Transforming Diagnostic Access



This paper highlights the common gaps in diagnostics through a study of six ASEAN member states– Indonesia, Malaysia, Singapore, Thailand, the Philippines, and Vietnam. It provides recommendations to address the common challenges, before deep diving to offer strategies that can be adopted to address these gaps.



Transforming Diagnostic Access

A ROADMAP FOR ASEAN

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02 **Executive Summary**

As COVID-19 has highlighted, access to a strong and diverse diagnostics infrastructure was, and remains, crucial in tackling significant challenges to healthcare and the global economy. Early detection of diseases is not only critical in improving health outcomes for patients, but it also provides overall economic benefits when medical conditions are screened, diagnosed, and treated before they become too advanced. Despite its importance, diagnostics has persistently suffered low visibility and has been the weakest link in the cascade of care.

The infrastructure left behind by the COVID-19 pandemic should not go to waste. Rather, it should be leveraged for screening of other diseases, to help ensure that ASEAN can: maintain a healthy population and productive workforce to continue driving its economy; and achieve the health cluster goals it had set out under the ASEAN Post-2015 Health Development Agenda (APHDA).² Particularly, to "strengthen health systems and access to care" and meet the demands of a growing population that is projected to be aged by 2050³, diagnostics must be included in the discussion.

The EU-ASEAN Business Council (EU-ABC), therefore, advocates harnessing the current momentum to continue advancing the case for the value of diagnostics. The region must work towards raising the visibility of diagnostics, assess the value of diagnostics beyond the short-term budgetary dimension, and increase investment in diagnostics infrastructure to enhance testing capabilities. This will be paramount to the strengthening of healthcare capacities to guarantee that safe, cost-effective, and quality care is offered to patients.

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This paper highlights the common gaps and risks in diagnostics through a study of six ASEAN member states- Indonesia, Malaysia, Singapore, Thailand, the Philippines, and Vietnam. It provides recommendations to address the common challenges, before deep diving to offer strategies that can be adopted to address these gaps. Overall, these recommendations are targeted to highlight the importance, and subsequently advocate for the better adoption of screening and diagnostics.

It is time to look at healthcare systems alongside the innovative diagnostic solutions that exist, to radically transform access for innovation to make its way to patient care. This is vital for ASEAN as it transitions to an endemic stage, ensuring that it develops a more resilient healthcare system that can continue battling against the current pandemic, as well as help ASEAN member states (AMS) in the early detection, prevention and treatment of high burden diseases.



APHDA Goals for 2021 - 2025⁴

ASEAN Health Clusters 1		
Promoting Healthy Lifestyle	1	To a thro
	2	To e all a
ASEAN Health Clusters 2		
Responding to All Hazards and Emerging Threats	1	To p com negl
	2	To e to pi disa
	3	To p threa impa
ASEAN Health Clusters 3		
ASEAN Health Clusters 3 Strengthening Health System	1	To p acce care trad
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Strengthening Health System	2	acce care trad To a towa

chieve health potential of ASEAN Community hugh promoting healthy lifestyle.

ensure healthy lives and promote well-being for t all ages.

promote resilient health systems in response to municable diseases, emerging infectious diseases, lected tropical diseases and zoonotic diseases;

enhance regional preparedness and response ublic health emergencies and ensure effective aster health management in the region.

prepare and respond to environmental health ats and other hazards, including the health acts of climate change in the region.

provide the ASEAN Community with universal ess to safe, affordable, quality, holistic health and essential medical supplies, including itional and complementary medicines; and

dvance health care deliveries by adapting ards innovation and digital health technology.

promote health care delivery to vulnerable ulation, such as among others, women, dren and migrant workers.

romote access to safe food.

strengthen food safety risk analysis in ASEAN.

03 Summary of Recommendations

Government-led initiatives



- Accelerate Adoption of Diagnostics
- Building a Regional Diagnostics Strategy for ASEAN
- Collaborate with Private Stakeholders
- Directing Funds to Develop Diagnostics Infrastructure and supporting national screening programmes
- Establish National Health Screening Programmes for Citizens based to support disease elimination and strategies of World Health Organisation (WHO)
- Fit-for-Purpose Value Assessment Frameworks for Diagnostics
- Grooming an Adaptable Workforce ٠
- ٠ Adopt hybrid testing network models that include centralised labs and point of care solutions

Community-led Initiatives

- Educating Individuals on the Importance of Screening & Testing
- Driving the Adoption of Technology where the Patients are

Corporate-led Initiatives



- MNCs Subsidising Costs of Screening for Employees
- Insurance Companies to include Screening as part of their Packages
- Incorporate Mandatory Screening for Individuals employed in select trades to safeguard well-being of staff

Introducing Diagnostics 04

At the time of writing, the World Health Organisation (WHO) has recorded around 15 million deaths arising from COVID-19.5 Given its fatality rate, this formed the primary motivation behind world governments' rapid response in mobilising funds and resources needed to support healthcare systems. Ironically, while COVID-19 has initially exposed testing capacity as an Achilles' heel within the medical infrastructure, it has also provided the golden opportunity to augment the importance of diagnostics and its indispensable role in managing public health challenges.

