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CENTER FOR INDONESIA'S STRATEGIC DEVELOPMENT INITIATIVES

TEST CAPACITY AS A PREREQUISITE FOR NEW NORMAL

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New Normal: are we ready?

New Normal or as the government calls it, the Adaptation of New Habits, becomes the government's narrative in lifting social restrictions. In other words, the government allows people to resume their activities amid a significant increase in COVID-19 cases. In the past week alone, the average daily case has reached 1,500 cases. In just a matter of days, the number of cases in Indonesia will surpass the first epicenter, China. Although the Government of Indonesia feels ready to reopen again the economic activity, health indicators show the opposite. Epidemiological, health system, and surveillance indicators show that there are no provinces that meet all WHO criteria to reopen the economy (1).

Test as the frontline for fighting against COVID-19

The notion that health workers are the frontline in handling COVID-19 is not entirely wrong. However, an adequate testing capacity should be the Government's leading strategy to reduce the rate of transmission of the SARS-CoV-2 virus. Several countries have proven successfully breaking the chain of transmission of COVID-19 through massive test strategy. Massive testing may isolate cases and prevent the spread of the epidemic immediately. Adequate test capacity, supported by sound technology and innovative test kits with high sensitivity and specificity, may have a good impact on the economy. The government may lift social restrictions or lockdowns only if a holistic test, trace and isolation strategy is in place. However, the COVID-19 testing strategy is highly dependent on the availability of access, speed and accuracy of tests (sensitivity and specificity) which often become the main obstacles.

There are several types of examinations for COVID-19 circulated in Indonesia, namely:

1. Molecular tests
RT-PCR (Reverse Transcription Polymerase Chain Reaction) became the gold standard of COVID-19 examination using biomolecular technology to detect the presence of viruses through nasopharyngeal and oropharyngeal specimens. This type of test requires a fairly high level of laboratory security (at least Biosafety Level 2) and skilled personnel.

2. Antibody serological tests
This type of test is most commonly found on the market in the form of rapid test kits. Serological testing is not a diagnostic tool, although we can use this test to see current or previous infections based on antibodies found in the patient's blood. Because it is not as sensitive as PCR, false negative can be an issue because IgM antibodies generally form after 7-10 days of infection; while IgG antibodies take at least 4 weeks to appear. In addition, false positives can also occur due to the possibility of cross reactivity with other corona viruses. A study in the UK even indicated a decrease in antibody levels in positive patients over time (7). Dalam revisi ke-5 Pedoman Pencegahan dan Pengendalian COVID-19, Kementerian Kesehatan RI tidak lagi merekomendasikan penggunaan *rapid test* antibodi untuk diagnosis COVID-19.

3. Antigen swab test
This test detects viral proteins in the specimen from the results of nasopharyngeal swabs. This method is more effective at the onset of symptoms when the virus is actively reproducing. Antigen tests have a sensitivity of between 60-80%.

We have not tested enough

Indonesia's PCR test capacity has indeed increased significantly. At the beginning of the outbreak, Indonesia's test capacity was still below 100 per day. To date, the average test capacity has reached 13,000 per day, with an accumulative number of 749,626 people tested. This number is equivalent to a test ratio of 2.80 per 1,000 population (as of July 22, 2020). DKI Jakarta Province accounts for half of this number. Even so, the Indonesian government must not be complacent, let alone feel safe, since Indonesia's testing capacity still does not meet the WHO minimum standards. With a population of 270 million, Indonesia must at least carry out tests to 270,000 people per week or 40,000 people per day to reach the WHO standard, which is 1 test every 1,000 people per week.

Inequality in access to COVID-19 test also occurs in various provinces. Figure 1 shows that during the period of July 12-18, 2020, only DKI Jakarta, DI Yogyakarta, West Sumatera, South Sulawesi and Bali Province met the number of PCR tests according to WHO standards. While East Java, which has a rapid surge in cases and is a new epicenter in Indonesia with a cumulative number of cases that has surpassed Jakarta, has a positivity rate of around 20% with a test number of only 0.4 per 1,000 population per week.

