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BIOSAFETY AND BIOSECURITY IN PUBLIC HEALTH LABORATORIES

Infectious diseases pose a continuing menace to all people regardless of age, gender, life style, ethnic background or socioeconomic status. Though some have been conquered by antibiotics, vaccines and other advances, new infectious diseases are constantly emerging like HIV/AIDS, Legionnaires disease, Lyme disease, Hanta virus pulmonary syndrome, West Nile virus, SARS, Avian flu offer instructive example. Other infectious diseases such as Tuberculosis and Bacterial pneumoniae re-emerge in drug resistance forms or through Bioterrorism. Because we cannot predict occurrence of new diseases, public health laboratories play an important role in handling such situations and always need to be well prepared for the unexpected.

The laboratory workers who play key role in investigation of the prevailing diseases are always at risk of exposure to infectious agents that cause disease ranging from inapparent to life threatening infections and accidents in laboratory which include splashes and spills, needle stick injuries, cuts, mouth pipetting and scratches or bites from animals. The CDC reported two cases in 2002 in which 2 technicians injured themselves while working with infected animal tissues and contracted West Nile Virus as a result. Many similar incidents have been reported in the literature. However, a number of such incidents go unreported.

Formulation and implementation of effective biosafety programme is very important in public health laboratories. The initial step in biosafety programme is assessment of risk to the laboratory worker. **Risk assessment guidelines are based on:**

- the pathogenicity of the infectious agent
- the mode of transmission
- worker related risk factors
- the source and route of infection
- the design of the laboratory facility.

Strategies for the prevention and management of laboratory associated infections are based on:

- the containment of the infectious agent by physical separation from the laboratory worker and the environment.
- employee education about the occupational risks and availability of an employee health program.

Adherence to the biosafety guidelines mandated by various government and accreditating agencies reduce the risk of acquiring laboratory associated infections and accidents.

BIOSAFETY IN PUBLIC HEALTH LABORATORIES

Definitions

Biosafety: Development and implementation of administrative policies, work

Table 1 – Showing the classification of the microorganisms as per the biosafety level requirement				
Biosafety Level	**1**	**2**	**3**	**4**
Infectious Agents	Unlikely to cause disease in healthy workers or animals Low individual and community risk	Can cause human or animal disease but unlikely to be a serious hazard Moderate individual risk, limited community risk Effective treatments available	Cause serious human or animal disease but not ordinarily spread by casual contact High individual risk, low community risk	Cause very serious human or animal disease, often untreatable and transmitted. High individual risk, high community risk
Examples of infectious agents in this risk level	E.coli, B.subtilis	Hepatitis B virus, *Entero* viruses, many influenza viruses, Human immuno-deficiency viruses, Salmonella sps, meningococcus	B.Anthracis, Q Fever, Myc. tuberculosis, Hantaviruses	Ebola viruses, Monkey virus, Foot and Mouth Disease, Avian influenza virus

practices, facility design and safety equipment to prevent transmission of biologic agents (Biohazards) to workers, other persons and the environment.

Biohazardous agent: CDC defines a biohazard as "an agent of biological origin that has the capacity to produce deleterious effect on human i.e. micro organisms, toxins and allergens derived from those organisms; allergens and toxins derived from higher plants and animals.

According to the factors determining the hazardous effect of the organisms, four levels of risk have been defined. (Table 1)

Risk Group 1: (Low-individual and community risk) – By biological agent that is unlikely to cause disease.

Risk Group 2: (Moderate individual risk, low community risk) – Any pathogen that can cause human disease but under normal circumstances unlikely to be a serious hazard to laboratory workers, community live stock or the environment. Laboratory exposures rarely cause infection leading to serious disease. Effective treatment and preventive measures are available and the risk of spread is limited.

Risk Group 3: (high individual risk, low community risk). Any pathogen that usually causes serious human disease or can result in serious economic consequences but does not ordinarily spread by casual contact from one individual to another or that causes diseases treatable by antimicrobial or anti parasitic agents.

Risk Group 4: (high individual risk, high community risk). Any pathogen that usually produces very serious human disease, often untreatable, and may be readily transmitted from one individual to another or from animal to human or vice versa, directly or indirectly or by casual contact. Effective treatment and preventive measures are generally not available.

GENERAL RECOMMENDATIONS UNDER BIOSAFETY

Good laboratory technique is fundamental to laboratory safety. Important concepts in

laboratory safety are listed below:

Entry/access to laboratory area

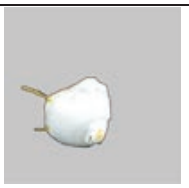
- Have a biohazard sign (Fig. 1) displayed on the doors of the rooms where infectious agents are handled.

