

Letters: A Bioterror Risk-Assessment Methodology

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Although numerous scientists and stakeholders recognize a need for increased security measures at microbiological laboratories, Richard Gallagher speaks for many by asking, "Is it possible that we could have a more measured public debate? A more objective assessment of the threat?"¹

We contend that biosecurity measures at bioscience institutions should be based on an intellectually defensible risk-assessment approach, which evaluates the probability and consequences that biological material would be maliciously stolen and used as a biological weapon. We believe that this approach would accomplish at least three important goals: 1) help prioritize the various security risks associated with biological materials; 2) help determine how best to protect against those risks; and 3) help establish a credible rationale for an appropriate level of biosecurity.

Under current US regulations, everything listed as select agents must legally be protected by the same security measures, but most experts agree that *Bacillus anthracis* has greater potential as a bioweapon than *Rickettsia rickettsii*. An agent-based risk-management methodology² that applies a graded approach would improve the likelihood that scarce security resources would be allocated specifically to those biological materials judged to be at greatest risk from theft or sabotage. A graded approach is used for safety: Based on a safety risk assessment, agents are placed in a biosafety level. Similarly, agents would be placed in a biosecurity level based upon a security risk assessment that reflects their attractiveness to adversaries. Attractiveness would be proportional to both the ease (or difficulty) in deploying the agent as a weapon (weaponization potential), and the consequences that would ensue if an attack were successful.

The security risk of an agent may differ from its safety risk. For example, some agents used in BSL-2 facilities, such as *B. anthracis*, may be more attractive to adversaries and should be better protected than some BSL-3 agents, such as West Nile virus. Hence, biosecurity levels should not be the same as biosafety levels. However, the process that characterizes the wide acceptance of biosafety levels by the microbiology community should serve as a model for the implementation of biosecurity levels.

We foresee that the overwhelming majority of biological agents would be assigned to a biosecurity level associated with minimal security. The highest levels of security would be required for only a few agents, perhaps including those that have been eradicated from nature. Biosecurity levels would enable higher security than that currently mandated by federal regulations for those few agents that represent true weapon threats, and lower levels of security for those agents that would be much less likely to be targets for theft by an adversary.

As a result, the biosecurity levels would help to appropriately allocate scarce security resources, and ensure that biosecurity systems achieve genuine national security objectives. This concept of biosecurity levels should be developed and vetted through a collaboration of experts in biological weapons, public and agricultural health, microbiology, and security. Analogous to the widely accepted US biosafety levels, the biosecurity levels would help federal agencies, such as USDA and NIH, apply uniform criteria to grantees, and could form the basis for standardizing biosecurity internationally. Widely accepted biosecurity standards would help facilitate international collaborations by creating more uniform standards.

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References

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2. J. Gaudioso, R.M. Salerno, "Biosecurity and research: Minimizing adverse impacts," *Science*, 304:686-7, April 30, 2004.