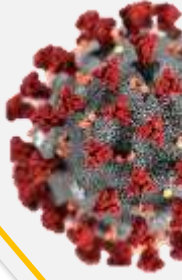




TESTING STRATEGIES FOR SARS-CoV-2



INTRODUCTION

Implementation of objective-driven and sustainable testing strategies for COVID-19 supports the overall public health response to the pandemic and helps mitigate its impact on vulnerable populations and healthcare systems, while ensuring that societies and economies can continue to function.

Testing strategies should be flexible and rapidly adaptable to change, depending on the local epidemiology, transmission, population dynamics and resources.

This rapid review provides evidence on testing strategy for COVID-19 in a few epidemiological situations, including general population-wide testing, as well as targeted testing of individuals following a request from the crisis preparedness response centre for possibility of strategy enhancement.

EVIDENCE

There were several articles and guidelines retrieved from the scientific databases such as Medline, EBM Reviews, EMBASE via OVID, PubMed and from the general search engines [Google Scholar and US Food and Drug Administration (USFDA)] on testing strategies for SARS-Co-V-2, categorized accordingly to general population-wide testing and certain targeted testing.

A. GENERAL TESTING STRATEGY FOR SARS-Co-V-2

Reference	Evidence statement
WHO ¹	<p>As part of the Strategic Preparedness and Response Plan, WHO developed testing strategy recommendations. The foundation of this strategy is threefold:</p> <ul style="list-style-type: none"> • All countries should increase their level of preparedness, alert, and response to identify, manage, and care for new cases of COVID-19; laboratory testing is an integral part of this strategy. • Countries should prepare to respond to different public health scenarios, recognizing that there is no one-size-fits-all approach to managing cases and outbreaks of COVID-19. • Each country should assess its risk and rapidly implement the necessary measures at the appropriate scale and prepare for a testing and clinical care surge to reduce both COVID-19 transmission and economic, public health, and social impacts.

Depending on the intensity of transmission, the number of cases and laboratory testing and surge capacity, it may be necessary to prioritize who gets tested according to health objectives. WHO has outlined critical priority actions for preparedness, readiness, and response actions for COVID-19 and has defined four transmission scenarios:

1. Countries with no cases (No Cases);

WHO recommends that all suspect cases be tested for COVID-19 according to WHO case definitions. Demonstrating that COVID-19 is not circulating in a given population requires adequate surveillance. All countries are encouraged to critically assess surveillance and respiratory syndrome testing strategies. An assessment of possible risk areas and populations (e.g. related to travel to high-risk countries) may require a more intensified testing strategy. Medical professionals should also be alert and request testing when encountering patients with unexpected clinical presentations or when there is an increase in hospital admissions in a specific demographic group. Even before any COVID cases have been detected nationally, it is critical to prepare for the possibility of increasing transmission and plan for surge COVID-19 testing capacity.

2. Countries with one or more cases, imported or locally detected (Sporadic Cases);

WHO recommends that all suspected cases be tested for COVID-19 according to WHO case definitions. When the first case of COVID-19 is detected in a country, investigations should be carried out to determine the source of the infection (e.g. imported case, local human transmission, or possible animal-to-human transmission). This investigation may include genetic sequencing of the newly detected virus where feasible. It is recommended that the detection of a first case be confirmed by one of the WHO COVID-19 Reference Laboratories. All other recommendations listed in the no-case scenario above still apply; however, each sporadic case requires aggressive and active case finding, isolation and care, and comprehensive contact tracing and quarantine.

3. Countries experiencing clusters of cases related in time, geographic location, or common exposure (Clusters of cases);

WHO recommends that all suspected cases be tested for COVID-19 according to WHO case definitions. All recommendations in the previous two transmission scenarios remain applicable, including considerations in the investigation of cases and clusters of COVID-19. Plans should be adopted to improve national testing capacity, as needed, and assess the effectiveness of the laboratory network. Intensify investigation of cases and clusters and SARI/ILI surveillance. When clusters become large, it is critical that testing of suspected cases continues so that cases can be isolated, contacts can be quarantined, and chains of transmission can be broken.

4. Countries experiencing larger outbreaks or sustained and pervasive local transmission (Community transmission).

Faced with community transmission over large areas of the country, laboratories will need to be prepared for the significant increase in the number of specimens that need to be tested for COVID-19. Testing constraints should be anticipated, and prioritization will be required to assure the highest public health impact of reducing transmission using available resources.

	<p>Prioritized testing strategies</p> <p>As the virus does not respect borders, a country can simultaneously have areas with no cases and areas with community circulation. Thus, different testing strategies might be needed within the same country. For areas within a country with no circulation, the objectives remain to test all suspected cases in an effort to detect first cases in new areas or settings as rapidly as possible, and take immediate measures to prevent (further) spread in that region.</p> <p>Testing in areas with community transmission and in settings where testing capacity cannot meet needs must be prioritized. This prioritization should focus on the early identification and protection of vulnerable patients and health care workers. Focused testing in health care facilities ensures that infection prevention and control measures can be correctly implemented such that vulnerable patients who do not have COVID are protected from nosocomial COVID-19 infection. Testing among vulnerable populations and risk groups will be important for early treatment to minimize progression to severe disease. Results of testing of specific populations (e.g. patients requiring hospitalization for respiratory disease) can give a rough estimate of the size of the outbreak in the area and be used to monitor trends.</p> <p>The WHO laboratory testing strategy guidance (2020) highlighted in the setting of limited resources in areas with community transmission, prioritization for testing should be given to:</p> <ul style="list-style-type: none"> • People who are at risk of developing severe disease and vulnerable populations, who will require hospitalization and advanced care for COVID-19. • Health workers (including emergency services and non-clinical staff) regardless of whether they are a contact of a confirmed case (to protect health workers and reduce the risk of nosocomial transmission). • The first symptomatic individuals in a closed setting (e.g. schools, long-term living facilities, prisons, hospitals) to quickly identify outbreaks and ensure containment measures. All other individuals with symptoms related to the close settings may be considered probable cases and isolated without additional testing if testing capacity is limited.
<p>Europe CDC²</p>	<p>The implementation of objective-driven and sustainable testing strategies for COVID-19 supports the overall public health response to the pandemic and helps mitigate its impact on vulnerable populations and healthcare systems, while ensuring that societies and economies continue to function.</p> <ol style="list-style-type: none"> A. Control transmission B. Monitor incidence and trends and assess severity over time C. Mitigate the impact of COVID-19 in healthcare and social-care settings D. Rapidly identify all clusters or outbreaks in specific settings E. Prevent (re-)introduction into regions/countries with sustained control of the virus <p>Depending on the epidemiological situation, more than one strategy may be employed simultaneously to meet the objectives. This applies when countries and/or regions within a country are experiencing a variety of epidemiological situations or when there are certain populations that could be disproportionately affected (such as ethnic minorities, specific age groups). Appendix 1 provides</p>

an overview of the testing guidance to achieve the objectives listed above depending on the epidemiological situation in the general population and key messages on COVID-19 testing.

