Egyptian Journal of Animal Health

P-ISSN: 2735-4938 On Line-ISSN: 2735-4946
Journal homepage: https://ejah.journals.ekb.eg/

Biosafety in laboratories: History, Application and Expected community outcomes

Momtaz A. Shahein, Essam M. Ibrahem, Essam E. Kamel, Emad R. Zaki, Heba H. Hassan, Dalia M.A. Elmasry and Amany N. Dapgh
Animal Health Research Institute, Agricultural Research Center, Giza, Egypt.

Article Review

Article History
Received in 29/10/2020
Received in revised form 8/11/2020
Accepted in 27/12/2020

Biosafety is a strategic and integrated approach to analyzing and managing relevant risks to human, animal and plant life, health and associated risks for the environment. It is based on recognition of the critical linkages between sectors and the potential for hazards to move within and between sectors, with system-wide consequences.

Biosafety guidelines are a set of policies and procedures necessary to observe by personnel working in various facilities for handling the microbiological agents such as bacteria, viruses, parasites, fungi and other related pathogens.

Dealing with pathogenic microorganisms) requires precautions that guarantee the safety of humans and the environment, responsible authorities and researchers have therefore developed regulations and guidelines that in some detail describe containment measures and working instructions.

Despite containment measures and guidelines, laboratory infections, usually occur more or less Institutions requiring strict adherence to these biosafety guidelines include clinical and microbiological laboratories, biomedical research facilities, teaching and training laboratories and other healthcare institutions (e.g., clinics, health centers, hospital facilities). These guidelines provide proper management and regulation of biosafety programs and practices implemented at all levels of the organization.

Essential components of the biosafety guidelines contain some or all the following, depending on the available facility:

Biorisk assessment and identification; specific biosafety measures, which cover the code of practice, physical plant such as laboratory design and facilities, equipment acquisition and maintenance, medical surveillance, staff training, safe handling of chemicals, with fire, radiation and electricity safety among others.

Additional components such as commissioning and certification guidelines for the facilities.

A comprehensive system incorporating the most important aspects of biosafety and biosecurity (i.e. Biorisk), which encompasses both policy and management aspects, is necessary. On the institutional level a policy must be formulated and should be endorsed

Corresponding author: Dalia M.A. Elmasry , Reference Laboratory for Veterinary Quality Control on Poultry Production, AHRI, ARC, Giza, Egypt.
E-mail: dr_daliaelmasry@yahoo.com
DOI: 10.21608/EJAH.2021.134827

by the executive management.

On the operational level, the management system should subsequently be improved, implemented and continually supervised and educational raising activities are needed to ensure a good application.

The biosafety guidelines must be clear, practical and suitable for each facility and must be available for easy reference by all staff and must be reviewed, and updated regularly. The technical guide cannot alone ensure a safe working environment without the commitment of each person to adhere adequately to the biosafety guidelines at all times. **(Kimman et al. 2008).**

History of Biosafety:

At first, a worthy milestone on biosafety was referred as "microbiological safety" dates back to 1908 where Winslow demonstrated a novel method of examination to enumerate bacteria present in the air (**Winslow ,1908**).

Additional study described laboratory-acquired brucellosis which also revealed that similar infections could pose a threat to man has no relation to lab work **(Yagupsky and Baron, 2005)** .

The principles of biosafety have developed together with the history of the American Biological Safety Association (ABSA).

As briefly described by the Federation of American Scientists, the first meeting was held in 1955 with the members of the military, as the focus addressed "The Role of Safety in the Biological Warfare Effort".

The next meetings attendees included the US Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), universities, laboratories, hospitals and representatives from the industries. From then, written regulations covered the shipment of biological agents, safety training and programs, with the development of biological safety level classification (**Bayot and Bhimji 2018**).

Biosafety studies on the individual or group of agents became the focus in the 1980s. Some from studies focusing on specific biohazard levels of pathogens and other new strategies were developed to enhance biorisk assessment capacities, biosecurity, and biocontainment measures including the regulation of biosafety through national and international policies. Other activities such as in agriculture and biotechnology are now considering biosafety applications.

Laboratory-Acquired Infections (LAIs)

Laboratory-acquired infections (LAIs) were considered significant because of the high risk in the laboratory workforce relative to the public, although the exposure to infectious agents can be higher in other groups of healthcare workers.

