Background:

We would like you to be a panelist for the discussion on promoting "institutional champions" of biosecurity, personnel reliability and culture of responsibility. The purpose of the panels is to provide a variety of perspectives that will serve as a springboard for a plenary discussion. Toward this end, panelists are asked to speak for 5-7 minutes and to address the following questions:

- *Who should be the institutional champions of biosecurity, personnel reliability, and culture of responsibility?*

- *What are specific ways that institutional leaders can convey their commitment to these concepts and foster "buy-in" by all employees at all levels?*

- *Are there specific ways to incentivize laboratory leadership to promote a culture of responsibility among lab personnel?*

- *Are there any lessons to be learned from other arenas? For example, does your institution have "institutional champions" in other areas? What role do they play and what strategies do they utilize?*

Presentation:

My comments are broadly focused on biosecurity, not only the most scary select agents. For example, it is clear that Salmonella, Shigella, and a number of other common pathogens have demonstrated potential for bioterrorism or biocrime – in fact, because they are readily accessible and manipulatable, microbes like these may be more likely to be used by someone intent on causing harm.

Also, to set the stage, we have to be aware that many scientists feel like the growing amount of required paperwork, including compliance and auditing requirements coupled with the associated training expectations, inhibits their ability to focus on research. It is not uncommon for a scientist to have to document compliance in many different areas – for example, I have to regularly certify compliance for:

- Biosafety
- Recombinant DNA
- Shipping of biohazards
- Radiation safety
- Animal care
- Human subjects
- Sexual harassment
- Conflict of interest
- Occupational health
- and probably a few others that I can't recall.

All of these issues are very important, but they loose their sense of urgency when there are so many. Furthermore, most scientists want to focus on their lab work, publications, and writing the next grant, not a seemingly endless pile of compliance paperwork.

Thus, although getting scientists to focus on responsibilities related to biosecurity is critical, it will not be easy. Nevertheless, I think it could be done in a manner that will integrate multiple compliance issues – in fact, virtually all of these issues are focused on scientific responsibility and awareness of the concerns and regulations.

An institutional champion is essential to ensure its widespread success of such an effort. I think the institutional champion must have three qualities:

1. Scientific expertise (respect)
2. Influence (carrots)
3. Authority (sticks)

First and foremost, the institutional champion must be respected by the research scientists, which generally means that the person must have a solid record of experimental research in a relevant field. Such respect is critical to build a sense of personal responsibility and collegial collaboration (vs the alternative perspective "this is yet another stupid requirement designed by bureaucrats who do not understand research").

The Institutional Biosafety Committeee (IBC) should be a close collaborator in this process. The primary responsibility of the IBC is oversight of recombinant DNA regulations, but at many (maybe most) institutions IBCs also have a responsibility for evaluating research on pathogens. Nevertheless, several factors often limit the authority of IBCs:

– IBC staff does not engender the respect of the scientists they monitor (because they are not experimental scientists);

– scientists who are members of the IBC evaluate proposals but do not directly correspond with the scientists who submitted the proposals;

– the institutional official charged with overseeing the IBC is often an Assistant or Associate Dean with administrative responsibilities but limited (if any) scientific credentials.

  [Note that this is in contrast to the situation at certain institutions like the University of Chicago where our moderator is the Assistant Dean for Biosafety and Associate Professor of Microbiology.]

Second, the institutional champion must have a role as an institutional leader with control over issues that matter to scientists (such as space and institutional support). Without this influence the champion may command respect of close colleagues, but is less likely to be known and respected by researchers in different fields. For example, engineers working in synthetic biology may not think that an expert in virology understands the issues in their field. However, the institutional champion is likely to command greater influence if viewed as a leader with broad scientific perspectives and the ability to shape the institutions scientific vision – coupled with some resources to reward "good behavior".

Third, the institutional champion must have sufficient authority to invoke clout when needed. In any group, there are some people who think that they know more than others and do not play by the rules. There are serious consequences for noncompliance with select agents, but often the ability to enforce compliance with other biosafety issues is limited. Compared to animal care committees, human subject committees, and radiation safety committees, IBCs often lack effective consequences to enforce compliance. In coordination with the institutional champion, IBCs should have a level of authority comparable to these other committees to ensure the attention of noncompliant researchers.

Although the top-down approach of an influential institutional champion and a robust IBC are critical for the integration of a "culture of responsibility" into the scientific psychic, it will not be a success unless coupled with education.

In many ways this is similar to the process led to the training of graduate students in responsible conduct of research. Prior to the requirement by federal agencies several decades ago[1], a few "true believers" developed courses on "Scientific Survival Skills" for students in their graduate programs. In contrast to most compliance training programs, responsible conduct of research courses embraced active learning approaches – students were engaged and intellectually challenged, not simply begrudgingly putting in the time to complete a requirement. Hence, the concepts were committed to long-term memory and could be applied later in their careers. The favorable response of students coupled with a strong recommendation from the Institute of Medicine led to the rapid spread of "Responsible Conduct of Research" courses in graduate programs.

Because student training in the "Responsible Conduct of Research" is now required by federal funding agencies, these courses reach the majority of graduate students in the sciences in our country – that is, most of the people who will go on to become the next generation of scientists. However, few of these courses include biosafety and biosecurity or even discuss the concept of dual use. If awareness of biosecurity issues and the "culture of responsibility" was integrated into these courses, it would take us a long way to building the culture over the next decade. In addition to the long term inpact, these students would also bring an immediate awareness and sensitivity to biosafety and biosecurity issues into their labs where they are currently doing research.

Coupled with the top-down approach of an institutional champion and IBCs, this bottom-up approach could have a major impact on the NSABB goals. Professional societies could play a key role in reaching the people sandwiched in the middle of these top-down/bottom-up approaches -- the PIs. By promoting a professional code of conduct, integrating biosafety and biosecurity topics into professional meetings, encouraging consideration of biosafety and biosecurity concerns during peer review, and providing training opportunities, professional societies could help build a culture of responsibility by making this an expectation of scientific peers.

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[1] For a brief history, see http://journals.lww.com/academicmedicine/Fulltext/2007/09000/The_History,_Purpose,_and_Future_of_Instruction_in.3.aspx

Although these approaches may work for larger academic institutions, some institutions, particularly smaller colleges, do not have sufficient internal expertise for such self- monitoring. In some cases they may be able to fulfill this need by partnering with IBCs at larger research universities, but in other small institutions biosafety and biosecurity issues simply fly beneath the radar. Given the availability of pathogens, genetic engineering tools, and synthetic biology tool kits in teaching labs and small research operations that are not federally funded, it is important to reach the administrators, faculty, and students at these institutions as well.

Finally, it is worth noting that the ideals described in the NSABB report:

> "Leadership that values security, fosters a sense of vigilance and responsibility among personnel, and encourages teamwork, camaraderie, and close personal working relationships [is] the most effective and feasible way to enhance personnel reliability"

… not only have benefits to national security, but also describe a productive environment where it is fun to do science.

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