



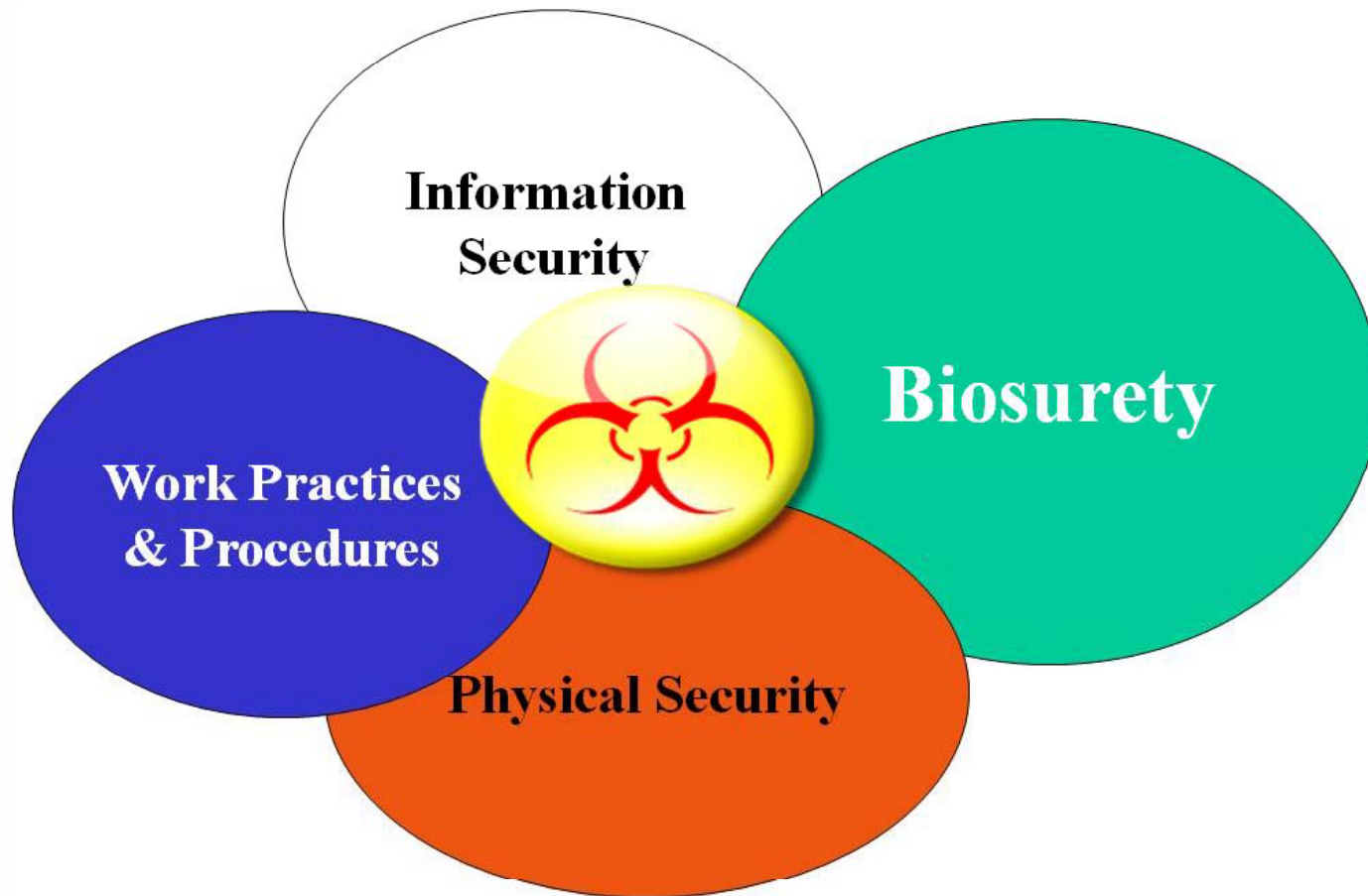
MIDWEST RESEARCH INSTITUTE

Thinking More About Biosecurity (Attitudes and Opinions on Biosurety)

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Serving Clients One Breakthrough at a Time

Integration of Biosurety as Part of Biosecurity





Why Should You Care?

