Development and implementation of evidence-based laboratory safety management tools for a public health laboratory

M.S. Keckler[a,b,*], **K. Anderson**[a], **S. McAllister**[a], **J.K. Rasheed**[a], and **J. Noble-Wang**[a]

[a]Centers for Disease Control and Prevention, National Center for Emerging Zoonotic and Infectious Diseases, Division of Healthcare Quality Promotion, Clinical and Environmental Microbiology Branch, United States

[b]Centers for Disease Control and Prevention, Center for Surveillance, Epidemiology and Laboratory Services, Laboratory Leadership Service Fellowship, United States

Abstract

We developed an evidence-based continuous quality improvement (CQI) cycle for laboratory safety as a method of utilizing survey data to improve safety in a public health laboratory setting.

• **Expert Opinion**: The CQI cycle begins with the solicitation of laboratory staff input via an annual survey addressing potential chemical, physical and radiological hazards associated with multiple laboratory activities. The survey collects frequency, severity and exposure data related to these activities in the context of the most pathogenic organisms handled at least weekly.

• **Gap Analysis**: Step 2 of the CQI cycle used survey data to identify areas needing improvement. Typically, the traditional two-dimensional risk assessment matrix is used to prioritize mitigations. However, we added an additional dimension – frequency of exposure – to create three-dimensional risk maps to better inform and communicate risk priorities.

• **Mitigation Measures**: Step 3 of the CQI cycle was to use these results to develop mitigations. This included evaluating the identified risks to determine what risk control measures (elimination, substitution, engineering, administrative or PPE) were needed. In the 2016 iteration of the CQI cycle described here, all mitigations were based on administrative controls.

• **Evaluation and Feedback**: The last step of the CQI cycle was to evaluate the inferred effects of interventions through subsequent surveys, allowing for qualitative assessment of intervention effectiveness while simultaneously restarting the cycle by identifying new hazards.

Here we describe the tools used to drive this CQI cycle, including the survey tool, risk analysis method, design of interventions and inference of mitigation effectiveness.

Keywords

Laboratory safety; Occupational health; Evidence-based interventions; Survey; Continuous improvement; Quality management

1. Introduction

Laboratory safety is first, and most importantly, an occupational health concern for the estimated 290,988 public health workers in the United States (Beck et al., 2014). However, contaminated or infected employees can also transmit occupationally acquired pathogens outside the laboratory, making any actual or perceived safety breach in a public health laboratory a serious concern (Fleck, 2004; Blaser and Lofgren, 1981; Hawkes, 1979). In 2014, a series of safety incidents among multiple federal agencies drew extensive national media attention to the issue of safety in public health laboratories (McCarthy, 2014). These safety failures can erode trust in the public health system (Cohen, 2014), which has the potential to decrease compliance with public health agency recommendations (Ward, 2017). Therefore, the consequences of laboratory incidents in public health laboratories can be severe and widespread, even when occupational health risks are low (Centers for Disease Control and Prevention, 2014).

While incidents involving biological hazards are often the focus of laboratory-related safety discussions, it is well known that laboratories contain many potential hazards - including chemical, physical, and radiological (World Health Organization, 2004; Chosewood and Wilson, 2009; Occupational Health and Safety Administration, 2011). Unfortunately, current data about laboratory incidents is difficult to obtain as there is not yet a standardized system for reporting of laboratory incidents (Chamberlain et al., 2009; Dirnagl et al., 2016; Blaine, 2012). However, some insight into laboratory incidents can be gained using Bureau of Labor statistics, which show that of the incidence rate (2011–2016) of nonfatal occupational injuries and illnesses involving days away from work in medical and diagnostic labs is 100/10,000 full-time workers. Of these 100 illnesses or injuries, the source of 1% were directly related to chemicals and chemical products. The other 99% of illnesses and injuries came from a variety of potential chemical, physical and biological hazards which underlie the Occupational Injury and Illness Classification System 2.01 source categories of containers, furniture and fixtures (15%), machinery (5%), parts and materials (8%), persons, plants, animals and minerals (26%), structures and surfaces (17%), tools, instruments and equipment (4%), vehicles (10%) and other sources (13%). While it is difficult to relate these reported source categories with the underlying hazards, the breadth of incident sources does make obvious the need for laboratory safety risk assessments to consider all-hazards – not just biological. In addition to hazard types, there is a growing body of knowledge about various contributors to workplace safety (e.g. the effects of mental workload (Charles and Nixon, 2019); the need for leadership training (Gravina et al., 2019); the importance of occupational ergonomics (Fasanya and Shofoluwe, 2019) and the effects of worker personality on safety behavior (Jong-Hyun et al., 2018), which have not been well-studied in the laboratory setting.

While laboratory safety has long been a priority in public health laboratories (Moskowitz, 1948; Cook, 1961; Fuscaldo et al., 1980), multiple gaps remain between published best practices and the actual implementation of these practices in laboratories (Westgard, 2017; Herrmann-Werner et al., 2013; Van Noorden, 2013). There are many regulations, guidelines and standards relevant to the work performed in laboratories, but strategies for

implementation of these guidelines are left to individual laboratories to develop (World Health Organization, 2004; Chosewood and Wilson, 2009; Richmond and Nesby-O'Dell, 2002; Ned-Sykes et al., 2015; 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73 - Select Agent Regulations, 2018; International Organization for Standardization, 2017; Miller et al., 2012; 42 CFR 493, 2018; United States Code, 1988; International Organization for Standardization, 2018; International Organization for Standardization, 2003; International Organization for Standardization, 2012; 29 USC, 1910, 2018). Laboratory Quality Management Systems (LQMS) can provide a framework for document and process controls, as well as risk assessment and monitoring procedures to improve laboratory safety (Ahlin and Weiss, 2007; Lord, 1990; Nichols, 2011); however, LQMS in public health laboratories are frequently focused on patient safety and test result accuracy as opposed to occupational health and safety (Allen, 2013; Lippi and Guidi, 2007; Njoroge and Nichols, 2014).

The laboratory managers and staff who develop, document and implement laboratory procedures bring their own beliefs, knowledge, education, training, attitudes and experience to their work, and this can affect how they identify and interpret laboratory hazards (Buxton et al., 2011; Steelman and Alexander, 2016; Senthil et al., 2015). Laboratory risk assessments are complex and differ significantly from laboratory to laboratory making a standardized risk assessment approach difficult. However, obtaining a measure of worker perceptions regarding laboratory safety can improve risk management (Xia et al., 2017; Tziaferi et al., 2011). These are compelling reasons why better integration of safety and quality management in public health laboratories is needed (Sciacovelli et al., 2007).

To determine a standardized process of assessing and mitigating laboratory risk, we chose to develop a standardized, evidence-based continuous quality improvement (CQI) cycle. The cycle starts with the solicitation of expert opinion regarding laboratory hazards through an annual survey. Next is the gap analysis of the survey data to identify potential laboratory hazards and perform risk analysis. Based on the gap analysis, we then design and implement targeted mitigation measures. With the subsequent annual survey, the cyclic process ends when data is compared with the previous year to infer the effectiveness of the mitigation interventions and begins again by identifying new hazards or risks to target. Here we describe the development of the survey tool and risk assessment method and the application of these tools to design and evaluate evidence-based interventions.

1.1.   Significant results summary

- Developed practical tools for use by laboratory staff and safety personnel including:
  - Annual all-hazards survey tool designed to gather laboratory safety data.
    - ♦ Tailored to the highest risk group pathogen handled at least weekly
    - ♦ Collected information on severity, probability and exposure for biological, chemical, physical and radiological hazards associated with equipment and processes performed in the lab.

- Method for stratifying the risk of microorganisms handled in a BSL-2 laboratory

- Three-Dimensional Risk Assessment Tool designed for analysis of survey data

- Identified laboratory-specific risks for targeted intervention

  - Potential underutilization of engineering controls

  - Potential underreporting of near-misses

  - Potentially low awareness of process hazards

- Measured significant differences in survey responses after interventions

  - Staff training increased use of engineering controls

  - Increased incident reporting burden may cause lower near-miss reporting

  - Hazard awareness was increased through presentation of survey results

2. Materials and methods

2.1. CQI stage one - expert opinion

To start the CQI cycle, data is collected from our laboratory staff regarding their perceptions related to laboratory safety using a survey, which utilizes a non-random sampling methodology that is purposive to assess risk and develop mitigation measures in a specific federal public health laboratory. The anonymous survey is offered to all staff in the laboratory on an annual basis, but its completion is not mandated. Because the sampling is purposive, results from this survey are not generalizable to other laboratories. However, the survey tool can be tailored to any laboratory.

2.1.1. Survey development—Reviews of multiple guidelines for laboratory safety (World Health Organization, 2004; Chosewood and Wilson, 2009; Miller et al., 2012; 29 USC, 1910, 2018) were completed to formulate survey questions in the following categories: Regulatory Requirements, Biologicals (to identify the highest risk organisms worked with at least weekly), Equipment (inclusive of biological, chemical, radiological and physical hazards), Process (inclusive of biological, chemical, radiological and physical hazards), Mitigation (inclusive of elimination, substitution, engineering controls, administrative controls and personal protective equipment (PPE)), Quality Controls, Safety Culture and Safety Communications. We chose these categories to organize the survey with a goal toward obtaining a comprehensive picture of laboratory staff perceptions related to laboratory safety. The full text of the survey can be found in the supplementary information Appendix A. The specific focus for each category in the survey follows.

2.1.1.1. Regulatory requirements (Questions 1 and 2).: Question 1 (Q1) elicited data for the identification of work that requires external oversight. This included identification of work involving recombinant DNA, clinical tests, animals, humans, dual use research of

concern or transfer of materials from BSL3 or BSL4 level laboratories. An additional question collected self-reported data on compliance with these regulations (Q2).