Several works of literature and mail surveys with an attempt to evaluate the risk of infection associated with employment in a clinical or research laboratory. New studies and reviews led to the identification and description of hazards unique to the laboratories, which later formed a basis for the development of approaches to prevent the emergence of LAIs **(Sulkin, 1961**; **Sewell, 1995**).

The incidence of laboratory-acquired infections varies among institutions conducting surveys to a specific of laboratories and facilities. Monitoring and evaluation of LAIs are still absent for some institutions which could be caused by the difficulties in the reporting schemes and lack of accurate data interpretation.

The reporting of LAI is not similar to that of notifiable diseases which is highly regulated for each healthcare institution across countries as implemented by their ministries of health. An example of Laboratory-acquired infections would be a person infected with tuberculosis, who could have an infection with TB bacilli but with no signs and symptoms, thus, cannot be considered as TB disease.

The need for data collection for current LAIs should highlight the importance of improving biosafety, then LAI databases were created to contain all recently published studies and to verify its relevant findings.

In 2018, Siengsanan and Blacksell presented the results of a rapid review of LAI studies within the Asia-Pacific. Regarding potential biorisks for zoonotic diseases, viruses predominate, followed by bacteria and parasites. The importance of biorisk assessment and management was also emphasized, including preventive practices.

Strict biosafety measures are a must for these working environments to protect themselves as

well as the community **(Siengsanan-Lamont and Blacksell 2018)**.

Specimen Requirements and Procedure

All specimens collected from patients require the application of biosafety measures. It starts with the instructions provided by the healthcare worker to the patient. Clear statements with explanations and step-by-step procedures are necessary, especially for patients who will collect the specimen. Healthcare workers, including laboratory staff, should be well-oriented especially when they are to collect specimens directly from patients. Personal protective equipment (PPE) must be worn at all times during the specimen collection **(Cornwell 1992**; **Hersi et al. 2015)**, also the Universal precautions must be applied .

Several procedures exist for collecting sterile and non-sterile sample specimens. Good strategies were developed recently to minimize hazards either during or after sending the specimens to the laboratory. For example, the use of the evacuated tube system (ETS) prevented the contact of the patient's blood from the site of extraction to the phlebotomist and the external environment during venipuncture. **(Ialongo and Bernardini 2016)**

This is much safer than the previous practice of manual transferring blood samples from the syringe to the tube (**Fujii et al. 2013**). Sputum collected in a clear and transparent container will aid in efficient Supervision and assessment of sputum quality which is safer than reopening the cap. (**Karinja et al. 2015).**

Safe handling and processing of specimens

Clinical laboratory scientists must perform laboratory procedures accurately and safely (**Sewunet et al. 2014**). PPE must be worn out while inside the premises of the laboratory and throughout the diagnostic procedure. There is a proper sequence of donning (putting on) and doffing (removing) PPE as recommended by the US Centers for Disease Prevention and Control (CDC).

Generally, donning starts with gowning, wearing a mask (or respirator), goggles (or face shield) and gloving. Doffing may be done by removing gloves, goggles, gowns, and mask followed by proper hand washing.

Pathogen-specific and risk-specific biosafety measures are shown to be more practical and cost-effective. For example, low and medium-risk procedures do not need a containment facility and infrastructure which are designed only for high-risk procedures.

Safe handling and processing of specimens can be conducted in biological safety cabinets (BSC) to prevent inhalation of generated aerosols when performing a microbiological procedure**(Kruse et al. 1991**). The purpose of using BSC must be well differentiated from using fume hoods, in which the latter is only necessary for handling chemicals and not for infectious microorganisms.