(Fig. 1)
Biohazard sign

- Entry to laboratory working area should be only for laboratory personnel.
- Doors to the laboratory should be kept closed, should preferably be self-closing type.
- No smoking, eating, or drinking or use of cosmetics to be allowed in laboratory area.

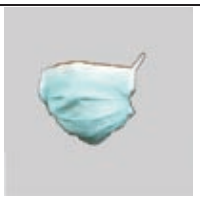
Protective barriers (Fig. 2)

Goggles



N-95 Mask

Gown



Triple Layer Mask

Gloves

Shoe cover

Personal Protection

- While working in the laboratory always wear laboratory coat.
- Have all the personnel protective equipments (As shown in Fig. 2) ready & use them as per the procedural requirement.
- Wear gloves for all procedures that may involve direct or accidental contact with blood/infectious materials. After use, gloves should be removed carefully without touching infected surface, disposed off in container containing disinfectant solution. Hands should be washed with soap & water before and after any procedure.
- Laboratory coat should not be worn outside the laboratory area i.e. canteen, library, toilet or staff common room.
- Used/unused laboratory coat should not be placed in the same cupboard with street clothes or food articles etc.
- Laboratory personnel should receive suitable immuno/chemoprophylaxis e.g. Hepatitis B vaccination, meningococcal meningitis vaccination, oral doxycycline for workers handling plague, leptospiral bacteria.

General procedural precautions

- Mouth pipetting must be strictly avoided.
- Materials/articles must not be held in the mouth. Do not lick/wet labels for sticking.
- All technical procedures should be such that they minimize the formation of aerosols and droplets. In the district laboratories do not perform any procedure that generates lots of aerosolization unless there is an access to biological safety cabinet.
- Do not use hypodermic needles and syringes for pipetting devices.
- All spills, accident or exposure to infectious materials, must be reported to laboratory in charge and a record should be maintained.
- Display written procedures for the “clean up all spills”.

Procedure to clean up all spills

- Pour 1% freshly prepared Sodium hypochlorite; spill over it in sufficient quantity.
- Cover the spills with paper towel or absorbent materials.
- Leave for 15-20 minutes.
- Clean it.
- Wipe up the whole spill with fresh absorbent material using gloved hands and place in a contaminated waste container.
- Wipe the surface with soap and water.

Laboratory working areas

- Keep your laboratory area neat, clean and free of materials that are not required.
- Decontaminate your work surface after any spill and at the end of the working day using 1% sodium hypochlorite.
- All contaminated materials, specimens, cultures, must be decontaminated in the laboratory premises before final disposal or cleaning for reuse.
- If there are windows in laboratory area, they should have arthropod/mosquito & fly proof mesh.

Biosafety Management

- Have one person responsible for biosafety activities who may be designated as biosafety officer.
- Health check up of laboratory staff at regular intervals.
- Immunization against diseases which are feasible must be given regularly, especially Hepatitis B.
- Biosafety officer should train lower staff regularly.

BIOLOGICAL SAFETY CABINETS

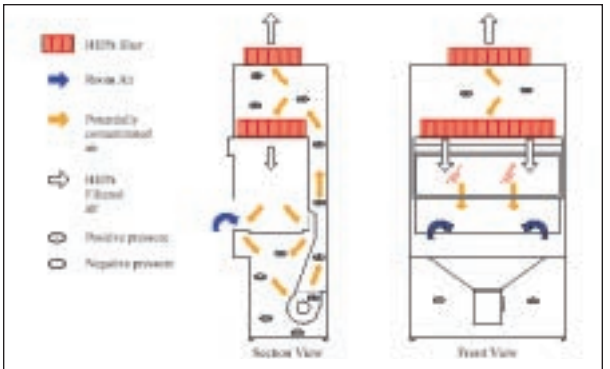


Fig. 3 - Class II type Biological Safety Cabinet

Biological safety cabinets or other physical containment devices should be used for all manipulations that may cause splashes, droplets, aerosols of infectious material (e.g. centrifugation, grinding, blending, vigorous shaking or mixing, sonic disruption, opening of containers of infectious materials whose internal pressure may be different from ambient pressure etc.) The cabinet afford increasing protection as the biosafety level of cabinet increases. The required level of cabinet selected is based upon:

- the hazard potential of the agent,
- the need for protection of personnel
- the extent to which aerosols may be produced while doing experiments (For most microbiological organisms encountered in clinical laboratories, a biosafety cabinet level of I, II and III are used depending on the type of pathogen handled). In a district public health laboratory, a class-II biosafety cabinet as shown in Fig.3 is desirable and should be used.

