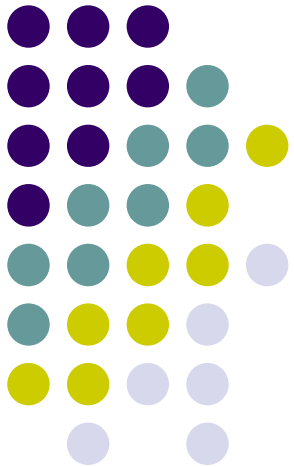
Controlling Dangerous Pathogens: A Prototype Protective Oversight System

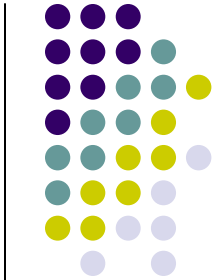
Elisa D. Harris

Center for International and Security Studies at Maryland



Biological Weapons Convention Experts Meeting
Geneva, Switzerland
August 19, 2008

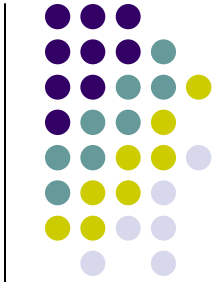
Introduction



- Prudent *and* effective oversight essential to managing risks from advances in biosciences and biotechnolgy

- Oversight measures must:
  - Protect right of scientific investigation *and* norm against destructive applications of biology
  - Provide reassurance to scientists they will not be subject to excessive regulation *and* to society that power of biology is being used appropriately

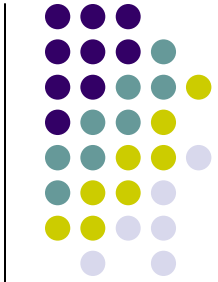
Essential Features



- Range of options for oversight –> minimal self governance to maximal regulation;
- Certain features must be included to avoid false choice between science and security:

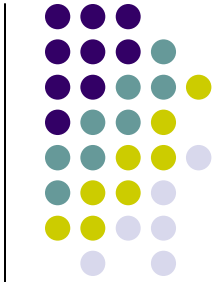
  1. activities subject to oversight must be clearly defined;
  2. review should be by independent experts under a tiered system linking level of oversight to level of risk;
  3. risk assessment process should consider both intentional misuse and unintended outcomes
  4. oversight should apply to all relevant activities, whether government, academic or private sector;
  5. compliance should be mandatory, not voluntary;
  6. system should be harmonized nationally, regionally, internationally.

CISSM Approach



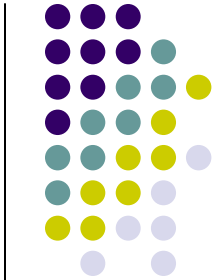
- Global implementing body at top;
- Oversee & approve research of extreme concern (i.e., involves more dangerous pathogens than now exist):
  - Work with eradicated agent;
  - Work with agent assigned BSL4/ABSL4
  - *De novo* synthesis of above
  - Expanding host or tissue range of listed agent
  - Construction of antibiotic/vaccine resistant listed agent

CISSM Approach, cont'd



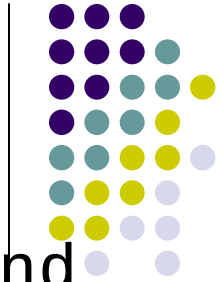
- National review body at next level;
- Oversee & approve research of moderate concern (i.e. involves pathogens already identified as public health threats):
  - Increasing virulence of listed/related agent
  - Insertion host genes into listed/related agent
  - Increasing transmissibility/environmental stability listed/related agent
  - Powder or aerosol production of listed/related agent
  - Powder or aerosol dispersal of listed/related agent
  - *De novo* synthesis of listed/related agent
  - Construction of antibiotic/vaccine-resistant related agent
  - Genome transfer, genome replacement or cellular reconstitution of listed/related agent

CISSM Approach, cont'd



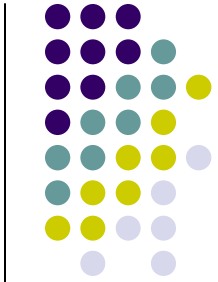
- Local review body at foundation;
- Oversee research of potential concern (i.e., increases weapons potential of benign pathogens)
  - Work with listed agent not covered above
  - Increasing virulence of nonlisted agent
  - Increasing transmissibility/environmental stability of nonlisted agent
  - Powder or aerosol production of nonlisted agent
  - Powder or aerosol dispersal of nonlisted agent
  - *De novo* synthesis of nonlisted agent
  - Genome transfer, genome replacement, or cellular reconstitution of nonlisted agent

System in Practice



- Licensing/accreditation of relevant facilities and researchers;
- Peer review of proposed project;
- Risk-benefit assessment:
  - Biosafety Rating: whether proposed research plan minimizes risk to public and environment.
  - Adequacy of Research Plan: incl whether there are scientific reasons why same outcome cannot be pursued through other means.
  - Public health rationale: incl whether research will advance understanding of disease causing properties of existing pathogens.
  - Biodefense rationale: incl whether work being done in response to validated or theoretical threat.
  - Current necessity of work: incl whether there are medical countermeasures available for use against agents to be constructed.
  - Potential impact: incl whether proposed results will inform policy

Impact of CISSM System



- Review of journals 2000-mid2005 suggest minimal impact on US researchers:
  - <1% publications involving bacteria, viruses, prions would have been affected
- Overall: 310 US facilities 2,574 researchers (53 facilities 137 researchers in multiple levels)
  - International: 12 facilities 185 researchers
  - National: 14 facilities 133 researchers
  - Local: 231 facilities 2,119 researchers
- Impact in other countries would be much more limited

Conclusion

- Recognize an internationally harmonized, mandatory oversight system is an ambitious goal; pending achievement, other, more incremental, measures should be pursued:
- Education, awareness raising, codes of conduct to sensitize individual scientists;
- Inclusion of dual-use review requirement in national biosafety arrangements;
- Harmonization of standards by like-minded countries;
- Building on existing WHO guidelines for laboratory biosafety & biosecurity; help develop dual-use guidelines for use by member states;