2.1.1.2. Biologicals (Questions 3 through 12).: To elicit data for evidence-based risk assessment of microbiological hazards in the laboratory, we formulated questions to obtain self-reported data on work with pathogens (Q3) using two techniques.

2.1.1.2.1. Definition of stratified risks within risk group 2.: Risk Group 2 (RG2) microorganisms that have been handled in the laboratory over the last 5 years were subdivided into three substrata (High, Moderate, Low) based on a combination of literature review and expert opinion. We categorized organisms as high risk (Q4) if they were on the Department of Health and Human Services (DHHS) and United States Department of Agriculture (USDA) Select Agents and Toxins List (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73 - Select Agent Regulations, 2018) or have been reported as the confirmed source of a laboratory-associated infection or exposure (LAI/E) in relevant reviews of the LAI/E scientific literature (Baron and Miller, 2008; Singh, 2009; Wurtz et al., 2016; Silver, 2015; Miller et al., 1987; Campbell et al., 2015; Sullivan et al., 1978; Pike, 1976; Pike and Sulkin, 1951; Vesley and Hartmann, 1988). Microorganisms that have been confirmed as foodborne infections (FI) (Powell, 2016) or healthcare-associated infections (HAI) (Magill et al., 2014) were categorized as medium risk (Q6). The remainder of the RG2 microorganisms were categorized as low risk (Q8). The genus name of all microorganisms in each substrata category were included in the survey text to aid respondents in answering questions about these risk categories.

2.1.1.2.2. Use of skip logic.: Since most public health laboratory staff work with multiple pathogens, we designed the survey to use conditional logic to obtain the highest risk category microbes (Q4, Q6 and Q8) with which the respondent worked with at least weekly (Q5, Q7 and Q9). Additional questions (Q10, Q11, and Q12) provided free-form entry of additional pathogens but since these only yielded two responses which were included in the low risk category, they were not included separately in this analysis. A flowchart of the conditional logic structure is included in the Supplemental Materials Appendix B. This allowed the responses of each individual to identify the work to consider when answering the remainder of the survey.

2.1.1.3. Equipment (Question 13).: Question 13 asked for responses related to the frequency of usage, frequency of error and severity of error for potentially hazardous laboratory equipment. This was an all-hazards exercise as each piece of equipment potentially represents biological (i.e. aerosol production or difficult to clean), chemical (i.e. use of hazardous chemicals or potential for spills) or physical hazards (presence of high voltage or pinch points). Responses were used to calculate a risk score using a modification of the Severity, Probability and Exposure (SPE) Model (Cram, 2004) as explained in Section 2.2.1. Three-Dimensional Risk Analysis.

2.1.1.4. Process (Question 17).: Question 17 asked staff about the frequency of performance, frequency of error and severity of error for potentially hazardous laboratory activities and processes. Each process contains some unique combination of biological,

chemical or physical hazards. Responses were used to calculate a risk score as explained in Section 2.2.1. Three-Dimensional Risk Analysis.

2.1.1.5.   Mitigation (Question 12, 14 and 18).: These questions asked staff about the frequency of use of multiple risk controls including administrative controls (e.g., procedures, job aids, training), engineering controls (e.g., biosafety cabinets, chemical fume hoods, dead air boxes) and Personal Protective Equipment (PPE) (e.g., gloves, lab coat, safety glasses) when working with biological agents (Q12), equipment (Q14) and processes (Q18). Questions 14 and 18 were not included in our analysis as they were removed from the 2017 survey since the results did not differ from the results of question 12 in the 2016 survey, indicating that they were of little added value.

2.1.1.6.   Quality controls (Questions 15, 16 and 19).: These questions obtained data from staff regarding the frequency of availability of written protocols (Q15), proportion of these protocols under document control (Q16) and frequency of adherence to these protocols (Q19).

2.1.1.7.   Safety Culture (Questions 20, 21 and 22).: These questions obtained data from staff regarding the frequency of occurrence of safety culture-related issues in the laboratory (Q20), the frequency of notification of incidents and near misses by scenario (Q21) and the perceived priority of safety at various institutional management levels (Q22).

2.1.2.   Safety survey reliability and validity

2.1.2.1.   Content validity.: The content validity of the survey was assessed by a team of six subject matter experts (SME) which included non-supervisory laboratory scientists with additional expertise in safety and quality, as well as supervisory laboratory scientists with experience in managing both laboratory quality and safety. As a group, the education level of the SME was 67% PhD and 33% MS with general laboratory experience ranging from 7 years to over 30 years. The group met multiple times to discuss what should be measured by the survey and then each SME reviewed draft survey question and answer sets through three iterations to finalize the survey. Lastly, each SME took the online survey in its final form as a small pilot to address any remaining issues before release of the survey in 2016.

2.1.2.2.   Internal consistency reliability (coefficient alpha).: The internal consistency reliability (coefficient alpha) of the survey and the Cronbach's alpha for each of the scales used in the survey was determined using IBM SPSS Statistical Software Version 24 (IBM, California). Ideally, the Cronbach's alpha should be no less than 0.70 and no more than 0.90 indicating that the scales used are reliable but not redundant (Streiner, 2003). Table 1 lists the internal reliability of the scales used in this survey.

2.1.3.   Safety survey administration—The 2016 laboratory safety survey contained 33 questions and was sent to 36 laboratory staff using an anonymous online survey through the SurveyMonkey® platform. In 2017, the survey was 31 questions and was sent to 54 laboratory staff. The respondents were given two weeks to complete the survey, which took an average of 16 min to complete (n = 83). In May 2016, 34 staff responded (Response Rate

= 94%) while in August 2017, 49 staff responded (Response Rate = 91%). In accordance with the Paperwork Reduction Act, no more than 9 non-federal employees were surveyed in either year.

2.1.4.   Demographic questionnaire—To define the sample population in more detail without compromising the anonymity of the laboratory safety survey, we administered a separate questionnaire to collect demographic information about our staff in-between the 2016 and 2017 safety surveys. Respondents answered questions about their age category, education and experience. The demographics questionnaire was sent in March of 2017 (10 months after the 2016 survey and 2 months prior to the 2017 survey) using an anonymous online survey through the SurveyMonkey® platform. It was sent to 40 laboratory personnel of which 36 responded (Response Rate = 90%). In accordance with the Paperwork Reduction Act, no more than 9 non-federal employees were surveyed. The full text of the demographic survey is in the supplementary information Appendix C.

2.2.   CQI stage two - gap analysis

Once the survey data was collected, the next step was to perform a gap analysis. This analysis included reviewing the responses to all survey questions with a team of SMEs to identify areas for improvement, performing a three-dimensional risk analysis to identify areas of higher relative risk among equipment and processes, and reviewing the most current biosafety guidance and scientific literature. Gap analysis results (i.e. risk maps and areas identified for improvement) were reviewed by laboratory leadership for awareness and adjustment if needed.

2.2.1.   Three-dimensional risk analysis—To standardize the approach to prioritizing interventions and to maintain the usability of this survey as a practical tool with which to improve laboratory safety in a public health laboratory, a method was needed to perform risk analyses using survey data. Our goal in this effort was to establish a reproducible method for analyzing survey results to prioritize safety interventions. In addition, we wanted a method that would be straightforward to perform, provide semi-quantitative results for trend analysis, and provide an easily interpreted output (a risk map) for use in prioritizing safety interventions. To expand the granularity of the more traditional two-dimensional risk matrix, we chose to utilize the Severity, Probability and Exposure (SPE) Model of risk assessment and requested that respondents provide their estimation of:

- **Severity** (*s*) - How likely it is that an error in equipment usage or process performance would lead to injury or exposure.

- **Probability of Error** (*p*) - How likely it is for an error to occur while using a specific piece of equipment or performing a specific process.

- **Exposure** (*e*) - How often a piece of equipment is used or a process is performed.

The scale used for perceived probability of error (*p*) and severity (*s*) was weighted as follows: Highly Likely (75–100%) = 5; Moderately Likely (50–74%) = 4; Somewhat Likely (25–49%) = 3, Not Likely (1–24%) = 2 and Not Used (0%) = 1. Exposure (*e*) was weighted

Author Manuscript   Author Manuscript   Author Manuscript   Author Manuscript

as follows: Daily = 4, Weekly = 3, Monthly = 2 and Yearly = 1. These weights are designed to provide a maximum risk score of 100 for ease of comparison and ranking of risk scores for prioritizing planning interventions. We then applied this model to various pieces of laboratory equipment (n = 25) and multiple laboratory processes (n = 14). We calculated the mean of all responses for each variable ((e), (p) and (s)) for each activity or instrument and the variables were plugged into the following equation:

$$Relative\ Risk = Severity\ (s) \times Probability\ (p) \times Exposure\ (e)$$

This method allowed all data to be analyzed in a standardized manner and provides a method by which laboratory risks can be compared and prioritized. Risk scores of 80–100 are considered critical, 60–79 very high, 40–59 high, 20–39 moderate and 1–19 low and are graphed as radar maps for ease of risk visualization.

2.3. CQI stage three – mitigation measures

Safety staff and laboratory scientists reviewed and discussed the biological, chemical and physical hazards identified during the gap analysis to determine if it was possible to eliminate, substitute or isolate the hazards. Engineering controls, administrative controls and PPE requirements were also considered and a list of suggested mitigations was prepared. The suggestions from safety staff were discussed with additional laboratory staff to determine the best mitigation to implement.

2.4. CQI stage four – evaluation and feedback

The final stage of the CQI cycle in 2016 was to present the results of this process to the laboratory staff and solicit feedback on the survey and the process. However, in 2017, we presented results, solicited feedback and compared the survey data from 2016 and 2017 to analyze the efficacy of the 2016 mitigation measures.

