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Review Article

CLINICAL RESEARCHINCOURSEOFCOVID-19 PANDEMIC: CHALLENGES AND MANAGEMENT

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A B S T R A C T

The transmission of the virus causing COVID-19 as a pandemic with the highest morbidity and mortality rate across the world. As the large body of literature reveals a high influence rate of infection and transmission of COVID-19 among the health care professionals, researchers, technicians, and other corona warriors. Although they have to be routinely exposed to the unusual conditions at this hour of unprecedented crisis due to COVID-19 transmission. might be more likely to infected by COVID-19 than others. Hence, the management of clinical research laboratories should be incorporated for the prevention and control prospect. The aim and objective of this review were to minimize the risk and transmission of COVID-19 among health care professionals, patients and the general public. Guideline and protocol were design with the help of the World Health Society and Other Health care alliances to incorporate the management and control of nosocomial transmission during the COVID-19 pandemic. Hereby this review explores emerging evidence regarding this subject, trying to address each issue, challenges, and precautions.

INTRODUCTION

The coronavirus pandemic (COVID-19) emerged from the Wuhan, Hubei province, China, and associated with pneumonia(Xu *et al*. 2020). Moreover, from the past two decades, COVID-19 is the third infection caused by the Coronaviridae family with an intense transmission from person to person(Shereen *et al*. 2020). The respiratory tract is a primary site of damage and induces multiple organ failures with a high mortality rate. Therefore, to prevent the spread of COVID-19 among the population and healthcare professionals is an unconditional priority. The majority of cases were asymptotic and believe symptoms depend on the severity of infection (Agalar and Ozturk Engin 2020). Although the use of safety measures like personal protective equipment by a healthcare professional and laboratory experts can retain the exposure of transmission. Moreover, healthcare professional strictly pursues the guideline for the use of safety measures. In this review, we are discussing the measures to be followed for the safety of healthcare professionals regarding COVID-19 with the management of COVID-19 waste.

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Importance of research lab safety and management during a pandemic

Worldwide spreads and transmission of Coronavirus disease (COVID-19), the research labs community must aware and incorporate the safety management associated with this pandemic. Being a new disease there is a knowledge gap on how to manage research labs to minimize the risk of infection and transmission among the Health care professionals and other associated corona warriors. Although rapid testing and isolation, clinical and laboratory managements, control and prevention of infection will not only important to individual who were suffering or suspecting with COVID-19 (World Health 2020c) meantime it is also important to health care professionals and other general public who are at risk from hospital-acquired infection and transmission.

Lab safety and management during this unfamiliar condition are key to minimize the spread of this virus. Research labs practitioners, fellows, administrators of the organization, governments and other regulatory bodies must prepare for a considerable increase in safety equipment and kits,(Organization 2003; Xie *et al*. 2020) with a target not just on infrastructure and training programs, but also on lab management as well. (Qiu *et al*. 2020)

Research labs and researchers are triage to allow the rationing of infrequent lab resources might be needed. However, researchers must target and find the unanswered research questions, including the new high throughput interventions, applications and experimental therapies. Collaboration should be incorporated at the local, regional, national and international research labs will offer the best intellectual input for prevention and control of the infections. (Baud *et al*. 2020)(Tran *et al*. 2012)

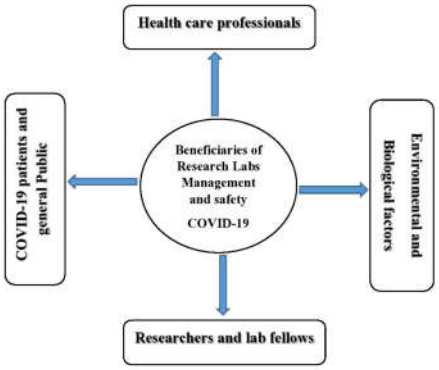

Figure 1 Beneficiary groups and departments of research lab management and safety.

Precaution during clinical Specimen collection and preservation

During the pandemic, the healthcare personnel was the frontline with a maximum exposure of transmission. Thus, the safety of healthcare personnel is a key requirement; the exertion of admission triage protocol by the hospital administration is a primary response against the pandemic or a patient with acute respiratory infection symptoms (Prevention 2020c). Though, the protocol considers the wearing of a mask by the patient all time and waiting area were equipped with a sanitizer, ventilated and social distancing should be strictly followed by patients (Prevention 2020b). In addition, physical barriers such as plastic and glass will ensure no direct contact of health care with a patient while collecting the specimen.

