducted, these could be essential for institutions to consider.

Although many biosafety professionals (57% overall; 79% from institutions conducting field collection activities) indicated they felt adequately prepared to review field collection protocols, most (73% overall; 71% from institutions conducting field collection activities) had not received formal training related to field research safety or were compelled to extrapolate from their traditional biosafety training or training obtained in other safety disciplines (many of which are laboratory-based). This is ironic for a profession that has generally excelled at training to increase awareness and knowledge of controls for biosafety levels within the laboratory based on the understanding of historical LAI occurrences. For those few who have been trained in field research safety issues, survey text responses indicated that they relied primarily on the experience and expertise of field researchers at their institutions who have developed protocol-specific training or more generic departmental-based training. Notably, while no survey respondents indicated they had obtained field research-based training specifically targeted to biosafety professionals, many (64% overall; 87% from institutions conducting field collection activities) indicated that training on field research safety issues would be helpful, and even more (71% overall; 93% from institutions conducting field collection activities) would consider taking such a training course. This suggests that training on field research safety is a topic that ABSA or other biosafety training organizations or programs should strongly consider, with the caveat that it must be targeted to biosafety professionals and presented broadly enough to be applicable to most types of field collection activities involving potentially infectious biological specimens. Since survey responses also clearly showed that such a course should be offered in a variety of formats, such as a pre-conference course at the ABSA annual biosafety conference, as a stand-alone course, or as an online course, these formats should be considered to maximize availability to the greatest number of biosafety professionals. Additionally, training

programs such as the National Biosafety and Biocontainment Training Program (NBBTP, 2013) may be ideal to include as part of the standard curriculum.

Overall, 44% of responses indicated that this topic should not be a mandatory competency on the CBSP certification exam, and 27% were unclear as to whether it should be a mandatory competency. Fifty-six percent (56%) of the responses from CBSPs indicated it should not be a mandatory competency. Presumably this is because field collection protocols are not universally applicable to all institutions or practicing professionals, and because it is a broad topic that may be difficult to narrow into fair and reasonable questions. To paraphrase a text response: “The importance of this topic will depend on the amount and type of field research activities conducted at the institution; thus, this area may not be common enough to require it as a competency for biosafety certification.” Therefore, there does not appear to be any urgency to include this topic on the certification exam.

The data obtained in this study suggested the need to develop standard guidance for field collection of biological specimens specifically for biosafety professionals; this guidance should also provide a format from which tools can be obtained for use during the risk assessment process and subsequent implementation of controls during the conduct of the field research project. However, the data appeared to show the absence of consensus on professional guidelines in terms of the content and how such a guidance document should be designed. Currently, the *BMBL* and the World Health Organization (WHO) *Laboratory Biosafety Manual* (WHO, 2004) do not address the issues of field collection of biological specimens or peripheral risks related to field research activities. Although elements of the data from this survey could serve as the impetus for the development of guidelines and training specifically for biosafety professionals, further discussion is warranted to reach consensus on how such guidance and training would most effectively benefit the profession. Perhaps training courses could be built around: 1) the settings identified in the survey where field collection activities primarily occur (e.g., outside the typical research laboratory, or in a field clinic or hospital setting during an infectious disease outbreak situation); 2) the types of field research being conducted (e.g., collection of animal specimens, plant specimens, and waste water specimens in the field); and 3) the identified key elements of review and consideration for biosafety professionals during the risk assessment and oversight process. A focus group discussion at a forum such as the ABSA annual biosafety conference would be an appropriate venue for this dialogue to occur.

It is important to note that shortly after this survey was conducted the National Park Service (NPS) published a document entitled “Safe Work Practices for Handling Wild Animals” as part of a larger occupational health and safety guidance manual for its employees (USNPS, 2008). This document was created, in part, in response to the fatality of a NPS employee during an occupational encounter with a mountain lion (Wong, 2009). While the focus is on NPS employees, this document could serve as a model for the creation of training targeted to biosafety professionals. The document introduced a plan—essentially a prepare-and-execute model for field research activities that defined the task and the context in which it will occur—to understand the hazards (e.g., physical, biological, chemical) and to carry out protective actions based on the level of risk (USNPS, 2008).

