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DOCTORS WITHOUT BORDERS

[Event summary] Local production of diagnostics to meet needs in Asia

Date: Wednesday, 3 November 2021
Recording: https://www.youtube.com/watch?v=ii4C3LyjVW8&list=LL&index=1

Moderator: Mr. Howie Severino / Veteran Filipino Journalist

MSF has been responding to the COVID-19 pandemic in its operations and has seen first-hand the challenges that low- and middle-income countries face in accessing medical tools such as diagnostics. This event hosted by MSF has brought together key stakeholders from the Asian region to reflect on where we stand on local production of diagnostics in the Asian region, and what steps should be taken towards a stronger and more diversified market in the Asian region through local production of diagnostics to meet our needs.

Presentation: Dr. Stijn Deborggraeve, Diagnostics Advisor Infectious Diseases at Médecins Sans Frontières (MSF) Access Campaign

In 2021, MSF conducted bench reviews and interviews with 67 manufacturers, donors, and global health actors and developed recommendations in four key areas to improve local production of diagnostics in low- and middle-income countries (LMICs):

1) Create an enabling funding and procurement environment to promote local production.
2) Promote open intellectual property (IP), technology transfer, and access-oriented R&D for local manufacturers.
3) Ensure that local production is sustainable and meets local health needs.
4) Strengthen regulatory mechanisms and public trust in locally manufactured products.

Full report of the study and recommendations can be found at following link:
https://msfaccess.org/improve-local-production-diagnostics?utm_source=Advocacy&utm_medium=email&utm_campaign=LocalProdDiag

Presentation: Dr. Jaime Montoya, Chair of the ASEAN Diagnostics Initiative and Executive Director of Department of Science and Technology Philippine Council for Health Research and Development (DOST-PCHRD)

Dr. Montoya presented on the ASEAN Dx Initiative which works to develop diagnostic products that address unmet clinical needs in the ASEAN region. This initiative was launched with the aim to commercialize and make available locally developed diagnostic products in ASEAN member states. The Initiative pursues public-private partnerships (PPP) and connects them as allies to the ASEAN Dx Initiative.

Already before the COVID-19, the ASEAN Dx Initiative has developed a Strategic Planning Panel (SPP) and launched in 2019 a first call for proposals to support local production of diagnostics for dengue, tuberculosis (TB), hepatitis, malaria, and other diseases relevant for the Asian region. The call in 2019 attracted 22 proposals, among which 7 projects were shortlisted and 4 projects have been funded: 2 projects on TB and 2 projects on dengue. Despite some projects being delayed due to COVID-19, the Biotek-M Dengue Aqua Kit (Lab-in-a-mug project) led by Philippines with partnership with Indonesia moved forward and is ready for implementation this year.

In 2022, the Dx Initiative will run ASEAN Serosurveillance Study on COVID-19 and ASEAN Dx preparedness capacity building work.

Presentation: Dr. Ricardo Jose Guerrero, Research Fellow at Ateneo Research Institute of Science and Engineering (ARISE) & Engineering Lead at Bayan Biomedical Research Group

Before COVID-19, there were only a few facilities within Philippines to run COVID-19 PCR test. With funding from the DOST-PCHRD, the lab started to research on PCR tests. In the process of conducting research, there were multiple challenges the lab faced, which can be broken down into 3 categories with following recommendations to tackle the problems:

1) Challenge with procurement and supply chain: there is a fragile supply chain and a slow procurement process. To overcome this, it is recommended to establish a consolidated scientific supplier directory; create dedicated pathways for scientific good procurement; and prioritise the development of local production of finished, semi-finished and raw materials.
2) Challenge with medical device regulations: lack of implementing rules and regulations based on ASEAN Medical Device Directive (MDD) for in vitro diagnostics. FDA regulations running with the assumption of foreign manufacturers and external regulatory approval, thus lacking guidelines for clinical/performance testing. A closer coordination between diagnostic research funders and FDA to establish nominal pathway to market would be needed along with effort to make easier access to regulatory and certification expertise for academic researchers.
3) Intellectual property and interest: gap between stakeholders (government, industry, and academia) on what is the KPI it wishes to achieve. To close this gap, there need to be an alignment of stakeholder metrics balancing novelty, impact, and commercial potential. There also should be clear policies on collaboration for academic-academic, and academic-industry partners and a target R&D for context specific impact.

