International Journal of Advances in Medicine
Firmansyah Y et al. Int J Adv Med. 2021 Oct;8(10):1611-1614
http://www.ijmedicine.com
pISSN 2349-3925 | eISSN 2349-3933
DOI: https://dx.doi.org/10.18203/2349-3933.ijam20213720

Case Report

Contamination in COVID-19 sample - the elaboration between medical and legal impact

Yohanes Firmansyah[1,2]*, Ernawati[3], Darren Gosal[4], Imam Haryanto[5], Hendsun[2]

[1]Faculty of Health Law, Veteran National Development University of Jakarta, Jakarta, Indonesia
[2]Faculty of Medicine, Tarumanagara University, Jakarta, Indonesia
[3]Department of Public Health, Faculty of Medicine, Tarumanagara University, Jakarta, Indonesia
[4]Faculty of Medicine, Atmajaya University, Jakarta, Indonesia
[5]Department of Business Law, Faculty of Law, Veteran National Development University of Jakarta, Jakarta, Indonesia

Received: 11 August 2021
Revised: 08 September 2021
Accepted: 09 September 2021

***Correspondence:**
Dr. Yohanes Firmansyah,
E-mail: yohanesfirmansyah28@gmail.com

ABSTRACT

The impact of COVID-19 is enormous on various aspects of human life around the world, especially in the health system. The gold standard used to detect COVID-19 is nucleic acid amplification-based molecular testing. The fact in the field showed that this testing is prone to contamination, leading to misinterpretation and diagnosis. This error has the potential to have further legal implications. This study was a case report using a juridical-normative approach from various primary and secondary sources. A 26-year-old man has tested positive for COVID-19. After further investigation, it was found that there was a diagnosis error due to the contamination of the testing sample in the laboratory where the sample was examined. The contamination that occurs is not only the fault of health workers but is a series of impacts from problems in hospital regulations, the government, and the community's components. This incident affects legal responsibility for health workers and medical consequences on the community. COVID-19 infection is not only closely related to medical problems but also closely related to social and legal issues. Whoever, especially health workers, will receive legal and social impacts other than hospitals, the government and the community from this incident.

Keywords: Nucleic acid amplification-based molecular testing, Contamination, COVID-19, Legal impact

INTRODUCTION

Starting in December 2019, there were a series of unexplained pneumonia cases in Wuhan city, China. On 12 January 2020, the World Health Organization (WHO) gave the terminology of this new virus as novel coronavirus 2019 (2019-nCoV). On 30 January 2020, WHO announced the epidemic status of the 2019-nCoV infection and warned of a public health emergency that has become a serious problem at the international level. WHO officially gave the terminology 2019-nCoV as corona virus disease 2019 (COVID-19), also called as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1] Until 16 March 2021, infection with SARS-COV-2 has infected 119,603,761 people worldwide, with a total death of 2,649,722. The countries with the highest cases were the United States with 52,969,629 cases, Europe with 41,185,704 cases, and Southeast Asia with 13,917,115 cases.[2] Indonesia reported 1,425,044 confirmed cases and 38,573 deaths (CFR: 4.4%) on 15 March 2021.[3]

The President of the Republic of Indonesia, Joko Widodo, is committed to tackling the COVID-19 pandemic as soon as possible through various strategic steps by forming a COVID-19 handling unit under the control of the national board for disaster management which is later changed to a

COVID-19 handling task force tasked under supervision of committee for handling COVID-19 and national economic recovery. The strategic steps that have been implemented from the beginning until now are the implementation of large-scale social restriction (LSSR), especially in areas with a high incidence, routine hand washing and hygiene, and closing access to foreign countries.

All of these regulations are contained in presidential decree number 11 of 2020 regarding the determination of public health emergency related to COVID-19, which in its implementation is stated in government regulation number 21 of 2020 concerning large-scale social restrictions in the context of accelerating handling of COVID-19.[4,5]

A further problem from the increasing number of COVID-19 cases is related to the lack of number and capacity of human resources. This has an impact on increasing the working hours of health workers to deal with COVID-19 cases. Health workers affected are doctors, nurses, midwives, laboratory technical officers, and others.