- There are currently variations in federal biological reliability programs
 - Any facility that accepts DoD funding/select agents must comply with DoD Biosurety regulations
 - DoD program is most defined and stringent, there may be a government tendency to push it to other federal and state agencies
- Impacts biosafety program.
- There are better ways of improving/monitoring personnel reliability-you may have some ideas
- Research funding implications



Recently Completed Studies

- Congressional Research Report March 5, 2009, Oversight of High-containment Biological Laboratories.
- American Association for the Advancement of Science Report: Biological Safety Training Programs as a Component of Personnel Reliability, March 2009
- National Science Advisory Board for Biosurety (NSABB): Enhancing Personnel Reliability among Individuals with Access to Select Agents, May 2009
- Defense Science Board: Department of Defense Biological Safety and Security Program, May 2009
- Trans-federal Task Force on Optimizing Biosafety and Biocontainment September 2009
- National Academy of Sciences Report on (Personnel Reliability Sept 2009)

Recent Personnel Reliability Recommendations

- **Defense Science Board (May 2009):**
 - Monitoring: “Make changes to monitoring activities to improve effectiveness without introducing overly intrusive measures.” “Review the usefulness of the two-person rule in preventing insider threats”
 - Scientific Enterprise: “Balance risk of a malevolent insider against detriment to the laboratory mission.”
 - Compliance inspections: “provide resources for a single independent inspection team comprised of authoritative individuals”.

DoD recognizes that current Biosurety program is harming the scientific enterprise



Recent Personnel Reliability Recommendations

- National Science Advisory Board for Biosecurity (NSABB): Enhancing Personnel Reliability among Individuals with Access to Select Agents.
 - No national Personnel Reliability Program recommended
 - Current SRA process should be strengthened.
 - Culture of responsibility and accountability should be enhanced.
 - **Professional societies should encourage on ongoing dialog about PRP!**
 - List of select agents and toxins should be reduced or stratified.

NSABB recommends WHO approach to personnel reliability

Survey Design

- Biosafety questions
- Biosecurity questions
- Attitudes on aspects of biosurety
- Demographic questions

- Redundancy built into questions
- Use of scaled responses





Survey Demographics (ABSA)

- 149 Responded to the questionnaire
- 92.5% from the U.S. (106 responded)
- 88.7% ABSA Members (106 responded)
 - RBP (5.7%)
 - CBSP (9.4%)
- Employment Sector (106 responded)
 - 41.0% Academic
 - 31.4% Government
 - 22.9% Industry/Private
 - 4.8% Other

