DEVELOPING A BEHAVIORAL HEALTH SCREENING PROGRAM FOR BSL-4 LABORATORY WORKERS AT THE NATIONAL INSTITUTES OF HEALTH

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The events and aftermath of September 11, 2001, accelerated a search for personnel reliability test measures to identify individuals who could pose a threat to our nation's security and safety. The creation and administration of a behavioral health screen for BSL-4 laboratory workers at the National Institutes of Health represents a pioneering effort to proactively build a BSL-4 safety culture promoting worker cohesiveness, trust, respect, and reliability with a balance of worker privacy and public safety.

SINCE THE 1960s, THE U.S. government has invested significant resources to examine behavioral risk assessments associated with espionage and sabotage. The events and aftermath of September 11, 2001, accelerated a search for personnel reliability test measures to identify individuals who could pose a threat to our nation's security and safety. Clinicians, researchers, public health scientists, and policy analysts in the military, intelligence, and safety communities have been asked to identify valid testing instruments that can be efficiently administered to provide assurance that workers are not perpetrators of criminal acts or terrorism.¹ Two examples of a trusted insider engaging in violent acts are the alleged involvement of a career federal scientist introducing anthrax-laden letters into the U.S. postal system and the alleged premeditated killings by a military physician who was seemingly motivated by distorted religious and/or political ideologies.

The scientific community has acknowledged there is no "magic bullet" psychological test or screening instrument that can detect or predict an individual's covert intent to commit espionage or terrorism.² The National Academy of Sciences and the National Science Advisory Board for

Biosecurity separately published findings and recommendations regarding the lack of efficacy of polygraphs, personality assessment tools, and integrity tests; both groups favor creating a laboratory safety culture of responsibility, accountability, and trust to protect against terrorist actions involving biological agents.²⁻⁴

The recognition of the necessity of protecting public safety in the event of an act of bioterrorism has resulted in an expansion of the number of high and maximum containment research laboratories in the United States and the world.⁵ In an effort to ensure that biomedical research is performed in the safest and most responsible manner possible, the National Institutes of Health (NIH) established the Biological Surety Program (BSP) in 2006. The NIH developed the program to reflect the unique human and security factors associated with biosafety level 4 (BSL-4) laboratories. The BSP sets forth control measures to ensure there is a trained, responsible, and reliable workforce, with rigorous procedures to protect employee health and the maintenance of a safe work environment. The BSP's goals also include preserving research integrity and protecting valuable research materials and products. The program encompasses policies and procedures

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related to safety, security, agent accountability, medical qualification, and personnel reliability. Although the constructs of biosafety and biosecurity are not synonymous, their operations frequently overlap. The NIH Behavioral Health Screen was developed as part of its biosurety program and is integrated with laboratory biosafety.

The safety and reliability of personnel who handle the world's most dangerous pathogens in BSL-4 laboratories is a high priority of the NIH. Maximum containment laboratories are designated for exotic agents that present high individual risk to workers from laboratory-generated aerosols and other exposures and for which there are no or limited vaccines or treatment options.⁶ When scientific personnel exercise proper microbiological technique and careful adherence to standard operating procedures, maximum containment laboratories are exceptionally safe.⁶

Even with protective measures, working in a BSL-4 laboratory can be stressful. Personnel who work in positive pressurized suits are restricted in their movement, have limited peripheral vision, may experience prolonged noise from the biocontainment suit air supply line, and are often confined to small areas for extended periods. Fast-moving breathing air supplied to personal protective suits can cause dehydration, and the opportunity for personnel to take work breaks, including the use of restroom facilities, can be restricted by complex entry and exit requirements. Workers must be vigilant for potential suit tears, faulty equipment, and medical emergencies. Such chronic stressors may have an impact on safe employee performance over time.⁷

The Biological Surety Program includes the Personnel Reliability Program, which has 4 components:

1. A comprehensive background investigation (verification of the accuracy and truthfulness of a worker's professional credentials and life experiences, including any arrests and convictions, contacts with terrorist-related activities, a collective foreign threat assessment, and illegal cyber activity);
2. Maximum biocontainment laboratory-specific training;
3. Medical examinations to assure physical fitness for duty; and
4. A behavioral health screen, designed to help assess the worker's psychological resilience and individual attitudes toward laboratory safety and personal responsibility.

