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Laboratory medicine's pivotal function in coronavirus illness (COVID-19)

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Introduction:

The advent of the novel coronavirus, SARS-CoV-2, and the subsequent global pandemic of coronavirus disease (COVID-19) have profoundly altered the landscape of modern healthcare. In the face of this unprecedented challenge, laboratory medicine has emerged as a linchpin in the battle against the spread and impact of the virus. This research endeavors to illuminate the pivotal role that laboratory medicine plays in various facets of managing COVID-19, encompassing diagnostics, prognostics, therapeutics, and epidemiology. COVID-19, caused by the novel coronavirus SARS-CoV-2, has presented an unparalleled public health crisis, transcending geographical boundaries and socioeconomic disparities. Effective management of the pandemic relies heavily on rapid and accurate identification of cases, timely monitoring of disease progression, and informed decision-making regarding patient care and public health interventions. Laboratory medicine serves as the cornerstone of these endeavors, offering a plethora of diagnostic modalities, from traditional molecular assays to cutting-edge technologies such as next-generation sequencing and serological testing. (Lippi & Plebani, 2020) Moreover, laboratory-based investigations are instrumental in elucidating the pathogenesis of COVID-19, facilitating the development of targeted therapeutics and vaccines. By analyzing viral dynamics, host immune responses, and genetic determinants of disease severity, laboratory researchers contribute invaluable insights that inform clinical practice and public health policies. Furthermore, the role of laboratory medicine extends beyond the realm of individual patient care to encompass population-level surveillance and epidemiological research. Robust laboratory surveillance systems enable early detection of outbreaks, monitoring of viral mutations, and assessment of transmission dynamics, thus empowering public health authorities to implement timely and targeted interventions to mitigate the spread of the virus. (Ağalar & Engin, 2020) Despite the remarkable strides made in combating COVID-19, challenges persist on multiple fronts, ranging from the ongoing evolution of the virus to the equitable distribution of diagnostic resources and the optimization of laboratory workflows. This research aims to delve into these complexities, shedding light on the evolving role of laboratory medicine in the context of the COVID-19 pandemic. In summary, this study underscores the indispensable contributions of laboratory medicine to the multifaceted battle against

COVID-19, emphasizing the critical importance of interdisciplinary collaboration, technological innovation, and evidence-based approaches in navigating the challenges posed by this unprecedented global health crisis.

This research aims to delve into these complexities, shedding light on the evolving role of laboratory medicine in the context of the COVID-19 pandemic and charting a course forward toward more effective strategies for pandemic preparedness and response. In summary, this study underscores the indispensable contributions of laboratory medicine to the multifaceted battle against COVID-19, emphasizing the critical importance of interdisciplinary collaboration, technological innovation, and evidence-based approaches in navigating the challenges posed by this unprecedented global health crisis.

History of COVID-19 Pandemic

in 2019, China reported unusual pneumonia cases from an unknown virus in Wuhan City, leading to the current pandemic. The WHO identified a new virus, 2019-nCoV, which is part of the Coronaviridae family, including SARS and MERS. Wuhan was quarantined from January 23 and events for the Lunar New Year were cancelled. The WHO declared the outbreak a global health emergency of international concern on January 30, with death toll in China reaching 170. The virus had spread to all 31 provinces and new cases were confirmed in Australia, Canada, Germany, Japan, Singapore, the US, the UAE, and Vietnam. Li Wenliang died on February 7, and Hong Kong introduced prison sentences for breaching quarantine rules. The first confirmed case of COVID-19 in Africa was recorded in Egypt and Nigeria on February 27th, 2020. The WHO declared the coronavirus outbreak a pandemic on March 11th, 2020, with the virus spreading to about 181 countries and territories.