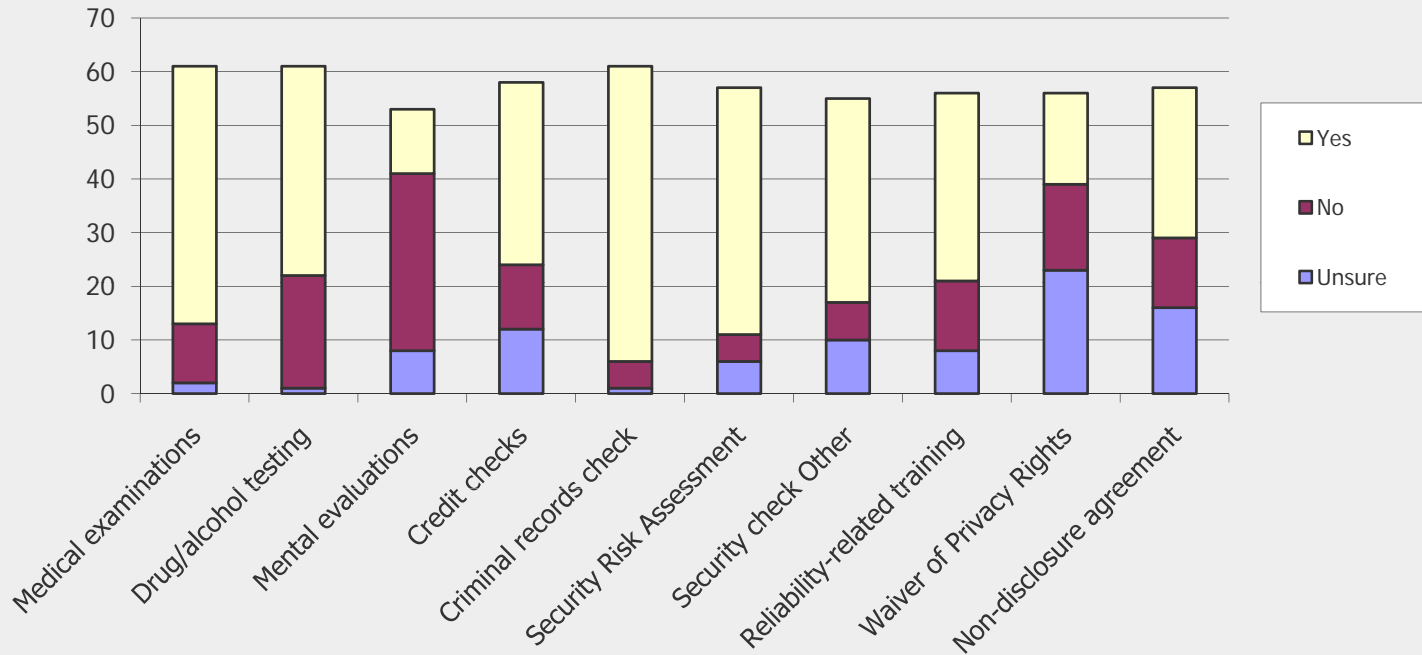


Survey Results: Background

- Employer currently uses a personnel reliability (Biosurety) program (PRP) (149 responded)
 - 48.6% Yes
 - 51.4% No
- Personal involvement in the PRP (124 responded)
 - 55.6% Yes
 - 15.3% No
 - 29.0% Not applicable
- Does this PRP affect the biosafety program in a positive way? (110 responded)
 - 50% Agree or Strongly agree
 - 20% Strongly disagree or Moderately disagree
 - 30% No opinion



My employer's current reliability program contains the following initial or annual components (check all that apply):



Least Common PRP component: Mental Evaluations
Most Common PRP component: Criminal Records Check