All NIH employees, contractors, and visitors who enter a BSL-4 laboratory are subject to BSP enrollment.

The integration of the NIH Behavioral Health Screen into its biosurety program represents a pioneering effort to proactively build a BSL-4 safety and security culture that promotes worker cohesiveness, trust, respect, and reliability with a balance of worker privacy and public safety.

This article presents best practices developed and refined during the 3 years of program implementation, with a discussion of each topic, the issues considered in its development and refinement, and future directions. To our

knowledge, no other BSL-4 laboratory has used this methodology to screen worker behavioral health.

ARTICULATING THE PURPOSE OF THE BEHAVIORAL HEALTH SCREEN

Our approach in crafting a behavioral health screen began with identifying factors that would increase a worker's vulnerability to stressors associated with working in a BSL-4 maximum biocontainment laboratory. Four behavioral vulnerabilities were identified as increasing the risk for worker accidents and injuries: clinical levels of depression, anxiety (stress), substance abuse, and high-risk safety attitudes. Depression and anxiety relate to a worker's ability to maintain focus and concentration on completion of assigned tasks. Substance abuse relates to the ability to function without impairment due to use of alcohol or nonprescribed medications or drugs. Willingness to comply with institutional safety rules and procedures, acceptance of personal responsibility for one's safety, and resilience to stress are integral components of working safely in a hazardous, high-risk environment.

An in-person interview is conducted with the laboratory worker by the BSP certifying official and the BSP psychologist. During this interview, the worker is given the opportunity to review each document contained in his or her NIH biosurety file and to discuss his or her philosophy regarding laboratory safety as well as any concerns about working in the BSL-4 laboratory. The interview provides an opportunity for the certifying official and the program psychologist to reinforce themes of individual and laboratory team safety. Workers are encouraged to use the services of the Employee Assistance Program (EAP) as a support vehicle to manage life stressors in a confidential, supportive, and respectful environment. The substance of the interview is confidential, and workers are asked to raise any topic or ask any questions they have regarding the behavioral health screening program, the biosurety process, and any issues related to their work in the laboratory.

It was determined from the beginning that the behavioral health screen would not serve as a mechanism "to catch a thief" or other potentially bad actor in the maximum biocontainment laboratory. When the behavioral health screen identifies an individual with a vulnerability, as outlined in one of the medical measures (anxiety, depression, substance abuse), the confidential services of the EAP and/or the Occupational Medical Service are provided as a mechanism to enhance personal mental health and resilience. When the behavioral health screen identifies an individual with problematic safety attitudes, the certifying official determines what potential courses of action are available to enhance the worker's positive safety attitudes. If an individual is removed from the NIH biosurety program, there is no current requirement to notify the Centers for

Disease Control and Prevention (CDC) of the reason for removal. In the near future, these procedures may change to reflect recommendations of the Federal Expert Security Advisory Panel for Biological Select Agents and Toxins Security. As was recently noted in a compilation of strategies to enhance workforce security:

Almost every case involving an insider threat [is] due to an individual crisis. . . . [T]he return on investment of an EAP cannot be underestimated . . . offer[ing] guidance and support to employees with personal problems that may affect their state of mind, which in turn can impact workplace behavior, performance, and well-being. It can make a critical difference in interrupting forward motion of a potential insider who is in crisis and whose solution is the intent to compromise information.^{1(p8)}

Excessively intrusive security measures can dissuade scientists from pursuing their research involving emerging infectious diseases.^{8,9} The creation of a safety culture custom-tailored to the unique working conditions associated with the BSL-4 laboratory was paramount in the creation of the NIH Behavioral Health Screen. By acknowledging the enhanced physical and psychological resilience required of a BSL-4 worker, and providing a transparent, realistic, and employee-friendly mechanism to assess this resilience, sound safety practices are modeled individually and collectively, and security risks are reduced.