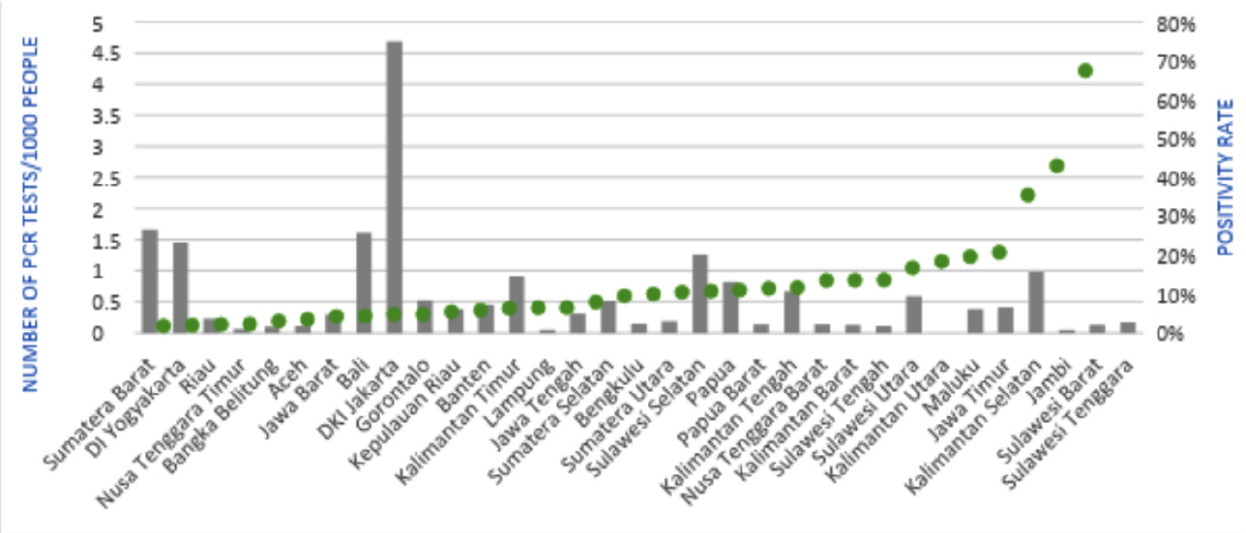

Figure 1. Comparison of the number of PCR tests per 1000 population and the positivity rate by province (Data source: Ministry of Health, 2020; data on the number of PCR tests / 1000 people for the period July 12-18, 2020; positivity rate data as of June 29, 2020)

In addition to the number of PCR tests per week, one important indicator of easing the Large-Scale Social Restriction (PSBB) and opening of economic activity is the positivity rate. The positivity rate is the proportion of positive tests of the total number of people tested. As a prerequisite for the opening of the economy during a pandemic, WHO requires a positivity rate of under 5% for 2 consecutive weeks. Based on the WHO Situation Report of Indonesia on July 15, 2020, the Special Province of Yogyakarta and Banten had positivity rates of under 5 percent for 2 weeks in a row. On a side note, a positive ratio of above five percent indicates that there is not enough test being done because it only focuses on testing people who are symptomatic and have a high likelihood of being positive. While studies (2) in several countries show that 40-45% of COVID-19 cases are asymptomatic or with mild symptoms. Without testing, there would not be

cases found. The intention to not conduct a massive test in an area might be a strategy to keep the positive cases low in that area.

A sufficient number of tests will generally correlate with a positive ratio of under five percent in a population. We can reflect at South Korea which conducts massive tests and is able to reach 27 tests per 1,000 population and therefore has a positivity rate of only 1%. Figure 1 shows that the 3 provinces with the highest positivity rate (Sulawesi Tenggara, Sulawesi Barat and Jambi) have a very low number of tests. This appears to correlate with the limited number of laboratory facilities in the province, as shown in Figure 2.