Moreover, trained healthcare professionals were assigned for the collection of a respiratory specimen with protective measures (Qian *et al*. 2020). Furthermore, COVID-19 transmission can be restricted with adherents on a general guideline. Hand hygiene is the basics of primary safety measures and ensures the use of 70-95% alcohol-based sanitizer with a regular interval of time, after and before exposure with patients or going to an isolated area (World Health 2020f). In addition, the use of personal protective equipment (PPE) can eliminate the chances of transmission while collecting samples from the suspected patient of COVID-19. However, health institutions will ensure the use and properly discard of PPE by healthcare. While equipping the PPE the healthcare professional should primarily ensure the sanitization of hand and follow the order of equipping the PPE (prevention 2018). During the removal of PPE the face mask should be equipped until leaving the designated area, this practice minimizes the risk of exposure. According to the European Center for Disease and prevention control (ECDC), a surgical mask can be used according to the risk of exposure with aerosol instead of using FFP2 and FFP3 mask (Control 2020).

In order for the collection of specimen for COVID-19 diagnosis is a crucial step, regarding the clinical outcome. The false-negative result can be the effect of the forged collection of specimens. Moreover, nasopharyngeal, nasal mid-turbinate swab, nasopharyngeal wash and oropharyngeal specimen with the addition of stool and blood consider for the diagnostic testing of COVID-19 (Prevention 2020a). Furthermore, the swab containing the specimen should be collected in a sterile tube that contains Amies transport media, viral transport media or sterile saline. This practice will ensure the viability of viral content and minimize the growth of microorganisms (organisation 2000). However, the collected clinical specimen initially stored at 2-8^{o}C, although the variation among the temperature based on the delay in transportation for the laboratory. In case of delay in shipment or longer route than usual such as international shipment results freezing of specimen at -20 to -70^{o}C with a safety measure (see Table 1) (World Health 2020g). The variation among the temperature or repeated freezing and thawing will affect the real-time PCR result.

Table 1 Requirement of temperature for the delivery of specimens (organisation 2000)(World health Organization 2018).

Specimen	Temperature for less than two days delivery	Temperature for more than two days delivery
Stool	2-8^{o} C	-70^{o} C
Nasopharyngeal wash	2-8^{o} C	-70^{o} C
Serum	2-8^{o} C	-70^{o} C
Sputum	2-8^{o} C	-70^{o} C
Urine	2-8^{o} C	-70^{o} C
Brancheoalveolar lavage	2-8^{o} C	-70^{o} C
Nasopharyngeal and oropharyngeal swab	2-8^{o} C	-70^{o} C

Sample processing and care

The laboratories adhere to the diagnosis of COVID-19 in suspected or confirmed patients in clinical specimens to be supposed to adopt the procedures outlined for clinical laboratories. The primary site of confirming COVID-19 cases by checking the expression of specific sequence on RNA followed by qRT-PCR (Real-time polymerase chain Reaction). In addition, nucleic sequencing of a viral gene like N, E, S, and RdRP gene certify the viral infection by COVID-19(Udugama *et al*. 2020). Although serological testing considers for rapid testing and where the patient with a strong epidemiologic link with COVID-19 infection and gives the false-negative result. (World Health 2020f)

The serological testing falls under the point of care (POC) test, which is a type of decentralizing test for the community and population where access to the laboratories for patients is limited (World Health 2020e). However, the serological test depends on the detection of antibody produce against the viral infection, and qualitatively checks the concentration of antigen in the host body(World Health 2020a). The detection procedure utilizes sputum, nasopharyngeal swab, and blood followed by strip coated with antibody and gives a qualitative result. Although the controversy persists with a cross-reactivity against an antigen present in the host body(Bai *et al*. 2020)(World Health 2020f). Furthermore, the health care professional focused on testing should implicate the safety measures to prevent the infection and minimize the progression of COVID- 19. Moreover, safety measure was given in Table -2 which depicts the appropriate action according to the situation if healthcare professional contact

with and infection and define the type of clinical specimen collected for testing (World Health 2020b)(Epidemiology 2020).