Global Deaths from Select Diseases

Human Papillomavirus Cardiovascular Diseases Human Immunodeficiency Virus Hepatitis (B & C) COVID-19 total death cumulative

from 2020 - 2022

Prevention, screening and early detection are critical components in healthcare and should be given paramount focus whether it is for COVID-19, cancer, heart disease, infectious diseases or other serious health threats. High quality diagnostics is part of that equation. These tools exist to prevent or at least limit the impact of life-threatening health conditions. By keeping citizens healthy, national governments can alleviate the burden exerted on healthcare systems, and more importantly, lower the rate of absenteeism in the workforce, thereby increasing productivity at work, ultimately generating positive outcomes for the economy.11

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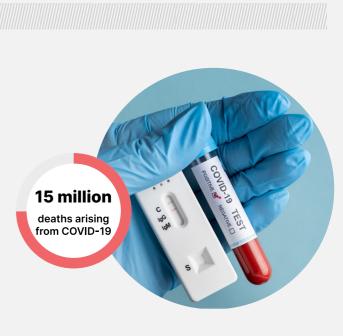
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Estimated Deaths per annum

342,000 ⁶
17,900,0007
680,000 ⁸
1,400,000 ⁹
15,000,000 ¹⁰

Diagnostics should no longer be perceived as a "reactive" approach and delegated just a supporting role in healthcare, only to be activated in times of outbreaks and emergencies. National leaders must start incorporating diagnostics as a "proactive" strategy and take the pandemic as the turning point to encourage the inclusion of diagnostics when countries are developing their Universal Health Coverage (UHC) packages. To create an optimal impact on patients and to engineer a resilient healthcare system, testing must be made safe, cost-effective, and accessible, for all.

Despite its merits, diagnostics has persistently suffered from low visibility which has brought about the following outcomes for the global diagnostics landscape:

1. Diagnostics: Weakest Link in the Cascade of Care¹²

Quality clinical care begins with testing - the gateway that directs the patient into the most appropriate care path. In enabling patients to have access to appropriate diagnostic tools, they can receive the most cost-effective therapy promptly. This not only slows down the disease progression that could potentially save lives, but it also brings additional benefits for the various stakeholders within the healthcare continuum:

The true value of diagnostics for various stakeholders in the healthcare continuum^{13, 14}

Value of knowing provides patients with accurate insights on their condition, pathway, and outcomes, to inform them of their role in the decision-making process

- Empower patients to take ownership of health .
- Enables individuals to plan with certainty on course of treatment
- Delays progression of diseases .
- Enhances treatment adherence

Encouraging the maintenance of a healthy population to increase well-being and productivity

- Curation and provision of optimal population-based screening strategy Enable higher efficiency of
- care delivery Manage public health
- Detect early outbreaks

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03

Patient Policy-makers OST. EFFE Physician DALYSAVE Value of **Diagnostics** Solutions Payer Provide

Improved clinical outcomes through early diagnosis and timely treatment lead to informed and potentially personalised treatment approaches and decision-making along the patient care pathway

- Timely diagnosis for patients
- Avoid unnecessary testing Enables timely clinical
- management for early prevention Intercept disease or slow its
- progression Provide optimal care selection for patients
- Better patient monitoring

Accurate allocation & coordination of point-of-care, lab diagnostic systems and hospital resources informed by patient access and needs will enable

- Improves triage and workflow Faster turnaround time from
- specimen collection to results Reduction in waiting time, time
- to diagnosis for patients Reduction in time lag between diagnosis & treatment initiation
- Reduced need for Emergency visits

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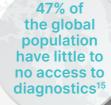
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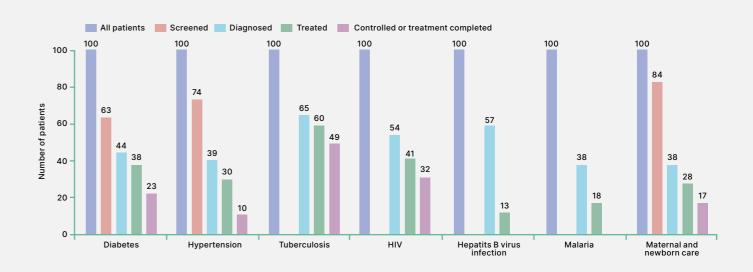
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only 19% of the population from low- and middleincome countries (LMICs) have access to the simplest form of diagnostics at primary care level¹⁶

no appropriate test is available for 50% of the top 20 diseases responsible for the most lives lost¹⁹

The Lancet Commission analysed the current state of diagnostics by conducting a study of six tracer conditions: (1) diabetes, (2) hypertension, (3) tuberculosis, (4) HIV, (5) Hepatitis B virus infection, and (6) Syphilis, and the findings pointed to one uniform conclusion - diagnosis is the biggest gap in the cascade of care.