Testing objective A

Control transmission to reduce the spread of SARS-CoV-2 and control transmission within the population, **all individuals with COVID-19- compatible symptoms** should be identified and tested for SARS-CoV-2 as soon as possible after symptom onset. Individuals testing positive need to be isolated in a timely manner and their contacts identified for systematic contact tracing.

- Control widespread community transmission
- Household testing
- Population-wide individual-initiated testing

Testing objective B

Monitor incidence and trends, and assessing severity over time ongoing, population-based surveillance of COVID-19 is essential throughout all phases of the pandemic in order to inform prevention and mitigation strategies.

- Primary care
 - all those with compatible symptoms should be tested for SARS-CoV-2 in the first instance, while all individuals with underlying conditions and the elderly should be tested for both influenza and SARS-CoV-2.
 - Existing sentinel surveillance systems based on syndromic case definition for influenza (both primary care and secondary care) complement the comprehensive syndromic system described above and should continue to operate according to standard procedures to ensure historical data comparability.
- Hospitals settings

Testing objective C

Mitigate the impact of COVID-19 in healthcare and social care settings

- Healthcare workers
- Hospitals
- Long-term care facilities (LTCF)
- Social protection services including home care

Testing objective D

Rapidly identify all clusters or outbreaks in specific settings. Early identification of clusters, isolation of cases and notification of contacts can prevent further spread within these settings and to the wider community.

- Occupational settings
- Schools
- Prisons
- Migrant detention and reception centres
- Other populations at risk - Homeless people are at increased risk of infection due to their living conditions, with many also having an increased risk of severe disease outcome

	<p>Testing objective E</p> <p>Prevent (re-)introduction into regions/countries with sustained control of the virus. In all other epidemiological situations, including the current situation in the EU/EEA and in the UK (September 2020), screening of travellers is not considered a cost-effective strategy for substantially preventing the cross border transmission of COVID-19.</p>
<p>UK Royal College of Pathologist ³</p>	<p>Principles of a national strategy ³</p> <p>The following seven principles underpin any form of diagnostic assessment and must be applied to a national testing strategy.</p> <ol style="list-style-type: none"> 1. The test is the right one, at the right time, and with the correct result. This result includes the appropriate clinical interpretation and, where not specifically designed and validated for home use, a test carried out by skilled trained laboratory professionals to recognised and accredited quality and service standards. 2. Testing must be carried out for a purpose: for diagnosis, for screening or for gathering data to understand the spread, or level, of disease in a population. Any testing programme must be clear as to its purpose, and the tests chosen appropriate for that purpose. 3. Problems in testing result in problems with care. With an infectious disease, this can have significant impact on disease spread, risk assessment, morbidity, mortality and population health. These problems arise from issues including poor specimen taking, poor labelling or poor transcription of details, slow turnaround of results, poor quality control, ineffective communication of the result, inappropriate application of the result, and lack of clinical input or oversight. 4. Data connectivity is a cornerstone of testing. It is a key aspect of improving quality. Links that connect primary and secondary care and public health bodies should be strengthened to ensure all results are available to clinicians when required, form a part of individuals' permanent health records and can be used, in an appropriate and legal framework, for public health purposes. 5. Testing standards must be upheld. Testing will be carried out in many settings, but must be carried out as part of a quality assured system, meeting accredited standards in regulated or approved settings. Accredited standards will apply to both laboratory and point-of-care testing. Different technologies will be used, depending on the clinical setting, clinical pathways and public health needs. 6. People being tested should be informed about why they are being tested, and the implications and limitations of their results. They should have access to those results. 7. At societal level, the more people who understand about the testing being performed, the more informed their consent will be. Information needs to be in plain language and accessible to all in a range of formats. National and international awareness is raised by media, professional bodies and programmes. <p>This strategy is based on a set of seven principles, which underpin four key workstreams:</p> <ul style="list-style-type: none"> • testing matched to purpose and pathways • innovation to adoption at pace • infrastructure and workforce for a stable future • SARS-CoV-2 is not the only virus.

- **EXISTING SARS CoV-2 TESTING IN MALAYSIA**

Annex 4c, 5d, 5e, 5f documented guidelines related to diagnostics and testing for SARS-CoV2, while Annex 8,12, 21 and 35 highlighted Infection Prevention and Control (IPC) measures and management of healthcare worker (HCW) and severe acute respiratory infection (SARI) cases in Malaysia. ⁴

The guidelines are as listed below:

- Annex 4c: Guideline on COVID-19 testing using antigen rapid test kit (RTK-Ag) for the health facilities, Ministry of Health Malaysia version 4.0
- Annex 5d: Clinical sampling for OPS/NPS at health center and field setting
- Annex 5e: Protocol on COVID-19 rapid molecular testing for the health facilities, Ministry of Health Malaysia version 1.0
- Annex 5f: Laboratory diagnosis of SARS-CoV-2 in suspected cases of COVID-19 at outpatient settings/targeted groups of COVID-19
- Annex 8: Infection Prevention and Control (IPC) measures in managing Person Under Surveillance (PUS), Suspected, Probable or Confirmed Coronavirus Disease (COVID-19)
- Annex 12: Management of close contact of confirmed case
- Annex 21: Management of Healthcare Worker during COVID-19 Pandemic
- Annex 35: Guidelines of infection control and clinical management of severe acute respiratory infection (SARI)/pneumonia TRO COVID-19

All COVID-19 laboratories in MOH are using real time Reverse Transcriptase Polymerase Chain Reaction (RT- qPCR) as a confirmatory test for COVID-19 infection which may take several hours of 6 to 8 hours for a completion. With the advancement of technology, research and development, real Rapid PCR platforms are being introduced recently. ⁴

These platforms enable results to be provided within 1 – 2 hours and are now available in hospital's laboratories in MOH. Rapid PCR allows faster case detection, diagnosis and management of COVID-19 patients. ⁵

Two rapid PCR tests available in MOH facilities are. ⁵

- GeneXpert - Xpert Xpress SARS-CoV-2 test
 - The Xpert Xpress SARS-CoV-2 test is an automated in vitro diagnostic test for qualitative detection of nucleic acid from SARSCoV-2 which is performed on GeneXpert Instrument Systems.
- QIAstat -Dx Respiratory SARS-CoV-2 Panel
 - This is a multiplexed nucleic acid real-time PCR test (NAAT) which can detect nucleic acid from 22 respiratory viral and bacterial organisms, including the SARS-CoV-2 virus.