Another important caveat is that despite this study being focused on the collection of biological specimens, countless peripheral risks could present regardless of whether the field research is conducted locally (e.g., near a university campus) or overseas (e.g., in a developing country rife with civil unrest or other hazards). These risks, whether physical, chemical, or otherwise, should always be considered in a comprehensive risk assessment review process for field research protocols. If biosafety (or other safety) professionals focus too narrowly on the biological hazards presented in a research project proposal, these peripheral risks could be overlooked. To paraphrase a few of the text responses received, “Most institutions likely have a gap for worker safety when it comes to coincidental exposures while doing other research—e.g., acquiring TB in a developing country while interviewing focus groups about an unrelated topic, catching Hanta virus while surveying other wildlife, catching Q-fever while shearing sheep,” “Field research safety challenges the traditional biosafety risk assessment paradigm as several extrinsic (often uncontrollable) factors must be considered and evaluated...for these reasons and others, this topic needs to be further addressed,” and “This is a broad and complex topic that does not get enough attention.” As previously mentioned, the development of a field research-specific risk assessment form could help to prompt this information from researchers.

Yet another intriguing issue identified by responses to this survey relates to the discussion of public perception during field research activities or responses to infectious disease outbreaks. Regardless of good intentions, a perceived risk and negative public perception exists if researchers were to, for example, perform field research activities in full personal protective equipment adjacent to areas where community bystanders may be unaware of the research and lack similar levels of protective equipment (e.g., research staff donning a full Tyvek suit, respirator, and protective gloves collect samples near community members in plain street clothes with no protection). Public mistrust in the absence of appropriate risk communication and management could lead to complications when performing field research activities.

When designing this survey, questions requesting information on field research-related occupational exposures to potentially infectious biological specimens, subsequent *bona fide* field-acquired infections, and other accidents or injuries sustained during field research activities were considered but ultimately intentionally omitted. The basis for this decision was rooted in the attempt to maintain survey participants' trust and avoid any worries that divulging such information would lead to potential breaches in confidentiality or institutional liability. Interestingly, several respondents provided feedback suggesting these data are important to obtain. Thus, future research could be conducted to create a compendium of occupationally-acquired field illnesses and/or injuries, potentially similar to the data compiled by Pike and Sulkin (1965) and Harding and Byers (2000) for laboratory-acquired infections. Perhaps this could be achieved through a combined approach using a meta-analysis of existing literature and a comprehensive survey of the biosafety profession to capture unpublished data.

Finally, consideration was given to determine if the data obtained in this survey were potentially skewed towards a certain demographic. Therefore, the results were compared to a 2013 ABSA membership survey on demographics (ABSA, 2013). Statistical significance

was observed in that a higher than expected number of CBSPs responded to our survey (25% of the total respondents) compared to the ABSA membership that is currently certified (11%), $\chi^2 (1, N = 145) = 31.75, p = < 0.0001$. As previously reported in the results, no statistical significance was found when comparing the oversight of field collection activities by CBSPs versus non-certified respondents. This is particularly intriguing since it is contrary to the outcome initially expected by the authors, especially since the study appears to be skewed towards more responses from CBSPs than expected. Additionally, a slightly higher proportion of individuals from public academic institutions responded to our survey (44% of the total respondents) compared to the ABSA membership survey (37%), $\chi^2 (8, N = 151) = 25.33, p = 0.0014$. This is not as surprising since public academic institutions typically share information readily and would be expected to participate.

Conclusion

The practice of biosafety is traditionally limited to the laboratory setting. However, particularly among academic institutions (public and private), 78% also conduct research protocols involving the field collection of biological specimens, according to the results of this survey. This represents a risk to staff and students who handle the biological specimens in the field. Such actions could lead to infections and illnesses from exposures if appropriate risk controls are not put into place, although this is not currently quantified. Data generated herein indicate many institutions have oversight mechanisms in place for protocols involving field collection activities. However, the need exists to develop and implement additional written guidance, training, and resources for biosafety professionals to adequately prepare the profession to address the safety and health issues associated with the field collection of biological specimens. Since the traditional training curriculum for biosafety professionals does not include this topic, the development of field research training specifically targeted to biosafety professionals is warranted.

The notion of acquiring diseases in the field is not new, but it is ironic that such gaps exist in the consideration of protocols involving the field collection of biological specimens.

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Biosafety Professionals Indicating Whether Their Institution Conducts Research Activities Involving Field Collection of Biological Specimens, By Type of Employer (n=149)

Figure 1.
Institutions conducting field collection of biological specimens, by type of employer

**Institutional Committee Charged to Review and Approve Safety Protocols
Involving Field Collection of Biological Specimens or Other Field Research
Activities (n=85)***

Figure 2.