CENTRAL LEGAL ISSUES

Beginning in the 1960s and extending to the current term of the U.S. Supreme Court, the federal government, through legislation, regulation, and judicial decisions, has upheld an employer's right to require that applicants successfully compete for positions using employment testing (which would include the NIH Behavioral Health Screen), with several conditions. Central among these conditions is that the employment testing measures are valid, job-related, consistent with business necessity, administered consistently and fairly, and do not adversely affect a legally protected group if effective alternative tests are available.¹⁰ The NIH Behavioral Health Screen for BSL-4 workers was designed to conform to these conditions.

In the 1971 decision of *Griggs v. Duke Power Co.*,¹¹ the U.S. Supreme Court held that employment tests must reflect a reasonable assurance of job performance and that testing requirements must have a manifest relationship to the job in question.

Title VII [of the Civil Rights Act of 1964] expressly protects the employer's right to insist that a prospective applicant . . . must meet the applicable job qualifications. Indeed, the very purpose of Title VII is to promote hiring on the basis of job qualifications. . . . Nothing in the Act

precludes the use of testing or measuring procedures; obviously they are useful. What Congress has forbidden is giving these devices and mechanisms controlling force unless they are demonstrably a reasonable measure of job performance.^{11,12}

The U.S. Supreme Court expanded worker protections regarding employment testing in the case of *Albemarle Paper Co. v. Moody*.¹³ Addressing the situation where an employer demonstrates that required tests are job-related, the Court found:

. . . it remains open to the complaining party to show that other tests or selection devices, without a similarly undesirable . . . effect, would also serve the employer's legitimate interest in "efficient and trustworthy workmanship" . . . [and] such a showing would be evidence that the employer was using its tests merely as a "pretext" for discrimination.^{13,14}

The standards for employment testing articulated in previous decisions were upheld by the U.S. Supreme Court in *Ricci v. DeStefano*.¹⁵ In this case, the city of New Haven invalidated firefighter promotion test scores because they would have resulted in the promotion of a disproportionate number of white and Hispanic firefighters compared to African American firefighters.¹⁶ The Court's decision described the city's action as "express, race-based decision-making . . . [and] whatever the City's ultimate aim—however well intentioned or benevolent it may have seemed—the City made its employment decision because of race."^{16(p13)} Having determined that the testing measures were job-related and consistent with business necessity, and that there was not an equally valid, less discriminatory alternative that could have been adopted, the city erred in subsequently invalidating test scores to avoid perceived potential liability. The apprehension of disparate impact legal liability, without evidence that the employment measure was invalid, not related to job performance, or unnecessarily broad, when a more equitable alternative was available, amounted to a "de facto quota system" and permitted the city to discard otherwise legitimate test results solely to achieve a preferred racial balance.¹⁶

The U.S. Supreme Court continued its focus on personnel reliability and security matters in the case of *National Aeronautics and Space Administration v. Nelson* (Docket No. 09-530, Decided January 19, 2011). Contractor employees of the National Aeronautics and Space Administration (NASA) challenged the agency's use of uniform standard employment background investigations for both civil service and contractor employees. The contractor employees specifically objected to 2 portions of the background investigation: a section asking applicants about treatment or counseling for recent illegal drug usage, and open-ended questions regarding employment suitability contained in a form letter sent to an applicant's designated references. Contractor employees claimed the Constitution

provided them a protected interest in avoiding disclosure of personal matters.