B. HEALTH CARE WORKERS (HCW)

Healthcare workers have been disproportionately affected and infected by SARS-CoV-2, constituting between 4% and 19% of all reported COVID-19 cases in China and Europe (3.8% in China, 4.6% in Germany, 9% in Italy and 19% in Spain). ⁵

- **Staff testing**³

There is recognition that SARS-CoV-2 detection and immune response assessments will extend to many different clinical and healthcare settings. **Wider staff testing** is required to understand infection prevalence and to inform infection prevention and control. This is key to controlling the spread and providing protection and reassurance to patients and staff coming into these

environments. To inform planning and countermeasures, this will entail both viral and antibody testing to identify those who have, and those who had, COVID-19. At present, antibody tests should not be used as a signal of immunity, given the current state of knowledge on this subject. It is important that gaps in knowledge are filled with sensible supportive data with accompanying guidance, to prevent unnecessary and potentially harmful untested technologies being used. Eventually, it is likely that vaccination and assessment of its outcome, in terms of the response achieved, will provide the best way forwards – as happens for many viral infections. However, lasting immune protection resulting from SARS-CoV-2 vaccination is not certain at this time.

To mitigate the impact of COVID-19, ECDC recommends that HCWs and staff working in social care and other high-risk settings are **tested periodically, irrespective of symptoms**. To achieve effective prevention and control, screening should be repeated regularly, (e.g. at least once a week or every two weeks). This should be accompanied by appropriate use of personal protective equipment (PPE) and daily monitoring of symptoms in staff that must be sent home if COVID-19-compatible symptoms appear. This approach applies at most COVID-19 transmission levels in the community, with the exception of communities where the virus has been consistently eliminated or where transmission has only been documented in sporadic clusters which have been promptly controlled and where measures are in place to reduce the risk of re-introduction.²

Different screening approaches have been reported (e.g. regular weekly testing of healthcare workers over a period of several weeks, testing of symptomatic staff and symptomatic household contacts or comprehensive testing of all healthcare workers in a hospital or ward. Modelling studies estimated that weekly PCR testing to screen healthcare workers and other high-risk groups, irrespective of symptoms, would reduce their contribution to SARS-CoV-2 transmission by 23% (95% UI 16 to 40), in addition to the reduction achieved by self-isolation following the appearance symptoms, assuming results are available within 24 hours.²

The National Health Service (NHS) England and NHS Improvement produced guidance to ensure patient safety, maintain public confidence and protect the health and wellbeing of NHS staff. For staff testing, NHS recommended.⁶

- i. Testing all staff with symptoms (or the index case if a household member).
- ii. Testing non-symptomatic staff working in situations where there is an untoward incident or outbreak or high prevalence.
- iii. Enrolment is the PHE's SIREN study with the primary objective of determining if prior SARS-CoV-2 infection in healthcare workers confers future immunity to re-infection. The staff will be tested every 2 weeks of PCR and antibody testing. However, frequency may be altered depending on national and regional epidemiology.

• **Identification of health worker infection**

Early detection of COVID-19 infection among health workers can be achieved through syndromic surveillance and/or laboratory testing and is a key strategy to prevent secondary transmission to patients, between health workers and throughout health-care settings. WHO advises the following.⁷

- i. **Syndromic surveillance** of health workers for COVID-19 symptoms should be performed before they enter the workplace. This should include:
 - Passive surveillance: encourage health workers to report symptoms to the occupational health professional or another designated officer in the facility before their shift (including via routine digital reporting forms where available), and during or after their shift.
 - Active surveillance: establish a confidential process for ensuring health workers are screened for symptoms of COVID-19, including fever, and any potential exposure risks on arrival for their shift.

(Symptoms to be monitored should include, at minimum: fever, dry cough, myalgia, arthralgia, fatigue, headache, shortness of breath, anosmia and age).

ii. **National and sub-national testing strategies** for health workers for detection of SARS-CoV-2 infections.

WHO recommends that health workers be prioritised for testing, regardless of whether they are a contact of a confirmed case (to protect health workers and reduce the risk of nosocomial transmission). Scenarios and testing strategies for health workers are as shown in Table 1.

WHO recommends RT-PCR and antigen-based testing for the diagnosis of SARS-CoV-2. The testing strategy should include: ⁷

- Testing health workers following exposure to SARS-CoV-2.
- Routine testing of health workers for COVID-19 surveillance.
 - The need should be decided using a risk-based approach and the following factors should be taken into account:
 - The intensity of transmission in the setting of the health facility(ies), for example in the presence of community transmission or intense outbreaks of COVID-19.
 - The capacities of the facility and laboratories to conduct the testing including financial and human resources available, as well as availability of testing materials and laboratory capacity.
 - The volume of patients identified as positive for SARS-CoV-2, admitted to the facility or being assessed by health workers.
 - The positivity rate among staff.
 - The number of staff who are ill but not diagnosed with COVID-19 and in quarantine as contacts for COVID-19, leading to inability to provide adequate and safe staffing levels.
- Testing health workers in long-term care facilities.