Institutional committee charged to review and approve field collection protocols

*All 17 “other” responses were in addition to another answer already provided, thus n=85

**For the purpose of this survey, a Biological Safety Committee was defined as a committee charged to review biosafety protocols not involving the use of recombinant or synthetic nucleic acid molecules or not otherwise required to be review by an IBC according to the *NIH Guidelines*.

***“Other” responses indicated review of protocols for safety considerations by an IACUC (13) or IRB (4) as follows: 11 of 13 respondents indicated review by a biosafety committee and IACUC; 2 of 13 reviewed by IACUC exclusively for safety considerations; 3 of 4 reviewed by a biosafety committee and IRB; and 1 of 4 reviewed by IRB exclusively for safety considerations.

Figure 3.

Biosafety aspects evaluated during initial protocol screening and risk assessment review of the institutional oversight committee

*More than 1 response may have been provided by each respondent

**Three (3) unique text answers were provided, which included the following considerations: Mechanisms for reporting and communication of field incidents to the host institution, Handling and storage of potentially contaminated field research equipment (i.e. animal traps), Permitting issues for conducting field research activities

Figure 4.
Level of preparedness and training indicated by biosafety professionals overseeing field research-related protocols

Biosafety Professionals Indicating Whether Additional Training on Field Research Would Be Helpful, Including Willingness to Consider Attending a Field Research Training Course (n=68)

Figure 5. Biosafety professionals indicating whether additional training on field research would be helpful, including willingness to consider attending training

Table 1

Examples of field collection activities involving potentially infectious specimens.*

Human Specimens:
Obtained in clinical setting
From field screening activities
During an emergency/disaster
Forensic samples
Animals/Plants/Fish/Insects:
Whole animals
Diseased parts
Specimens/Field necropsy
Exo-and endoparasites
Water Samples:
Ambient
From untreated sources
From badly polluted sources
Cooling towers
Mold/Fungi:
Routine sampling
Gross contamination
Food:
Routine screening for contamination
Food-borne illness outbreak investigation
Archeological Samples:
Retrospective investigation of infectious disease
Quality Assurance Testing:
Air, mold samples

* Not intended to be an all-inclusive list; other examples may exist.

Table 2

Training courses on field research obtained by biosafety professionals.

Survey Responses (Provided in Text Responses) Indicating Training Courses on Field Research Obtained by Biosafety Professionals	
<ul style="list-style-type: none">•	No formal course, but received on-the-job training related to field research safety issues
<ul style="list-style-type: none">•	No formal course, but received project-specific training on field research safety provided by principal investigator or academic department
<ul style="list-style-type: none">•	Attended a conference or symposium that covered field research topics specifically
<ul style="list-style-type: none">•	Attended a conference or symposium that focused on other topics but introduced aspects of field research
<ul style="list-style-type: none">•	Attended a “wilderness survival” course
<ul style="list-style-type: none">•	Attended a training on field research safety issues offered by an insurance provider
<ul style="list-style-type: none">•	Attended a training offered by field service unit of a veterinary school
<ul style="list-style-type: none">•	Academic courses not related to field research but information applicable to field research oversight (e.g., risk assessment, zoonotic diseases, etc.)

Table 3

Specific critical areas of training for biosafety professionals on field research safety.

Survey Responses (Provided in Text Responses) Indicating Specific Critical Areas of Training on Field Research Safety for Biosafety Professionals	
•	Field research safety best practices
•	Risk assessment/risk identification
•	Overview of zoonotic diseases
•	Emerging pathogens
•	Potentially hazardous wildlife
•	Regulatory issues related to field collection of biological specimens
•	Basic field survival skills
•	Communication in the field
•	Safe specimen collection/handling techniques for the field
•	Safe specimen transport techniques for biological specimens
•	Safety considerations and SOPs for wild animal trapping/handling/manipulation
•	Personal protective equipment
•	Hand hygiene/infection control
•	Personnel transportation safety considerations/vehicle driving safety
•	Field lab setup/considerations
•	Occupational health requirements for conducting field research
•	Travel medicine
•	Establishing/communicating locations to receive treatment (e.g., local clinics, hospitals)
•	Emergency response/mitigation in the field
•	Emergency evacuation plans
•	Overt exposure response
•	Field first aid