Etiology of COVID-19 Pandemic

A novel coronavirus strain, designated the COVID-19 virus (SARS-CoV-2; also referred to as the Severe Acute Respiratory Syndrome Coronavirus), has been identified as the causative agent of this peculiar pneumonia that originated in the Chinese megacity of Wuhan. It is a member of the Coronaviridae family and is an enveloped, non-segmented, single-stranded RNA virus with a positive sense. The pathogenicity of the virus has been attributed to the envelop, which facilitates viral assembly and liberation. "Corona" is the name given to the virus because, when observed through an electron microscope. The COVID-19 virus genome, similar to those of other coronaviruses, has a length ranging from 400 to 500 nanometers. It contains both structural and non-structural proteins, including helicase, papain-like protease, 3chymotrypsin-like protease, and spike glycoprotein.

Pathophysiology of COVID-19

Early in infection, the virus invades mucus-producing (Goblet) and ciliated lung cells. Mucus protects the lungs against infections and dryness. The cilia beat mucus toward the outside of the nasopharynx, cleaning the lungs of debris, including viruses. Cilia cells may be COVID19's favored hosts. These cells die and slough into the airways, filling them with debris and fluid, causing dry cough, shortness of breath, and pneumonia in both lungs. After recognizing the infection, immune cells flood the lungs. Hypersensitivity inflames and damages lungs. More cells are damaged and slough off into the lungs, obstructing them and worsening pneumonia. Increased lung scarring may cause respiratory failure. Patients with this stage of illness develop lung fibrosis, permanent lung impairment, or die. (Pourbagheri-Sigaroodi, et al. 2020)

Clinical and analytical data shows COVID-19 lung lesions. The virus develops honeycomb-like lung perforations. The over-reactive immune response, which damages diseased and healthy tissues, is likely to blame. Patients may need ventilators to breathe. Inflammation makes alveoli more porous.

Increased permeability leaks fluid into the lungs, reducing their ability to oxygenate blood and, in severe cases, flooding them, causing fatal breathing difficulties. The virus can also cause a cytokine storm, which causes widespread inflammation, blood vessel permeability, and fluid escape due to activated leucocytes overproducing cytokines like IL1B, IL-6, IL-8, CCL2, CXCL10, CCL2, CCL3, CCL5, etc. This hinders oxygenated blood flow, causing organ failure. (Hong, et al. 2020)

The significance of medical laboratories during a pandemic and public health crisis.

the significance of medical laboratories in the realm of public health, including the ability to monitor patients' responses to treatment and provide prompt, accurate, and timely diagnoses that enable appropriate treatment. The provision of informed judgments by medical laboratories concerning patients' hospital admissions and discharges can reach up to 70%. It provides guidance to healthcare professionals, including physicians and nurses, in the selection of appropriate laboratory tests and guarantees the correct collection of samples. In healthcare laboratories, medical laboratory services perform equipment installation, validation, and repair in an equivalent manner. Surveillance for infectious diseases such as Ebola, tuberculosis, HIV, malaria, and now COVID-19 requires a medical laboratory component. Quality assurance in healthcare facilities and the promotion of public health as a whole are achieved through the implementation of quality enhancement research in medical laboratories. (Goudouris, 2021)

The primary functions of medical laboratories during the COVID-19 pandemic have been identified as follows:

A. Etiological diagnosis

Medical laboratory scientists play a crucial role in the control of the COVID-19 pandemic, as they are responsible for accurate diagnosis and identifying underlying conditions that may complicate the prognosis of confirmed cases. The gold-standard for laboratory diagnosis is nucleic acid detection using Real-Time Polymerase Chain Reactions (RTPCR) or qPCR, which can be confirmed using Next Generation Sequencing (NGS). The Stop TB Partnership and Global Drug Facility have developed a new test for the detection of COVID-19 virus, the Xpert Express COVID-19 virus cartridge, which has received emergency use authorization from the United States Food and Drug Administration (FDA) on 21 March, 2020.

Several serologic methods are being developed based on the detection of Immunoglobin M (IgM) and Immunoglobin A (IgA) within 4 days of infection and IgG at about 14th day of infection. A combination of qPCR/RT PCR with IgM ELISA has the potential for increased detection rates. The COVID-19 Rapid Diagnostic Test (RDT) Kits use immunochromatography to probe for the presence of COVID-19 antibodies in patient's serum, which is appropriate for the convalescent phase of the disease.