The Supreme Court found no relevant distinctions between the job functions and duties performed by NASA's civil service workers and its contractor workers, and it upheld the government's interest in "... ensuring the security of its facilities and in employing a competent, reliable workforce."^{17(p14)} The Court held that the challenged portions of the background investigation did not violate the contractor workers' privacy rights and were reasonable, employment-related inquiries to further the government's interests in managing its internal operations.^{17(p3)} The statutory protections provided against unauthorized third-party disclosure of worker information, as set forth by the Privacy Act of 1974,¹⁸ were held to evidence appropriate concern for individual privacy.^{17(p4)}

Background investigations for NIH BSL-4 workers (civil service and contractor) are consistent with the *NASA v. Nelson* decision.¹⁹ Consistency of personnel reliability practices and experiences for all BSL-4 workers, both civil servants and contractors, further enhances the culture of safety by reducing the perception of employment class barriers.

Congress has enacted legislation relating to employment testing, including the Americans with Disabilities Act²⁰ (applying to private employers and state and local governments) and the Rehabilitation Act of 1973 (applying to federal employment).²¹ These acts prohibit employment discrimination against otherwise qualified applicants with disabilities. Employers are prohibited from inquiring about disabilities or requiring medical examinations until after a conditional job offer is made to an applicant. After making a conditional job offer, but before the person starts working, an employer can ask disability-related questions and conduct medical examinations if it does so for all individuals entering the same job category. Questions regarding disability and medical examinations must be job-related and consistent with business necessity. Employers are permitted to request medical information, based on a reasonable belief and objective evidence, that a specific employee will be unable to perform essential job functions or will pose a direct threat to job operations because of a medical condition. Medical tests cannot be used to screen out an individual with a disability, or a class of individuals, unless the employment test, as used by the employer, is shown to be job-related and consistent with business necessity.²² The portions of the NIH Behavioral Health Screen relating to medical conditions are administered consistent with the preceding guidelines.

SELECTING APPROPRIATE ASSESSMENT MEASURES

The behavioral health screen for BSL-4 workers examines significant behavioral safety issues that would likely result in

compromised job performance. The screening factors are clinically significant levels of depression and/or anxiety, and substance abuse, and from a management (nonclinical) perspective, the worker's personal philosophy of safety. This safety philosophy includes willingness to follow rules and regulations, willingness to comply with laboratory safety procedures, risk-taking behaviors, personal responsibility for one's personal safety, and ability to manage stress. (To protect the integrity of the NIH Behavioral Health Screen, the specific screening instruments used are not identified in this article.)

Clinically elevated measures of depression, anxiety, and substance abuse are associated with decreased worker productivity, accuracy, and safety.²³ The screening procedures are designed to maintain a balance of worker privacy and public safety. The medical screening instruments (depression, anxiety, and substance abuse) are domain-specific and do not elicit individual responses that relate to non-work-related measures. The screening tools are straightforward and brief, and most workers complete them in less than 45 minutes.

The screening instruments for depression and anxiety have been used extensively since their inception, and portions of the assessments were updated in the 1990s. The measures were developed expressly to assess the symptoms listed as criteria for depressive disorders in the third and fourth editions of the *Diagnostic and Statistical Manual of Mental Disorders*.^{24,25} Scores indicating elevated levels of moderate or higher anxiety or depression indicate the need for additional psychological or psychiatric evaluation.

The substance abuse screening instrument indicates whether an individual's use of drugs or alcohol is problematic. It is administered by the clinical medical staff as part of the worker's physical examination. Six questions are asked, with reference to remorse after drinking or using drugs, lack of memory of an event while under the influence of alcohol or drugs, deviation from expected behavior while using alcohol or drugs, drinking or using drugs to start the day, excessive use of alcohol on a single occasion, and frequency of excessive drinking. A positive response to any question can indicate the need for additional evaluation by a psychologist or psychiatrist.