Table 1: Examples of scenarios and testing strategies for health workers

Health-care Setting	Transmission scenario	Possible testing strategy target to consider (where resources allow)
Acute care	No cases or Sporadic cases	<ul style="list-style-type: none"> • Symptomatic health workers • Health worker identified as a contact of a SARS-CoV-2 case <ul style="list-style-type: none"> • Health workers associated with transmission to or from a patient or resident or with an outbreak investigation
	Clusters or Community transmission	<ul style="list-style-type: none"> • Symptomatic health workers • Health worker identified as a contact of a SARS-CoV-2 case <ul style="list-style-type: none"> • Health workers associated with transmission to or from a patient, a cluster, or with an outbreak investigation • Health workers working in any clinical area, identifying priority areas based on risk assessment (e.g. triage, emergency services or COVID-19 wards) where resources are limited.

		<ul style="list-style-type: none"> All health workers who work in COVID-19 services or facilities
Long-term care	All transmission scenarios	<ul style="list-style-type: none"> Symptomatic health workers Health workers identified as a contact of a SARS-CoV-2 case Testing of all health workers when a positive case of SARS-CoV-2 is identified in a resident or staff member Routine testing of health workers, if feasible

The Centers for Disease Control and Prevention (CDC) recommendations for SARS-CoV-2 testing of healthcare personnel (HCP) in four conditions.⁸

1. Testing HCP with signs or symptoms consistent with COVID-19.

- HCP with signs or symptoms of COVID-19 should be prioritised for SARS-CoV-2 testing
- Even mild signs or symptoms (e.g., sore throat) of possible COVID-19 should prompt consideration for testing

2. Testing asymptomatic HCP with known or suspected exposure to SARS-CoV-2.

- High risk exposure: Initial testing and if negative, repeat again about 5-7 days after the exposure. HCP should be excluded from work for 14 days following exposure.
- Low risk exposure: HCP may continue to work. However, CDC recommends screening for symptoms prior to starting work each day and using source control measures as described in CDC's infection control recommendations.
- When there is SARS-CoV-2 transmission occurring in the community, positive tests in HCP do not necessarily indicate transmission due to exposures in the workplace.

3. Testing asymptomatic HCP without known or suspected exposure to SARS-CoV-2 as part of expanded screening.

- Recommended for HCP working in nursing homes
- Conducted on HCP who have regular close contact (within 6 feet) with a large number of patients or who regularly care for persons with risk factors or medical conditions that increase the risk of severe illness.

4. Testing HCP who have been diagnosed with SARS-CoV-2 infection to determine when they are no longer infectious.

- A test-based strategy should be considered for HCP with severely immunocompromised
- A symptom-based strategy should be used in other HCP

CDC Criteria for Return to Work for Healthcare Personnel with SARS-CoV-2 Infection (Interim Guidance)
Symptom-based strategy for determining when HCP can return to work.

HCP with [*mild to moderate illness*](#) who are not severely immunocompromised:

- At least 10 days have passed *since symptoms first appeared* **and**
- At least 24 hours have passed *since last fever* without the use of fever-reducing medications **and**
- Symptoms (e.g., cough, shortness of breath) have improved

Note: HCP who are **not severely immunocompromised** and were **asymptomatic** throughout their infection may return to work when at least 10 days have passed since the date of their first positive viral diagnostic test.

HCP with [*severe to critical illness*](#) or who are severely immunocompromised:

- At least 10 days and up to 20 days have passed *since symptoms first appeared*
- At least 24 hours have passed *since last fever* without the use of fever-reducing medications **and**
- Symptoms (e.g., cough, shortness of breath) have improved
- Consider consultation with infection control experts

Note: HCP who are **severely immunocompromised** but who were **asymptomatic** throughout their infection may return to work when at least 10 days and up to 20 days have passed since the date of their first positive viral diagnostic test.

The US CDC does not recommend testing the same individual more than once in a 24-hour period.

The Imperial College London reported that the current testing strategy for HCWs in the UK focuses on PCR testing for infection among symptomatic individuals. The effectiveness of self-isolation based on symptoms depends on the amount of pre-symptomatic transmission from infections that become symptomatic, and the proportion of infections that are asymptomatic and their relative infectiousness. Assuming HCWs self-isolate as soon as symptoms appear, it was predicted to restrict onwards transmission from infected workers to other HCW and patients by between 16% and 57%.⁵

Current UK policy (21 April 2020) is self-isolation for 7 days from onset of symptoms among symptomatic individuals and for 14 days among household members to cover the period of risk for secondary infection, extending by 7 days among any household members subsequently developing symptoms. The use of testing to enable return to work of HCWs may be more useful when targeted at HCWs self-isolating because of COVID-19 symptoms among their household members. Weekly screening of HCWs and other at-risk groups using PCR or point-of-care tests for infection irrespective of symptoms is estimated to reduce their contribution to transmission by 25-33%, on top of reductions achieved by self-isolation following symptoms. The impact of regular PCR screening of HCWs on hospital and community SARS-CoV-2 transmission will depend on the extent of transmission among HCWs, from HCWs to the community and from HCWs to patients.⁵

C. PREADMISSION TESTING

Jackman JM et al conducted a systematic review of narrative synthesis, systematic search on May 25, 2020 using PubMed® and Google Scholar for relevant studies to determine evidence for pre-medical intervention or pre-operative COVID-19 diagnostic testing using search terms COVID-19 and pre admission. From 109 articles found initially, only two of the articles that addressed the accuracy of the COVID-19 test in symptomatic individuals were included into the review.⁹

In one of the studies, they screened patients using temperature, symptom questionnaire, travel history and imaging to determine who was more likely to have the virus and subsequently needed COVID-19 testing. It was stated in this study that only about **one percent of patients with COVID-19 admitted for management of colorectal cancer were found to be asymptomatic** and hence this does not justify universal screening for asymptomatic patients in this population.

One study recommended pre cancer intervention testing to rule out asymptomatic individuals with planned delay of procedure for COVID-19 positive individuals. The cancer patients were screened for likelihood of COVID-19 and those with a positive screen test were given a chest X-ray and COVID-19 diagnostic testing for symptomatic or at-risk individuals. Depending on how emergent the cancer treatment was, it was determined that emergency cases would proceed with cautions while cases that could have been delayed, would be postponed. The authors did not describe a recommended isolation period before rescheduling the procedure.

Two obstetrical studies which supported the use of pre-admission COVID-19 screening as a mechanism were included. However, neither of these studies proved that identifying COVID-19 exposure in asymptomatic pregnant patients had any proven benefit for the patient, fetus or HCW. As it stands, COVID-19 has not been proven to be vertically transmitted to the fetus in either symptomatic or asymptomatic patients.

