Day 2: Strengthening Assessment Tools and BSC Certification Programs

Questions to be answered by breakout groups

Groups A & B: Review and Critique the Proposed Assessment Tool

Facilitators: Candace Eastman (Group A) and Peter Minchella (Group B)
Recorders: David Cross (Group A) and David Turgeon (Group B)

- Does the tool adequately cover basic biosafety requirements, practices, procedures and programs?
- Is the tool practical to use? If not, what are suggested ways to improve tool practicality and utilization?
- Does the tool adequately address BSL-2/BSL-3 needs/requirements in resource-limited countries?
- Would some of the elements of the tool address the biosafety needs/requirements of Point of Care Testing facilities?
- Should the same "weights" be assigned to each element of the tool, e.g., should element 3.46 (After use, are gloves removed aseptically and hands washed?) have the same weight as 5.29 (Is there a controlled ventilation system that maintains directional airflow into the laboratory?)?

Group C: Discuss the utilization of two different laboratory designations

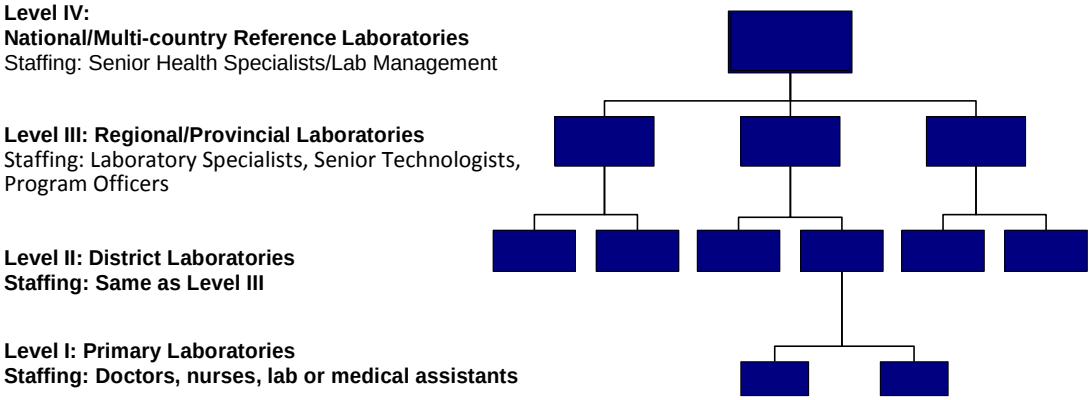
Facilitator: George Alemnji
Recorder: Pat Riley

- Laboratory tier designation per the Maputo Document (described below) with
- Biosafety Level Designations.

Can these two systems be integrated? What are the pros/cons of doing so?

Maputo Tiered Designation:
A consensus meeting of major stakeholders who were charged with making recommendations on laboratory testing standardization and harmonization in three major areas was held on 22-24 January 2008 in Maputo, Mozambique. The three areas discussed were: 1) testing needed at each level of a tiered, integrated laboratory network; 2) standardization of laboratory equipment and supplies at each level of a tiered laboratory network; and 3) key considerations to guide maintenance and service contracts for equipment at each level of a tiered laboratory network. This effort sought to strengthen laboratory capacity in resource-limited settings and determined that the best way to do this was through building sustainable laboratory capabilities provide access to high quality, rapid, and affordable diagnostic tests for the care, treatment, prevention and surveillance of HIV/AIDS, tuberculosis (TB) and malaria. A tiered, integrated laboratory network was proposed as providing the best model for service delivery across various levels of the public health system in resource-limited settings. Figure 1 (below) illustrates this designation, which is currently used in PEPFAR-supported countries.

Figure 1: The Tiered, Integrated Laboratory Network



The BSL Designation:

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause diseases in immunocompetent adult humans	Standard microbiological practices	None required	Open bench top, sink required
2	Associated with human disease. Hazard: percutaneous injury, mucous membrane exposure, ingestion	**BSL-1 practices plus:** • limited access • biohazard warning signs • sharps precautions • biosafety manual defining waste decontamination or medical surveillance policies	Primary barriers: Class I or II biosafety cabinets or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPE: laboratory coats, gloves, face protection as needed	**BSL-1plus:** • non-fabric chairs and other furniture easily cleanable • autoclave available • eyewash readily available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	**BSL-2 practices plus:** • controlled access • decontamination of all wastes	Primary barriers: Class I or II biosafety cabinets or other physical containment devices used for all manipulations of agents; PPE: laboratory	**BSL-2 plus:** • physical separation from access corridors • hands-free hand-washing- sink

		• decontamination of lab clothing before laundering • baseline serum	coats, gloves, respiratory protection as needed	• self-closing double door access • exhaust air not recirculated • negative airflow into laboratory • eyewash readily available in lab
4	Dangerous/exotic agents which pose high risk of life- threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	**BSL-3 practices plus:** • clothing change before entering • shower on exit • all material decontaminated on exit from facility	Primary barriers: All procedures conducted in Class III biosafety cabinets or Class I or II biosafety cabinets in combination with full-body, air supplied positive pressure suit	**BSL-3 plus:** • separate building or isolated zone • dedicated supply/exhaust, vacuum and decontamination system

Group D: Biosafety Cabinet Certification

Facilitator: David Bressler
Recorder: Jerry Pellegrini

- In order of importance, what do you believe are the limiting factors to establishing a sustainable BSC certification program in low to middle income countries?
- Given the importance of properly functioning biosafety cabinets (BSCs) to the overall safety of the public health laboratory environment - what innovative solutions have you seen employed in low to middle income countries to ensure that this capacity is maintained?
- The annual certification of BSCs is an internationally recognized best practice. Is this the only option for the safe maintenance and operations of BSCs?
- Is safe operation and use of BSCs well understood by laboratorians or is this a training gap? How is this gap (if it exists) being addressed?