2.4.1.   Efficacy analysis—We used two-tailed, two sample equal variance t-tests to compare 2016 and 2017 survey data to detect significant differences ($p < 0.05$) in responses from one year to another. Because the sample was non-random and the data was observational in nature, we cannot prove causality and can only infer that the interventions were the cause of changes in survey responses.

3.   Results

3.1. Demographics

To describe the sample population while maintaining respondent anonymity, we collected demographic data in a separate survey presented in Table 2. These demographics were collected in March of 2017 (10 months after the 2016 survey and 2 months prior to the 2017 survey) and therefore the demographics are most representative of the population sampled in 2017. The average respondent (see bolded categories) was a non-supervisory laboratory employee; 25–34 years of age with a Master's-level degree and 6–10 years of overall laboratory experience with 1–3 years in a federal public health laboratory. All respondents reported being vaccinated for Hepatitis B and 77% of respondents have never been injured in

a laboratory incident in any setting. Responses to the demographic questionnaire are presented as both total respondents and percent of sample population for each category.

3.2. Regulatory requirements (Questions 1 and 2)

Our laboratory functions in the past have included projects involving clinical testing, recombinant DNA research, dual use research of concern, human subjects research, animal research and transfer of materials from high-containment laboratories. Each of these functions require oversight from outside our laboratory. To gauge awareness of the requirements for external oversight, respondents were asked to identify which regulatory requirements were relevant to their work. There were no statistically significant changes from 2016 to 2017 in either the percent of staff doing work that requires external oversight, or in self-reported compliance using a two-tailed, two sample equal variance *t*-test.

Fig. 1 illustrates that the highest percentage of our staff (38% in 2016 and 50% in 2017) perform clinical laboratory testing that is overseen by the Centers for Medicare & Medicaid Services through the Clinical Laboratory Improvement Amendments (CLIA) regulations (United States Code, 1988). A lower percentage of staff work on recombinant DNA research (13% in 2016 and 9% in 2017), which is overseen by the Institutional Biosafety Committee (IBC) as required by the NIH Guidelines (Federal Register, 2016). This was followed by some staff performing work involving dual use research of concern (9% in 2016 and 13% in 2017) which is overseen by the Institutional Biosecurity Board (IBB) in accordance with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (Federal Register, 2014) and work involving human subjects research (6% in 2016 and 9% in 2017) which is overseen by the Institutional Review Board (IRB) in accordance with the Protection of Human Subjects (Common Rule) (Code of Federal Regulations, 2018). The least number of staff reported that they performed work related to the transfer of infectious materials out of high containment laboratories (0% in 2016 and 3% in 2017) overseen by the Laboratory Safety Review Board (LSRB) as per institutional policy or animal research work (6% in 2016 and 0% in 2017) which is overseen by the Institutional Animal Care and Use Committee (IACUC) in accordance with the Animal Welfare Act (Code, U.S., 1966).

3.3. Handling of microorganisms (Questions 3 through 12)

Staff were also asked a series of questions about RG2 microorganisms they handle in the laboratory and the frequency with which they worked with those microorganisms. As described in the methods section, the RG2 organisms were arranged into three substrata: High (select agents and known etiologic agents of LAI), Moderate (etiologic agents of FI and HAI) and Low (remaining organisms). Results reported in Fig. 2 show that while 12 (2016) and 17 (2017) persons work with high risk organisms, only a small portion of those staff work with these organisms at least weekly (3 and 4 in 2016 and 2017, respectively). Moderate risk organisms were handled by 21 (2016) and 27 (2017) staff and almost all 21 (2016) and 23 (2017) work with those pathogens at least weekly. Low risk organisms were handled by 2 and 3 staff in 2016 and 2017, respectively at least weekly. There were no statistically significant changes in the percent of staff self-reporting at least weekly work

with any risk group of pathogens from one year to another using a two-tailed, two-sample equal variance *t*-test.

3.4. Equipment (Question 13)

Respondents were given a list of 25 types of equipment and were asked to identify the frequency at which they used that type of equipment. In addition, they were asked to categorize the likelihood of an error occurring and the likelihood of that error leading to an injury or exposure. The responses were weighted and calculated as detailed in the Section 2.2.1. Three-Dimensional Risk Analysis. Results are reported as single and combined risk maps using relative risk scores in Fig. 3. The top five perceived risks in 2016 (Fig. 3A) were 1. Freezers, 2. Waterbaths, 3. Electrical, 4. Needles and 5. Heat. In 2017 (Fig. 3B) they were 1. Machinery, 2. Compressed Gas, 3. Glass, 4. Electrical and 5. Needles. Further analysis demonstrated that the largest increases in perceived risk involved autoclaves (Fig. 3C). The risk map for autoclaves illustrated that the increased perceived risk was due to an increase in both the reported frequency of usage and frequency of error (Fig. 3D).

3.5. Process (Question 17)

Respondents were given a list of 14 laboratory processes and were asked to identify the frequency at which they performed those processes. In addition, they were asked to rank the likelihood of an error occurring and the likelihood of that error leading to an injury or exposure. The responses were weighted and scored as detailed in the Section 2.2.1. Three-Dimensional Risk Analysis. Results are reported as single and combined risk maps using relative risk scores in Fig. 4. The top five perceived risks in 2016 (Fig. 4A) were 1. Explosion, 2. Repetitive Motion, 3. Spills, 4. > 500 ml Cultures and 5. Aerosol. In 2017 (Fig. 4B) they were 1. Spills, 2. Repetitive Motion, 3. Explosion, 4. Aerosol and 5. Biological Inactivation. Further analysis demonstrated that the largest increases in perceived risk involved biological inactivation (Fig. 4C). The risk map for biological inactivation illustrated that the increased perceived risk was due to an increase in both the reported frequency of usage and severity (Fig. 4D).

3.6. Mitigation (Question 12, 14 and 18)

Respondents were asked to indicate the different mitigation strategies they use to control risk in the laboratory. Fig. 5 presents the self-reported data showing that in 2016, 96% of staff used administrative controls (e.g. training, procedures) while only 83% used engineering controls. For PPE, 100% of staff used body and hand PPE but only 31% used eye PPE. All respondents (100%) had been vaccinated previously for Hepatitis B. In 2017, 100% of staff used administrative and engineering controls. PPE use for body and hands remained at 100% while eye PPE usage increased to 97%. All respondents (100%) again reported that they had been previously vaccinated for Hepatitis B. Increases in the use of engineering controls (e.g. biosafety cabinet, chemical fume hood) and eye and face PPE were significant by two-tailed, two-sample equal variance *t*-test ($p < 0.05$). Respiratory protection is not necessary for most of our procedures and the percentage of use remained essentially the same from 2016 (37%) to 2017 (40%).

3.7. LQMS indicators (Questions 15, 16 and 19)

Respondents were asked to gauge the frequency at which: (1) their work processes are documented in written protocols, (2) these protocols are in a document control system and (3) staff members are adhering to these protocols. Allowable answers were Always (100%); Mostly (60–99%); About half of the time (40–59%); Seldom (1–39%) and Never (< 1%). As shown in Fig. 6, the median response in 2016 corresponded to work processes always being documented and these protocols mostly being in a document control system. Responses also indicated that staff mostly adhered to the protocols. In 2017, the only change was a decrease in the number of processes that are documented from always to mostly but there were no statistically significant changes by two-tailed, two-sample equal variance t-test.

3.8. Safety culture (Questions 20, 21 and 22)

Respondents were asked to categorize the frequency of occurrence of unsafe behaviors (disorganized work spaces, inattention, misuse of PPE, non-aseptic practices, lack of foresight, intentional risk taking, failure to report incidents) and workplace issues (rushed staff, facility issues, lack of resources, equipment issues, lack of administrative controls) that could contribute to the probability of a safety incident (data not shown). Allowable answers were "Daily, Weekly, Monthly or Yearly". None of the median responses corresponded to "Daily" or "Weekly" Disorganized work spaces and rushed staff had median responses that corresponded to "Monthly" for both 2016 and 2017. The median response for all other unsafe behaviors or workplace issues corresponded to "Yearly".

We also elicited opinions on the perceived priority of safety at various institutional management levels. Allowable answers included "Safety is a top priority; Safety is low priority; Safety is not considered; or Who is this group?". The results were aggregated into levels corresponding to non-supervising staff (Level 1) through the various levels of supervisory management (Level 2, 3, 4 and 5). For all levels, the median response indicated that safety is a top priority (data not shown). There were no significant changes from 2016 to 2017 by two-tailed, two-sample equal variance t-test for either of these questions.

Lastly, we asked for staff perspectives about how frequently they would expect that various incidents would be reported (Absolutely would report (100%); Most likely (70–99%); It could go either way (30–69%); Doubtful (1–29%); Would not report (0%)). For both 2016 and 2017, the median response corresponded to absolutely would report for any probable exposure, possible exposure, release or a major injury. In 2016, respondents indicated that they absolutely would report a minor injury but this value dropped to most likely would report in 2017. For near misses, both 2016 and 2017 median responses corresponded to "It could go either way". Only the median responses for minor injury reporting were significantly decreased ($p > 0.05$) from 2016 to 2017 by two-tailed, two-sample equal variance t-test (Fig. 7).