The authors concluded that:

- None of the studies showed evidence-based need for a universal screening programme of asymptomatic patients.
- Hand hygiene and proper sterilization technique is needed more than universal screening. Universal PPE use, hand hygiene and the practice of personal preventive measures should be the major component in decreasing the spread of COVID-19 in the hospital setting. Universal screening of obstetric patients is also not yet indicated as there is no proven vertical transmission, teratogenicity or effective treatment for COVID-19.
- Until COVID-19 testing sensitivity approaches the 98% specificity of current COVID-19 diagnostic testing, HCW must be cognizant of the false sense of security that a false negative COVID-19 test results may bring. HCW must also remember that they themselves may pose a risk to the patient and continue to always use PPE at this time.
- They recommended use of telehealth tools to screen preoperative patients or obstetric patients before admission.
- They also suggested in COVID-19 PCR screening **should be** limited to population surveillance and contact tracing public health programs, until COVID-19 testing becomes cheaper, quicker and more accurate in its results particularly a higher sensitivity, as well as if there is a proven treatment or intervention for COVID-19.⁹

Nakamura I (2020) in an observational study implemented universal PCR screening for all patients on admission for 16 weeks (11 May 2020-30 Sept 2020) at Tokyo Medical University Hospital. Total PCR testing done (nasopharyngeal specimen) was 6224. Total number of positive tests were 2/6224 (0.03%). The result of this study indicated a low positive COVID-19 rate among asymptomatic patients who come to the hospital. They indicated that universal PCR testing might be overly labour-intensive and not cost-effective. They concluded appropriate hand hygiene procedures, universal masking and environmental surface cleaning should be emphasized. PCR testing before admission alone is not sufficient to prevent nosocomial risk.¹⁰

Schlosser M et. al. (2020) in an observational study evaluated COVID-19 testing processes and patient protections for resumption of elective surgery. Two strategies for pre-surgical COVID-19 testing were piloted:

- algorithm-based testing according to risk of exposure,
- expanded testing of all pre-surgical and pre-procedural cases

Regardless of the testing process used, all facilities had adopted the series of **recommended universal precautions including universal masking, social distancing, screening and access controls and patient cohorting**. Data were gathered from electronic health records of all surgical cases between April 19 and May 22, 2020; this includes both elective (where case schedule data was >24 hours prior to surgery complete time) and emergent (case scheduled <24 hours prior to surgery complete time) surgeries. The overall positive result was low; 251 cases had a positive COVID-19 test (overall 0.49% of those tested, and 0.18% of all cases). A total of 93,626 cases meeting the definition of elective were scheduled. Of these, 36,834 were tested and 138 had a positive test (0.37% of those tested, 0.15% of all elective cases). Prevalence of asymptomatic COVID positive patients in the pre-surgical population is less than 1% and vary among facilities. With an estimated prevalence of 0.5%, and estimated cost of \$75 per test, the direct cost to identify a single positive COVID-19 test in the elective pre-surgical population is \$15,000. Neither of the two strategies identify a substantial number of asymptomatic COVID-19 patients.¹¹

The US CDC recommended the administration of universal PCR screening for all pre-admission patients, depending on testing capacity and disease prevalence. However, this testing strategy may return negative results for patients who are tested during the incubation period, resulting in false-negative results for patients who later become infectious.⁸ The Public Health England guidelines recommend screening all patients on admission and re-screening all inpatients again after five to seven days.⁶

The ECDC outlines in their testing strategies to mitigate the impact of COVID-19 in healthcare and social care settings.²

- When there is **documented community transmission** and **if testing capacity allows**, all patients should be tested for SARS-CoV-2 on admission to the facility and managed as possible COVID-19 cases until the test result is available. Patients should be monitored daily for COVID-19 compatible signs and symptoms, and tested again on Days 3-5 after admission if no signs and symptoms have developed before. Admissions for elective surgery should be tested 24-72 hours before admission and admitted only after a confirmed negative result.
- If SARS-CoV-2 **transmission in the community is very low or absent**, patients should be checked for COVID-19 compatible symptoms on admission and monitored daily during hospital stay. Testing needs to be done when symptoms develop.
- In situations of **insufficient testing capacity** to screen all patients on admission, screening of specific patient populations in healthcare settings can be considered to prevent virus introduction to sensitive areas where vulnerable populations are treated (such as oncology or delivery wards, neonatal intensive care units and organ transplantation units).
- Scheduled surgical patients were tested 24-48 hours pre-surgery and advised to self-isolate until surgery.
- In pregnant women, the screening test may be performed for the expected week of delivery. If the delivery is scheduled, the test should be done 24-72 hours in advance.

F. PREOPERATIVE TESTING STRATEGY

i. Surgical patients

In a systematic review by Schlosser M et. al. (2020), which included 39 studies, they found that 29 of those recommend screening for all surgical patients prior to surgery. Most recommendations consist of testing at least 48 to 72 hours prior to surgery, with some recommendations including quarantine until test results arrive or concurrent chest imaging. In some instances, testing is recommended only for patients with clinical symptoms or those undergoing high-risk surgeries, such as transplant or lung resection. Testing of asymptomatic patients, particularly in high

prevalence areas, has also been proposed, although the rate of perioperative complications and postoperative fatality has ranged widely, from 0% to 66.6%.¹¹

Another systematic review by Hojaij FC et al. compiled 39 studies with aims to analyse different perspectives concerning Covid-19 pandemic situation and to provide recommendations that could guide surgeons and entities toward screening, elective and emergency surgeries, decision making and operating room management. This review included and considered relevant if it:

- is related to the COVID-19 pandemic
- suggested approaches directly affecting surgery dynamics (e.g., reducing staff numbers, remodeling the circulation of staff and patients in the operating room, using different protection methods for patients and staff, and adapting different equipment usage)
- suggested any kind of screening for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for surgical patients, or
- had any kind of recommendation about elective procedures.

