

Annexure A

Further background and rationale for the expanded testing criteria

PCR testing for coronavirus is a new test but follows familiar testing procedures and therefore could be done on several machines which the NHLS already had in place. Hence when the COVID-19 epidemic reached South Africa the NHLS could rapidly respond to the need for testing and shift their operational procedures to perform large volumes of PCR testing. However, a high global demand for PCR test reagents resulted in the NHLS having great difficulty in procuring them. This test reagent shortage then led to a marked reduction in PCR testing capacity at the NHLS, compared to what they had predicted they would be able to provide. A large backlog in testing then built up and the PCR testing turn-around time increased considerably. The Health Department consequently had to temporarily limit which groups of people could be tested to reduce the demand on the NHLS laboratories. To this end PCR testing criteria were developed and implemented since the beginning of June 2020. These criteria are listed below.

Current PCR Testing Criteria

1. People with coronavirus symptoms admitted to hospital
2. Health Care Workers who develop coronavirus symptoms
3. Health Care Workers who are in quarantine and asymptomatic at day 8 but need to return to work
4. People with symptoms of coronavirus in clusters but in low prevalence discrete small areas (Rural Areas) where containment is still possible
5. People at high risk of severe disease (those aged >55 years with coronavirus symptoms; those of any age with coronavirus symptoms and with one or more of the co-morbidities; people in care homes and old age home with coronavirus symptoms) in high prevalence areas such as the Cape Metro.

Capacity to expand PCR Testing Criteria

The coronavirus epidemic in most parts of the Western Cape province has however now entered a slowly declining phase. This decline in infections, together with an improved and importantly sustainable supply of test reagents to laboratories, has resulted in increased laboratory PCR testing capacity. It is therefore prudent to use this increased testing capacity for those groups of patients who can most benefit from testing. Over the past three weeks the numbers of patients receiving a PCR test has steadily dropped (in tandem with the COVID-19 epidemic decline) and the turn-around time for testing has similarly decreased. The NHLS laboratories PCR testing capacity has increased to the point where they could comfortably manage 25,000 – 30,000 tests per week, while we are currently performing 12,000 tests per week. Unfortunately, the ability to perform swabbing will probably decrease as core health services are incrementally re-escalated, and this will be compounded by logistical difficulties encountered when the temporary structures erected as waiting and swabbing areas are dismantled. This potential difficulty in swabbing, together with the possible increase in turn-around time, was considered during discussions around expanding the PCR testing criteria.

Proposed Principles to follow when expanding PCR Testing Criteria

Implementing a test criterion only if there is a clear and explicit benefit from adding that criterion was proposed as an approach to follow, rather than simply expanding testing because greater test capacity is available. To operationalise this a Testing Advisory Group was established composed of virologists, infectious disease specialists, family physicians, public health specialists, occupational health specialists and managers. That group formulated the following set of 6 principles for deciding on whether to include any proposed test criterion, or not:

1. Each criterion should have a clear rationale and convey individual and/or group benefit
2. The additional number of tests that will flow from the criterion should be estimated
3. Adequacy of laboratory testing capacity to absorb the tests flowing from the test criterion should be assessed
4. Effect on numbers and logistics of swabbing should be determined
5. Effect on turn-around time should be considered
6. Apply a staggered approach to expanding testing and assess the effect of implementing some criteria before adding more criteria

These criteria were then applied by the Testing Advisory Group to determine if various suggested groups of people should be added to the current PCR testing criteria, or not. The outcome of those discussions are shown in Table 1 below (criteria that are recommended to be adopted) and Table 2 (criteria that are not recommended to be adopted at the present time).

Recommendations based on Applying Principles to proposed Testing Criteria

The Testing Advisory Group considered and discussed several proposed criteria for expanded testing. These are shown in the two tables below with Table 1 listing the criteria which are recommended to be added to the testing criteria list. Table 2 then contains criteria which are not recommended to be added to the testing criteria list at present, but which could be re-considered after the effect of adding the criteria in Table 1 on PCR testing and swabbing capacity has been assessed.

Table 1: The table below lists test criteria which were proposed and which were accepted by the Testing Advisory Group and are **recommended** to be implemented.