USE OF THE CABINET

Start-up procedures when preparing for work in the Biological safety cabinet

- Switch on the UV light and run the blower of the cabinet at least 1-2 hours prior to starting work.
- When starting work, turn off UV lights if on and ensure that the switch is in the appropriate position.
- Turn on fluorescent light and cabinet blower, if off.
- Check the air intake and exhaust grilles for obstruction.
- If the cabinet is equipped with an alarm, test the alarm and switch it to the “on” position. Confirm inward airflow by holding a tissue at the middle of the edge of the viewing panel and ensuring that it is drawn in.
- Disinfect the interior surfaces with a suitable, non-corrosive disinfectant.
- Assemble all material required for the procedure and load them into the cabinet; do not obstruct the air grilles; the working surface may be lined with absorbent paper with plastic backing; segregate “clean” items from “contaminated” items.

Table 2 - Classification of biomedical waste, containers used, colour coding & final disposal				
Sl. No.	**Waste Category**	**Type of containers**	**Color code**	**Disposal method**
1.	Human/animal infectious waste eg. blood, body fluids, body parts	Plastic bags with Biohazard sign.	Yellow	Incinerator/Deep burial
2.	Microbiological waste eg. Used culture media etc.	Plastic bags/plastic containers	Red	Autoclave/chemical treatment followed by incineration
3.	Solid/Sharp waste eg. Scalpel, blade, needles, lancet, disposable syringes, petri plates	Plastic puncture resistant containers	Blue/white	Autoclave/chemical treatment/shredding followed by deep burial
4.	Chemical waste	Plastic bags	Black	Deep burial
5.	Animal waste	Plastic bags	Orange	Incineration/deep burial

- Wait 5 minutes to purge airborne contaminants from the work area.

Procedures for working in the cabinet

- Wear protective clothing and gloves as appropriate.
- Perform operations as far to the rear of the work area as possible.
- Avoid movement of materials or excessive movement of hands and arms through the front access opening during use. When you do enter or exit the cabinet, do so from straight on. Allow the cabinet to stabilize before resuming work.
- Keep discarded, contaminated material to the rear of the cabinet; do not discard materials in containers outside the cabinet.
- Do not work with open flames inside the cabinet.
- If there is a spill during use, surface decontaminate all objects in the cabinet; disinfect the working area of the cabinet while it is still in operation (Do not turn the cabinet off).

Follow these procedures upon completion of the work

- Allow the cabinet to run for 5 minutes with no activity.
- Close or cover open containers before removing them from the cabinet.
- Surface disinfect objects in contact with contaminated material before removal from the cabinet.
- Remove contaminated gloves, dispose them of as appropriate; wash hands.
- Do not clean gloves, and ensure that all materials are placed into biohazard bags within the cabinet.
- Using a suitable non-corrosive disinfectant (e.g. 70% ethanol), disinfect interior surfaces of cabinet; periodically remove the work surface and disinfect the area beneath it (including the catch pan) and wipe the surface of the UV light with disinfectant.
- Turn off the fluorescent light and cabinet blower when appropriate (some cabinets must be left on at all times; if you are unsure, check with your cabinet certifier, safety officer or building maintenance personnel).
- Turn on the UV light if appropriate (do not turn on when people are working close by); UV light must be tested to ensure that it is emitting a germicidal wavelength (ask your cabinet certifier to perform this test regularly).
- Put your cabinet under AMC and get a certificate for its performance.

WASTE MANAGEMENT

Bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animal

or in research activities pertaining thereto or in production or testing of biologicals. The classification of biomedical waste and category wise disposal is depicted in Fig.4 and Table-2.

The key to minimization and effective management of health-care waste is segregation (separation) and identification of the waste. Appropriate handling, treatment, and disposal of waste by category reduces costs and does much to protect public health. Segregation should always be the responsibility of the waste producer, should take place as close as possible to where the waste is generated and should be maintained in storage areas and during transport.