Diagnostic preparedness is essential for the successful containment of any outbreak, as poor diagnostic preparedness has contributed to delays in the identification of recent outbreaks for multiple pathogens, such as Lassa fever, Ebola, Yellow fever, and Zika. This includes the availability of diagnostic methods and kits, adequate training and knowledge, rapid response to outbreaks and emergency situations, biosafety practices, and logistic matters. (Vieira, et al., 2020)

B. Patient monitoring

Laboratory monitoring of COVID-19 patients is crucial for containing the pandemic. Medical Laboratory Scientists (MLS) carry out tests to monitor disease progression, prognosis, and detect post-recovery complications. They determine a patient's recovery status before allowing them to return to the community. MLS determine viral load and leukocyte count before and after treatment. Recovered patients are discharged after confirmation of negative viral status by at least two consecutive PCR tests. However, some patients turned positive again after being discharged, possibly due to inadequate treatment or inadequate testing. The overburdened healthcare system may pressure doctors to discharge patients who have not fully recovered to free up beds for newly infected patients.

MLS also investigate the dynamics of the spread of the disease, its pathogenesis, genetic evolution, prevention, and control measures. They conduct periodic pathogenicity and immunogenicity studies to detect new serotypes and test for herd immunity in the community. Herd immunity reduces the risk of infection among susceptible individuals in a population by providing a protective barrier. As herd immunity increases, the incidence of disease decreases.

The threshold of immunity needed for this indirect protection depends on factors such as virus transmissibility, immunity nature, and geographical distribution. Scientists are currently requesting plasma samples from fully recovered patients to study the nature of antibodies produced. (Mohamadian, et al. 2021)

C. Surveillance

Medical Laboratory Scientists control disease outbreaks in addition to diagnosing and monitoring. They participate in all infection control programs, including community and hospital infection surveillance. They help the infection control program employ laboratory services for epidemiology efficiently. They assist facility cleaning and disinfection, including biological monitoring. Help create health hazard policies for hospitals and outside environments. Take action if a commercial product appears tainted. Check hospital staff and surroundings for infection. Prevent outbreaks by advising on specimen collection,

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transport, and management. They planned to retain all specimens delivered to the lab for analysis, which may harbor lethal diseases that could start the next pandemic. The MLS is required to maintain laboratory biosafety throughout everyday operations. Work on COVID-19 virus must be done in a Biosafety Level 3 (BSL-3) or BSL-2 facility as recommended by the International Standard Organization. They advise on using antimicrobials wisely, especially COVID-19-treating antivirals. They organize, simplify, and expedite laboratory test findings to improve patient clinical outcomes and flatten the illness curve. They provide laboratory results, monitor them for abnormalities, and notify clinicians. Hundreds of Medical Laboratory Scientists operate in over twenty research laboratories globally to find a cure and vaccination for COVID-19. Numerous broad-spectrum antiviral and vaccine safety and effectiveness trials are underway with promising results. WHO and FDA promise to eliminate testing and certification bottlenecks. The MLS is crucial to validating testing techniques and kits. The MLS in the Medical Laboratory Science Council of Nigeria (MLSCN) In vitro Reference Laboratory are testing the new COVID-19 quick diagnostic test kits that have flooded the Nigerian market for accuracy and specificity. In addition to the foregoing responsibilities, high-power MLS advises government pandemic containment policies. Some are COVID-19 Containment Task force members at various levels. Medical Laboratory Scientists play these and other vital roles in pandemic containment. (Frater, et al. 2020)

Advancements and Challenges in Laboratory Diagnostics for COVID-19 Management

The COVID-19 pandemic, caused by the novel coronavirus SARS-CoV-2, has underscored the critical role of laboratory diagnostics in disease management. From the early stages of the pandemic, the development and implementation of reliable diagnostic tests have been essential for identifying cases, tracking transmission, and guiding public health interventions. Initially, reverse transcription polymerase chain reaction (RT-PCR) assays emerged as the gold standard for COVID-19 diagnosis due to their high sensitivity and specificity. However, the rapid global spread of the virus necessitated the exploration of alternative diagnostic technologies to meet the growing demand for testing.