4. Discussion

Designing an effective laboratory safety program requires data to formulate safety interventions that are evidence-based (Cote et al., 2016; Yarahmadi et al., 2016; Smith and

Morrato, 2014; Kimman et al., 2008; Birnbaum et al., 2016), but data on laboratory safety are limited in various ways. Limitations of published safety data include only being relevant to a specific pathogen (Leunda et al., 2013; Tyshenko et al., 2011; Rozell, 2015; Wagar, 2016; Li et al., 2012; Pedrosa and Cardoso, 2011; Le Duc and Franz, 2012), a single type of laboratory (Shurtleff et al., 2012; Dickmann et al., 2015; Elduma, 2012; Higgins et al., 2013) or a single laboratory process (Ahlin and Weiss, 2007; Burke, 1993; Serafini et al., 2016; Wedum, 1964; Gillespie and Gibbons, 1975; Nimunkar et al., 2017). These lessons learned are difficult to apply in public health laboratories due to the complexity of working with a large number of microorganisms and performing a breadth of testing services using a variety of laboratory equipment and processes while fully complying with numerous standards, regulations and guidelines. More comprehensive and standardized strategies are needed to effectively integrate evidence-based safety with quality management systems in public health laboratories (Pedrosa and Cardoso, 2011; Salerno and Gaudioso, 2015; Westgard, 2013; Person, 2013; Jairaman et al., 2017; Janssens, 2014; Lentz et al., 2015). We have presented results that incorporated the expert opinion of our laboratory staff to address risk and create a laboratory safety-specific continuous improvement cycle to inform laboratory safety interventions.

We chose to begin the CQI cycle by collecting expert opinions about laboratory-specific hazards through a survey of staff members for two reasons. First, it is the laboratory staff who have the most expertise and experience in laboratory activities and the safety in the laboratory ultimately rests with them. Second, understanding how our staff perceive risks is critical to implementing and maintaining effective laboratory safety programs (Xu et al., 2014; Robertson et al., 2015; Kleiner et al., 2015; Schulte et al., 2012; Chung et al., 2015). The survey was designed to improve our understanding of risk in the laboratory setting. First, although all microorganisms are handled in our biosafety level 2 (BSL2) laboratory (Charles and Nixon, 2019) and are RG2 agents, some of our microorganisms are considered to be more pathogenic or transmissible than other RG2 microorganisms. While biosafety levels are invaluable benchmarks for basic laboratory safety (World Health Organization., 2004; Chosewood and Wilson, 2009), they are, by necessity, very general and should mark the beginning of a more rigorous assessment of microorganism risk (Gravina et al., 2019; Buxton et al., 2011). To seek more precision in how we managed biological risk, we sought to stratify our RG2 microorganisms into high, moderate and low risk categories. Second, we also utilized skip logic in the survey to ascertain the most pathogenic microorganisms that each staff member works with at least weekly. This enabled us to obtain frequency and severity data to better define our microorganism-associated risks and provided the biological context for respondents to use when responding to the remainder of the survey (Fig. 2).

The CQI cycle continued with a gap analysis to identify and prioritize risks. We chose a three-dimensional risk analysis method using data on the probability of error, severity of error and likelihood of exposure, as opposed to the traditional two-dimensional matrices (probability and severity of error) (Manuele, 2001). This provided a method to identify risks at a more granular level and to better understand how staff in our laboratories perceive equipment (Fig. 3) and process (Fig. 4) risks. The output of this method is a risk map that offers a graphical presentation of risk by probability, severity and exposure. Graphical risk communications have been shown to contribute to successful safety interventions (Severtson

and Henriques, 2009). This approach to hazard identification, risk analysis and risk communication was successful in raising awareness of laboratory safety amongst our staff and engaging them in these processes.

Understanding and prioritizing the risks leads to the next step in the CQI cycle – the design of mitigation measures. For example, in 2016, we identified the following as areas for targeted intervention:

- Potential underutilization of engineering controls (Fig. 5)

- Potential underreporting of near-misses (Fig. 7)

- Potentially low awareness of process hazards (Fig. 4)

To address engineering controls, we performed refresher training for all staff on biosafety cabinet usage. We also developed and implemented a laboratory-specific risk assessment procedure, which was used to expand and tailor the safety section of multiple laboratory procedures to raise awareness of hazards specific to those activities. Lastly, we implemented a new laboratory incident response and reporting notification program to address near miss reporting.

To close out the CQI cycle, we elected to utilize the data from the subsequent annual survey to evaluate the effects of the interventions. In 2017, engineering control use (Fig. 5) and process awareness was increased (Fig. 4) which was consistent with successful interventions in this area. In both cases, institutional efforts in laboratory safety and risk assessment training occurred in the same timeframe and most likely amplified the effectiveness of our efforts. Interestingly, responses indicated that staff were less likely to report minor injuries in 2017 (Fig. 6) despite issuance of both institutional and laboratory-specific policies regarding incident response and notification. It has been shown in other laboratory settings that additional restrictions and requirements on laboratory activities are not always beneficial (Shurtleff et al., 2012) so it is important to determine if the incident notification intervention – as designed – should be reevaluated. The collection of data on an annual basis also allows evaluation of interventions that are generated from outside this process. For example, in 2017 we observed a significant increase in eye PPE (Fig. 5) due most likely to a new institutional policy requiring the use of safety glasses in all laboratories. Evaluating the efficacy of interventions using data from a subsequent survey is an inferential process. The data we collect is non-random and any changes that occur after an intervention may not necessarily be caused by the intervention. However, the evaluation of data on an annual basis allows us to infer how perceptions of laboratory safety are changing which restarts the CQI cycle by identifying new hazards and risks to address.

We have centralized requests for IBB, IBC, LSRB, IACUC and IRB protocol approvals which allows us to compare the data we collected about external oversight to what our records show indicating that staff are aware of these oversight requirements (Fig. 1). We also collected data consistent with our current understanding of barriers to safety. For example, a major barrier to staff compliance with laboratory safety directives is lack of time (Shakoor et al., 2016). Our data is consistent with this as rushed laboratory staff, along with disorganized

laboratory areas and facility issues, were the most frequently reported workplace conditions that could potentially lead to a safety incident.

There are obvious limitations to this method of data collection and analysis. We observed a potential for self-reporting bias as 100% of staff reported using administrative controls, while also reporting that only 60–99% of other staff members were doing the same. Future surveys will use a new scale with smaller ranges for this answer to try to detect the extent of this bias (i.e. was the reported 60–99% of staff who use administrative controls actually closer to 60% or closer to 99%). In addition, inferring efficacy of interventions is also limited as there is no way to prove that any change in responses is due to a targeted intervention as opposed to be due to changes in the workforce, laboratory goals or external directives.

Successful interventions to improve safety include training (Coelho and García Díez, 2015; Olson et al., 2009; Pallozzi et al., 2003) and the establishment of core competencies for biosafety (Chamberlain et al., 2009). We utilized training interventions with success in significantly increasing the reported use of engineering controls (Fig. 5) and raising the level of awareness regarding laboratory process risks among laboratory staff (Fig. 4). We also implemented a knowledge transfer assessment after safety training, which allowed additional trainings and interventions to identify and address gaps in trainer expertise as well as staff knowledge. It is vital that public health laboratories establish and maintain high safety standards. However, the diversity and complexity of the work performed in public health laboratories makes it difficult to maintain, monitor and continuously improve laboratory safety management. The tools and observations described here can be used to enhance engagement of expert staff and provide a means of generating practical evidence-based safety interventions within a Quality Management framework.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements

References

29 USC, 1910, 2018 29 USC 1910. Occupational Safety and Health Standards for Laboratories Department of Health and Human Services, Editor.

42 CFR 493, 2018 42 CFR 493 - Standards and Certification: Laboratory Requirements Department of Health and Human Services, Editor.

Ahlin PA, Weiss RL, 2007 Risk management and compliance in pathology and laboratory medicine. Clin. Lab. Med 27 (4), 859–873 vii. [PubMed: 17950902]

Allen LC, 2013 Role of a quality management system in improving patient safety - laboratory aspects. Clin. Biochem 46 (13–14), 1187–1193. [PubMed: 23648455]

Association of State and Territorial Public Health Laboratory Directors (ASTPHLD), 1997 Regulatory closure of cervical cytology laboratories: recommendations for a public health response. MMWR Recomm. Rep 46 (Rr-17), 1–19.

Baron EJ, Miller JM, 2008 Bacterial and fungal infections among diagnostic laboratory workers: evaluating the risks. Diagn. Microbiol. Infect. Dis 60 (3), 241–246. [PubMed: 17997259]

Beck AJ, Boulton ML, Coronado F, 2014 Enumeration of the governmental public health workforce, 2014. Am. J. Prev. Med 47 (5 Suppl 3), S306–S313. [PubMed: 25439250]

Birnbaum LS, Burke TA, Jones JJ, 2016 Informing 21st-century risk assessments with 21st-century science. Environ. Health Perspect 124 (4), A60–A63. [PubMed: 27035154]

Blaine JW, 2012 Establishing a national biological laboratory safety and security monitoring program. Biosecur. Bioterror 10 (4), 396–400. [PubMed: 23210833]

Blaser MJ, Lofgren JP, 1981 Fatal salmonellosis originating in a clinical microbiology laboratory. J. Clin. Microbiol 13 (5), 855–858. [PubMed: 7240398]

Burke RL, 1993 Managing risk under CLIA (Clinical Laboratory Improvement Amendments). Med. Group Manage. J 40 (3), 30–34.

Buxton JA, et al., 2011 Using qualitative methods to investigate risk perception of Canadian medical laboratory workers in relation to current prion disease infection control policies. J. Toxicol. Environ. Health A 74 (2–4), 241–247. [PubMed: 21218349]

Campbell MJ, et al., 2015 Characterizing accidents, exposures, and laboratory-acquired infections reported to the National Institutes of Health's Office of Biotechnology Activities (NIH/OBA) involving recombinant DNA biological agents. Dissertation Abstr. Int.: Section B: Sci. Eng

Centers for Disease Control and Prevention, 2014 CDC Report on the Potential Exposure to Anthrax. Int. Microbiol, 17(2), pp. 119–127. [PubMed: 26418856]

Chamberlain AT, et al., 2009 Biosafety training and incident-reporting practices in the United States: a 2008 survey of biosafety professionals. Appl. Biosaf.: J. Am. Biol. Saf. Assoc 14 (3), 135–143.