Follow management at every step from the site of generation

- ⇨ Segregation.
- ⇨ Collection.
- ⇨ Transportation.
- ⇨ Storage.
- ⇨ Treatment to disinfect/disinfections.
- ⇨ Final disposal

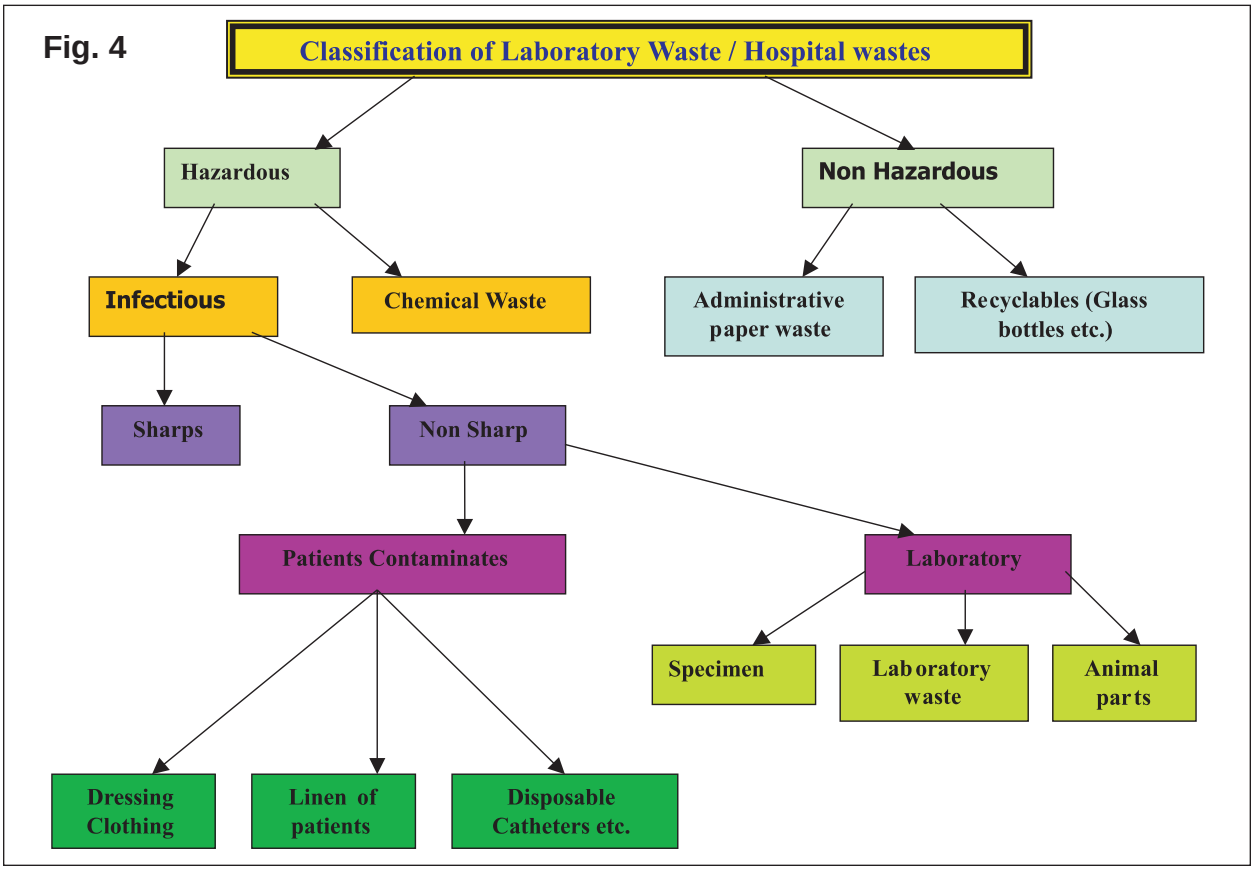
- ➢ Segregate the different category of waste at the point of generation.
- ➢ Discard infectious wastes if possible in disinfectant solution.
- ➢ Discard sharp waste i.e. needles, blades etc in a puncture proof containers. After the container is 2/3 filled it should be autoclaved*/* shredded and land filled for decontamination.
- ➢ If you have nothing for decontamination deep bury in a secure area.

The most appropriate way of identifying the categories of health-care waste is by sorting the waste into colour coded plastic bags or containers as shown in Table-2.

BIOSECURITY IN THE PUBLIC LABORATORIES

Today the facilities for handling infectious agents need not only be for a biosafety program but for biosecurity purpose/plan which should also be in place. While

Fig. 4



biosafety deals with all aspects of containment to prevent any exposure to and accidental release of pathogens, biosecurity is needed to be implemented to prevent the theft, misuse or intentional release of pathogens. Recently, concern has increased regarding possible use of biologic, chemical and radioactive materials as terrorism agent. In the U.S., recent terrorism incidents have resulted in the substantial enhancement of existing regulations and creating new strategies to prevent such incidents.

