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COVID 19,Risk of Infection and Biosafety Protocols in Diagnostic Laboratories

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Abstract

Over several decades, plenty of records of lab. workers contracting disease due to the infectious materials have been documented. About 80 percent of these cases are thought to be directly associated with the formation of aerosols during the lab. works with potentially infectious samples. Small liquid or solid particles of aerosols suspended in the air for a while or spread over a wide range of distances and then inhaled easily. However, they can be settled rapidly on surfaces such as skin and ventilation systems if the diameters of particles are higher than 5 microns. Effective steps should regularly be used to protect staff and the environment, or to reduce the extent of the aerosols production. Measures containing the aerosol are to be applied where physical containment at practice 2(P2) and above levels is needed for the research operation.

In most cases the safely equipment's and precautions must be available in all time in the lab. and comply with the required level of Biosafety for any type of the laboratory work (including the relevant biological agents, SARS-CoV-2 in this case). Staff who working with suspected or confirmed specimens of COVID-19 or of SARS-CoV-2 should be completely protected from such infectious materials. Good biosafety practices have been recognized to avoid or mitigate the spread of infection (i.e., SARS-CoV-2). Standard precautions expected to be already used by laboratories as stated in the general guidelines and they should follow standard laboratory practices. Practices related with these biosafety requirements must be proceed when dealing with samples/specimens from SARS-CoV-2. This involves microbiological as well as clinical laboratories conducting routine serum, blood, sputum (respiratory) and other sample diagnostic, analytical, or other research-related studies.

Keywords: Biosafety, aerosol, COVID 19.

Biological safety/ Overview

Safety in biological aspects introduces general surveillance beyond activities that including biohazardous agents, monitoring and assessment of containment systems efficiency and maintenance. It provides advice and assistance on the processing and shipment of biohazardous agents as well as consulting services on some issues concerning biological safety.

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Several researchers have conducted experiments in some infections spreading within the workers in laboratories of microbiology during the past half-century[1-3]and have distinguished a variety of possible pathogens that are obviously more common than other causative agents within these laboratories. These pathogens are usually falling among viruses, bacteria, rickettsiae, and fungi. In order to reduce the risk of infection, knowledge related with those organisms, with a high potential to invade normal humans, can contribute to choose of adequate precautions. The risk of laboratory staff being exposed can be reduced by using safely lab.tools. The initial purpose of disinfectant is to manage aerosols, but proper and safe equipment can effectively be used in a wider context to separate the worker in biology laboratories from the hazardous or infectious substance, that being processed[4].

Laboratory workers must treat the material properly according to specified standards. Containment levels vary from the lowest level (1) of biosafety until(4). In the USA, certain levels have been defined by the Disease Control and Prevention Centers. The same biosafety levels are specified in the EU in the Directive. Four biosafety levels (BSLs) that usually apply to biological materials are included in these requirements. Laboratory workers assumed to be intensively trained in a certain range of skills for handling potentially hazardous materials, depending on the level[5, 6].

Aerosol Generation during Laboratory Procedures

The greatest possible risk for contamination is aerosols forming during normal laboratory procedures such as pipetting, mixing, and centrifuging. Laboratory procedures that could produce maximum levels of aerosols, ex. centrifugation as well as homogenization, have been reported[7, 8].Liquid or dry particles of aerosol can either 5 micron or less in diameter and we assume that they released through several standard processes in lab. These fine particles do not settle down easily and might be spreading through a ventilation system, or instead of transported by air currents over long distances. Aerosol particles are derived to the lungs alveoli if inhaled. On the other hands droplets more than 5 micron stay briefly on air and are non-breathable. Droplets tend to settle rapidly on inanimate surfaces because of their density or may be accumulated particularly in top part of the respiratory tract within skin or mucous layer. Droplet, clothing as well as lab. tools can directly or indirectly seek high risk of infection to the skin, eye mucosal membrane, nose and mouth, [9].Primary and secondary barriers to mitigate the possibility of accidental bio aerosol infection (i.e. centrifuge rotors and homogenizers contained) have been developed for protection measures. For example, a biosafety cabinet (BSC) could be a primary barrier. An autoclave (BSL-2) may be a secondary barrier, or an installation within a facility like a dedicated anteroom or ventilation device could act as the barrier in a higher-level situation. Special training may be required to deal with these infectious products, depending on the safety requirements in place. It is the responsibility of the laboratory supervisor to correctly training laboratory staff[5, 7].