Charles RL, Nixon J, 2019 Measuring mental workload using physiological measures: A systematic review. Appl. Ergon 74, 221–232. [PubMed: 30487103]

Chosewood LC, Wilson DE, 2009 Biosafety in microbiological and biomedical laboratories 5th ed. HHS publication. U.S. Dept. of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, Washington, D.C. xxii, 415 p.

Chung D, et al., 2015 Social signals of safety and risk confer utility and have asymmetric effects on observers' choices. Nat. Neurosci 18 (6), 912–916. [PubMed: 25984890]

Code of Federal Regulations, 2018 45 CFR 46 - Protection of Human Subjects (Common Rule)

Code, U.S., 1966 7 U.S.C. § 2131 Animal Welfare Act (AWA)

Coelho AC, García Díez J, 2015 Biological risks and laboratory-acquired infections: a reality that cannot be ignored in health biotechnology. Front. Bioeng. Biotechnol 3, 56. [PubMed: 25973418]

Cohen J, 2014 Lab safety. Alarm over biosafety blunders. Science 345 (6194), 247–248. [PubMed: 25035464]

Cook EB, 1961 Safety in the public health laboratory. Public Health Rep 76, 51–56. [PubMed: 13695240]

Cote I, et al., 2016 The next generation of risk assessment multi-year study—highlights of findings, applications to risk assessment, and future directions. Environ. Health Perspect 124 (11), 1671–1682. [PubMed: 27091369]

Cram RS, Anadarko Algeria Corporation LLC, 2004 3D model for qualitative risk assessment. In: Seventh SPE International Conference on Health, Safety and Environment in Oil and Gas Exploration and Production Society of Petroleum Engineers Inc, Calgary, Alberta, Canada.

Dickmann P, Sheeley H, Lightfoot N, 2015 Biosafety and biosecurity: a relative risk-based framework for safer, more secure, and sustainable laboratory capacity building. Front. Public Health 3, 241. [PubMed: 26539427]

Dirnagl U, et al., 2016 A laboratory critical incident and error reporting system for experimental biomedicine. PLoS Biol 14 (12), e2000705. [PubMed: 27906976]

Elduma AH, 2012 Assessment of biosafety precautions in Khartoum state diagnostic laboratories, Sudan. Pan Afr. Med. J 11, 19. [PubMed: 22514753]

Fasanya BK, Shofoluwe M, 2019 Occupational ergonomics: emerging approaches toward improved worker productivity and injury reduction. In: In: Goonetilleke R, Karwowski W (Eds.), Advances in Physical Ergonomics & Human Factors. AHFE 2018. Advances in Intelligent Systems and Computing, vol. 789 Springer, Cham.

Federal Register, 2014 79 FR 57589 Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern U.S. Government, Editor.

Federal Register, 2016 81 FR 22286 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), N.I.H. (U.S.), Editor.

Fleck F, 2004 SARS outbreak over, but concerns for lab safety remain. Bull. World Health Organ 82 (6), 470.

Fuscaldo AA, Erlick BJ, Hindman B, 1980 Laboratory safety: theory and practice Academic Press, New York xiv, 357 p.

Gillespie EH, Gibbons SA, 1975 Proceedings: Laboratory autoclaves–dangers and safety. J. Clin. Pathol 28 (9), 754.

Gravina NE, King A, Austin J, 2019 Training leaders to apply behavioral concepts to improve safety. Safety Sci 112, 66–70.

Hawkes N, 1979 Smallpox death in Britain challenges presumption of laboratory safety. Science 203 (4383), 855–856. [PubMed: 419409]

Herrmann-Werner A, et al., 2013 Best practice" skills lab training vs. a "see one, do one" approach in undergraduate medical education: an RCT on students' long-term ability to perform procedural clinical skills. PLoS One 8 (9), e76354. [PubMed: 24086732]

Higgins JJ, et al., 2013 Implementation of a personnel reliability program as a facilitator of biosafety and biosecurity culture in BSL-3 and BSL-4 laboratories. Biosec. Bioterrorism: Biodefense Strategy, Pract., Sci 11 (2), 130–137.

International Organization for Standardization, 2003 ISO 15190:2003 Medical Laboratories - Requirements for Safety

International Organization for Standardization, 2012 ISO 15189:2012 Medical Laboratories - Requirements for Quality and Competence

International Organization for Standardization, 2017 ISO 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

International Organization for Standardization, 2018 ISO 45001:2018 Occupational Health and Safety

Jairaman J, Sakiman Z, Li LS, 2017 Sunway medical laboratory quality control plans based on six sigma, risk management and uncertainty. Clin. Lab. Med 37 (1), 163–176. [PubMed: 28153364]

Janssens PM, 2014 Practical, transparent prospective risk analysis for the clinical laboratory. Ann. Clin. Biochem 51 (Pt 6), 695–704. [PubMed: 24553437]

Jong-Hyun L, et al., 2018 The effects of personality types on self-reported safety behavior: Focused on plant workers in Korea. Accid. Anal. Prev 121, 20–27. [PubMed: 30205283]

Kimman TG, Smit E, Klein MR, 2008 Evidence-based biosafety: a review of the principles and effectiveness of microbiological containment measures. Clin. Microbiol. Rev 21 (3), 403–425. [PubMed: 18625678]

Kleiner BM, et al., 2015 Sociotechnical attributes of safe and unsafe work systems. Ergonomics 58 (4), 635–649. [PubMed: 25909756]

Le Duc JW, Franz DR, 2012 Genetically engineered transmissible influenza A/H5N1: a call for laboratory safety and security. Biosec. Bioterrorism 10 (1), 153–154.

Lentz TJ, et al., 2015 Aggregate exposure and cumulative risk assessment—integrating occupational and non-occupational risk factors. J. Occup. Environ. Hygiene 12 (sup1), S112–S126.

Leunda A, et al., 2013 Laboratory activities involving transmissible spongiform encephalopathy causing agents: risk assessment and biosafety recommendations in Belgium. Prion 7 (5), 420–433. [PubMed: 24055928]

Li Z, et al., 2012 Aerosolized avian influenza virus by laboratory manipulations. Virology J 9 p. 146–146. [PubMed: 22866888]

Lippi G, Guidi GC, 2007 Risk management in the preanalytical phase of laboratory testing. Clin. Chem. Lab. Med 45 (6), 720–727. [PubMed: 17579523]

Lord JT, 1990 Risk management in pathology and laboratory medicine. Arch. Pathol. Lab. Med 114 (11), 1164–1167. [PubMed: 2241529]

Magill SS, Edwards JR, Fridkin SK, 2014 Survey of health care-associated infections. N. Engl. J. Med 370 (26), 2542–2543.

Manuele FA, 2001 Innovations in Safety Management: Addressing Career Knowledge Needs Wiley, New York xiv, 251 p.

McCarthy M, 2014 Biosafety lapses prompt US CDC to shut labs and launch review. BMJ 349, g4615. [PubMed: 25022658]

Miller JM, et al., 2012 Guidelines for safe work practices in human and animal medical diagnostic laboratories. Recommendations of a CDC-convened, Biosafety Blue Ribbon Panel. MMWR Suppl 61 (1), 1–102. [PubMed: 22217667]

Miller CD, Songer JR, Sullivan JF, 1987 A twenty-five year review of laboratory-acquired human infections at the National Animal Disease Center. Am. Ind. Hyg. Assoc. J 48 (3), 271–275. [PubMed: 3578038]

Moskowitz S, 1948 Safety for laboratory technicians. Mon. Rev. New York State Dep. Labor. Div. Ind. Hyg 27 (8), 29 passim.

Ned-Sykes R, et al., 2015 Competency guidelines for public health laboratory professionals: CDC and the association of public health laboratories. MMWR Suppl 64 (1), 1–81.

Nichols JH, 2011 Laboratory quality control based on risk management. Ann. Saudi Med 31 (3), 223–228. [PubMed: 21623049]

Nimunkar AJ, et al., 2017 Reducing thumb extensor risk in laboratory rat gavage. Appl. Ergon 58, 151–155. [PubMed: 27633208]

Njoroge SW, Nichols JH, 2014 Risk management in the clinical laboratory. Ann. Lab. Med 34 (4), 274–278. [PubMed: 24982831]

Occupational Health and Safety Administration, 2011 Laboratory Safety Guidance

Olson R, et al., 2009 Observational learning and workplace safety: the effects of viewing the collective behavior of multiple social models on the use of personal protective equipment. J. Safety Res 40 (5), 383–387. [PubMed: 19932320]

Pallozzi WA, et al., 2003 Novel training concepts and techniques used to increase safety awareness in the laboratory animal facility. Lab. Anim. (NY) 32 (6), 38–42.

7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73 - Select Agent Regulations, 2018 Department of Health and Human Services and the United States Department of Agriculture, Editor.