Definition

Bio-security: Protection of high consequences microbial agents and toxins or critical relevant information against theft or diversion by those who intend to pursue intentional misuse.

Biologic terrorism: Use of biologic agents or toxins e.g. pathogenic organisms that affect humans, animals or plants for terrorist purposes.

Recommended measures to be undertaken for biosecurity implementation:

- Select agents potentially encountered in clinical Laboratories: The agents of most relevance to clinical laboratories are the six pathogens (designated by CDC as "Category A") causing disease or agents which are believed to pose the most risk to national security as they may easily be cultured or acquired and can result in high mortality rates and can cause public panic. These agents include *Bacillus anthracis, Clostridium botulinum toxin, Brucella sp*. (abortus, melitensis and suis), *Yersinia pestis*, Smallpox (variola major) *Francisella tularensis* and the agents causing viral hemorrhagic fevers i.e. Ebola and Marburg viruses etc.
- Any select agent or toxin identified in diagnosis should be reported immediately to appropriate agency.
- The culture or toxin of any select agent used in diagnosis should be destroyed appropriately.
- Any of select agent/organism that is not absolutely required for patient care, proficiency testing or educational purpose must be destroyed properly and the destruction should be documented.
- It is very important to ensure that access to select agents is appropriately restricted.
- Access to incubation, refrigeration, freezer or other storage and working areas for the select agents must only be accessible to authorized personnel.
- Restrict access to certain other high-risk areas of the laboratory that contain radioactive, toxic or infectious materials.
- In case of storage, establish a system of accountability for select agents. Maintain up to date inventory of seed stocks, toxins and agents in long-term storage.
- Develop appropriate safe procedures for transporting select agent specimens into the laboratory.
- Develop and implement an emerging response plan as preparedness for emergent situations.
- Establish a protocol for reporting adverse incidents to appropriate high agencies.

However, the applications of these recommendations to a particular laboratory operation should be based on a risk assessment of the special agents and activities, rather than used as a universal and generic code applicable to all situations.

General procedures to be followed in case of accidental/intentional release of pathogens

The release of pathogens accidentally or intentionally should be dealt with an organized and systematic way as it can affect entire staff/community/equipment / materials etc. The pathogens may be received in different forms like liquids, solids, and gas aerosol. Standard operative procedures to handle all types of samples should be available with all the laboratories

and every eventuality must be catered for. Identify a responsible person in each hospital/laboratory and display his/her contact/mobile number in the laboratory/ hospital.

1. Immediate Action

- Inform emergency service immediately
- Responsible person/authority should be informed immediately
- Record all the accidents at work
- Immediate action needs to be taken by the superiors which include:
  - To evacuate personnel quickly in accordance with plan of action if the contamination is caused by aerosol/ powdery solid or volatile agent.
  - If the contaminate is powder, avoid air currents. Doors must be closed and ventilation hoods to be switched off.
  - Restrict access to the contaminated area.
  - Organize prompt decontamination of all exposed personnel by appropriate method laid down for the purpose
  - Decontaminate the premises and all exposed equipments and materials.

2. Evacuation of Personnel

Under biosafety precautions, evacuate all personnel who have chance to get exposed/ all serious cases etc.

3. Decontamination

Decontamination of personnel as per guidelines laid down for individual pathogens leading to illness. Any serious patient should be attended immediately.

Remember

- Never rub or scrub the skin, which may facilitate the penetration of contaminant/ pathogen through skin.
- Never induce vomiting in an accident victim if organism enters by mouth absorption.

4. Decontamination of premises and equipment

- Notify to safety officer/CMO designated for the purpose.
- Mark the contaminated area with permanent marker.
- Put on appropriate protective clothing like coverall, mask, goggles, gloves etc.
- Do not touch anything with naked hands.

IF THE CONTAMINANT IS POWDER

- Switch off all forms of ventilation to prevent risk of dispersion.
- Clean the contaminated area using cloth/paper impregnated with solvent of known decontaminant.
- Change the filters of biosafety cabinet after decontamination.
- Use wet method to clean equipment or premises (use soapy water, detergents or decontaminants in aqueous solution).
- Efforts should be such to avoid the spread of hazardous material.

IF THE CONTAMINANT IS LIQUID

Use absorbent products for absorbing liquids and then dispose them off after de-contamination. Use procedures as recommended for spill.

Always make eye bath/shower/medical services available near laboratory.

...about CD*Alert*

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