The increase in working hours causes a high workload accompanied by a lack of time for rest. The subsequent impacts cause harm to the mental and physical health of health workers. This problem prompted the author to write this paper, namely the occurrence of sample contamination in the COVID-19 examination due to various problems causing (iceberg phenomenon) and the impact resulting from misinterpretation of the laboratory results (pandora box).

CASE REPORT

A 26-year-old male has a history of contact with a confirmed case of COVID-19. The contact history is known after three days of exposure. This man did not experience any symptoms during the monitoring period and was then advised to be examined at one of the referrals. After 3×24 hours, the results of the examination came out and were declared positive for SARS-CoV-2. The results of the examination did not include the cycle threshold (CT) value. The man felt that he was not exposed to COVID-19, so he conducted examinations in 2 different laboratories and private hospitals two days after the first sampling. Both tests showed negative results for SARS-CoV-2.

This report was forwarded to the local health office. After thorough digging of information, it was finally found that contamination had occurred in the laboratory on the first examination date. This contamination causes a high number of positive SARS-CoV-2 in people who come to check themselves. The investigations were ongoing, and it was found that the laboratory staff had been working overtime, causing mental and physical exhaustion. The dispute ended without a claim.

DISCUSSION

Bio-contaminants as the cause of non-enforcement of the nucleic acid amplification-based molecular diagnosis

Polymerase chain reaction (PCR) or detection technology to determine changes in genetic information based on nucleic acid amplification plays an important role in elucidating the function and structure of genetic material in living things. This detection technology can show changes in genetic information at the molecular level, such as the deletion or insertion of a single nucleotide base and the duplication or translocation of a deoxyribonucleic acid (DNA) fragment in the genome. This also provides a real solution to determining the characteristics or conditions of a living thing that previously was only based on the appearance of its phenotype. The real impact of applying this technology is felt in various fields and life sciences, such as the health sector. Currently, there is a growing development of personalized medicine-based medicine and the elucidation of new diseases; agriculture, such as selection of plants or livestock that carry beneficial gene traits in the context of improving food quality; forensic fields such as accelerating the disclosure of crime mysteries through DNA analysis.[6]

Bio-contaminants are impurities that come from biological substances in the form of microorganisms (such as bacteria, fungi or molds) or biomolecules that make up an organism such as nucleic acids (DNA or RNA), proteins, lipids, carbohydrates, or hormones or waste products from the metabolism of organisms or cells such as ammonia, uric acid, lactic acid, humic acid as a result of the purification or sterilization process that is less than optimal and carried away and contaminate the environment that should not exist. Bio-contaminants in nucleic acid amplification-based diagnostics can be classified into two types, namely: bio-contaminants that cause false-positive results, and bio-contaminants that cause false-negative results.[7]

The first type of bio-contaminant is caused by: foreign genomes of bacteria, fungi or viruses in the form of circular or linear plasmids, or carry-over of PCR products from previous PCR activities being amplified during PCR and the size of the PCR products often shows identical in size to the gene amplicons that are the target of diagnosis, causing biased PCR results.[7] The PCR inhibitors are classified into the second type of bio-contaminant. In general, this class of bio-contaminants inhibits the PCR process by: intervening partially or completely on the function of Taq polymerase, and absorbing one of the PCR components (primary, dNTP, cofactor, and genomic template) so that the amplification process does not take place.[8]

Diagnosis and diagnosis errors

Diagnosis is a procedure performed by a doctor to determine the patient's condition. Diagnosis is also defined

as the result of the evaluation that has been done. Diagnostic indicators are carried out in several ways, namely by physical examination, laboratory tests, or others, and the use of computer technology in the form of programs that have been specifically designed in the assessment process.[9] The authority of doctors (general, specialists and dentists) who are registered with a registration certificate in carrying out their service duties in accordance with competence according to article 35 paragraph (1) of law no. 29 of 2009 concerning medical practice are as follows: interview with the patient regarding the patient's condition, perform a physical and mental examination, consider whether additional checks are needed or not, read the patient's diagnosis, decide on the schedule and method of patient examination, perform medical or dental procedures, write prescriptions for drugs and medical devices, issue a doctor's or dentist's certificate, store drugs in permitted quantities and types, and mix and handle over medicine to patients, for those who practice in remote areas where there are no pharmacies.[10]

