5.2. Health system impact

In general, mass testing is considered to be costly and can be challenging for a variety of reasons including accessibility, adherence, awareness, and training requirements.

Section 6.

Recommendation

The HTA Council **does not recommend at this time the use of IgM/IgG Rapid Diagnostic Test (RDT) Kits as a sole screening and diagnostic tool for COVID-19**, pending further scientific evidence on its accuracy. The Council is continuously on the watch for future evidence on its utility. However, **a parallel multi-site clinical trial is highly recommended** to be spearheaded by the Research Institute for Tropical Medicine (RITM) and designated healthcare facilities. Only those who will enroll in the RITM-led clinical trial research should have access to the rapid antibody-based test kits procured with government funds. In addition, the test kits to be funded by the government should be those that can differentiate between IgG and IgM.

The Council also recommends the exploration of studies using serology based RDTs but only in specific population groups for public health purposes, as recommended by WHO to inform public health policies. Another potential use is for monitoring and serologic survey to determine immunogenicity of COVID-19.

For local Government Units (LGUs) that are responding to a public clamor for expanded testing to cover specific population groups with higher exposure, please be advised that **the antibody-based testing itself is not recommended as a diagnostic test for COVID-19**. The antibody-based testing **must be used together with the Reverse Transcriptase Polymerase Chain Reaction** (RT-PCR) test and needs a **health expert for interpretation of results**. Moreover, the expanded testing should be part of a research activity, which requires systematic data collection. The Food and Drug Administration (FDA) certification is **not a permit for unrestricted public use**. In case the COVID-19 IgG and IgM RDT kits will be utilized by government and private institutions, there should be capable health teams (e.g., education, training and experience in infectious disease and public health) at the local government unit (LGU) level, possibly at the provincial/chartered city level to perform the test, in close coordination with RITM or other subnational hospitals also performing the RT-PCR test.

Further, the HTA Council supports the **Philippine Society for Microbiology and Infectious Diseases (PSMID) guidelines**, as quoted below:

1. Only Food and Drug Administration (FDA) approved kits should be used.
2. A COVID-19 antibody test CANNOT be used as a stand-alone test to definitively diagnose COVID-19 and CANNOT be used for mass testing, but only for monitoring patient status.

3. This should only be used in people who had onset of symptoms for at least 5 days (i.e. for IgM) and 21 days (i.e. for IgG).
4. Anyone who tests positive for IgM should be tested with an RT-PCR to confirm the positive test.
5. A negative IgM test DOES NOT rule out COVID-19 and the symptomatic patient should REMAIN ISOLATED and swabbed using RT-PCR for confirmation.
6. IgG-only positive individuals without RT-PCR should be labeled as presumptive past COVID-19 and not be officially counted as confirmed unless there is a further validation test in the future, or if validated with a PRNT (Plaque reduction neutralization test) or viral culture by a third party. If a patient is symptomatic, an RT-PCR should be done, and the patient should be quarantined. If a patient is asymptomatic, there is no need to test using an RT-PCR.
7. The IgG antibody can be used as an adjunct test to clear quarantined patients who remain asymptomatic at 14 days post discharge. The presence of antibodies typically indicates viral clearance. If IgG is positive, the patient can be released from self-quarantine. If IgG is negative, a repeat RT-PCR should be performed.
8. ONLY medical doctors can prescribe and interpret the use of the antibody-based test kits. These kits will not be available over the counter. In accordance with the FDA Advisory 2020-498 “Purchase and Administration of FDA Approved COVID-19 Rapid Antibody Test Kits” released on 01 April 2020, this product must be acquired using a prescription issued by a licensed physician and procured from a DOH licensed hospital or pharmacy.

Section 7.

References

1 Andreotti, PE., Ludwig, GV., Peruski, AH., Tuite, JJ., Morse, SS. & Peruski, LF. (2018). *Immunoassay of infectious agent*. Retrieved last 23 March 2020 from https://www.futurescience.com/doi/abs/10.2144/03354ss02

2 Communicable Disease Network Australia. (2020). *CDNA National Guidelines for Public Health Units*. Retrieved March 24, 2020, from https://www1.health.gov.au/internet/main/publishing.nsf/Content/7A8654A8CB144F5FCA2584F8001F91E2/$File/interim-COVID-19-SoNG-v2.2.pdf

3 Department of Health. (2020). *Updates on novel coronavirus disease 2019 (COVID-19)*. Retrieved last 23 March 2020 from https://www.doh.gov.ph/2019-nCoV

4 Department of Health. (2020). *Algorithm for triage of patients with possible COVID-19 infection in health care facilities*. Retrieved last 23 March 2020 from https://www.doh.gov.ph/2019-nCoV

5 Dong, E., Du, H., Gardner, L. (2020). *An interactive web-based dashboard to track COVID-19 in real time*. Retrieved last 23 March 2020. DOI:https://doi.org/10.1016/S1473-3099(20)30120-1

6 Dudden, A., & Marks, A. (2020, March 20). *South Korea took rapid, intrusive measures against Covid-19 – and they worked | Alexis Dudden and Andrew Marks | Opinion | The Guardian*. Retrieved March 24, 2020,