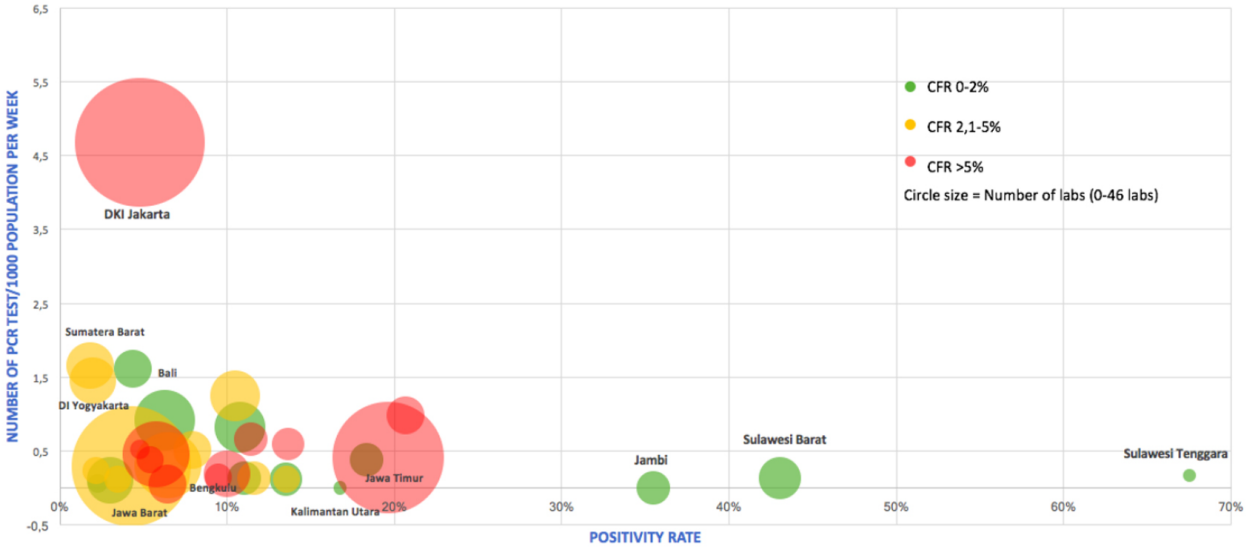

Figure 2. Graph of PCR test capacity, positivity rate, and CFR by province (Data source: Ministry of Health of Indonesia and Kawal COVID-19, 2020)

Figure 2 suggests how inequality in access to COVID-19 testing in various provinces in Indonesia has an impact on the positivity rate and case fatality ratio (CFR). Provinces with high positivity rate and low number of PCR tests incline to dominate provinces with CFR below 2% (green circle). This also shows an indication that suspected death cases in the province might not have been confirmed by PCR test.

The fact that COVID-19 is a new disease, there is a limited knowledge about it. However, the limited capacity of government of Indonesia in dealing with COVID-19 is the result of years of poorly functioning of health system and policies in the country. Indonesia does not apply basic knowledge of pandemic response from previous outbreaks experience just because the health system is simply not in place.

1. Test policy in Indonesia

At the beginning of the emergence of COVID-19 cases in Indonesia, the Health Research and Development Agency, the Ministry of Health (MoH) of Indonesia, imposed a policy to centralize testing as a way to maintain the quality and confidentiality of data. This slowed down the containment and preventive measures of the rapid infection. At the same time, data transparency is a big issue because the MoH also controlled the in and out of the information. Further, as an institution that is

entitled the right to issue operational licenses of COVID-19 test to laboratory facilities, the MoH did not open the access to all able public and private laboratories from the beginning. Unlike other countries, at the beginning of the pandemic, Germany immediately opened testing access to all laboratories to support the needs.

2. Availability of tools, laboratories and human resources

In March 2020, the MoH assigned 12 laboratories to test COVID-19. As of July 22, 2020, the National Disaster Management Agency (BNPB) as the Coordinator of the Task Force for the Acceleration of Responding to COVID-19 issued a list of 320 laboratories that may conduct COVID-19 testing, including RT-PCR (158); Molecular Rapid Test (TCM) (138); or both (24). Given the large number of laboratories, Indonesia can only carry out testing for an average of 22,967 specimens belonging to 13,139 people per day within the period of July 16-22, 2020. The fact that the number of samples tested is almost double the number of people tested, indicates the test for one patient may go up to 2 times. In fact, national newspaper Kompas reported there was a case when the same patient had to go through 24 PCR tests to ensure negative test results. Out of these laboratories, 46 laboratories – mostly are privately-owned – are off on Saturdays, Sundays and government holidays; with working hours of only 6 hours a day (3).

3. The delay of testing results

Limited capacity of the laboratory also causes delayed notification of patient test results. In some areas, the testing process may last for more than 7 days. At the beginning of the pandemic the results even required a minimum of 14 days to be finally out. The lag between the collection of specimens and the notification of test results causes the data announced by the government might not truly describe the epidemiological situation and the phase of this infection in real-time. This leads further to delayed treatment and necessary measures. Consequently, the cases of COVID-19 suspected death (suspect and probable; previously called People under Supervision [ODP] and Patients in Monitoring [PDP]) in Indonesia are significantly higher than positive death cases.

4. Limited test criteria

Studies in several countries show that asymptomatic cases account for 40-45% of the total cases (3). If the government only prioritizes testing on symptomatic people, transmission will continue to occur mainly by those without and mild symptoms. Dating back, initially the government only gave access to testing for people with predetermined symptoms. Then the government promised to pay for free PCR test for people with positive COVID-19 status. With the rolling of categorization for COVID-19 suspects and with increasing PCR capacity, the government provides free testing access to all people identified by health workers as suspect, probable and positive cases as stipulated in Minister of Health Decree Number HK.01.07/MENKES /238/2020. In some provinces, local governments target sellers at traditional markets and people living in dense and poor settlements. The government seems willing to make progressive efforts in testing. However, it is unfortunate that health workers who stand at the forefront are not being prioritized for regular testing.