Across all tracer conditions, there exists a prevailing diagnostic gap ranging between 35% to 62%.²¹ However, by minimising this diagnostic gap through increasing diagnostic coverage to 90%, the Lancet commission estimates one million premature deaths across the six tracer conditions could have been averted.²²





Figure 1 Diagnostics as the Biggest Gap in the Cascade of Care²⁰

AMS	Incidence of Cervical Cancer per 100,000	Total loss of earning due to mortality from the absence of diagnostics (USD)
Brunei	6.2	1,018,683,860
Cambodia	16.2	2,661,722,344
Indonesia (study conducted)	7.0	1,150,126,939
Laos	13.30	2,185,241,184
Malaysia	5.6	920,101,551
Myanmar	15.0	2,464,557,726
Singapore	3.5	575,063,469
Philippines	5.3	570,810,396
Thailand	12.8	2,103,089,259
Vietnam	5.7	936,531,936
	Grand Total	13,649,396,728

Table 1 Estimated Loss of Earnings due to Mortality from the Absence of Diagnostics (USD)

By quantifying the number of deaths averted against productivity cost, it reveals that the total loss of earnings from cervical cancer alone generates a significant economic loss for individual AMS. Especially when bearing in mind that the total loss of earnings depicted in this case study is strictly for the condition of cervical cancer alone. Multiplied across the six tracer conditions from the Lancet commission, a rough estimation would reveal each AMS may be incurring a minimal loss of earning of around USD 3.4 billion per annum from deaths that can be averted through diagnostics.

To further augment the case for diagnostics, studies to quantify the economic impact on other tracer conditions should be conducted to provide a holistic and accurate assessment on the potential savings that screening, and diagnostics can contribute to each AMS to advocate for its adoption.

3. ASEAN Health Clusters & the Role of Diagnostics

The EU-ABC proposed in an earlier report, "Learnings from COVID-19: An **Opportunity for ASEAN Governments to Establish Self-Care Policy to Improve** the Health & Well-Being of their populations", that national governments should encourage individuals to take ownership of their health. This is not only to warrant cost savings to the healthcare system without compromising the well-being of its citizens.²⁶ More critically, the push towards the promotion of self-care is in line with consumer attitudes across the four key ASEAN markets surveyed - Indonesia, Malaysia, Thailand, and Vietnam -reflected a growing desire of the populations to have governments do more to incentivise and support its citizens to adopt a selfcare approach²⁷, empowering them to take ownership of their health.

In enhancing diagnostics capability across the ASEAN region and incorporating it as part of the national UHC benefits of member states, ASEAN edges closer to achieving three of its Healthcare Cluster goals, namely: promoting a healthy lifestyle (Health Cluster 1); responding to all hazards and emerging threats (Health Cluster 2); strengthening health systems and access to care (Health Cluster 3).

2. Calculating the Value of Diagnostics

To calculate the premature deaths averted against financial savings for individual ASEAN Member States, the EU-ASEAN Business Council (EU-ABC) have selected cervical cancer in Indonesia as a baseline case study to quantify the mortality averted in economic terms.

As the second most diagnosed cancer and third leading cause of cancer deaths in females, cervical cancer has the second highest incidence rates across ASEAN members. Cambodia recorded the highest incidence of cervical cancer, five times higher than that of Singapore which recorded the lowest incidence rate out of the ten ASEAN member states (AMS).

Cancer	Brunei	Cambodia	Indonesia	Loas	Malaysia	Myanmar	Singapore	Philippines	Thailand	Vietnam	
Cervix	6.2	16.2	7.0	13.3	5.6	15.0	3.5	5.3	12.8	5.7	

Figure 2 Mortality Rate Incidences per 100,000 arising from Cervical cancer across ASEAN²³

In Indonesia, 17,253 deaths from cervical cancer were recorded in 2018, resulting in a total productivity cost of USD 1.72 billion. Noting from findings from a separate study that screening can reduce cervical cancer deaths by 67%²⁴, the EU-ABC estimates that the real cost incurred by the lack of screening in Indonesia is USD 1.15 billion per annum.