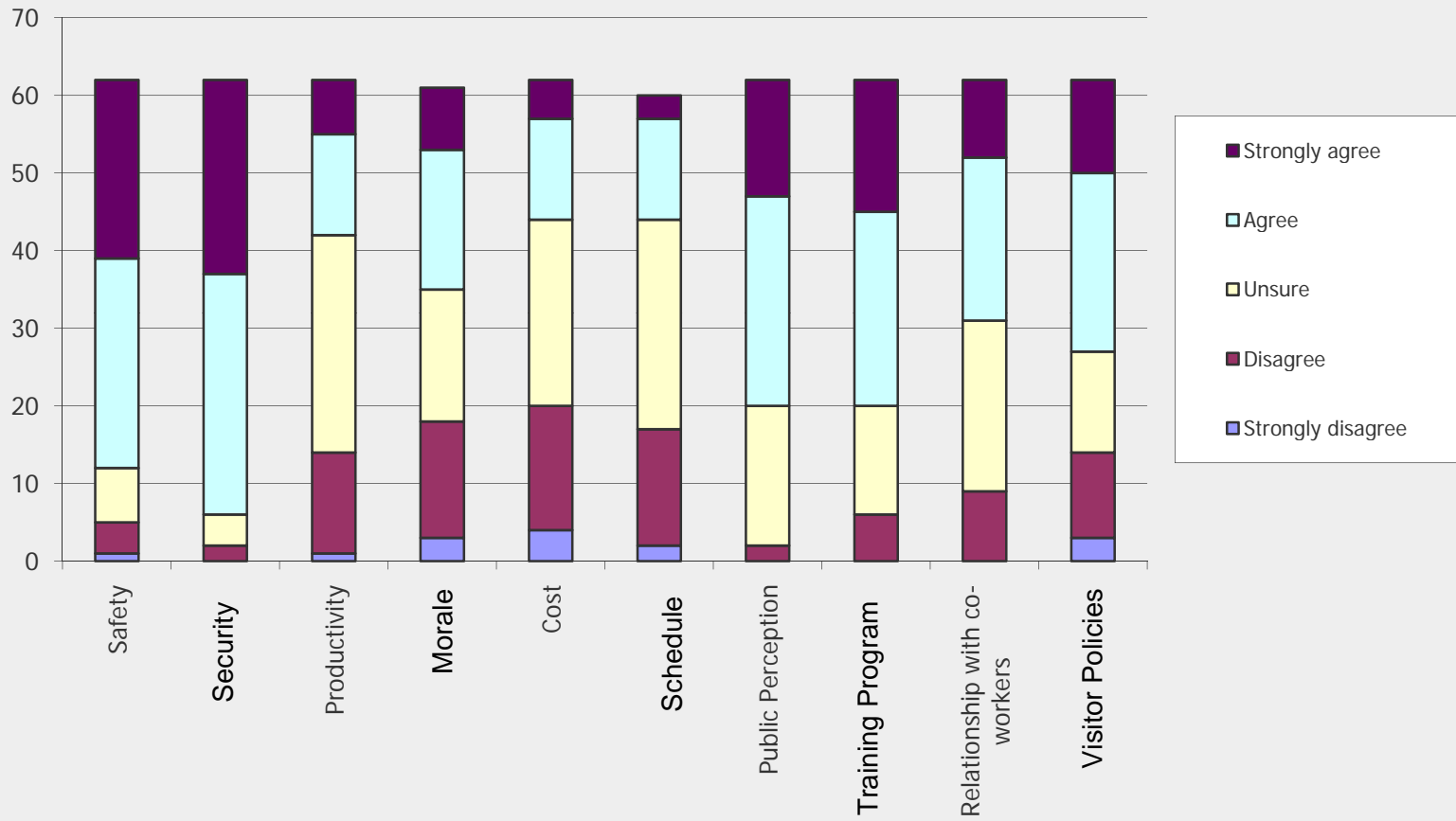


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 - 20% Strongly disagree or Moderately disagree
 - 30% No opinion



My employers personnel reliability programs affect the following program elements in a positive way:



Most biosafety professional respondents feel that PRP has a positive effect on biological safety and security



My employers personnel reliability program affects the following biosafety program elements in a positive way:



As before, most biosafety professional respondents feel that PRP has a positive effect on biological safety and security but (as before) there is a strong minority opinion



Survey Results: Regulation

- Should there be more or less mandatory federal regulations regarding safety training for select agent research? (109 responded)
 - 58.7% More
 - 41.3% Less
- Should biosafety professionals be licensed by the government to perform select agent work? (109 responded)
 - 24.8% Yes
 - 48.6% No
 - 26.6% Unsure



Survey Results-Professional Aspects

- Should biosafety professionals adopt a code or oath of conduct for select agent research? (109 responded)
 - 56.0% Yes
 - 23.9% No
 - 20.2% Unsure
- If new mandatory safety procedures training is required for persons working with select agents, should training be provided by safety personnel? (109 responded)
 - 84.4% Yes
 - 6.4% No
 - 9.2% Unsure