Advancements in diagnostic technologies have led to the development of innovative approaches for COVID-19 detection. Point-of-care testing (POCT) devices, capable of delivering rapid results outside of

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traditional laboratory settings, have played a crucial role in expanding access to testing and facilitating timely decision-making in clinical settings, emergency departments, and community-based screening programs. Moreover, nucleic acid amplification techniques, such as loop-mediated isothermal amplification (LAMP) and CRISPR-based assays, have demonstrated promise in providing faster and more cost-effective alternatives to conventional RT-PCR testing, with potential applications in resource-limited settings and decentralized testing facilities. (Chen, et al. 2020)

Serological testing has also emerged as a valuable tool for assessing the immune response to SARS-CoV-2 infection and estimating population-level seroprevalence. Serological assays detect antibodies produced by the immune system in response to viral antigens and can complement molecular testing by providing information about past infection and potential immunity. However, challenges remain regarding the interpretation of serological results, including the variability in antibody kinetics, cross-reactivity with other coronaviruses, and the limited understanding of protective immunity against COVID-19.

Despite these advancements, laboratory diagnostics for COVID-19 face several challenges and limitations. Supply chain disruptions and shortages of testing reagents, consumables, and equipment have hampered testing capacity and hindered efforts to scale up diagnostic testing globally. False-negative and false-positive results in RT-PCR testing have raised concerns about diagnostic accuracy and reliability, highlighting the need for quality assurance measures, standardized protocols, and proficiency testing programs to ensure the validity of test results. Additionally, variability in test sensitivity and specificity among different diagnostic platforms and assay designs has implications for clinical decision-making and public health surveillance.

The role of laboratory diagnostics extends beyond individual patient care to encompass broader public health objectives, including early case detection, contact tracing, and outbreak control. Laboratory data are integral to monitoring disease trends, identifying hotspots of transmission, and evaluating the effectiveness of containment measures. Moreover, laboratory diagnostics play a critical role in assessing the efficacy of COVID-19 therapeutics and vaccines, facilitating clinical trials, and guiding treatment decisions based on viral load monitoring and drug resistance testing.

Looking ahead, future advancements in laboratory diagnostics for COVID-19 management will continue to drive innovation and improve testing capabilities. Research efforts are focused on developing novel diagnostic technologies, enhancing assay performance, and addressing existing challenges in testing accessibility, affordability, and accuracy. Collaborative initiatives between academia, industry, and government agencies are essential for advancing diagnostic research, standardizing testing protocols, and ensuring equitable access to testing resources worldwide. (Pourbagheri-Sigaroodi, et al. 2020)

Conclusion:

The COVID-19 pandemic has highlighted the critical role of Medical Laboratory Science (MLS) in containing the virus. MLS play a vital role in testing potentially infectious clinical specimens from patients, and their professionalism is essential for patient outcomes. They develop methods for control of analysis processes, validate methods, and secure optimum procedures supported by guidelines and instructions.

Governments should mobilize MLS and ensure capacity building for quality performance in laboratory testing and monitoring of infectious diseases. The MLS should be fully integrated into a multidisciplinary team to effectively contain the pandemic. The government should play an unbiased role in fostering industrial harmony in the health sector, not promoting one professional body at the expense of the other.

To effectively contain the pandemic, the Federal government should allow other laboratories to test for the coronavirus, decentralizing testing to unbundle workload on the Nigeria Centre for Disease Control. The government should use funds and donations to fast track the completion of ongoing molecular laboratory projects.

The MLSCN must ensure laboratory protocols for COVID-19 diagnosis and monitoring are consistent with global best practice, create a reliable system for managing test results, and handle positive specimens and contaminated items properly. Standard Operating Procedures (SOPs) on laboratory waste management, sample collection, transportation, and testing should be developed, circulated, and updated periodically.

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