Age groups (years old)	Employment participation rate (%)	Annual earnings (in thousand IDR)	Total loss of earnings due to mortality (in thousand IDR)	Total loss of earnings due to mortality (in USD)
20 - 34	73.23	32,400	721,286,208	53,428,608
35 - 49	71.15	32,400	8,944,408,800	662,548,800
50 - 64	54.56	27,600	12,149,246,208	899,944,164
65 - 79	15.10	18,000	1,359,271,800	100,686,800
Total	-	-	23,174,213,016	1,716,608,372

Figure 3 Total Loss of Earnings due to Cervical Cancer Mortality in Indonesia in 2018²⁵

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With Indonesia as a baseline based on the findings from the existing study, the estimated costs for each AMS are as follows on the next page:

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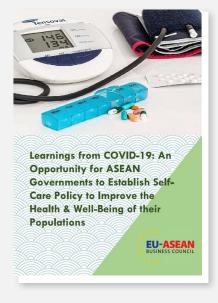
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 \land Intended to achieve Health clusters where diagnostics will aid to advance goals

Safety

system and access to care

05 Existing Landscape in ASEAN: **Overcoming Gaps in Diagnostics**

The landmark report produced by the Lancet Commission in 2021 rallied for a global transformation in access schemes for diagnostics.²⁹ How can this change in diagnostics landscape benefit ASEAN? Apart from its economic benefits and merits in attaining the ASEAN Health Cluster goals, the adoption of diagnostics can also be incorporated in population-level surveillance to aid ASEAN member states monitor infections and non-communicable diseases (NCDs). For a region like Southeast Asia that faces an epidemic of chronic NCDs responsible for 60 percent of deaths

in the region,³⁰ the adoption of screening and diagnostics can be a tool to reduce the mortality arising from NCDs.

To leverage the benefits of diagnostics, ASEAN must work towards overcoming the existing gaps in the diagnostic infrastructure across the region to ensure that symptoms are detected at the primary stages for early treatment, especially for preventable diseases. The following are some of the common gaps that is shared across six AMS -Indonesia, Malaysia, Singapore, Thailand, the Philippines, and Vietnam - that must be addressed to tap onto the merits of diagnostics:

Low Visibility for Diagnostics

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X		

- Under-appreciation and lack of inclusion of diagnostics and screening in universal health coverage
- Value of vaccines and essential medicines take precedence over diagnostics, although diagnosis is the gateway to appropriate care

Financial Barriers

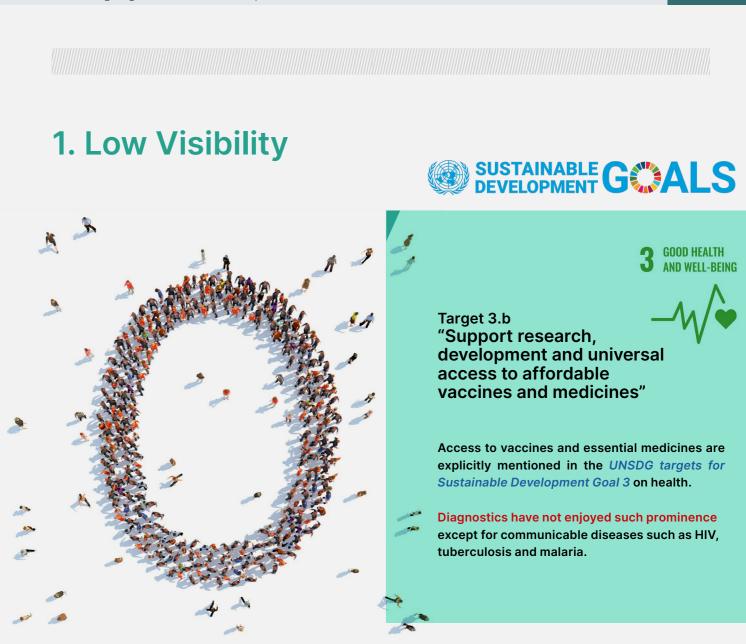


- Healthcare expenditure across AMS fall below minimum sustainability threshold recommended by WHO
- Value of screening assessed in isolation without full consideration about the benefits and cost-savings in the long-term

Capacity Constraints



- Shortage of manpower in the healthcare sector across AMS
- · Healthcare systems with clinics at local and community levels remain underinvested and under-developed



Fundamentally, low visibility for diagnostics has been the primary cause of its neglect. Prior to the COVID-19 pandemic, diagnostics have persistently been under-appreciated, and their importance in Universal Health Coverage and antimicrobial resistance has received insufficient attention to gain traction. As the case highlighted by the Lancet Commission has reflected, medicines have predominantly obtained greater importance than diagnostics. As the Essential Medicine List (EML) has highlighted, countries have traditionally emphasised the value of vaccines and essential medicines. Diagnostics, on the other hand, have yet to enjoy such prioritisation.

Given that ASEAN currently prioritises the agenda of promoting a healthy lifestyle and tackling the issue of modifiable risk factors, national programmes emphasise the importance of healthy eating (nutritious & balanced diet); and the adoption of a healthy lifestyle (reducing tobacco use and alcohol consumption, increasing physical exercise). All the while neglecting to incorporate diagnostic screening as part of the holistic approach in the patient-care continuum, and especially not for conditions such as oncology.