Pedrosa PB, Cardoso TA, 2011 Viral infections in workers in hospital and research laboratory settings: a comparative review of infection modes and respective biosafety aspects. Int. J. Infect. Dis 15 (6), e366–e376. [PubMed: 21497126]

Person NB, 2013 Developing risk-based quality control plans: an overview of CLSI EP23-A. Clin. Lab. Med 33 (1), 15–26. [PubMed: 23331726]

Pike RM, 1976 Laboratory-associated infections: summary and analysis of 3921 cases. Health Lab. Sci 13 (2), 105–114. [PubMed: 946794]

Pike RM, Sulkin SE, 1951 Laboratory-acquired infections in the United States. Tex Rep. Biol. Med 9 (2), 346–347. [PubMed: 14835469]

Powell MR, 2016 Trends in Reported Foodborne Illness in the United States; 1996–2013. Risk Anal 36 (8), 1589–1598. [PubMed: 26709453]

Richmond JY, Nesby-O'Dell SL, 2002 Laboratory security and emergency response guidance for laboratories working with select agents. Centers for Disease Control and Prevention. MMWR Recomm. Rep 51 (Rr-19), 1–6.

Robertson MM, et al., 2015 Sociotechnical approaches to workplace safety: Research needs and opportunities. Ergonomics 58 (4), 650–658. [PubMed: 25728246]

Rozell DJ, 2015 Assessing and managing the risks of potential pandemic pathogen research. mBio 6 (4), e01075–e1115. [PubMed: 26199335]

Salerno RM, Gaudioso JM, 2015 Laboratory Biorisk Management: Biosafety and Biosecurity CRC Press, Taylor & Francis Group, Boca Raton xxii, 242 pages.

Schulte PA, et al., 2012 Interaction of occupational and personal risk factors in workforce health and safety. Am. J. Public Health 102 (3), 434–448. [PubMed: 22021293]

Sciacovelli L, et al., 2007 Risk management in laboratory medicine: quality assurance programs and professional competence. Clin. Chem. Lab. Med 45 (6), 756–765. [PubMed: 17579529]

Senthil A, et al., 2015 Perception and prevalence of work-related health hazards among health care workers in public health facilities in southern India. Int. J. Occup. Environ. Health 21 (1), 74–81. [PubMed: 25482656]

Serafini A, et al., 2016 Use of a systematic risk analysis method (FMECA) to improve quality in a clinical laboratory procedure. Ann. Ig 28 (4), 288–295. [PubMed: 27479765]

Severtson DJ, Henriques JB, 2009 The effect of graphics on environmental health risk beliefs, emotions, behavioral intentions and recall. Risk Anal.: Off. Publ. Soc. Risk Anal 29 (11), 1549–1565.

Shakoor S, et al., 2016 Barriers to implementation of optimal laboratory biosafety practices in Pakistan. Health Security 14 (4), 214–219. [PubMed: 27400192]

Shurtleff AC, et al., 2012 The impact of regulations, safety considerations and physical limitations on research progress at maximum biocontainment. Viruses 4 (12), 3932–3951. [PubMed: 23342380]

Silver S, 2015 Laboratory-acquired lethal infections by potential bioweapons pathogens including Ebola in 2014. FEMS Microbiol. Lett 362 (1), 1–6.

Singh K, 2009 Laboratory-acquired infections. Clin. Infect. Dis 49 (1), 142–147. [PubMed: 19480580]

Smith MY, Morrato E, 2014 Advancing the field of pharmaceutical risk minimization through application of implementation science best practices. Drug Saf 37 (8), 569–580. [PubMed: 25005707]

Steelman ED, Alexander JL, 2016 Laboratory animal workers' attitudes and perceptions concerning occupational risk and injury. J. Am. Assoc. Lab. Anim. Sci 55 (4), 419–425. [PubMed: 27423148]

Streiner DL, 2003 Starting at the beginning: an introduction to coefficient alpha and internal consistency. J. Pers. Assess 80 (1), 99–103. [PubMed: 12584072]

Sullivan JF, Songer JR, Estrem IE, 1978 Laboratory-acquired infections at the National Animal Disease Center 1960–1976. Health Lab. Sci 15 (1), 58–64. [PubMed: 565343]

Tyshenko MG, et al., 2011 Expert elicitation for the judgment of prion disease risk uncertainties. J. Toxicol. Environ. Health A 74 (2–4), 261–285. [PubMed: 21218351]

Tziaferi SG, et al., 2011 Risk assessment of physical hazards in greek hospitals combining staff's perception, experts' evaluation and objective measurements. Safety Health Work 2 (3), 260–272.

United States Code, 1988 42 U.S.C. § 263a - Clinical Laboratory Improvement Amendments

Van Noorden R, 2013 Safety survey reveals lab risks. Nature 493 (7430), 9–10. [PubMed: 23282341]

Vesley D, Hartmann HM, 1988 Laboratory-acquired infections and injuries in clinical laboratories: a 1986 survey. Am. J. Public Health 78 (9), 1213–1215. [PubMed: 3407823]

Wagar E, 2016 Bioterrorism and the role of the clinical microbiology laboratory. Clin. Microbiol. Rev 29 (1), 175–189. [PubMed: 26656673]

Ward PR, 2017 Improving access to, use of, and outcomes from public health programs: the importance of building and maintaining trust with patients/clients. Front. Public Health 5, 22. [PubMed: 28337430]

Wedum AG, 1964 Laboratory safety in research with infectious aerosols. Public Health Rep 79, 619–633. [PubMed: 14177793]

Westgard JO, 2013 Perspectives on quality control, risk management, and analytical quality management. Clin. Lab. Med 33 (1), 1–14. [PubMed: 23331725]

Westgard SA, 2017 Rhetoric versus reality? Laboratory surveys show actual practice differs considerably from proposed models and mandated calculations. Clin. Lab. Med 37 (1), 35–45. [PubMed: 28153368]

World Health Organization, 2004 Laboratory biosafety manual, 3rd ed. World Health Organization, Geneva viii, 178 p.

Wurtz N, et al., 2016 Survey of laboratory-acquired infections around the world in biosafety level 3 and 4 laboratories. Eur. J. Clin. Microbiol. Infect. Dis 35 (8), 1247–1258. [PubMed: 27234593]

Xia N, et al., 2017 Do we see how they perceive risk? An integrated analysis of risk perception and its effect on workplace safety behavior. Accid. Anal. Prev 106, 234–242. [PubMed: 28645020]

Xu Y, et al., 2014 Controlled versus automatic processes: which is dominant to safety? The moderating effect of inhibitory control. PLoS ONE 9 (2), e87881. [PubMed: 24520338]

Yarahmadi R, Moridi P, Roumiani Y, 2016 Health, safety and environmental risk management in laboratory fields. Med. J. Islam Repub. Iran 30, 343. [PubMed: 27284544]
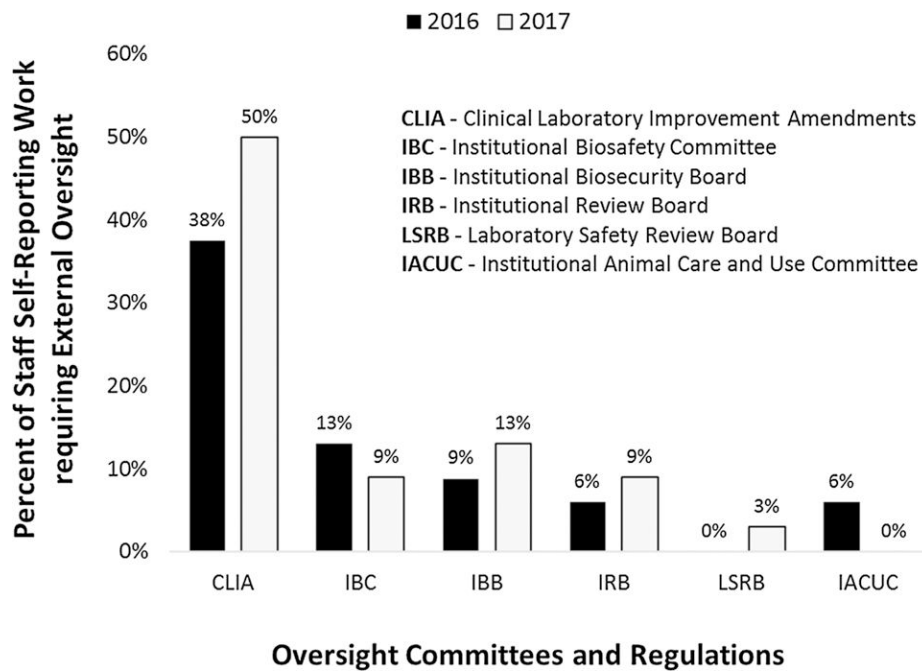
Fig. 1.
Work requiring external oversight. Total percent of staff who self-report that their work requires external oversight by Clinical Laboratory Improvement Amendments (CLIA), Institutional Biosafety Committee (IBC), Institutional Biosecurity Board (IBB), Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Laboratory Safety Review Board (LSRB) for 2016 (black) and 2017 (grey).