When dealing with specimens keep hands away from the face and should remain inside the cabinet. Unnecessary movements inside the BSC are prohibited to prevent changes in the flow of air. For instance, the crossing of arms during the laboratory procedure is inadvisable. Also, ensure to disinfect the BSC before use. In procedures done in the absence of a BSC, a well-ventilated area must be secured and maintained before considering it as a bench work area. When gloves become heavily contaminated, wear new gloves. Do not reuse gloves in other procedures nor soiled masks or respirators. Molecular biology laboratories perform procedures that require the use of different rooms for (sample preparation, DNA extraction, amplification and sequencing) so, we need for additional biosafety measures **(Beilby 2006).**

Proper disposal of wastes is necessary to prevent disease transmission. Waste segregation must be appropriately employed (e.g., infectious and non-infectious waste). Waste disposal through burning may not be practical nowadays. Hence, alternative disposal mechanisms must be finalized and institutionalized in each healthcare institution **(Singh et al. 2001).** Environmental impact is always a consideration when making decisions for waste disposal and specific steps should be written on standard operating procedure manuals and work instructions intended for laboratory staff involved. Recording and reporting procedures must be free from possible contamination and should of in a clean and dedicate space. (**Ezzelle et al. 2008**).

Similarly, wearing gloves when encoding via a computer or when using the phone is forbidden due the risk of the laboratory work, one

person must be well-trained and supervised to perform biosafety measures at work, while non -authorized personnel must have restricted access to the laboratory, especially when a diagnostic test is in process.

Testing Procedures

The biosafety guidelines are part of the overall quality management systems implementation. For newly established facilities, ensure biosafety before the start of operations. Workflow inside the laboratory must facilitate an efficient means for carrying out processes by the lab workers. Activities involving dirty areas (e.g., a specimen receipt, sample preparation, etc.) should be kept separate from the clean areas like: (e.g., microscopy, use of automated instrumentation, recording of results, etc.). Procedures for laboratory workflow can be tested through observation and evaluation by a designated biosafety officer, laboratory supervisor or an independent consultant who can conduct monitoring activities and provide technical helping.

Labs using BSC, a smoke pattern test using in-house or commercial testers may be regularly performed to assess for good airflow before use. Anemometers may be used to check for air velocity. BSC certification provided by a service professional must be secured before use and continually re-certified once a year. **(Whistler et al. 2016).**

Before performing any laboratory test, the provision of required training on biosafety to the laboratory workforce is vital, either as a focused training program or as part of the training curriculum for certain laboratory procedures. Laboratory managers, section heads and supervisors should receive biosafety training as well, including topics on bio risk management and biosafety program implementation. Effective supportive supervision of laboratory staff working in any facility is a key factor for the sustained implementation of quality laboratory services. **(Heiby 1998).**

The integration of the monitoring of biosafety practices with monitoring of laboratory processes should proceed based on set criteria or standards. Certain indicators which indirectly assess the overall biosafety may include the presence of an updated procedure manual and work instructions, a list of trained staff with regular competency or proficiency tests, with regular quality control and maintenance of laboratory equipment. Regular medical consultation for staff can early detect the risk of infection.

Moreover, the presence of laboratory signage such as a biohazard symbol to recommended sites of the facility, with a well-organized mechanism for disposal of wastes can significantly minimize the risk of accidents and incidents both inside and outside the laboratory. Laboratory accreditation and certification may also aid in ensuring that biosafety measures get implemented in accordance with the written guidelines (**Rim and Lim 2014**).

Factors help or hinder the biosafety measures

Several factors impede the application of laboratory-related biosafety measures within the facility. **These may include:**

- The absence of a technical document containing specific biosafety guidelines
- Poor biosafety skills (for example, on spills management) because of lack of training
- The continuous presence of laboratory hazards and increased vulnerability due to poor execution of biorisk assessment, reduction, and management activities
- Use of substandard laboratory supplies

Poor equipment maintenance

As well as the biosafety guidelines are more likely to be poorly implemented in facilities because of:

- Poorly written guidelines, including the nonspecific procedures
- Unclear roles and responsibilities for each worker
- Lack of review and updating process of existing guide

Poor dissemination and access to such guidelines.

Reporting the results

Results of testing procedures done for biosafety checks must be recorded, consolidated and interpreted regularly either daily, weekly, monthly, quarterly, or as applicable). The results may show a trend that may signal a need either for equipment maintenance, or replacement. Frequent incidents associated with a particular process may demonstrate a need to have a review and modification of the procedure. Involved staff should willingly report accidents

inside the laboratory. Lab workers should not be reluctant to report such events as these may become a future source of infection. The basic data and critical findings encountered relative to implementing biosafety guidelines can improve existing practices and limit the bio-risks from all personnel. **(Karim and Choe 2000**).