As listed on the health priorities of the select ASEAN countries summarised in Annex 1, the lack of recognition for screening and diagnostics is a common problem across all countries, regardless of their income level. Whilst the six ASEAN member states recognise the need to build a sustainable healthcare system and to battle NCDs, diagnostics was not mentioned as part of the strategy to achieve these aims. It was only recently, in the 15th ASEAN Health Minister meeting, that ASEAN stated "the availability of vaccines, diagnostics and therapeutics" are priority areas for capabilities development.³¹

2. Financial Barriers

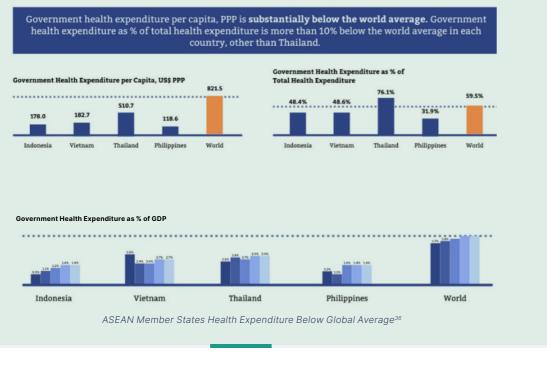
Lack of sufficient budget allocated for healthcare spending is another impediment to diagnostics. Although healthcare expenditure in Southeast Asia is revealed to have increased by 250% between 1998 and 2010, health expenditure per capita in ASEAN remains stagnant around 4% of GDP – as compared to the OECD average of 9.5%.³² As the EU-ABC has reported in a previous publication "*Sustainable healthcare investment as an economic driver: the time for ASEAN to act is now*", on average, the healthcare expenditure for ASEAN countries as a percentage of GDP "falls below the 5% minimum sustainability threshold recommended by WHO."³³

Health exp	Health expenditure as a % of GDP												
Selected A	SEAN countr	Developed countries											
Malaysia	Singapore	Indonesia	Vietnam	Philippines	Thailand	Canada	Germany	UK					
3.8%	4.5%	3.1%	5.7%	4.4%	3.7%	10.5%	11.1%	9.8%					

Table 2 Healthcare Expenditure for Select ASEAN Member States³⁴

	Indonesia	Vietnam	Thailand	Philippines
Estimated total healthcare expenditure	US\$40 billion	US\$19 billion	US\$25 billion	US\$17 billion
Healthcare expenditure per capita (2017)	US\$115	US\$130	US\$247	US\$133

Healthcare Expenditure for the Select ASEAN Member States³⁵



With health expenditures across the region stagnating, one of the hurdles for ASEAN is to earmark the financial resources needed to include diagnostics and screening as part of the existing universal healthcare coverage packages of individual member states. These funds would encompass the need to create more screening & diagnosis for laboratories to obtain accreditation, upgrade existing diagnostics facilities, as well as train and employ technically competent personnel to operate diagnostic equipment.³⁷

One of the common issues witnessed across ASEAN countries is the tendency to overlook the long-term benefits of diagnostics for short-term cost savings. To manage the limited funding in healthcare, AMS tend to neglect the investment in diagnostics. Choosing to instead focus on the "quick-wins" with management of acute care, rather than the more holistic, integrated, and preventive care routines which can potentially reap returns in the long run. **Value**, as it seems, is measured solely in short-term budgetary terms when, in fact, other assessments – value to patients, physicians, healthcare providers, professionals, and healthcare systems – should be taken into consideration for a more comprehensive assessment.

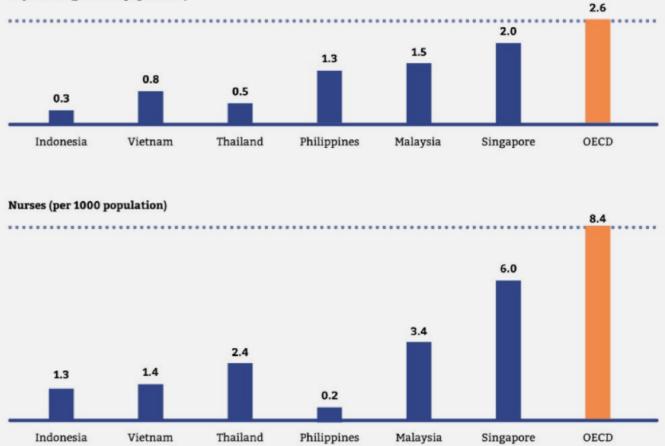
One of the common issues witnessed across ASEAN countries is the tendency to overlook the long-term benefits of diagnostics for short-term cost savings.