Number of Staff Self-Reporting Handling of Stratified RG2 Microorganisms on at least a Weekly Basis

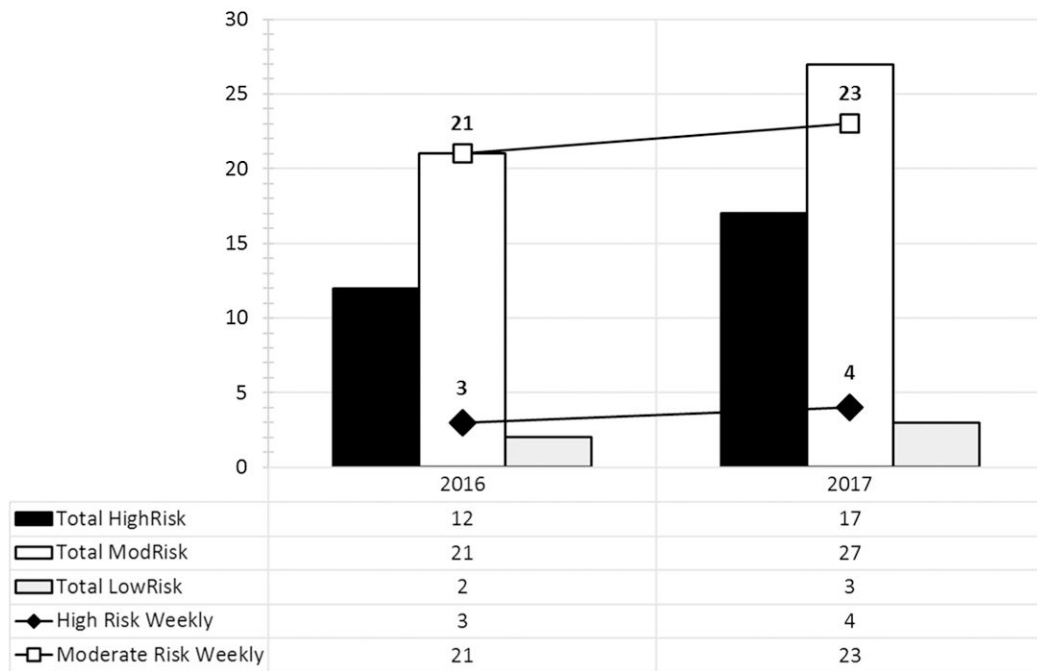|	2016	2017
■ Total HighRisk	12	17
☐ Total ModRisk	21	27
☐ Total LowRisk	2	3
◆ High Risk Weekly	3	4
☐ Moderate Risk Weekly	21	23

Fig. 2.

Work with pathogens. Total percent of staff self-reporting work with high (black columns), moderate (white columns) and low risk organisms (grey columns) with number of persons working with high risk organisms (black diamonds) and moderate risk organisms (white squares) at least weekly for 2016 (left) and 2017 (right).
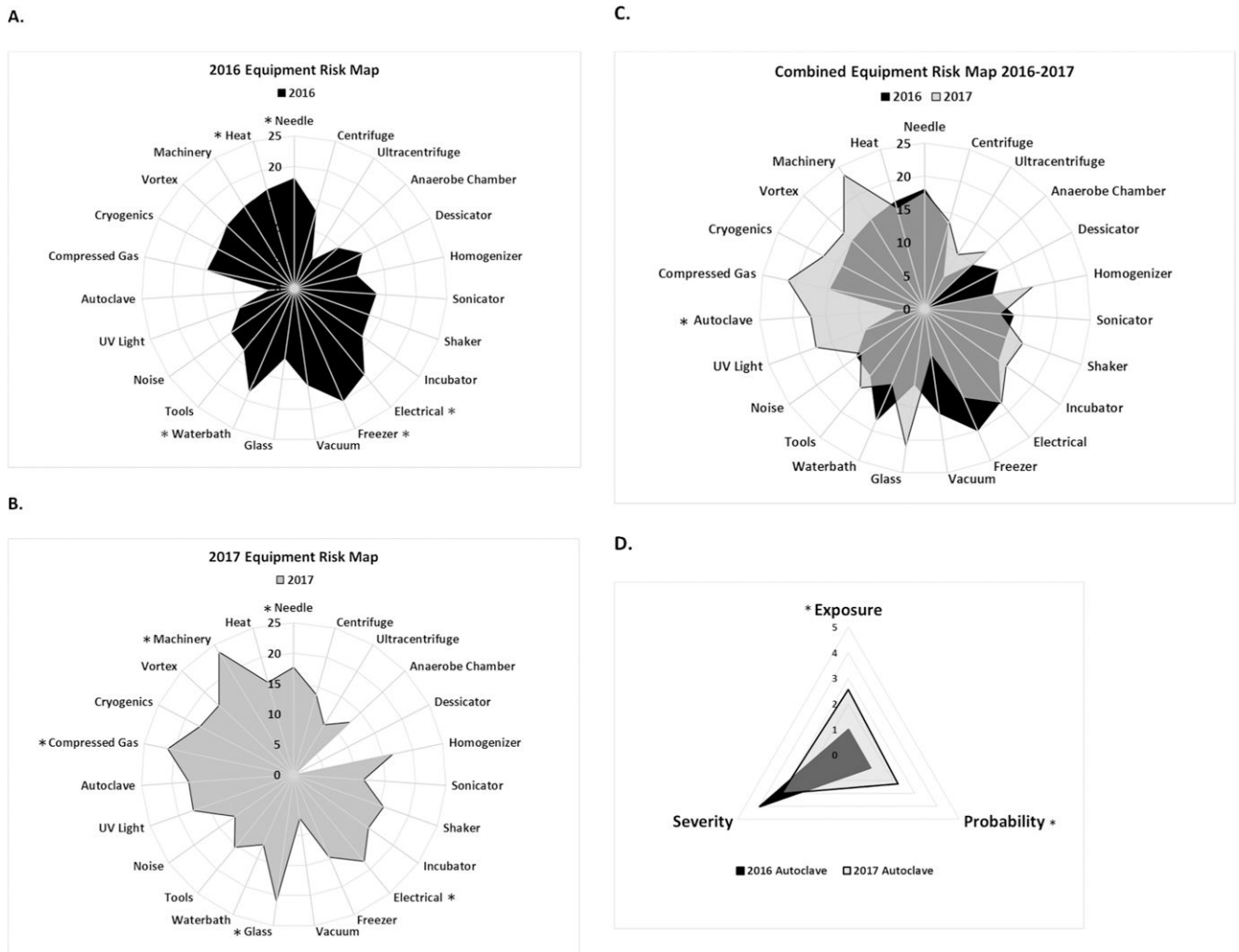
A.

B.

C.

D.

Fig. 3.
Equipment risks. Types of laboratory equipment assessed for relative risk for 2016 (A) and 2017 (B) with asterisks denoting the top five perceived risks. Changes in perception (C) and root causes of these perception changes from 2016 (black) and 2017 (gray) (D) are shown with asterisks denoting the greatest change in perceived risk (C) and the primary root cause (D).

Keckler et al. Page 23

Fig. 4.
Process risks. Types of laboratory processes assessed for relative risk for 2016 (A) and 2017 (B) with asterisks denoting the top five perceived process risks. Changes in perception (C) and root causes of these perception changes from 2016 (black) and 2017 (gray) (D) are shown with asterisks denoting the greatest change in perceived risk (C) and the primary root cause (D).
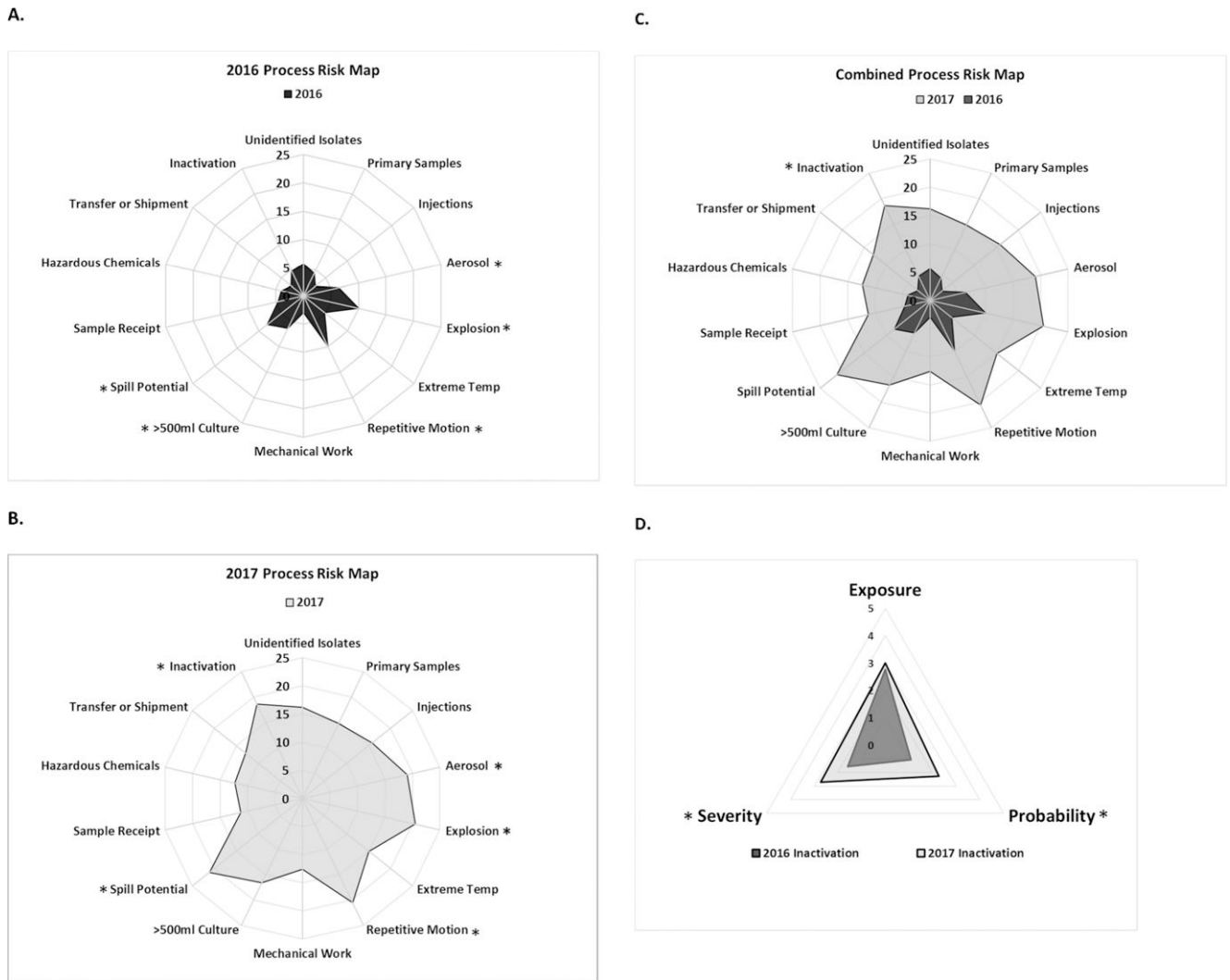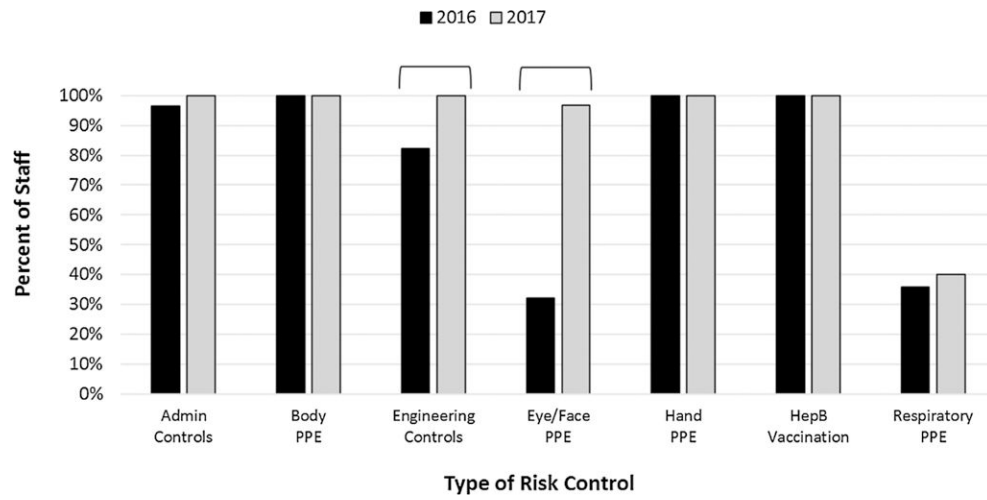
Saf Sci. Author manuscript; available in PMC 2020 August 01.