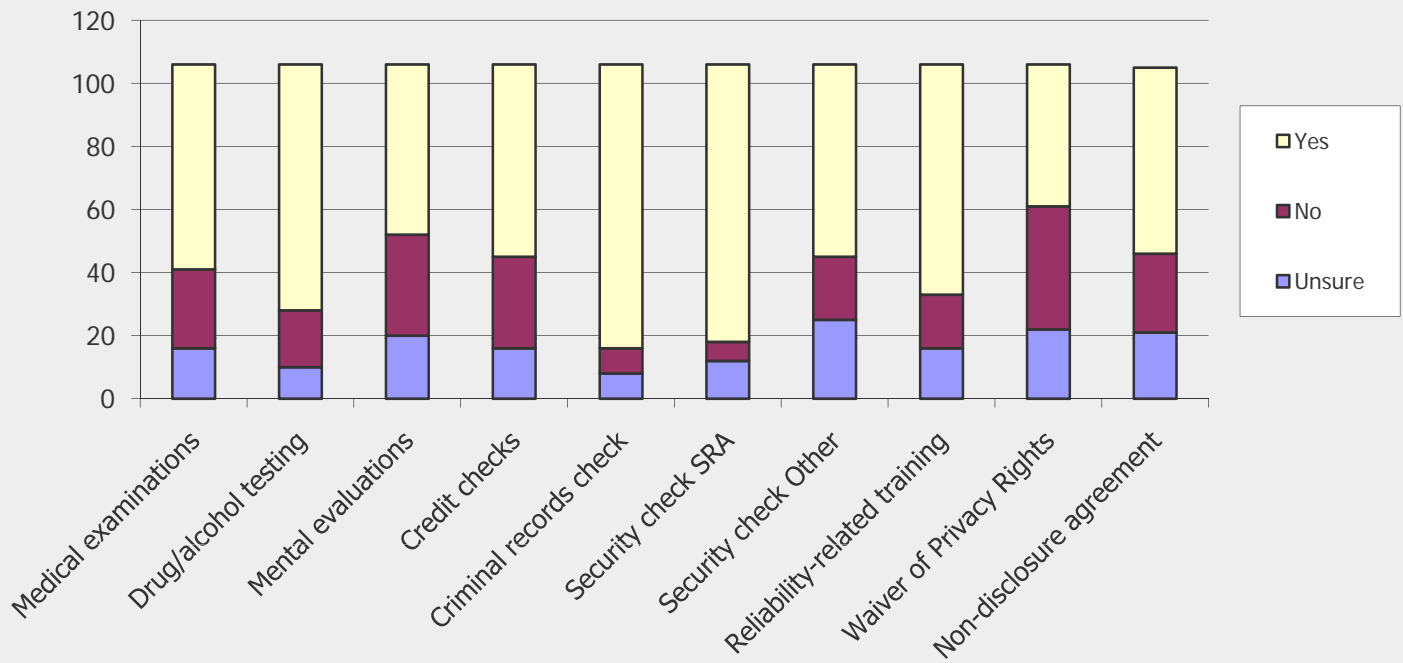
Survey Results-Professional Aspects

- Regarding training provided by safety personnel, should these trainers be required to be trained themselves before training others? (109 responded)
 - 82.6% Yes
 - 1.8% No
 - 4.6% Unsure
 - 11.9% Not applicable
- The U.S. Government established different regulations and guidelines for working with BSAT; the convergence to a single set of requirements, guidelines and regulations is needed (106 responded)
 - 77.3% Strongly agree or Agree
 - 15.1% Moderately disagree or Strongly disagree
 - 7.5% Have no opinion





There should be a single national standard for the following aspects of any personnel reliability programs?



Most biosafety professional respondents feel that there should be national standards set for PRP