Biosafety level 1 (BSL-1)

The lowest safety standard for biological material handling is BSL-1. This form of substance poses no or only a low risk to healthy adult people and presents limited possible risk to laboratory workers and the community. It contains many types of infectious, non- infectious bacteria and viruses, such as canine hepatitis, varicella (chicken pox), E. coli, as well as particular cell cultures.

Within laboratory, biological staff are able to carry out their experiments on open bench tops, and it's not necessary to use special equipment. Normal microbiology procedures are typically adequate to protect laboratory staff and employer in other buildings, for example, since no mouth pipetting is permitted, and all work surfaces should be decontaminated once work is completed. Any food stuff and smoking are not permitted. Workers normally wear lab coat, eye protection as well as gloves[2,4,10].

Biosafety level 2 (BSL-2)

Higher security standards are required for all activities in a BSL-2 laboratory than in a BSL-1 laboratory. It involves numerous microorganisms (ex. viruses and bacterial cells) that can result mild illnesses or are not easily reduced by lab. setting, such as influenza A, measles, hepatitis A, B, and C, dengue fever, Lyme disease, Salmonella, mumps, Bacillus subtilis, etc. Due to their ability to cause human illness, great caution must be taken to avoid percutaneous injury, and if necessary, workers are subject to regular medical supervision. A BSC would be used by workers in a BSL-2 laboratory as a key barrier for potentially dangerous aerosols. During normal work processes such as mixing, pipetting, and centrifuging, these aerosols are usually created, so these activities should be performed under a BSC. It is important to take special precautions with sharps that can cause injury and to limit access to BSL-2 laboratories[10, 11].

Biosafety level 3 (BSL-3)

This level is concerning with the production, education, clinical, diagnosis, research facilities in which procedures are performed with indigenous or exogenous materials that can be after inhalation leads to serious or potentially fatal disease. It contains different bacteria and viruses that can introduce severe, lethal diseases in humans, but for which there are vaccines or other therapies, such as Bacillus anthracis, SARS corona virus, Hendra virus, Salmonella typhi, Mycobacterium tuberculosis Coxiella burnetii, Rift Valley fever virus, Rickettsia rickettsia, and yellow fever virus[12, 13].Laboratories for BSL-3 are constructed to be quickly decontaminate. Moreover, these laboratories should use regulated or "directional" air flow to ensure that air current passed from outside the lab. (such as hallways) to the laboratory areas. Two self-closing, or interlocked, doors, sealed windows and wall surfaces, and filtered ventilation systems are other engineered safety features. Depending on the biological risk assessment, In addition, BSL-3 laboratories should have access to decontaminate equipment for waste materials, for example an incinerator, an autoclave, or any other procedures.. Relevant instruction in the handling of pathogenic and potentially lethal agents is given to laboratory users and is supervised by competent scientists who are skilled in working with such agents. This is called a warm or neutral environment[14].

Biosafety level 4 (BSL-4)

BSL-4 requires the handling of very hazardous and exotic biological materials that, as a result of aerosols, can cause infection within the laboratory. In dealing with biological hazards at this point, the use of a Hazmat suit and a self-contained oxygen supply is mandatory. There will be several toilets, A vacuum room, an ultraviolet light room and other protection measures intended to remove any biohazard traces at the entrance and exit of the

bio lab level 4. Several airlocks are used which are electronically Locked to prevent the simultaneous opening of both doors. Both air and water facilities going to and coming from a level 4 biosafety laboratory will undergo similar decontamination processes to minimize the risk of accidental release [9, 12].