5. Procurement mechanism

The government has simplified procurement procedures related to certification, production, and distribution of medical devices as well as personal protective equipment – produced locally and imported – to accelerate the fight against COVID-19 in Indonesia. The procedure is regulated in LKPP Regulation No. 13/2018, Presidential Instruction No. 4/2020 and PMK No. 7 of 2020 which state that imported medical devices no longer require a long authorization. Since March 30 2020, imports of donated and commercial medical devices only require a recommendation from the Head of the National Task Force of COVID-19. However, the slow process of bureaucracy led to material and medical equipment being held for months at the Customs Office. In some cases there was the closure of several laboratories in Jakarta due to the stock out of reagents.

The limitations of PCR also triggered the public to look for alternative test. Since March, there has been hundreds of the antibody rapid test kits imported from various countries. Unfortunately, policies on the use and distribution of antibody rapid tests in Indonesia were not available on time. Recommendations for the use of new equipment were issued several months later by the MoH and a team of health experts in the National Task Force. Meanwhile, there has been found in some areas, some health devices and PPE do not comply with specifications and standards.

Increasing testing capacity is compulsory

With a daily number of tests of 13,000 a day, Indonesia must catch up and increase the PCR testing capacity to 40,000 per day. Several approaches are available:

Pooled testing (group testing)

Pooled testing or group testing, also known as 'Dorfman Testing', was discovered in 1943 and was used to detect syphilis and AIDS. Pooled testing is an approach by combining 6-10 samples in one test with one reagent. However, there are some notes regarding pooled testing. Testing with this method will be more effective in populations with low infection rates (e.g. <5%) and in a homogeneous population, for example one office or one household (household pooled testing). If the test results are positive, then a retest is needed for each sample to find out which one is positive. False negatives may occur due to the dilution of samples (4).

Although WHO has not yet issued recommendations regarding the use of pooled testing methods to detect the SARS-CoV-2 virus, this approach has been applied in several countries, such as China and Germany. America also begins to consider this method. In West Sumatra, this approach has already been applied to the suspect and probable groups. In Fact, West Sumatra is the second province after DKI Jakarta with the highest number of tests in Indonesia, as many as 1.6 per 1,000 people per week. In addition to being efficient, this approach can help local governments to decide when to apply or lift social restriction/lockdown in an area immediately. This method can be a more cost-effective and faster alternative for countries with limited capacity. The pooled testing mechanism must still be accompanied by a strong contact tracing and isolation strategy.

Increase the capacity of Molecular Rapid Testing (GeneXpert)

The need for rapid increased capacity globally drives the use of molecular rapid testing for SARS-CoV-2 as an alternative. Indonesia alone has 998 GeneXpert machines which were originally intended for Tuberculosis (TB). Based on the MoH data as of July 22, 2020, there are 138 TCM used for COVID-19 examination. In a day the laboratory can conduct test for 334 people. This means that one laboratory only tests 2-3 people per day. In addition to increasing the capacity of laboratories, skilled workers and working hours, Indonesia needs to increase the number of tools and reagents to increase the number of test significantly.

Differences between RT-PCR and TCM:

Variable	RT-PCR	GenExpert
Sensitivity	Roche: 100% Abbott: 100%	100%
Specificity	Roche: 100% Abbott: 100%	100%
Extraction	Yes	No
Transcription	Yes	Yes
Processing time	4-6 hours	45-60 minutes
Cost/sample (IDR)	Rp 1,2-1,4 million	Rp 70.000-280.000 /reagent
Number of samples/day	150-200	256 (for 16 slot machine)
Number of active labs	158	138
Additional of 10.000 test/day	- 67 machines (@1,2M) = ±80,4 M - Reagent (@1 million) = Rp 10 billion	- 78 (16 slot) machines = Rp ±70 billion - Cartridge (@Rp 280.000) = Rp 2,8 billion

To meet the testing target, we must increase the number of tests to 40,000 in one day. For every additional 10,000 tests per day, Indonesia requires a minimum of Rp 80 billion for the procurement of PCR equipment and Rp 10 billion for reagents per day. Another option, Indonesia requires Rp 70 billion for GeneXpert and Rp 2.8 billion for cartridge needs per day. When compared to PCR, GeneXpert has several advantages. Aside of being cheaper, it can also conduct tests faster with lower operational costs. GeneXpert also minimizes the risk of contamination because it uses a closed system (biosafety level 2A). When the pandemic is over, this tool can still be used for examining TB, Hepatitis C, Hepatitis B, HIV and Dengue Fever. The challenge is the limitations of GeneXpert tools and cartridges produced in America.