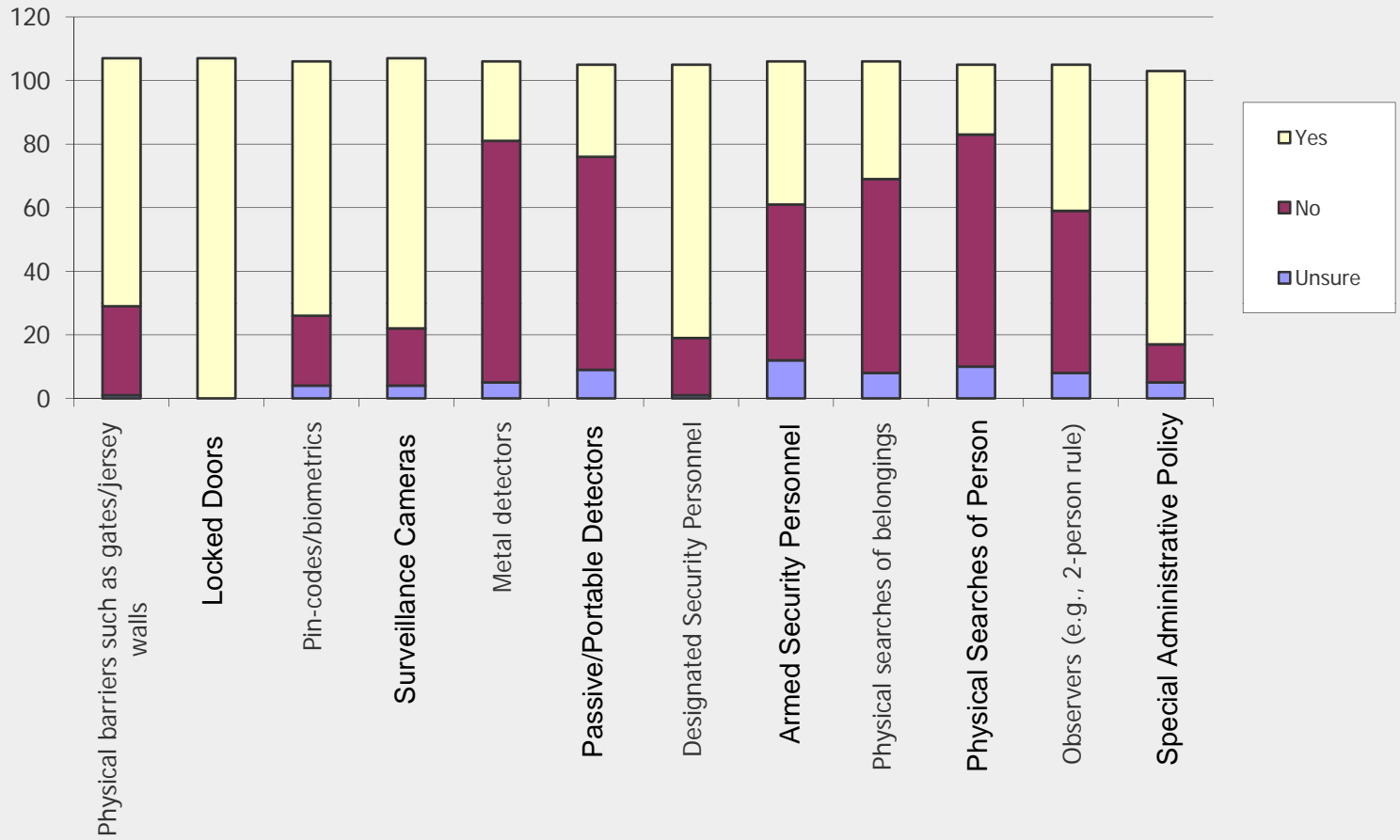


Survey Results-Biosecurity

- CCTV is an absolute requirement to maintain appropriate laboratory security (106 responded)
 - 37.7% Strongly agree or Agree
 - 53.8% Moderately disagree or Strongly disagree
 - 8.5% Have no opinion
- The two-person integrity rule is essential for mitigating the risk of unauthorized diversion of BSAT(106 responded)
 - 51.9% Strongly agree or Agree
 - 41.5% Moderately disagree or Strongly disagree
 - 6.6% Have no opinion



Physical security measures at my place of employment include (check all that apply):



The most common physical security measures include locked doors, administrative policies and designated security personnel

Survey Results-Background Checks

- The current investigative program to allow access to BSAT laboratories under the DHHS, referred to as an SRA, is adequate (106 responded)
 - 51.9% Strongly agree or Agree
 - 26.4% Moderately disagree or Strongly disagree
 - 21.7% Have no opinion
- The NACLC is a more appropriate background investigation for allowing access to BSAT (106 responded)
 - 32.1% Strongly agree or Agree
 - 30.2% Moderately disagree or Strongly disagree
 - 37.7% Have no opinion