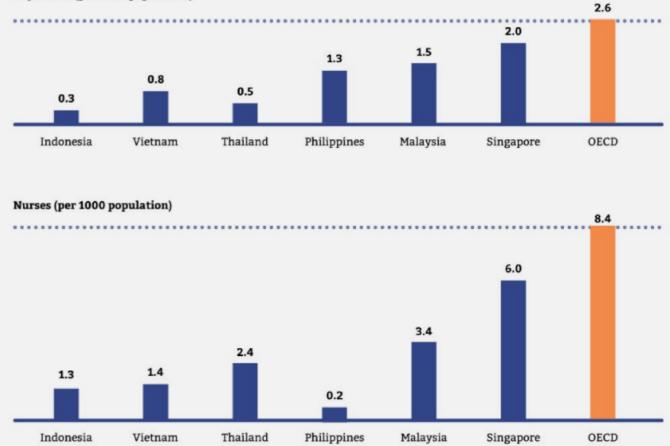
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3. Capacity Constraints

Diagnostic services in ASEAN, particularly for those classified under low- and mid- income countries (LMICs), are often challenged by poor laboratory infrastructure and technology, lack of equipment, inadequate quality assurance programs, and weak supply chains for reagents and consumables that are needed to perform the tests.³⁹

Physicians (per 1000 population)





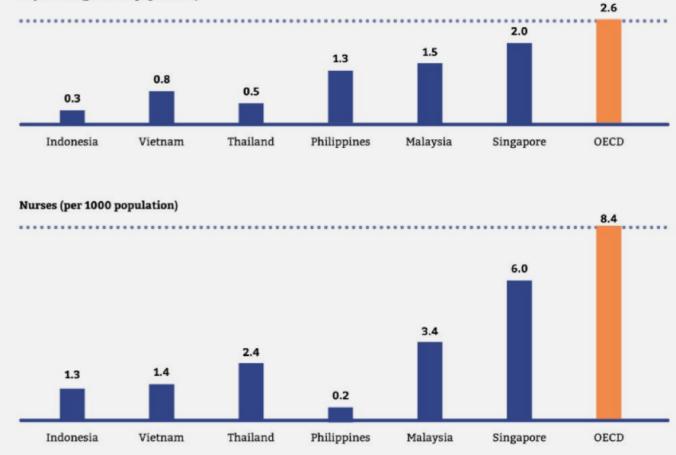


Figure 5. Shortage in Medical Personnel Across ASEAN

This will be a severe problem in ASEAN where healthcare professionals – nurses and physicians – per 1,000 population, are less than the OECD minimum (Figure 5).⁴⁸ To meet the healthcare demands of the population by 2030, the WHO highlighted that Southeast Asia would need to expand the healthcare workforce by 4.7 million.^{49,50} This figure is strictly for healthcare workers such as nurses and midwives alone. For diagnostics - where the nature of the industry is more niche - the outlook is bleaker.

On top of the existing manpower constraints, there is also an issue with accessibility. As the World Bank and the WHO reported in 2017, half of the world still lacks access to essential health services, with the most severe cases faced by LMICs.⁵¹ Indonesia, for one, an archipelago comprising of more than 17,000 islands and home to over 270 million people, faces significant health disparities across the geographic regions and socioeconomic groups due to the lack of access to testing and basic healthcare facilities in remote areas.⁵² The level of accessibility to diagnostics and screening facilities varies from the urban capital of Jakarta, to the rural areas of Sumba where the absence of diagnostic lab networks continue to limit the access to diagnostics for patients.

Taking the case of COVID-19 and the ease of self-testing even in rural areas for the early detection and containment of the diseases as an example, the decentralisation model has served as a potential solution to tackle the problem of accessibility. Nonetheless, lack of investment in developing centralised testing capability means that clinics at the provincial and local levels remain under-equipped in providing screening and testing for medical conditions that the most vulnerable population residing in rural areas of LMICs require.

ASEAN Member State	Income Grouping	State of Diagnostics Infrastructure
Indonesia ⁴¹	Lower-middle	1,300 laboratories for a population size of 270 million
Vietnam ⁴²	Lower-middle	122 medical laboratories accredited by Vietnamese Ministry of Science and Technology serving a population size of 97.34 million
Myanmar ⁴³	Low	169 laboratories with only 4% of population having access through private insurance
Laos ⁴⁴	Lower-middle	Poor laboratory capacity with only limited pool of labs that is accredited. Diagnostic accuracy is also low, averaging at 47.7% ⁴⁵

Table 2 State of Diagnostics Infrastructure in select ASEAN Member states⁴⁰

An additional barrier to the adoption of diagnostics within the region is the problem of the global shortage of staff that can support diagnostics testing. In high-income countries (HICs), it is estimated that an additional 480,000 to 576,000 staff are needed to support diagnostic testing in the field of pathology and laboratory medicine (PALM). Another 360,000 to 432,000 personnel are needed to support medical imaging.⁴⁶ The impact of the shortfall in healthcare personnel is not limited to the HICs. Rather, it is a global problem faced by HICs and LMICs alike. As the Lancet Commission estimated, by 2030, the projected shortfall in global healthcare workforce capacity is estimated to range from 15 million to 18 million.47

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06 Recommendations

The recommendations proposed below will be tailored to the actions that can be undertaken by the various stakeholders to improve the diagnostics landscape across ASEAN. While the recommendations raised differ in approach, the nature of each is targeted towards making diagnostics a priority within the region. Through the inclusion of which in the national health agenda of AMS, ASEAN will be one-step closer towards achieving its UHC goals by 2030.