Of the 39 selected publications, 21 were research articles, five were opinion papers, four were editorials, and nine were grouped as “others”. Most of the articles were related to surgical interventions in the gastrointestinal tract, followed by articles on head and neck and general surgeries. Other, less frequent, surgeries were vascular, trauma, oral and maxillofacial and thoracic. The results showed that:

- Twenty-nine articles recommended screening for SARSCoV-2 in patients elected for surgery. The most prevalent recommendation was to perform polymerase chain reaction (PCR) testing of nasal swabs in all surgical patients.
- With respect to surgical schedules, a little fewer than one-half of the articles recommended postponing all elective surgeries. Around 13% of the articles did not offer any direct recommendations with respect to elective surgeries.
- The review also offered recommendations about surgical practice, including reorganization of the operating room schedule to provide only essential surgical services, guaranteeing psychological support to surgical staff, increasing protective measures to level 3 standards, and utilizing telemedicine for consultations that do not require physical evaluation.

The authors concluded that:

- Any **elective surgery that can be delayed should be postponed**, taking into consideration that it may take two to three months for the healthcare situation to return to normal.
- **All surgical patients should be screened for COVID-19**, with preference given to PCR tests.
- Regarding surgical practice recommendations, **surgical staff should be reduced to the minimum**, without compromising the procedure and any operation should be performed by the most experienced surgeon, so that the procedure time is reduced.
- An institutional **workflow to assist medical staff in decision making and in dealing with mental health issues** should also be established.¹²

ii. Obstetric patients

Bianco A et al. (2020) conducted an observational study to evaluate the rate of COVID-19 infection in their obstetric population presenting for scheduled deliveries, as well as the concordance or discordance rate among their support persons during the initial two-week period of testing. The observational study conducted at Mount Sinai Health system in which all women who were scheduled for a planned delivery within the from April 4 to April 15, 2020. Both the patients and the support persons were administered a standardized screen specific by telephone interview. (See Figure 1) Those support persons who screened positive were not permitted to attend the birth. All patients and screen negative support persons underwent SARS-CoV-2 testing.¹³

All patients must answer these questions.

1. Do you have fever or feel hot?
2. Do you have a cough, shortness of breath, or a sore throat?
3. Are you vomiting, or do you have diarrhea?
4. Do you have a rash?

Figure 1: Telephone Screening Tool

During the study period, 155 patients and 146 support persons underwent SARS-CoV-2 testing. The prevalence of asymptomatic COVID-19 infection was 15.5% (CI 9.8 to 21.2%) and 9.6% (CI 4.8 to 14.4%) among patients and support persons, respectively. The rate of discordance among tested pairs was 7.5%. Among patients with COVID-19 infection, 58% of their support persons also had infection; in patients without infection, fewer than 3.0% of their support persons had infection. The authors concluded that they found that more than **15% of asymptomatic maternity patients tested positive for SARS-CoV-2 infection despite having screened negative with the use of a telephone screening tool**. Additionally, 58% of their asymptomatic, screen-negative support persons also tested positive for SARS-CoV-2 infection. Alternatively, testing of the support persons of women who had tested negative for COVID-19 infection had a low yield for positive results. This has important implications for obstetric and newborn care practices as well as for healthcare professionals.¹³

E. TESTING OF PERSON UNDER SURVEILLANCE (PUS)

Annex 12 of the Ministry of Health COVID-19 guidelines highlighted the management of close contact of confirmed cases. The overall management of Asymptomatic Close Contact was:⁴

- All asymptomatic close contact identified should be tested for COVID-19 using RT-PCR.
- All asymptomatic close contact will be assigned as **Person Under Surveillance**. They will be required to undergo 14 days home surveillance under supervision and observation order.
- If RT-PCR positive, this person will be admitted to hospital and treated as confirmed COVID-19 case (Annex 2e)
- If RT-PCR is negative, continue home surveillance. At any point, this person developed symptoms, this person will be managed as a suspected case (refer Annex 2, 2a and 2b). Annex 12
- At Day 13, RTK (Ab) will be conducted to this person, and if the result of RTK (Ab) is negative, no symptoms developed, the release order will be issued at Day 14 (Annex 17).

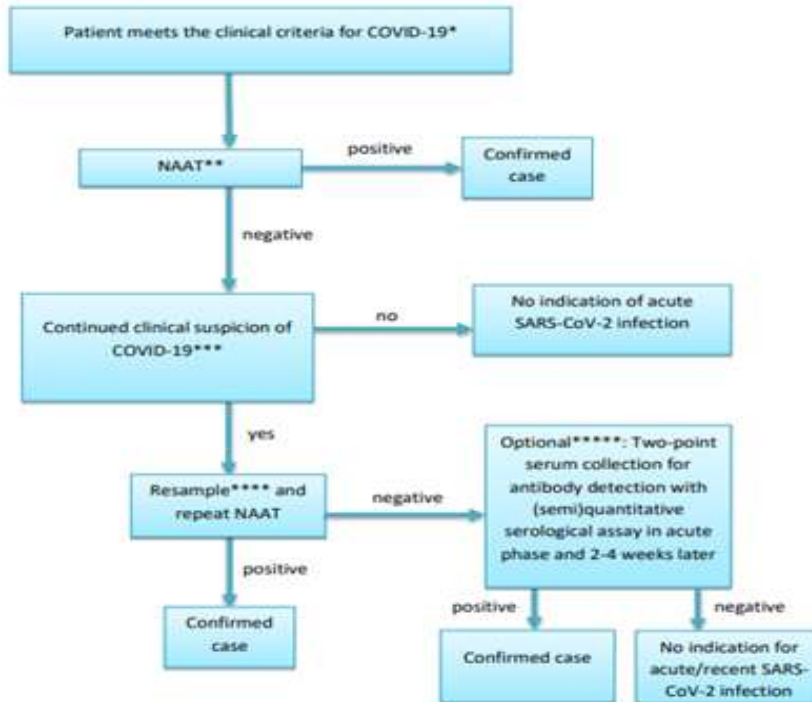
The WHO Interim Guide on diagnostic testing for SARS-CoV-2 highlighted algorithm for the detection of SARS-CoV-2 infection in individuals with clinical suspicion for COVID-19, as below:¹⁴

Serum specimens

If negative NAAT results are obtained from a patient in whom SARS-CoV-2 infection is strongly suspected, a paired serum specimen could be collected. One specimen taken in the acute phase and one in the convalescent phase 2-4 weeks later can be used to look for seroconversion or a rise in antibody titres. These two samples can be used retrospectively to determine whether the individual has had COVID-19, especially when the infection could not be detected using NAAT.

See Figure 1 for the diagnostic algorithm for cases requiring clinical care and are suspected to have COVID-19.