Biologically safe work environment

Ensuring quality and biologically safe work environment fosters good and effective delivery of laboratory and clinical services for patients. While performing complex laboratory procedures, staff can work with a certain level of confidence they won't contract any infection or disease. The spread of infectious agents from facilities to other healthcare workers, patients and from the community is preventable with the application of good biosafety practices.

Lab Safety

Biosafety monitoring can be part of quality control measures and quality assurance programs in the laboratory or any healthcare institution.

It must be an important component of competency tests for staff and must be an essential factor of organizational plans and goals.

Enhancing The Healthcare Team Outcomes

Biosafety, as implemented in laboratories and related facilities, supports the aims and principles of infection control, as implemented in hospitals and clinics **(Mehta et al. 2014).** Lik-ewise, adherence to biosafety guidelines takes a collaborative approach from all professionals including non-laboratory healthcare personnel. Respirator fit testing, for example, can be carried out at regular intervals (once a year), in partnership with the infection control committee (ICC) or an infection control nurse of a hospital facility (**Murphy 1992).**

Laboratories may seek the advice of laboratory staff in the application of biosafety measures when handling certain infectious agents or products. Clinicians may work with laboratory professionals, nurses, pharmacists, sanitary officers, among others, in coming up with organizational strategies as part of the healthcare-associated infection program in hospitals and medical facilities. Now, biosafety has expanded to research facilities such as in animal research (**Collins et al. 2017**). International conferences from various institutions still exist which concentrate on sharing of best practices and harmonization of biosafety guidelines at the regional, national and global scale.

Biosafety has been an emerging concern for occupational health (**Thelaus et al. 2017).** Educational intervention on biosafety is highly essential so that staff can be fully equipped with the correct knowledge of biosafety principles and can be able to demonstrate or enhance proper biosafety skills for all healthcare workers (**Ritterson and Casagrande 2017).**

Finally, the best practices for healthcare, research, and other institutions would always require a team commitment and cooperation to achieve a biologically "safe and secure" workplace and community.

Chemical Storage and Use in biological Laboratories

A variety of utilities, including those identified below, have a correct chemical inventory (**Fall 2012)**.

Ordering effectively: A detailed inventory lets laboratory managers monitor the materials in the laboratory and whether more products have to be purchased before double/excess orders are made.

Reagents place: The placement of reagents in identifying and recording positions makes it faster and simpler to find the reagent contained in the laboratory with products already present in the laboratory before ordering.

Disposal deliberately: A detailed inventory allows to distinguish non-use materials and to monitor materials with short shelf life, even those which can become hazardous over time.

A good answer: In order to allow fire and hazmat reporters to plan a secure & productive response to on-campus incidents, chemical inventories offer useful information in addition to the EIP.

Observing the boundaries of toxic materials: Fire and construction regulations regulate the amount of unsafe content which can be kept in a position depending on a variety of building conditions. The Homeland Security Department has established unique chemicals of significance that may require additional security precautions to protect against deliberate release, robbery or sabotage when held over specified thresholds. Precise (quantitative and

qualitative) monitoring of chemical inventories helps the risk of life protection of harmful substance overages to be detected and remedied.

Efficient communication of risks: A detailed chemical inventory facilitates the detection and disclosure of threats associated with materials to prospective consumers. The inventory also acts as a benchmark for complete access to protection data sheets.

More safe storage: An correct inventory can help to relieve any work related to finding locations in which incompatible items are stored together and help plan how reliable and safety handling and separating methods can be used.

REFERENCES

Bayot ML and Bhimji SS. 2018. Biohazard Levels.

Beilby J. 2006. Diagnostic molecular biology. The Clinical biochemist. Reviews. Feb; 2006.

Collins DE, Reuter JD, Rush HG and Villano JS. 2017.Viral Vector Biosafety in Laboratory Animal Research. Comp. Med 67 (3). 215 –221

Cornwell-Smith N. 1992. Personal protective equipment for employees. BMJ (Clinical research ed.). Aug 22; 1992.

Ezzelle J,Rodriguez-Chavez I.R, Darden J M, Stirewalt M, Kunwar N, Hitchcock R, Walter T and D'Souza MP.2008. Guiding principle son good clinical laboratory practice: bridging operations between research and clinical research laboratories. J. Pharm. Med. Anal. 2008.

Fall, 2012. Biological and Chemical Safety Manual. Biochemical Manual. University of South Dakota. 2012.