At this level, agents with an antigenic relationship close to or equivalent to Biosafety Level 4 agents are handled until sufficient data is collected, either to validate continuing work at this level or to collaborate with them at a lower level. The BSL 4 laboratory should have a Class III biological safety cabinet in combination with a positive-pressure, air-supplied full-body suit, but can use a Class I or II BSC. BSL 4 laboratories are typically housed in separate buildings or a completely isolated, dedicated supply and exhaust ventilation area, serving as a second barrier. Exhaust streams are filtered through high-efficiency particulate air (HEPA) filters,[15, 16]depending on the agents used.

laboratories providing coronavirus SARS-CoV-2/(COVID-19) diagnosis

Coronaviruses are non-segmented positive-sense RNA enveloped viruses which are widely distributed in humans and animals[17, 18].Infections caused by many human coronaviruses (HCoVs) were initially only mild and were thus known as overlooked pathogens. Since the onset of extremely pathogenic acute respiratory syndrome, coronavirus 1 (SARS-CoV-1) (2002 and 2003) and coronavirus (MERS-CoV, 2012)[19], Middle East respiratory syndrome[19],it is obvious that coronaviruses can cross the species barrier and cause human infections which are life-threatening, thus requiring greater attention than the initial HCoVs[20]. Disease of Coronavirus (COVID-19) has been reported by WHO as spreading around the world in more than 203 countries, including the Western Pacific, Africa, USA, Europe, and South East Asia. It becomes most critical issue and serious disease due to extended geographical area, fail to control measures, limited information in human epidemiology as well as veterinary, immunity and pathogenesis due to high transmissibility, extreme disease and associated mortality, therefore rapid identification and isolation of cases in order to contain them has become essential demand [21].

For laboratories dealing with specimens of suspectedCOVID-19 patients, effective biosafety procedures are of major concern. When specimens from a patient with suspected or confirmedCOVID-19 are delivered, clinicians take the responsibility to inform the laboratory. This can be achieved by completing forms of paper or electronic test request correctly, or by communicating directly with the clinical diagnostic laboratory. Before sending specimens to the laboratory, it is possible that clinicians may not have identified COVID-19 as a potential diagnosis prior to sending specimens to the laboratory. During laboratory work, risk evaluation is very critical. Therefore, for the processing of biological specimens from patients with suspected or confirmed COVID-19, clinical laboratories must carry out their own risk assessments [22].

In accordance with the Biosafety Level 2 (BSL2) practices and procedures defined for the basic laboratory, WHO recommends that all laboratory diagnostic work and PCR analysis on clinical specimens from suspected or confirmed individuals of being infected with novel coronavirus should be follow this level of safety [23].

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Specimen collection

Appropriate specimen selection, storage , packaging and transport should be authorized only by qualified personnel, ensuring that sufficient standard operating procedures are in use in compliance with national or WHO guidelines18 and that all specimens should be regarded as potentially infectious[21].

Diagnosis

Suspected cases with nucleic acid amplification tests, such as real-time reverse transcription-polymerase chain reaction, should be screened for the virus. (RT-PCR) with nucleic acid sequencing confirmation when required. The extraction of viral RNA should be performed in a biosafety cabinet in a BSL-2 or similar facility, which will further be used to amplify targeted genes, like nucleocapsid (N), RNA polymerase (RdRp) spike (S), envelope (E), and RNA-dependent[24]. Serological tests are still under progress, and field surveys can help to better understand the epidemic, enforce control measures, and also to understand cross-reactivity with other viruses once they become usable.

Risk Assessment

To define and minimize risks and decide if enhanced biosafety precautions are needed based on situational needs, a site-specific and activity-specific risk assessment should be performed. The level of containment, equipment for personal protection (PPE) and the administrative, practical work and required engineering monitoring for the proposed research are definedvia possible risk of using the biological material (i.e. virus or clinical sample; type of sample) and the intended methods in which carried out on the material. In most cases, SARS-CoV-2 is transmitted from person to person by precipitation or inhalation of big droplets on mucosal surfaces of respiratory tract. Other ways distinguished include touch with contaminated objects and aerosol inhalation, reproducing during large volume handling, etc.[25].