Presentation: Dr. Raul Destura, CEO of Manila Healthtek

When the COVID-19 pandemic hit, the Philippines faced limitations to access the PCR diagnostic technology due to limited supply. The company aimed to develop a PCR test that met all the following criteria: sensitive, specific, single-step, multiplex, confirmatory, and more than anything affordable. Within a few weeks, the company made the "GenAmplify™ COVID 19 rRT-PCR Detection kit" that met these criteria.

The most important aspect of the test was that it lowered the cost of test in Philippines from 80 USD to 8 USD. This was possible due to the "Bayanihan spirit" which refers to the Filipino culture of working together as a community to achieve a common goal. The project was enabled by a government-academia-industry partnership: the Philippines DOST, University of the Philippines, and Manila HealthTek combining resources. The company was able to expand the manufacturing capacity to 20,000 tests per day and to date, almost 400,000 patients were tested using this local kit.

Presentation: Dr. Berlin Tran, Vietnamese researcher in digital and political economy currently working with the University of Economics Ho Chi Min City / Ms. Van Nguyen Thi Hong, Regulatory Affairs Director of Sunstar JSC

Vietnam was successful in containing COVID-19 during the first 3 waves but only during the 4th wave with the Delta variant local tests were introduced. Testing has been at the core of the country's response and the change during the 4th wave was the decentralization of tests which were previously strictly centralized.

Most of the scientists interviewed foresaw the need for locally developed diagnostics as early as end of 2019, due to Vietnam's large population and proximity to epicentres. In 2020, 3 different teams launched research for diagnostics but due to lacking on funds, research coordination, and commercialization plan, only one research reached commercialization. Compared to the challenges as bit as Goliath, the researchers were comparable to David in following aspects:

- Lacking funding for R&D and clinical trial: some had to rely on personal and institutional funds.
- No guidance on how to meet international quality standards.
- Lack of buffer fund to mitigate risk of initial production.

- No experience in finding distribution partners and logistical costs exceeding break-event point to export.

As for Sunstar, the company conducted R&D in collaboration with two public institutions for PCR and LAMP tests. Eventually the PCR test was certified for public use in Vietnam and EU CE. However, the company still faces challenges to commercialise and to export for same reasons as above. Furthermore, it is important that diagnosis needs to be followed by immediate treatment that is produced locally, thus easily accessible, and applicable.

Presentation: Dr. Eduardo Banzon, Principal Health Specialist in the Southeast Asia Regional Department of the Asian Development Bank (ADB)

The COVID-19 brought disruption on how products were moved around as many countries did not have manufacturing capacity for any of the medical products. Many producers failed to supply the products in sufficient quantities which further fired the discussion of local production. But the issue of local production comes with its set of challenges. The decision to build local manufacturing needs to come with market analysis, which is not always straight-forward. A clear understanding of the diagnostic market needs to precede, including the size of the market.

Some important factors to consider include which therapeutic areas to focus on, considering the number of tests per country; who are the manufacturers and suppliers, with aim to have visible players in the region which are lacking at this point in the diagnostics market; how the equipment and consumables are priced and sold, with aim to have a cost and price model; and how the government will pay or finance them, with the national health insurance scheme involved.

Sone areas of innovation opportunities for the region could include point-of-care (POC) diagnostics; low-cost lab-based diagnostics; IT-driven innovations; molecular diagnostics for specific disease like TB and dengue; innovation in ways diagnostics are sold; or innovation in ways diagnostics facilities area organized.