Recommendations

Public sector-led initiatives	Community & Corporate-led initiatives
A. Accelerate the adoption, value recognistion and integration of diagnostics in the care delivery system	Community A. Education is key
B. Building a regional diagnostic strategy for ASEAN	
C. Collaborate with private stakeholders	Community
D. Directing funds to develop diagnostics infrastructure	B. Driving the adoption of technology
E. Establishing and supporting national health screening programmes for citizens to support disease elimination as part of resolutions and strategies of WHO	Corporate C. Companies (MNCs) subsiding cost of
F. Fit-for-purpose value assessment framework for diagnostics	screening for employees
G. Grooming an adapted healthcare workforce	Corporate
H. Adopting hybrid testing network models that include centralised & point-of-care solutions	D. Insurance companies to include screening as part of their packages

Public sector-Led Initiatives

Given the decade-long neglect in developing and prioritising diagnostics, the primary onus will be on national governments to lead the charge and develop programmes to harness the current momentum and develop the current discussion on diagnostics into prominent action.

A. Accelerate the Adoption of Diagnostics

Lessons from COVID-19 have taught the global health community and the public that healthcare systems are in dire need of an upgrade. The silver lining of the pandemic was that we can make targeted investments quickly and create fast and effective change, when the need arises. It also made prominent the importance of diagnostics. The pandemic stimulated the deployment of rapid innovation that enhanced testing capacity, and new technologies have emerged to enable individuals to self-test, self-diagnose, and self-monitor at the convenience of their homes. Overall, COVID-19 prompted the rapid strengthening of testing and surveillance capacity.

The lessons learned, innovations developed, and good practices adopted during COVID-19 should not end when we move to the endemic stage. As the receptiveness of individuals across the region towards the adoption of self-care is rising⁵³, ASEAN should incorporate diagnostics as part of the broader self-care policies (educating the public about the importance of early testing and encouraging regular testing either at clinics or in the convenience of their homes) to alleviate the financial burden of rising healthcare costs. To do so, ASEAN should continue to acknowledge the value of diagnostics and advocate for its development and adoption to prevent the spread of communicable diseases and help manage the heavy state of NCDs across the region. It is imperative for AMS to leverage the increased diagnostics infrastructure initiated by the COVID-19, and to accelerate and scale up effective screening, diagnostics and treatment of infectious, cardiometabolic and oncology related diseases.

COVID-19 has created the perfect storm for ASEAN to witness first-hand how easy access to diagnostics can save lives. The region should, therefore, maintain advocacy of diagnostics and deepen its commitment to rapidly enhance healthcare infrastructure and logistics capability for testing.

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B. Building a Regional Diagnostic Strategy for ASEAN

As a region, ASEAN shares similar healthcare challenges. The ongoing battle against HIV and tuberculosis on the communicable disease front; and the persistently high mortality rate brought about by hepatocellular carcinoma and heart failure, are just some examples of the common challenges. Diagnostics is one of the solutions to a common problem. ASEAN, as a whole, must strengthen the political will for the adoption of diagnostics as means of prevention and management of diseases.

Upon acknowledging its importance and establishing uniform commitment in developing testing capabilities, the region should work towards curating a regional diagnostics strategy as recommended by WHO to address the common ailments across the member states.

To craft the regional Essential Diagnostics List (EDL) list, ASEAN member states should refer to the Essential Medicines List and ensure that the EDL complements the EML to provide quality care for patients. Thereafter, the committee made up of the ASEAN health ministers, private stakeholders, and experts should periodically review the regional EDL to ensure that it addresses the gaps, remains relevant to and reflective of, the healthcare priorities and needs of the region.

C. Collaborate with Private Stakeholders

Private stakeholders are also key partners to create awareness and advocate for the importance of diagnostics screening. Leaders of individual AMS should leverage traction on public-private partnerships to develop collaborations across industry, and alongside with non-profit organisations improve healthcare infrastructure and access to diagnostics to close the healthcare gaps.

ASEAN Health Ministers (AHM) can collaborate with stakeholders and independent experts to identify the national needs and the list of in vitro diagnostics that should be made available at point-of-care clinics and central laboratories across the region to ensure timely and life-saving diagnoses for ASEAN citizens. For this to occur, multi-stakeholder collaboration is necessary to ensure that patient-centred care is provided holistically and cost-effectively. Medical information collected can be easily, *and securely*, shared across the relevant stakeholders to identify the top medical conditions to be addressed across the region.