Figure 1: Diagnostic flow diagram for the detection of acute SARS-CoV-2 infection in individuals with clinical suspicion for COVID-19



* Clinical management of COVID-19 (Interim Guidance), World Health Organization [99].

** If antigen detection would be incorporated into the testing algorithm, how this needs to be done depends on the sensitivity and specificity of the antigen test and on the prevalence of SARS-CoV-2 infection in the intended testing population. For more information see section below on "Rapid diagnostic tests based on antigen detection" and the specific guidance: [Interim guidance on antigen detection in the diagnosis of SARS-CoV-2 infection using rapid serological tests](#) [12].

*** Continued clinical suspicion can, for example, be the absence of another obvious etiology, the presence of an epidemiological link, or suggestive clinical findings (e.g. typical radiological signs).

F. TESTING OF SEVERE ACUTE RESPIRATORY INFECTION (SARI)

The case definition of SARI according to the MOH guideline is available as in Appendix 2.

- Hospital Setting

European CDC recommends that throughout the pandemic all individuals presenting to healthcare facilities with SARI are tested for both SARS-CoV-2 and influenza during the influenza season. Testing for other respiratory viruses, such as RSV, should continue as before, taking the local testing capacities and clinical judgement into consideration. Early identification of other pathogens (e.g. influenza or Legionella) in risk groups should inform clinical treatment, as well as infection prevention and control (IPC) measures and public health action that might be different to those for COVID-19. The use of multiplex molecular testing systems should be considered in these settings, if available.²

SUMMARY/CONCLUSION

There was limited evidence retrieved on testing strategies for general population and targeted population, with varying strategies used in different context. The evidence demonstrated that testing strategies should be flexible and rapidly adaptable to change, depending on the local epidemiology, transmission, population dynamics and resources. Objective for testing in order to control transmission has to be identified, namely; reliably monitor SARS-CoV-2 transmission rates

and severity; mitigate the impact of COVID-19 in healthcare and social care settings; detect clusters or outbreaks in specific settings and maintain sustained control of COVID-19 once achieved. Depending on the epidemiological situation, more than one strategy may be employed simultaneously to meet the objectives.

In terms of testing of pre-admission cases for COVID-19, evidence demonstrated low positive COVID-19 rate among asymptomatic patients who come to the hospital before admission (pre admission) tested for COVID-19 (range between 0.03% to 0.49% in elective patients for surgery). However, higher percentage were seen in pre-delivery in obstetric department with screening of asymptomatic patient as it showed that 15% cases were positive of COVID-19, vary with study location. Universal PPE use, hand hygiene and the practice of personal preventive measures should be the major component in decreasing the spread of COVID-19 in the hospital setting. Universal screening of obstetric patients is also not yet indicated as there is no proven vertical transmission, teratogenicity or effective treatment for COVID-19.

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OVERVIEW OF TESTING GUIDANCE TO ACHIEVE OBJECTIVE OF TESTING (ACCORDING TO EUROPE CDC)

Objective	Epidemiological situation	Population to test
Control transmission	All situations	<ul style="list-style-type: none"> All possible cases*. All high-risk exposure (close) contacts of confirmed cases, irrespective of symptoms**. <p><i>If resources allow,</i></p> <ul style="list-style-type: none"> Re-test high-risk exposure (close) contacts that test negative and remain asymptomatic**.
	Widespread community transmission	<ul style="list-style-type: none"> All population of a country/region/municipality/neighbourhood/community. <p><i>Possible approaches include household testing, inviting everyone to present for testing and facilitating access to voluntary testing.</i></p> <ul style="list-style-type: none"> All high-risk exposure (close) contacts of confirmed cases, irrespective of symptoms**. <p><i>If resources allow,</i></p> <ul style="list-style-type: none"> Re-test high-risk exposure (close) contacts that test negative and remain asymptomatic**.
Monitor incidence and trends, and assess severity over time	No local transmission	<ul style="list-style-type: none"> ILI/ARI (sentinel primary care) SARI (hospital)
	Sporadic cases, cluster of cases or community transmission	<ul style="list-style-type: none"> All possible cases* (comprehensive surveillance) ILI/ARI (sentinel primary care) SARI (hospital) All high-risk exposure (close) contacts irrespective of symptoms, depending on testing capacities**. <p><i>If testing capacity is exceeded,</i></p> <ul style="list-style-type: none"> A systematic sample of all detected possible cases and their symptomatic contacts**.
Mitigate the impact of COVID-19 in healthcare and social-care settings	No local transmission	<p>All possible cases* among staff, patients/residents and visitors. This implies that the presence of signs and symptoms among patients/residents is verified upon admission and during the first 14 days of hospitalisation/residence.</p>
	Sporadic cases, clusters of cases or community transmission	<ul style="list-style-type: none"> All staff periodically, irrespective of symptoms. All patients/residents, upon or just prior to admission; All possible cases*. All contacts (high-risk and low-risk) of confirmed cases in all health-and social-care settings**. <ul style="list-style-type: none"> If a case is detected in an LTCF or in certain hospitals or hospital wards hosting patients at high risk of severe COVID-19, all staff and residents of the LTCF and hospital or hospital ward should be tested, irrespective of symptoms. <p><i>If resources allow and it is logistically feasible,</i></p> <ul style="list-style-type: none"> All patients/residents that test negative upon admission to the hospital should have a follow-up test on Day 3–5. This should be in combination with daily checks for the presence of COVID-19 signs and symptoms during the first 14 days of hospitalisation.
Identify clusters or outbreaks in specific settings	No local transmission or sporadic cases, clusters of cases	<ul style="list-style-type: none"> All possible cases*. All high-risk exposure (close) contacts, irrespective of symptoms**. All contacts (high-risk and low-risk) exposed in specific settings or events known to cause the virus to spread, such as choir performances, weddings, funerals, bars, other social events**. Wider testing in prisons, detention and reception centres and certain occupational settings where a case has been identified.
	Community transmission	<ul style="list-style-type: none"> All possible cases*. All high-risk exposure (close) contacts, irrespective of symptoms**. All contacts (high-risk and low-risk) exposed in specific settings or events known to cause the virus to spread, such as choir performances, weddings, funerals, bars, other social events**. Wider testing in prisons, detention and reception centres and certain occupational settings where a case has been identified. Incoming prisoners or migrants at detention centres, and prisoners or migrants returning to a facility following a hospital stay or medical procedure. <p><i>This objective implies that monitoring systems are in place to detect symptoms of possible COVID-19 infection in settings where people congregate.</i></p> <p><i>If resources allow:</i></p> <ul style="list-style-type: none"> Re-test high-risk exposure (close) contacts that test negative and remain asymptomatic**.
Prevent (re-)introduction into regions/countries with sustained control of the virus.	No locally acquired cases in community	<ul style="list-style-type: none"> Testing individuals coming from other areas that have not yet achieved sustained control of the virus on arrival, plus quarantine. Re-test at Day 14 to lift quarantine with two negative tests

