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RESEARCH ARTICLE

THE DEMAND FOR FALSE POSITIVE COVID-19 PCR GUIDELINE

*Bayan Hashim Al Sharif

Department of Preventive medicine, King Abdullah Medical City, Makkah, Saudi Arabia

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ABSTRACT

The COVID-19 pandemic started in 2019, and multiple public health preventive measures have been taken, such as PCR tests preoperatively and for pre-and post-travel requirements. However, preventive health services have faced different dilemmas, particularly the issue of false-positive PCR test results, which were confirmed as the repeated tests were negative. People face different consequences after a positive PCR test result, such as postponing surgery, absence from work, and financial problems, all of which negatively impact people's lives. Health care practitioners working in preventive medicine and public health departments bear the brunt of the anger from patients when they encounter such cases. Therefore, there is a need for a fixed guideline regarding the false positive swabs and how to clear the person from isolation when all criteria suggest the person is no longer contagious.

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INTRODUCTION

On the 31st of December 2019, the WHO office in Wuhan City, China, was notified of clusters of cases of "pneumonia of unknown cause⁽¹⁾" Since then, multiple public health preventive measures have been taken: quarantine of exposed persons, isolation of infected persons, restrictions, travel bans, cancellation of elective surgery, reduced workforce in hospitals, and remote working have been effective in limiting the number of infections⁽²⁾⁽³⁾. Currently, the gold standard for COVID-19 diagnosis is based on a molecular test of the reverse transcription-polymerase chain reaction (RT-PCR), which aims to detect the RNA of the virus in respiratory samples such as nasopharyngeal swabs or bronchial aspirate⁽⁴⁾⁽⁵⁾. It is used as a screening tool preoperatively and for pre-, and post-travel requirements⁽⁶⁾. However, there is a high chance of either false positive or false negative results; false-negative results have been discussed in many articles because of the significant consequences of undetected cases in the community. Negative test results of suspected COVID-19 patients may require repeated PCR tests, and clinical features combined with CT imaging could help in patient diagnosis and COVID-19 infection diagnosis⁽²⁾.

However, research regarding false positive PCR have been underestimated and rarely mentioned in published research.

A positive swab have a massive negative impact on people's lives. From a human and social point of view, where scheduled operations for patients are postponed⁽⁷⁾, home quarantine and its negative psychological effects such as depression, post traumatic distress and stigma⁽⁸⁾. Economic and personal aspect as they spent a lot of money to pay for tickets and hotels as they spend a lot. There is a huge gap and major lack the guideline regarding false positive result and when to decide to isolate or clear the patient.

Pitfalls of COVID PCR diagnosis may relate to many factors

External and internal Quality of the sample: Mix up of reagents, contamination with target sequences, or cross-contamination of samples reported reducing positive result and vice versa with the negative⁽⁹⁾.

Sampling procedures: A review published in 2020 stated that samples taken from the lower respiratory tract of COVID-19 patients showed greater sensitivity than those from the upper respiratory tract⁽⁴⁾. Nasopharyngeal samples yielded more accurate results than throat samples⁽¹⁰⁾. Another factor may be related to the person who collects the samples, including improper technique resulting in swabs not reaching the target

*Corresponding Author: Bayan Hashim Al Sharif,
Department of Preventive medicine, King Abdullah Medical City,
Makkah, Saudi Arabia.

site of the nasopharynx and inadequate collection of secretions.

Sensitivity and specificity of the test itself: A systematic review and meta-analysis published in 2021 showed that nasopharyngeal and throat swabs had a 73.3% sensitivity, and throat swabs had a 98.6% specificity⁽¹¹⁾.

History of previous infection: In 2020, a study published in China showed that positive PCR test results might persist for up to 42 days from when the first symptoms appeared. In the same study, three consecutive PCR tests were performed for 70 patients, and 21 patients (30 %) had a positive third-time RT-PCR test, even though the previous two tests yielded negative results⁽¹⁰⁾.

The following examples are real case scenarios that any health practitioner may face.

Case scenario 1: A 30-year-old man underwent a COVID-19 swab test as a requirement for travel. The result was positive. Based on the history of prior infection, it was revealed that he had had the COVID-19 infection 20 days prior. He was asymptomatic, had no contact history with any positive patient and had no history of visiting any public place.

Case scenario 2: A health care worker traveled from his residence in Country A to his place of work in Country B. According to the guidelines of Country B, he should be tested on the sixth day. The worker underwent the swab test, and the result was negative. However, since country B has guidelines to assess the COVID-19 situation for each person, the worker was required to isolate and undergo a second test. The second test was positive. The health care worker was asymptomatic, and a third test was performed, which was negative.

Case scenario 3: A 32-year-old female patient was administered a swab test as a requirement for her driving license, and the result was positive. Based on the patient's contact-tracing history, there was no history of contact with any COVID-19 positive patient and no history of visiting public places, and given that the patient was asymptomatic, the physician ordered a second PCR test. The result was negative.

Case scenario 4: A physician who had a COVID-19 six months prior had received a COVID-19 booster shot and was planning to travel back to his country. A swab test was taken at a government hospital as required by the airline; however, on the same day, he was informed that tests performed at this hospital were not accepted by the airline. Therefore, he took another swab test on the same day in a private hospital. The patient was asymptomatic and had no contact history with any positive patient. When the results were revealed, one was positive and the other was negative. Therefore, the patient underwent a third swab test in the hospital where he had received a positive test result. The third swab test result was negative.

Case scenario 5: A health care worker planning to travel back to his country underwent a PCR test, which was negative. For some reason, he had to postpone his travel. After four days, he underwent a second PCR test, the result was positive; he was asymptomatic. He had a history of COVID-19 infection was one year prior, and he had already gotten a booster dose of the

COVID-19 Pfizer vaccine. He had no history of contact with anyone with a confirmed case of COVID-19. The swab test was repeated the next day, and the result was negative.

Case scenario 6: An asymptomatic male patient underwent a pre-travel swab test, and the result was positive. A second swab test also had a positive result. He was then required to undergo ten days of isolation before being cleared. Currently, there are no guidelines for such cases. What should be done in an urgent situation like traveling? Should repeat testing be done after a 24-hour interval? Furthermore, if results are negative and the patient is asymptomatic and fully vaccinated with no significant tracing history, should the result be considered a false-positive?

A clear guideline is needed to address this topic.

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