Author Manuscript
Author Manuscript
Author Manuscript
Author Manuscript

Fig. 5.
Use of risk controls. Total percent of staff that handle pathogens and report the use of risk controls of various types for 2016 (black) and 2017 (gray). Brackets and p-values indicate significant increases in self-reported use of engineering controls and eye and face PPE from 2016 to 2017 based on a two-tailed, two sample equal variance *t*-test.
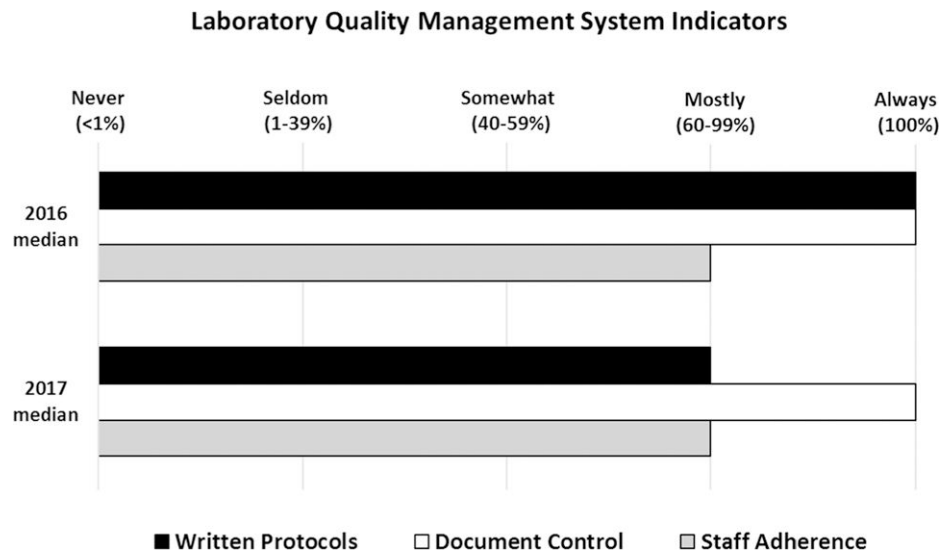
Laboratory Quality Management System Indicators

Fig. 6.
LQMS indicators. Bar graph presentation of the median response to questions about the frequency of work being covered by a written protocol (black), frequency of protocols being in a document control system (white) and frequency with which staff adhere to protocols (grey) for 2016 (top) and 2017 (bottom). Np statistically significant changes were observed.
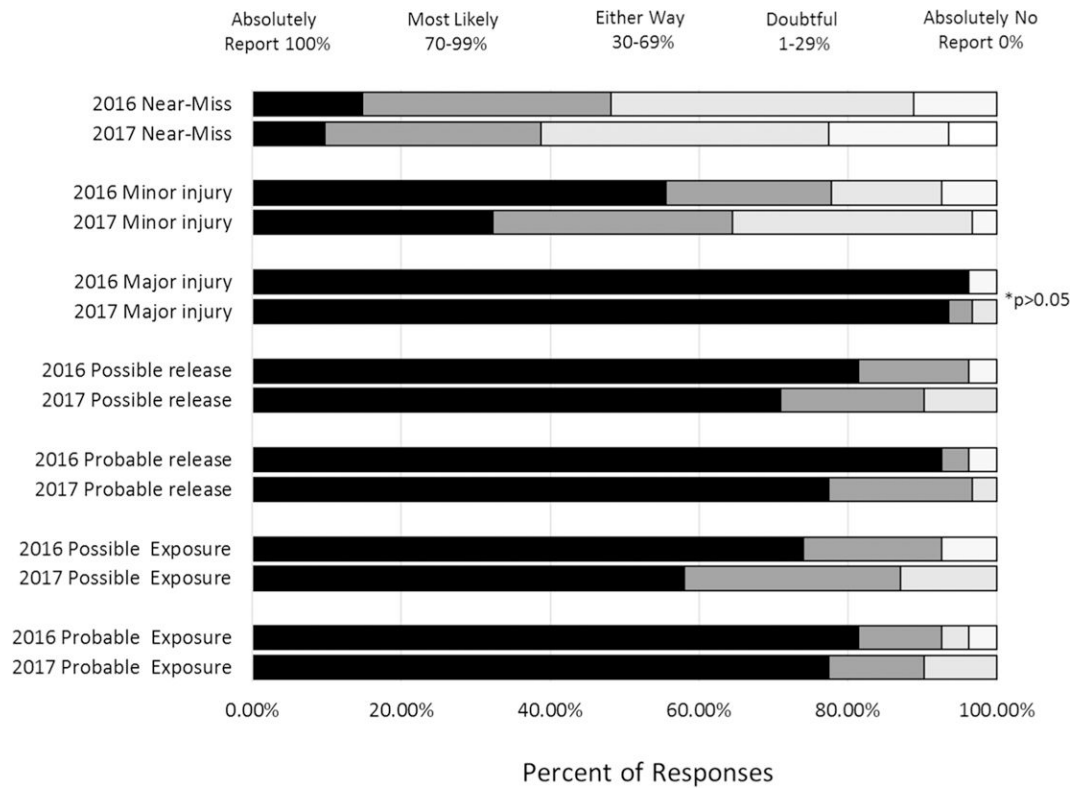
Incident and Near Miss Reporting

Fig. 7.
Safety culture for reporting incidents. Responses regarding staff likeliness to report various events for 2016 (top) and 2017 (bottom). For each scenario, the percent of responses corresponding with each answer are shown. Absolutely Report (100%) (black); Most Likely (70–99%) (dark gray); Either Way (30–69%) (medium gray); Doubtful (1–29%) (light gray); and Absolutely No Report (0%) (white). Only minor injury reporting changes from 2016 to 2017 were significant (p > 0.05) by two-tailed, two-sample equal variance *t*-test.

Table 1

Internal consistency reliability (coefficient alpha).

Scale name	Questions	Cronbach's alpha
Regulatory Compliance Frequency Scale	Q2	0.900
Biologics Frequency Scale	Q5, Q7 and Q9	0.889
Frequency of Use Scale	Q13 and Q17	0.786
Frequency of Error Scale	Q13 and Q17	0.875
Severity of Consequences Scale	Q13 and Q17	0.778

Table 2

Sample population demographics (n = 36).

Demographic	Category	Total	Percent
Age Group	< 24	0	0.0%
	25–34	**18**	**51.4%**
	35–44	8	22.9%
	45–54	6	17.1%
	> 54	3	8.6%
Highest Education Level	High School	0	0.0%
	Some College	0	0.0%
	Associates	0	0.0%
	Bachelors	8	22.2%
	Masters	**16**	**44.4%**
	Doctorate	12	33.3%
Management Level	Supervisory	8	22.2%
	Non-Supervisory	**28**	**77.8%**
Public Health Laboratory Experience	< 1	7	20.0%
	1–3	**8**	**22.9%**
	4–5	6	17.1%
	6–10	7	20.0%
	> 10	7	20.0%
Non-Public Health Laboratory Experience	< 1	2	7.4%
	1–3	6	22.2%
	4–5	5	18.5%
	6–10	**10**	**37.0%**
	> 10	4	14.8%
Hepatitis B Vaccination	**Yes**	**36**	**100.00%**
	No	0	0.0%
Previous Laboratory Injury	Yes	8	22.9%
	No	**27**	**77.1%**
Type of Public Health Experience	None	9	25.0%
	Federal	**25**	**69.4%**
	State	2	5.6%
	Local	0	0.0%
Type of Non-Public Health Laboratory Experience	None	5	11.6%
	Academia	**20**	**46.5%**
	Clinical	9	20.9%
	Private	9	20.9%