The management tool used to elicit information about an individual's attitudes toward personal safety consists of about 120 multiple-choice questions. The applicant's responses are provided for the certifying official's consideration as they apply to domains of risk avoidance, responsibility for personal safety, and stress tolerance. The individual's responses are used as a basis for discussion with the biosurety program applicant during the certification interview.

The behavioral health screening instruments are not stand-alone measures that determine if a candidate will be granted privileges to work in the BSL-4 laboratory; the screen results indicate whether additional evaluation by a clinical psychologist or psychiatrist is necessary to establish

that the worker is sufficiently psychologically resilient to withstand the stressors associated with working in a maximum containment laboratory suite.

The NIH Behavioral Health Screen for BSL-4 workers does not assess abnormal behavior or psychopathology beyond their specifically stated domains (depression, anxiety, substance abuse, and safety attitudes). It is our position that the information generated by personality inventories is not generally appropriate for behavioral health screening as it is overly invasive of a worker's privacy and, most importantly, because much of the information generated is not related to job performance. Compelling a laboratory worker to reveal significant psychological information that is not work-related is counterproductive to creating a safety culture of worker respect, resilience, and responsibility. Worker responses that are untruthful, or misrepresentations, can result in disqualification from participation in the Personnel Reliability Program, either temporarily or permanently, based on individual case review.

Prescribed medications are discussed between each worker and the physician or nurse practitioner during initial, annual, and/or periodic evaluations by Occupational Medical Service staff. If prescribed medications affect the behavioral health screen, that information is shared by the Occupational Medical Service physician or nurse practitioner and the program psychologist.

ADMINISTERING THE BEHAVIORAL HEALTH SCREEN

The administration of the NIH Behavioral Health Screen has 4 components: transparency, consistency, respect for the BSL-4 worker, and annual review.

Transparency

There are no hidden agendas in the NIH Behavioral Health Screen.²⁶ The purpose of the screen is clear: to assure the resilience of BSL-4 staff as measured by work-related behavioral health screening. The "why" and "how" of the behavioral health screen is explained to managers and staff at town hall meetings, laboratory meetings, and individually before each worker is screened. The concept of workforce resilience, that working in a maximum containment laboratory can be potentially stressful for a worker, and balancing the need to ensure worker, laboratory, and community safety with the behavioral health screen, is discussed in group forums and with individual workers. Questions regarding the utility and application of the behavioral health screen are responded to in a respectful and open manner, thus enhancing the credibility and fairness of the overall biosurety program. For example, the program has not been in process long enough to provide a valid sampling regarding its effect on injuries and accidents among BSL-4 workers.

Individual feedback regarding the behavioral health screening measures is provided privately, with an explanation regarding the relevance of the screen to performance of job duties and laboratory safety. Workers are encouraged to ask questions and are permitted to make copies of information contained in their biosurety files. The program psychologist is present with the certifying official in the worker's final interview and responds to any questions from the worker regarding the behavioral health screen. During the course of the interview, the program psychologist also discusses the availability and confidential nature of the Employee Assistance Program. The EAP provides a resource for workers to obtain confidential counseling and support services to assist them in both their private and professional capacities.

The worker's meeting with the certifying official provides a unique opportunity to reinforce the safety culture in the BSL-4 laboratory. Using the worker's responses to the safety inventory assessment as a resource for discussion, the certifying official and the worker have an in-depth dialogue about the worker's safety attitudes and philosophy toward his or her work in the maximum containment laboratory. The certifying official reiterates his or her willingness to meet with workers who have a concern about their role or that of others in a BSL-4 laboratory. The worker and the certifying official discuss the importance of peer reporting after role-playing incidents of concern.

Consistency

Every BSL-4 worker is treated consistently regarding the administration of the behavioral health screen. The worker's initial meeting with the program psychologist is arranged at the convenience of the staff member. The purpose of the behavioral health screen is discussed, and the worker has ample opportunity to raise any questions or concerns and to report any reason his or her responses could be influenced by a recent event, such as a divorce, bankruptcy, family death, or other significant workplace stress or life event.