* according to case definition [2]; LTCF: long-term care facility; ILI: influenza-like illness; ARI: acute respiratory infection; SARI: severe acute respiratory infection;

** Please see section 'Testing of contacts' for details on testing of contact persons.

KEY MESSAGES ON TESTING OF COVID-19

(ACCORDING TO EUROPE CDC)

- All people with COVID-19 symptoms should be tested as soon as possible after symptom onset. This requires easy access to testing for all, including non-residents. Test turnaround time should be minimised, people testing positive should isolate and timely contact tracing should be carried out, ensuring that all close contacts are tested, irrespective of symptoms. All patients with acute respiratory symptoms in hospitals and other healthcare settings, and all specimens from sentinel primary care surveillance should be tested for both SARS-CoV-2 and influenza during the influenza season to monitor incidence and trends over time.
- Healthcare and social care settings require intensive testing when there is documented community transmission. Periodic and comprehensive testing of all staff and residents/patients is recommended to prevent nosocomial transmission. Furthermore, all patients/residents should be tested upon or immediately prior to admission.
- Clusters or outbreaks may occur in certain settings, such as workplaces, educational facilities, prisons, and migrant detention centres. Testing policies and systems should be in place for rapid detection and control to protect the relevant populations in these settings and to protect the community from amplified transmission.
- Countries experiencing high SARS-CoV-2 transmission in a local community should consider testing the whole population of the affected area. This would enable identification of infectious COVID-19 cases and allow for their prompt isolation to interrupt chains of transmission.
- Depending on the epidemiological situation, size and population density of the affected area, such an approach could be less disruptive for society than having to introduce and ensure compliance with more stringent public health measures.
- To prevent re-introduction, countries or sub-national areas that have achieved sustained control of SARSCoV-2 circulation should, in addition to quarantine measures, consider targeted testing and follow-up of individuals coming from other areas within the same country, or from other countries that have not yet achieved sustained control of the virus.

CASE DEFINITION**SEVERE ACUTE RESPIRATORY INFECTION (SARI)⁵**

According to Malaysia Guidelines Infection Control And Clinical Management Of Severe Acute Respiratory Infections (SARI) / Pneumonia Tro Covid-19: (updated 5 December 2020)

An acute respiratory infection with:

- History of fever or measured fever of $\geq 38^{\circ}\text{C}$
- and cough
- with onset within the last 10 days
- requires hospitalization.

* Consider COVID-19 as a possible aetiology of patients with SARI under certain conditions (history of travelling, mass gatherings, religious gatherings etc.)

SUSPECTED CASE OF SARS-CoV-2 INFECTION

(three options, A through C)¹⁵

A. A person who meets the clinical **AND** epidemiological criteria:

Clinical criteria:

1. Acute onset of fever AND cough;

OR

2. Acute onset of ANY THREE OR MORE of the following signs or symptoms: fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnoea, anorexia/nausea/vomiting, diarrhoea, altered mental status.

AND

Epidemiological criteria:

1. Residing or working in a setting with high risk of transmission of the virus: for example, closed residential settings and humanitarian settings, such as camp and camp-like settings for displaced persons, any time within the 14 days before symptom onset;

OR

2. Residing in or travel to an area with community transmission anytime within the 14 days before symptom onset;

OR

3. Working in a health setting, including within health facilities and within households, anytime within the 14 days before symptom onset.

B. A patient with severe acute respiratory illness (SARI: acute respiratory infection with history of fever or measured fever $\geq 38^{\circ}\text{C}$, and cough; with onset within the last 10 days; and who requires hospitalisation).

C. An asymptomatic person not meeting epidemiologic criteria with a positive SARS-CoV-2 antigen-detecting rapid diagnostic test (Ag-RDT).

PROBABLE CASE OF SARS-CoV-2 INFECTION

(four options, A through D)

- A. A patient who meets clinical criteria above **AND** is a contact of probable or confirmed case or is linked to a COVID-19 cluster.
- B. A suspected case (described above) with chest imaging showing findings suggestive of COVID-19 disease.
- C. A person with recent onset of anosmia (loss of smell) or ageusia (loss of taste) in the absence of any other identified cause.
- D. Death, not otherwise explained, in an adult with respiratory distress preceding death **AND** who was a contact of a probable or confirmed case or linked to a COVID-19 cluster.

CONFIRMED CASE OF SARS-CoV-2 INFECTION

(three options, A through C)

- A. A person with positive Nucleic Acid Amplification Test (NAAT)
- B. A person with a positive SARS-CoV-2 Ag-RDT **AND** meeting either the probable case definition or suspected criteria A OR B
- C. An asymptomatic person with a positive SARS-CoV-2 Ag-RDT **AND** who is a contact of a probable or confirmed case.

CONTACT

A contact is a person who has experienced any one of the following exposures during the **2 days before and the 14 days after the onset** of symptoms of a probable or confirmed case:

1. face-to-face contact with a probable or confirmed case within 1 meter and for at least 15 minutes;
2. direct physical contact with a probable or confirmed case;
3. direct care for a patient with probable or confirmed COVID-19 disease without the use of recommended personal protective equipment;
4. other situations as indicated by local risk assessments.

Note: for confirmed asymptomatic cases, the period of contact is measured as the 2 days before through the 14 days after the date on which the sample that led to confirmation was taken.

Based on available evidence up to 18th Jan 2021

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Disclaimer: This rapid assessment was prepared to provide urgent evidence-based input during COVID-19 pandemic. The report is prepared based on information available at the time of research and a limited literature. It is not a definitive statement on the safety, effectiveness or cost effectiveness of the health technology covered. Additionally, other relevant scientific findings may have been reported since completion of this report.

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