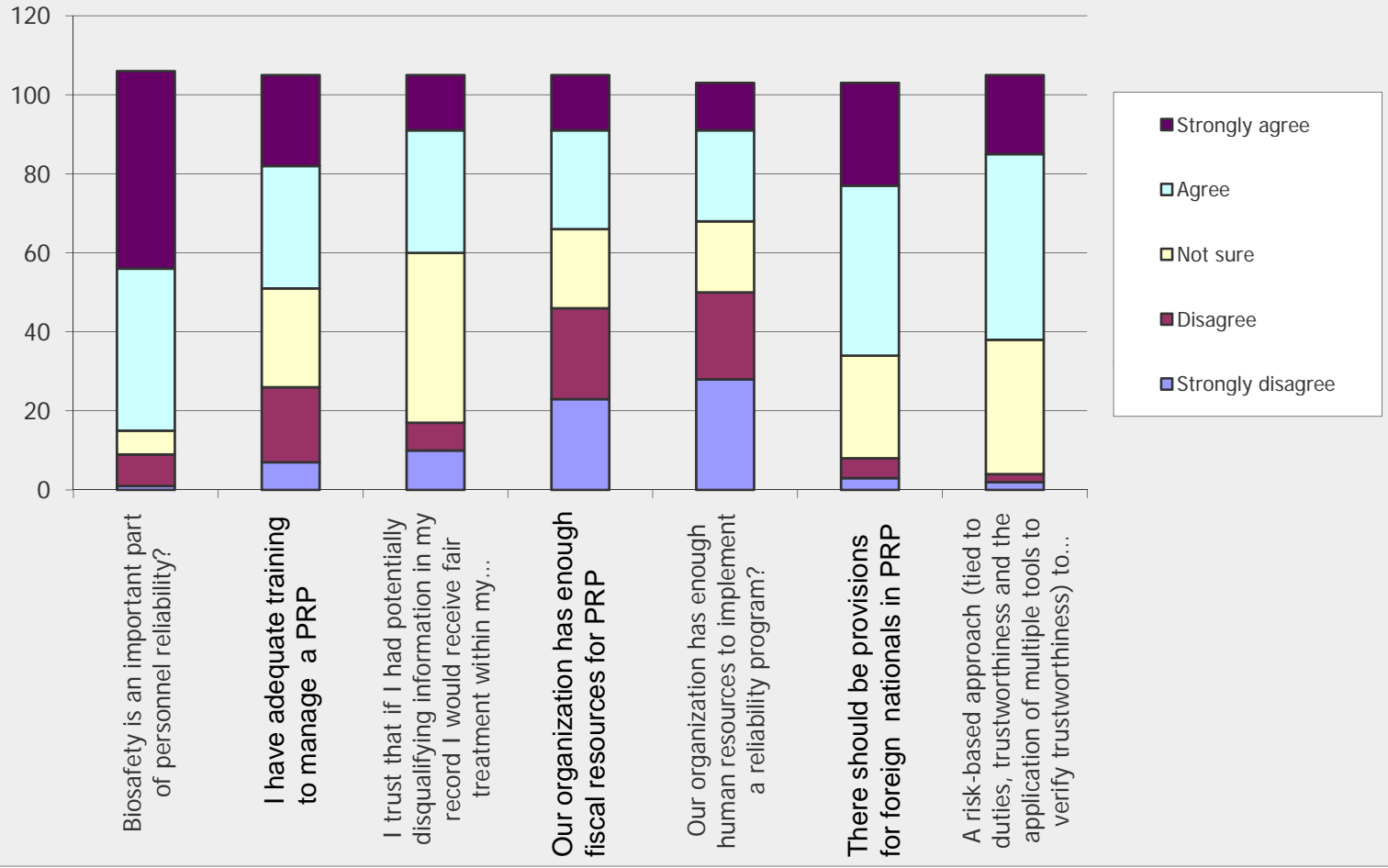
Survey Results-Medical and Behavioral

- Medical and behavioral surveillance (DOD and Army Biosurety) is the most effective program to mitigate the insider threat (106 responded)
 - 24.5% Strongly agree or Agree
 - 47.2% Moderately disagree or Strongly disagree
 - 28.3% Have no opinion
- Self-reporting of medical and personal issues that may affect access to BSAT laboratories is an adequate program to mitigate the various risks (106 responded)
 - 49.1% Strongly agree or Agree
 - 42.4% Moderately disagree or Strongly disagree
 - 8.5% Have no opinion





State your level of agreement



Most biosafety professional respondents may have concerns that their parent organization may not have enough fiscal or human resources for PRP

Survey Summary

1. There is a wide diversity of experience in ABSA with PRP: about 150 ABSA members (~9%) responded to most portions of the questionnaire.
2. The majority of ABSA respondents feel PRP is an important part of biosecurity and biosafety programs. However, ~20% do not agree with major aspects of the program, ~30% unsure.
3. Wide diversity of PRP approaches used in current PRP programs.
4. Some useful narrative comments were made on the utility of the survey.

Directions for the Future

1. Extend survey to all ABSA and CDC SRA registrants.
http://www.surveymonkey.com/s.aspx?sm=fFR_2bXs7ndGWHs0xLqgaZbQ_3d_3d
2. Gather fully burdened costing data for different lab types (i.e. government, academic, commercial) on PRP programs
3. Recommend changes to PRP that will minimize out-sourcing of science to countries without surety or minimal surety programs.
4. Implement regulations/guidelines that provide real improvements to biosecurity/biosurety vs. perceived security (e.g. counting vials)
5. Develop a unified (WHO-like) approach to personnel reliability and mitigate “holes” in all PRP programs while minimizing the effect on the scientific enterprise (local control).
6. Publish expanded survey results for use by policy makers.