No .	Testing Criterion	Rationale or Benefit	Estimated Numbers	Logistical Considerations	Effect on Test Turn-around Time	Effect on Swabbing
1	Pre-operative coronavirus asymptomatic patients awaiting surgery	<p>Reduced morbidity/mortality if operate on after recovered from infection</p> <p>Increased theatre time due to lack of need for aerosol settling time for test negatives</p> <p>Decreased positive patients admitted to hospital</p>	1200 per week	<p>Swabbing to be done in hospital OPD as part of pre-op work-up</p> <p>Should not delay emergency and urgent surgery</p> <p>Even though PCR test has false negative of 30%, based on the current point prevalence of asymptomatic active cases, the probability of a test negative having COVID-19 is very low (estimate 1: 10,000)</p>	Moderate	Moderate effect on swabbing at Hospital OPDs
2	Natural deaths occurring at home who had coronavirus symptoms	Improved ability to track the full extent of the epidemic via deaths	50 -100 per week	<p>Transport of deceased by undertaker to a health facility for swabbing would need to be arranged with undertakers, CCHCs and Hospitals.</p> <p>Fast-track swabbing in dignified manner at facilities would need to be implemented</p>	Minimal	Minimal
3	"Other Public sector essential workers" (SAPS, prisons, firefighters, municipal utilities,	Prevents prolonged sick leave (and repeated sick leave for the same people) for those who have coronavirus symptoms, but test negative.	1000 - 1100 per week	Swabbing to be done at mix of Workplaces (if they have access to health staff); private (if on medical aid) and public health facilities	Minimal as most on Medical aid	Minimal as most on Medical aid

	Eskom) who have coronavirus symptoms					
4	Offenders incarcerated in prisons who have coronavirus symptoms	To assist in identifying and containing potential outbreaks in confined conditions	100 -120 per week	Swabbing to be done by health staff at prisons	Minimal	None
5	Learners and staff attending school who have coronavirus symptoms	To assist in identifying and containing potential outbreaks in semi-confined conditions (schools): To track the effect of infections at schools on the overall population epidemic	350 - 450 per week	Swabbing to be done at public health facilities and private sector facilities	Minimal	Minimal
6	Workers at workplaces who have coronavirus symptoms	To prevent prolonged sick leave (and repeated sick leave) for those who have symptoms but test negative To assist in identifying and containing potential outbreaks at workplaces To track the effect of infections at workplaces on the overall population epidemic	2800 - 3200 per week	Swabbing to be done at mix of private (if on medical aid) and public health facilities	Moderate	Moderate

If after implementing the above criteria there is still sufficient swabbing and PCR testing capacity available to include further categories of patients in the testing criteria, then the addition of other categories will be considered.

Table 2: The table below lists test criteria which were considered but **NOT recommended** by the Testing Advisory Group at this stage, but which could be re-visited at a later stage.

No .	Testing Criterion	Rationale or Benefit	Estimated Numbers	Logistical Considerations	Effect on Test Turn-around Time	Effect on Swabbing
1	Patients presenting at all health facilities in the Metro who have coronavirus symptoms but are below 55 years of age and do not have co-morbidities	<p>Improved containment of the epidemic via active isolation and quarantining</p> <p>Improved ability to track the epidemic in the population</p> <p>Improved ability of patient to make decisions around their self-care and isolation</p>	5000 - 5400 per week	Swabbing to be done at public health facilities by staff who would be returning to core activities in a phased manner	Considerable	Considerable
2	Coronavirus Asymptomatic patients admitted to hospital	Improved ability to isolate in-patients	11000 - 11500 per week	<p>Unclear if emergency staff would do the swabbing or if some other staff (ward staff) would do the swabbing.</p> <p>Unclear how isolation logistics would be improved since patients would have to be placed in a general ward (i.e. not PUI ward and not COVID ward) while awaiting test results, which could be 2 - 3 days or more, noting the TAT. Might be more useful to simply apply universal IPC precautions with all patients.</p>	Large	Large

Although the above criteria are not recommended, it is noted that in a few special cases the clinician managing the patient might have to apply clinical discretion and test a specific patient, even if that patient does not in general meet the testing criteria.