After this discussion, the program psychologist presents the screening instruments for depression, anxiety, and safety attitudes, and the worker is again asked if he or she has any questions. Next, the worker is asked to complete the screening instruments, taking as much time as needed (most workers take less than 45 minutes). Following completion of the screens, the program psychologist scores the instruments immediately, and, if further screening is indicated, contacts the worker directly to inform him or her.

In such a case, the program psychologist schedules a meeting with the medical director of Occupational Medical Services to arrange for additional screening. The worker is given referral information to EAP or to a personal health-care provider, and an evaluation is made to determine if the worker's current BSL-4 laboratory privileges should be modified.

Worker Respect

Each worker is treated in a manner that reflects the NIH safety culture of valuing individual contributions to the safe operation of the BSL-4 laboratory. Individual concerns, including issues regarding employment, personal and family matters, and medical conditions, are taken seriously, and every effort is made to treat each individual collegially and respectfully.

Preservation of patient confidentiality is a central component of the behavioral health screening program. Employee medical information collected pursuant to the NIH behavioral health screening is maintained in accordance with the Privacy Act;¹⁸ Health Insurance Portability and Accountability Act²⁷ regulations are not applicable.²⁸

With workers for whom English is not their primary language, the program psychologist respectfully inquires about their comfort level in speaking and responding to written questions in English. If there is a concern, the behavioral screening instruments are administered with the assistance of a telephone translation service offered through the Occupational Medical Service. Using a telephone translator, the screening instrument questions are individually translated for the worker in his or her native language. The translator provides the program psychologist with the worker's responses, in English. The translator is not given the identity of the worker, to assure confidentiality and promote candor. During the certification interview, the certifying official makes additional efforts to ensure a fluent flow of communication with the worker.

Annual Administration

There are currently approximately 130 people in the NIH biosurety program who require behavioral health screening.²⁹ The screening process is conducted annually or more frequently if a worker experiences a significant event in his or her personal or professional life that indicates readministration of the behavioral health screen (eg, divorce, serious illness, on-the-job injury). Personnel are encouraged to report major life events, positive and negative, to their supervisors; if additional support is indicated, workers are respectfully referred to the program psychologist, the EAP, and/or the Occupational Medical Service. The certifying official is always available to supervisors for support and guidance.

WHAT WE'VE LEARNED AND FUTURE DIRECTIONS

The following practices and procedures are recommended regarding behavioral health screening and personnel reliability programs as they apply to BSL-4 workers:

- Ensure the entire process is transparent to participating workers.

- Conduct group or town hall meetings to describe the behavioral health screening process. These meetings are valuable in establishing participant comfort and confidence.
- Facilitate and encourage questions and discussions about the behavioral health screening.
- Administer all procedures consistently.
- Clearly state the Personnel Reliability Program requirements in job descriptions and announcements.
- Maintain tests and results securely in the occupational medical program to assure a high degree of participant privacy.
- Confirm the validity and reliability of each assessment instrument with an independent professional, with established application to successful performance of the worker's job duties.
- Ensure the safety message is clearly associated with the program.
- Ensure that test results are not the sole determinant of hiring or for BSL-4 laboratory access.
- Ensure that results from behavioral health screening tools are interpreted by a behavioral health professional, within the context of the worker's job assignment and considering his or her life events.
- Perform behavioral health screening on a routine basis and at least annually. Scheduled screening is useful in detecting changes that have occurred in individual workers and their laboratory group.

CONCLUSION

The creation and administration of the behavioral health screening represents a pioneering effort of the NIH to proactively build a BSL-4 safety culture promoting worker cohesiveness, resilience, trust, respect, and reliability with a balance of worker privacy and public safety. The resources of the NIH Employee Assistance Program are key components in maintaining this culture. Continuing adjustments and amendments will be made to reflect evolving requirements and realities of maximum containment research.

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