Fujii C, Ishii H and Takanishi A.2013. Safe venepuncture techniques using a vacuum tube system. Int J. Nur Practice; 2013.

Hersi M, Stevens A, Quach P, Hamel C, Thavorn K, Garritty C, Skidmore B, Vallenas C, Norris S L, Egger M, Eremin S, Ferri M, Shindo N and Moher D. 2015. Effectiveness of Personal Protective Equipment for Healthcare Workers Caring for Patients with Filovirus Disease: A Rapid Review. PloSone ;2015

Heiby J. 1998. Quality assurance and supervision systems. Q.A. brief. Jun; 1998

Ialongo C and Bernardini S. 2016. Phlebotomy, a bridge between laboratory and patient. Biochemiamedica. 2016;

Karim N, Choe CK. 2000. Laboratory accidents--a matter of attitude. The Malaysian J. Path.. Dec.; 2000

Karinja MN, Esterhuizen TM, Friedrich SO and Diacon AH. 2015. Sputum volume predicts sputum mycobacterium load during the first 2 weeks of ant tuberculosis treatment. J Cli Microbiol. 2015

Kimman TG, Smit E. and Klein MR. 2008. Evidence-Based Biosafety: A Review of The Principles And Effectiveness of Microbiological Containment Measures. Clini Microbio Rev. 2008

Kruse RH, Puckett WH and Richardson JH. 1991. Biological Safety cabinetry. Clinical Microbiology Reviews. Apr; 1991.

Mehta Y, Gupta A, Todi S, Myatra S, Samaddar DP, Patil V, Bhattacharya PK and Ramasubban S. 2014. Guiding principles for prevention of hospital acquired infections. Indian journal of critical care medicine: peer-reviewed, official publication of Indian Society of Critical Care Medicine. Mar; 2014.

Murphy DC 1992. Designing a respirator fit testing program. AAOHN journal: official journal of the American Association of Occupational Health Nurses. Nov; 1992.

Rim KT, Lim CH. 2014. Biologically hazardous agents at work and efforts to protect workers' health: a review of recent reports. Safety and health at work. Jun; 2014

Ritterson R, Casagrande R. 2017. Basic Scholarship in Biosafety Is Critically Needed To Reduce Risk of Laboratory Accidents. M Sphere. Mar-Apr; 2017.

Sewell DL.1995. Laboratory-associated infec-

tions and biosafety. Clin Microb Rev. Jul; 1995.

Sewunet T, Kebede W, Wondafrashm B, Workalemau B, Abebe G. 2014. Survey of safety practices among hospital laboratories in Oromia Regional State, Ethiopia. Ethiopian J Health Sc. Oct; 2014.

Siengsanan-Lamont, J. and Blacksell, S.D. 2018. A Review of Laboratory-Acquired Infections in the Asia-Pacific: Understanding Risk and the Need for Improved Biosafety for Veterinary and Zoonotic Diseases. Trop. Med. and Infec. Dis. Mar 26; 2018.

Singh Z, Bhalwar R, Jayaram J, Tilak VW. 2001. An Introduction to Essentials Of Bio-Medical Waste Management. Med. J. Armed Forces India. Apr; 2001.

Sulkin SE. 1961. Laboratory-acquired infections. Bacteriological Reviews. Sep; 1961

Thelaus J, Lindberg A, Thisted Lambertz S, Byström M, Forsman M, Lindmark H, Knutsson R, Båverud V, Bråve A, Jureen P, Lundin ZA, Melefors Ö. 2017. Network Experiences from a Cross-Sector Biosafety Level-3 Laboratory Collaboration: A Swedish Forum for Biopreparedness Diagnostics. Health Security. Jul/Aug; 2017.

Whistler T, Kaewpan A, Blacksell SD. 2016. A Biological Safety Cabinet Certification Program: Experiences in Southeast Asia. Applied biosafety: Journal of the American Biological Safety Association. Sep; 2016.

Winslow CE. 1908. A New Method of Enumerating Bacteria In Air. Science (New York, N.Y.). Jul 3; 1908.

Yagupsky P, Baron EJ 2005. Laboratory Exposures to Brucellae And Implications For Bioterrorism. Emerging Infectious Diseases. Aug; 2005.