Table 2 Type of action on the situation based and type of clinical specimen collection for the better result.

Condition	Action	Clinical specimen
A suspected healthcare professional, no risk factor	Consider for the home quarantine and no test required.	-
Suspected healthcare professional with a high-risk factor or severity	Recommend for testing	SputumAspiratelavage nasopharyngeal and oropharyngeal swabs nasopharyngeal wash
Healthcare professional with symptoms and recognized as contact with an infectious person	Recommend for testing	Nasopharyngeal and oropharyngeal swabs.
Healthcare professional with symptoms and no contact with an infectious person	Test recommend	Nasopharyngeal and oropharyngeal swabs or serological test

Management of Bio-waste materials

In order to deal with pandemic COVID-19, medical activities generate biomedical waste which requires the management. Therefore segregation of biomedical waste into hazardous and non-hazardous could reduce the financial burden and help to dispose of the waste by effective treatment procedures(Datta *et al*. 2018). Furthermore, the color coding and labeling of biomedical waste bags and containers with an international biohazard sign help to identify and categorize the waste (Board 2020). The biomedical waste generated from COVID-19 should be collected in two-layered leak-proof bags and categorized followed by treatment procedures (see Table 3).
Moreover, after the collection of biomedical waste, it can be treated on-site or transported off-site. The collection or transportation of waste, according to a storage facility, frequency of collection and size of waste generated by the facility (Eisted *et al*. 2009).During the collection, the non-infectious waste should be placed separately to avoid cross-contamination with a maximum time of 24 hours. The off-site dispose of hazardous waste contains leak-proof packing with labeling to avoid any accident with proper documentation. During the treatment and disposal of waste, it classifies in sharp, cytotoxic and organic waste (Body fluid, anatomical waste) followed by recycling, incineration and deep damping at dedicated biomedical wasteland (Basel Convention and World Health 2005).

Table 3 Categorization of COVID-19 Biomedical waste with treatment

Category	Discard Bag/ Container	Biomedical waste	Treatment
Red	Red Colour coded plastic bag, without chlorine	Recyclable contaminated waste(pipette tips, gloves, Gloves, syringes, falcon tubes, etc)	Autoclave than recycle
Yellow	Yellow Colour coded plastic bag, without chlorine	Clinical lab waste, Human/animal anatomical waste, Chemical waste	Incineration/ deep burial
Blue	Boxes/Container, leak-proof	Glassware waste	Autoclave than recycle
White	Translucent box, Leak and Puncture proof	Sharp object including metal	Autoclave or dry heat sterilization.

Routine Hygiene and Cleaning of Work Place

Routine hygiene and cleaning of the working area in the laboratory are part of standard precautions, which should be applied for control of infection and transmission of disease(Organization 2014). The surface or material known to be, or potentially be, contaminated by biological agents during laboratory operations must be correctly disinfected to control infectious risks (Kampf *et al*. 2020) (see Table-4). Proper processes for the identification and segregation of contaminated materials must be adopted before decontamination and/or disposal(World Health 2020d). The contaminated waste must be packaged in a leak-proof manner, for transfer to decontamination capacity.

Table 4 Type of disinfectant used with their percentage for the cleaning procedure (Hulkower *et al*. 2011)(Sattar *et al*. 1989)(Goyal *et al*. 2014).

Disinfectant	Percentage
Sodium hypochlorite	0.1%
Ethanol	62-71%
Hydrogen peroxide	0.5%
Benzalkonium	0.05-0.2%
Chlorhexidine digluconate	0.02%

CONCLUSION

Thus, Nationwide unusual conditions at this hour of unprecedented crisis due to COVID-19 transmission. Meantime Clinical research laboratories need special assistance and guidance as they have to be used infected patients samples for rapid testing and further proceedings, might be more likely to infected by COVID-19 than others. Hence, the management of Clinical research labs should be incorporated for prevention and control. This information will contribute to a better understanding of the management of laboratory and care of health care professionals and general public health to minimize the transmission and spread of infection, by following guidelines and protocol developed with the help of government regulatory bodies for people who routinely use to exposed with the risk of nosocomial transmission, further beneficial as a companion to minimize the infection or spreading of COVID-19.

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