At ADB there are financing opportunities for private sector that support development support of the country and innovative approaches; the bank also facilitates government and private sector to work together. But also importantly, there should be a regional cooperation which is an area ADB is also supporting.

Q&A

Q: How can a non-profit model be realized when funding is a major issue and mostly coming from foreign philanthropies, thus reducing portfolio of research due to some philanthropies wanting to develop products of their own interests?

- Dr. Stijn Deborggraeve: Sustainability is key in non-profit models and there is often need for external financial support in the start-up face. However, this is generally also the case for start-ups with a for-profit business model where profit is made only after few years. So far, external financing and investments in non-profit entities are from philanthropic organizations in high income countries but those investments should also come from regional financing schemes and not always depend on global mechanisms. A non-profit model does not mean that the company cannot make profit rather it means that the generated profit has public goals at its center, e.g., expanding R&D and improving access conditions.

Q: Are there plans for NCD diagnostics production through the ASEAN Dx Initiative?

- Dr. Jaime Montoya: There are plans for non-communicable disease. The reason the Dx Initiative first started with the communicable/infectious diseases was because it was the decision made by the SPP pre-pandemic. There is hope to expand to non-communicable diseases such as cancer, diabetes, cardiovascular diseases, etc.

Q: With recent developments in diagnostics, has this translated to lowering prices of PCRs? How and when can the public enjoy the benefits of these research?

- Dr. Raul Destura: The public is already enjoying the benefits when the local company benchmarks their product at the lowest price in the market. Also, with local diagnostics, the cost of technology was reduced because the company was able to negotiate with the supply of raw materials especially as the pandemic prolonged and more labs were created. This allowed Philippines to negotiate raw materials in bulk due to local production.
- Dr. Stijn Deborggraeve: The price of a test is not only the price set by the manufacturer but the total cost for the consumer including the mark-up costs distribution by distributors. Often the end price paid by both public and private labs are often very high due to the mark-ups along the supply chain.

Q: Whether the production of local diagnostics in Vietnam has also led to lowering of price?

- Dr. Berlin Tran: The latest price in Vietnam was around 30-35 USD, significantly lower than the 50 USD price that is often benchmarked. But access to test has been relatively easier in Vietnam and price consistent between different locations due to the system being regulated by the government.

Q: One of the main challenges in local production of diagnostics is the lack of local trust and local demand for locally produced diagnostics and countries/procurers preferring importing tests from companies based in high-income countries than procuring locally produced quality assured tests. What should be the strategies and actions to change this?

- Dr. Jaime Montoya: To build trust, there need to be a robust and trust-worthy regulatory system. At the onset of the pandemic there was a flood of diagnostics entering the market, including through donations. For LMICs, there is a tendency to depend on donated diagnostics at the onset of emergency. It is important for the regulatory authority to have a system to assess the quality of these donated tests.

Q: Diagnostic inequity between the developing and developed world is stark. One part of the world is able to play games and go for concerts, while the other finds it difficult to get tests even for jobs. Can local production of diagnostics solve this issue? Should WHO do something about the diagnostic inequity?

- Dr. Stijn Deborggraeve: There is indeed inequity in access to diagnostics between the North and the South, not only in access to quality diagnostic tests but also in how tests are used. WHO guidance on testing for COVID-19 is crucial for LMICs and WHO, as well as the relevant regional and national bodies, should aim to reduce the inequity in use cases for COVID-19 testing. Expansion of local production of diagnostic tests may improve access to COVID-19 test supply but it will not solve inequity in guidance.
- Dr. Ricardo Jose Guerrero: Having a better base for production not only for the finished product but also for the raw materials and semi-finished materials should bring down the cost-of-goods. The final price still continues to be high but if there are multiple suppliers including from raw materials to the end product, the final cost could be eventually brought down and the effect trickled down to the end-user.