

21 March 2022

s 9(2)(a)

By e-mail s 9(2)(a)
Ref H202202861

Tēnā koe s 9(2)(a)

RESPONSE TO YOUR REQUEST FOR OFFICIAL INFORMATION

Thank you for your request 22 February 2022 under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) for the information relating to PCR testing and COVID-19 vaccine. Please find a response to each part of your request below.

1 - Why is the PCR test being used to diagnose Covid-19? A PCR test is not capable of distinguishing mere contamination from infection. As long as the viruses remain on the mucous membranes and do not enter the cells of the body, a person is only contaminated, but not infected. In this case, the viruses do not replicate and therefore do not pose a risk of infection. Nevertheless, a PCR test will deliver a positive result for such people.

A PCR test can detect fragments of Reverse-Transcribed Ribonucleic Acid (RT-RNA) from the SARS-CoV-2 virus. This RNA is translated into Deoxyribose Nucleic Acid (DNA) also known as RT-DNA as it has been reverse-transcribed. The RNA sequence for SARS-CoV-2 has unique regions, meaning that the primers used in PCR tests to detect SARS-CoV-2 will amplify only a specific section found only in SARS-Cov-2. This is a definitive and highly-specific test. When this test is used in conjunction with a clinical assessment of patient's symptoms, the diagnosis of COVID-19 is highly robust.

2- People are required to self-isolate and are required to quarantine if they have a positive PCR test. Based on the points made above in question 1, that a PCR test can not detect infection, please explain the MOH advice and subsequent legislation that requires people to be quarantined and self isolate based on a positive PCR test result. I would also like to know the justification for previous lockdown measures and current traffic light settings based on "case" numbers rather than people infected?

Advice from the Ministry to the government about lockdown measures and the current traffic light system is publicly available, and can be found on the *Unite against COVID-19* website: www.covid19.govt.nz/about-our-covid-19-response/proactive-releases/alert-levels-and-restrictions/.

Information about self-isolation requirements is publicly available, and set out in the COVID-19 Public Health Response (Self-isolation Requirements and Permitted Work) Order 2022: www.legislation.govt.nz/regulation/public/2022/0046/latest/whole.html#LMS647742.

3 - Why is the PCR test being run at 40 cycles when it is known that 40 cycles increases false positives which in turn effectively "creates cases"?

If the test system only begins detection after a large number of replication cycles, the viral load is so low that active infection is ruled out. Studies show that a patient is considered "less infectious" above 25 cycles. In fact, the authors of a Canadian study failed to identify any replicable virus beyond 24 cycles .

The maximum number of PCR cycles is set by commercial assay manufacturers (in most cases, it is set to 40 cycles, at which point a reactive result would be called). Extensive specificity testing (testing of non-COVID-19-infected samples to look for false positives) has been performed by the manufacturers to guard against non-specific amplification at high cycle numbers before applying for certification. Additionally, each diagnostic laboratory also verified their assays' specificity before use to make sure that no false-positive test results are produced by testing SARS-CoV-2 negative samples repeatedly.

4 - Based on points 1,2 and 3 it has to be asked - Is the MOH purposely trying to create cases for the government to maintain the emergency status and therefore allow the roll out of the vaccine to continue and retain the restrictions and controls in place? Every positive test is included in the statistics as an alleged "new infection" and thus is the very metric on which political decisions are based. Case numbers therefore have significant impacts on all facets of society, including the mental, physical, emotional and financial well being of all individuals.

While the Act allows New Zealanders to ask for information from Ministers and government agencies, there is no requirement for agencies to create new information, compile information they do not hold, or provide/prove an opinion to respond to a request made under the Act. Your questions and supporting statements appear designed to engage in a debate about the government's COVID-19 vaccination programme rather than be a request for official information. The Act does not support requests where an opinion, comment, argument, or hypothetical statement is put to the Ministry for response, couched as a request for information. This question is therefore refused under Section 18(g) of the Act on the grounds that the information sought is not held by the Ministry.

5 - Given the Covid 19 vaccine does not have full safety approval, please explain how it is allowed that 64 of 147 deaths reported to CARM post vaccination can not be assessed due to insufficient information as at 31 January 2022? Every single death recorded post inoculation with a vaccine without full approval should be assessed. This is particularly vital given that the vaccine is called "safe and effective" and 90%+ of the population over 12 was required to take this vaccine if we were to move out of lockdowns and into the traffic light system.

Medicines are approved based on the expected benefits outweighing the risks of side effects. They are not given a safety approval. Provisional consent allows conditions to be imposed on the vaccine, restricting its use by healthcare professionals according to the data available at the time of approval. Provisional consent was included in the *Medicines Act 1981* to allow early access to medicines for New Zealand patients with a significant unmet clinical need. The process for investigating reports with a fatal outcome is published on the Medsafe website and can be found on www.medsafe.govt.nz/COVID-19/q-and-a-vaccine-safety.asp.

6 - Given the Covid-19 vaccine does not have full safety approval and has been rolled out to the entire population in NZ aged 5+, please explain and justify the decision to make injuries and deaths post vaccination only "encouraged" to be reported, rather than mandatory. It seems bizarre to make masks mandatory in public places to protect peoples health, but not the reporting of adverse reactions and deaths after a new vaccine that does not have full safety approval.

To make reporting mandatory, it would have to be included in legislation, and there would need to be a process to enforce reporting. Given that it cannot be proven that someone failed to recognise an adverse reaction, mandatory reporting cannot be enforced.

Under Section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by e-mail info@ombudsman.parliament.nz or by calling 0800 802 602.

Nāku noa, nā

A handwritten signature in black ink, appearing to read 'D. Carpenter', with a long horizontal line extending to the right.

Darryl Carpenter
Group Manager Testing and Supply
COVID-19 Health System Response