Working with potentially infectious material

In order to ensure the occupational safety of our staff in contact with suspected or confirmed clinical specimens of COVID-19 cases, it is important to take appropriate considerations to ensure that such material is treated in a safe way within laboratories properly prepared for research purposes. Any process with the potential to produce small particulate aerosols (for example, open tube sample preparation or overtaxing) must be carried out in a Biosafety Class II approved cabinet (BSC). Appropriate physical condition for centrifugation, restraint devices (for example, sealed rotors and safety buckets in centrifuge) must be utilized. Ideally, following a BSC centrifuge rotors [26]should be loaded and unloaded. Any laboratory procedure that produces aerosols and is conducted outside of a BSC (or extremely cleaned up suspicious spilling samples, for example) must be carried out with mask N95 [27-29]. During lab. procedures, protective equipment should be used by laboratory staff (PPE). When leaving the laboratory, PPE must be removed and hygienic

procedures, involving hand wash should be obligatory preserved. PPE must have disposable gloves and a laboratory coat with long sleeves, ideally elasticated or tailored cuffs. Further steps to establish isolated walls between the specimen and the workers, e.g. physical obstacles, such as a splash shield, safety cup for centrifuge, surgical or face shield in order to minimize the risk of infection in laboratory staff. It is important to be aware that masks or respirators are not an good alternative for biological safety cabinet in case high potential risk of aerosols being produced during samples processing [22]. An influenza immunization program will also help to provide laboratory staff with security and minimize employees' fear of infection in emergency situations[21].

Conflict of interests.

There are non-conflicts of interest.

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الخلاصة

على مدى العقود القليلة استطاعت التقارير المختبرية توثيق العديد من حالات الإصابات بالأمراض المعدية ضمن العاملين في هذه المختبرات. حوالي 80% من هذه الحالات يعتقد بكونها مرتبطة ارتباطا مباشرا بالرذاذ الجوي داخل المختبر نتيجة العمل مع عينات من المحتمل ان تكون معدية. الجزيئات الصغيرة السائلة او الصلبة لهذا الرذاذ قد تبقى لفترة طويلة داخل جو المختبر أو قد تنتشر لمسافات بعيدة حيث يتم استنشاقها بسهولة. يمكن لهذه الجزيئات أن تترسب بسهولة على الاسطح المختلفة مثل الجلد او انظمة التهوية خصوصا اذا كانت اقطارها اكثر من 5 مايكرون. نتيجة لما سبق أصبح من الواجب اتباع خطوات أو إجراءات فعالة ومنتظمة لحماية العاملين في المختبرات بالإضافة الى حماية البيئة أو تقليل انتاج مثل هذا الرذاذ الجوي. بعض الإجراءات تتضمن قياس مدى خطورة الرذاذ الجوي عندما تكون إجراءات السلامة البايولوجية عند مستوى P2او المستويات الاعلى من ذلك ضرورية للقيام بالتجارب المختبرية. في معظم الحالات, يجب ان تكون معدات السلامة و كافة الاجراءات الوقائية متوفرة داخل المختبر وفي جميع الاوقات وأن تكون ملائمة للمستوى المطلوب من السلامة البيولوجية لاي عمل مختبري (بما في ذلك العوامل البيولوجية, فايروس كوفيد 19). من الواجب حماية العاملين في المختبرات الذين يتعاملون من عينات مشتبه بها او مؤكدة الاصابة بفايروس كوفيد 19 . إجراءات السلامة الجيدة أصبحت مشخصة لتفادي ضرر إنتشار العدوى بفيروس سارس كوفيد 19. من المتوقع إن جميع الاجراءات الوقائية القياسية تكون متبعة من قبل العاملين في المختبرات والمذكورة في الارشادات العامة للمختبرات والتي تتماشى مع الاجراءات القياسية. هذه الإجراآت القياسية المتعلقة بمتطلبات السلامة البايولوجية يجب أن تطبق عند التعامل مع عينات افيروس سارس كوفيد 19. تشمل هذه الإجرات القياسية المختبرات الميكروبيولوجية والسريرية التي تتعامل مع عينات الدم ، المصل ، البلغم او غيرها من العينات المتعلقة بالبحوث.

الكلمات الدالة: السلامة البايولوجية، الرذاذ الجوي، كوفيد 19.