To be categorized as malpractice, negligence by a doctor in making a diagnosis must first be considered whether the doctor has carried out his duties based on his professional standards or even if the doctor in question is proven to have made a mistake in diagnosing, but the medical action taken is in accordance with the regulations, then this is not an act of medical malpractice/medical negligence.[9] Medical malpractice is determined that doctors must pay attention to several rules in carrying out their duties, these rules include:

Laws and regulations

Article 50 of law no. 29 of 2004 concerning medical practice

Obtain legal protection as long as carrying out duties in accordance with professional standards and standard operating procedures. Provide medical services according to professional standards and standard operating procedures.[10,11]

Article 24 paragraph 1 of law no. 36 of 2009 concerning health

Health workers as referred to in article 23 must comply with the provisions of the code of ethics, professional standards, rights of users of health services, service standards, and standard operating procedures.

Article 1 of law no. 36 of 2004 concerning health workers paragraph (14)

Standard operational procedure is a set of standardized instructions/steps to complete certain routine work processes by providing the correct and best steps based on mutual consensus to carry out various activities and service functions made by health service facilities based on professional standards.

Indonesian medical ethics code (-KODEKI)

Article 2

A doctor must always strive to carry out his profession in accordance with the highest professional standards.

Article 6

Every doctor must always be careful in announcing and implementing any new technique or treatment discoveries that have not been tested for truth and things that can cause public unrest.

Article 10

Every doctor is obliged to be sincere and use all their knowledge and skills to benefit the patient. In this case, they are unable to carry out an examination or treatment, and then with the patient's consent, they are obliged to refer the patient to a doctor who has expertise in the disease.

Article 11

Doctors must provide opportunities for patients to always be in touch with their families and advisors in worship and or in other matters.[12]

In determining a misdiagnosis as a result of a doctor's action is medical malpractice, it can be seen through the standards that have been determined below: it must be determined whether the doctor concerned fulfils the element of negligence, in this case, the doctor is required to work as carefully as possible to avoid diagnosis errors resulting from their inaccuracy, for example, an error in reading the results of their patient's examination; the actions of doctors in carrying out their duties must be in accordance with medical science, this is important as proof of doctors' actions that they have committed malpractice; the average expertise of medical personnel in the same category; occurs under similar conditions; and the pursuit of medical action must be in line with the actual intention of the medical act.[11]

Leenen divides five criteria for testing a doctor's actions to determine whether a doctor has been proven to have made a mistake, medical negligence or malpractice, as cited by Fred Ameln, namely: the doctor's actions must be carried out carefully (*zorgvildig hendelen*) and not negligent (*culpa*), if a doctor is proven to be careless and not careful, then they have fulfilled the element of negligence, and if they are not very careful, they fulfill the *culpa lata* element; the actions of doctors towards their patients must be in accordance with the standard of medical science (volgens *demediche standard*); average ability compared to the same category of medical expertise (*gemiddelde*

bewaamheid van gelijkemediche categorie); occurs under similar conditions (*gelijke omstandigheden*); and an effort that is proportional and has a real end goal for the action.[13]

CONCLUSION

The COVID-19 infection has caused a huge impact on human life. Like other aspects of human life, the law also plays a role in regulating medical aspects during the COVID-19 pandemic era. One of the hot legal and social issues is the possibility of contamination of COVID-19 test samples in nucleic acid amplification-based molecular tests. This can happen because of many underlying aspects ranging from burnout, inadequate regulation, and social pressure from the community. The contamination incident of the COVID-19 sample is the impact of various synergistic factors causing this (the iceberg phenomenon). Other impacts also appear on the general public, such as medical disputes, misdiagnosis, and social impacts for the wider community (pandora box).

ACKNOWLEDGEMENTS

Authors would like to express great appreciation to all participants that has helped to conduct this research.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

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Cite this article as: Firmansyah Y, Ernawati, Gosal D, Haryanto I, Hendsun. Contamination in COVID-19 sample - the elaboration between medical and legal impact. Int J Adv Med 2021;8:1611-4.