A more accountable procurement process

With the soaring needs for innovative diagnostic tools, Personal Protective Equipment (PPE) and medicines, the Ministry of Health and the Government Goods and Services Procurement Agency (LKPP) should work together for the acceleration and simplification of procurement through an electronic categorization system. This electronic catalog can be an instrument of price control that is transparent and accountable to avoid hoarding or monopoly.

Discharge COVID-19 patient criteria

In WHO's initial recommendations, health workers can discharge COVID-19 patients only when twice of the patient's PCR results show negative results within 24 hours. However, due to the limited number of PCRs in many countries and the latest scientific evidence, WHO issued the latest recommendations as of June 17, 2020. In its latest recommendations, WHO states that patients who have positive COVID-19 status for 10 days after the first symptoms appear/are confirmed positive (plus at least 3 days without symptoms), can be discharged from isolation without PCR follow-up test (5). This has been done in several countries including Singapore. That way the PCR test can reach wider groups. The Ministry of Health has also recently included the criteria for releasing these patients into revision 5 of the Minister of Health Decree number HK.01.07/MENKES /238/2020. The revision stated asymptomatic confirmed cases or with mild symptoms and moderate symptoms were not required for follow-up PCR test; except cases with severe critical symptoms being treated at a hospital and PCR tests are available. This revision emphasizes the use of PCR as an initial diagnostic tool and no longer for further negative confirmation.

Stop using rapid antibody tests for diagnostics and expand test criteria

The biggest question now arises as to who is most entitled to get free COVID-19 test when PCR test capacity is still limited. The absence of a screening mechanism also makes the government use antibody rapid tests as a primary screening tool given the cheaper price and fast results. Reactive antibody test results will be referred for PCR testing. But given the high tendency of false negatives, those rapid tests will not only provide an incorrect diagnosis and a false picture of the spread of infection, but will also delay containment and preventive measures. The Provincial Government of DKI Jakarta has replaced the role of antibody rapid tests with a self-assessment screening called the COVID Likelihood Meter (CLM) (6).

Another option is the antigen swab test. The antibody rapid test and the antigen swab test both have high variability. However, the antigen swab test can be relied upon to catch cases faster based on how it works. The advantages of both tests are that they are cheap, fast, do not require expensive equipment, and can be done in health care facilities yet do not require complicated training. In situations of limited resources, antigen swab testing can be an alternative screening where patients with positive results must be isolated and patients with negative results must be confirmed by PCR tests.

Community transmission indicates the need for massive and random tests at the community level. But with limited resources, the government should prioritize the tests for high-risk groups with comorbidities and immunocompromised. As well, those who are vulnerable to infection, living in densely populated areas, groups with high contact exposure, marginalized groups that are disproportionally affected, and high-risk health workers.

COVID-19 test must be affordable for all

In accordance with the mandate of Regulation Number 4/1984 concerning Pandemic, Regulation Number 36/2009 on Health, also the regulation in lieu of law or Perppu Number 1/2020 concerning pandemic financing, financing of outbreaks is fully borne by the government. The government should be able to reallocate the state budget to increase the capacity of PCR tests, not to procure anymore antibody rapid tests,

especially not yet to tourism, video contests and other activities that are not relevant to COVID-19 emergency measures. Considering the commercialization of the tests, it is important that the government regulates and sets price cap to ensure affordable access to tests. Other countries, such as China, South Korea and Singapore have made PCR tests free of charge and available to all citizens. At a global level, stakeholders must also allocate more resources focusing on, not only finding vaccines, but also creating faster and more affordable innovative test kits.

To break the chain of transmission, affordable access to test for everyone is mandatory. Increase in test capacity must go hand in hand with improved surveillance systems, contact tracing, and isolation measures. A well-functioning system requires health workers to track, carry out tests, and isolate 20-25 contacts from each one positive confirmed case of COVID-19. The government must work even harder in creating policies that favor development and the transformation of a national health system that is responsive to pandemics and creates an enabling environment to encourage active community involvement. The decision of the government to reopen the economy must also go along with the availability of massive and affordable test access, quality health services, tracing systems and isolation as a whole package. The government may not be able to eradicate this pandemic from Indonesia, but the government can make optimal efforts to reduce transmission as minimum as possible, especially to head towards new normal.

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