D. Directing Funds to Develop Diagnostics Infrastructure and Supporting National Screening Programmes

There is a clear economic case for the investment in diagnostics. This is especially so if the analysis of the investment in diagnostics is measured in the returns in terms of deaths and DALYs averted (Section 1, Table 1). When evaluated from an economic viewpoint, the investment case is equally convincing as a more productive workforce directly translates to more economic gains.

The EU-ABC reiterates the view that whilst the healthcare budget falling below global standards is a problem in ASEAN, the larger issue at hand is the ineffective use of these already limited funds. Most ASEAN countries have underinvested in cost-effective healthcare services such as primary care, long-term care, and preventive care. Accounting for less than 10% of total healthcare expenditures allocated for preventive care, ASEAN countries must relook at the allocation of funds earmarked for healthcare. By re-evaluating the effective allocation of these funds from within the health budget, AMS can prioritise the investment in diagnostic infrastructure that will be an investment that pays off in the long term

E. Establish National Health Screening Programmes for Citizens to Support Disease Elimination as Part of Resolutions and Strategies of WHO

To ensure rapid uptake of diagnostics, AMS should look towards incorporating diagnostic programmes as part of the universal health coverage benefits for citizens, to encourage screening for the detection of medical conditions early. Further, screening programmes should also be in-line with the elimination strategies and health resolutions of the WHO. For example, to reduce the risk factor of cancer through early detection and appropriate treatment as per the 2017 WHO Cancer Resolution.⁵⁴

Screening programmes at the national level should minimise the sole emphasis on acute care, but also embrace diagnostics as part of the strategy to address the problems posed by chronic diseases. Ideally, AMS can develop a holistic approach for disease management that involves the Inclusion of screening for chronic diseases - oncology and cardiometabolic related illnesses – in national health packages, alongside acute care, for better patient care management.

In Singapore, for example, the "Screen For Life" (SFL) has been introduced by the Ministry of Health. The SFL is, simply, a national screening programme that offers eligible citizens and permanent residents (PRs) subsidised screenings that is recommended based on age and gender (for more, refer to regional snapshot *Singapore* in the next section).

ASEAN member states should relook to incorporate diagnostics for national priority medical conditions to be included in the existing UHC packages. Viewed in the short term, by subsidising the cost of diagnostics, the governments are encouraging patients to get tested. Through early detection and diagnosis, treatment can commence in the primary stages. In the long term, timely intervention can aid patients to reduce out-of-pocket expense needed for treatment.



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Fit-for-Purpose Value Assessment F. **Frameworks for Diagnostics**

The concept of value and its measurement for in-vitro diagnostics (IVD) is different than that of medical devices or pharmaceuticals. Diagnostics are complex interventions which can provide information on a wide range of conditions depending on the contextual factors and the perspective taken. The benefits of IVDs are wide-ranging, encompassing the following:

- 1. Improved clinical benefits for patients;
- 2. Societal gains of early detection and prevention of disease progression;
- 3. Value of knowing for individual patients;
- Economic savings and resource efficiencies for healthcare providers and health systems; 4.
- 5. Improved patient management by healthcare professionals.

Despite in-vitro diagnostics results influencing as much as 70% of clinical decisions, less than 1% of healthcare expenditure is invested in diagnostics.⁵⁵ There is therefore a need for the full value of diagnostic information to be captured, taking into account of what matters to patients, society and to all other players involved in healthcare delivery.

Assessors and decision-makers on funding and reimbursement should consider the full breadth of value that diagnostic information can provide, including:

- 1. From a patient perspective: direct/indirect impact on relevant outcomes;
- 2. From a health system perspective: impact on use of resources by different actors, in different healthcare pathways and settings, and over time.
- 3. Missed or late diagnosis, rehospitalisation, inefficient use of healthcare resources & poor patient engagement pose a significant barrier to high quality & optimal patient care highlighting the needs for timely diagnosis, treatment & effective monitoring through diagnostic information.

G. Grooming an Adaptable Healthcare Workforce

With relatively few physicians, nurses, and midwives across majority of the ASEAN member states, it is unsurprising that there is also a lack of skilled workers to perform and interpret test results, especially in rural areas of each member state. To remedy the three primary issues: (1) lack of technicians to operate devices; (2) shortage of physicians to interpret results; (3) lack of maintenance service providers for medical equipment, ASEAN must prioritise the expansion of the workforce capacity to meet the needs of the currently over-burdened healthcare system. This can be done by relooking at how labour-intensive processes can be simplified with digital diagnostics, to avail the workforce to undergo training to upgrade their skills; and, also by expanding the pool of healthcare workers who are allowed to perform testing and interpret results.

COVID-19 Testing & Interpretation of Results

Traditionally

Only nurses and medical professionals allowed to conduct testing and interpretation of results.

Upskilling curricula for existing healthcare professionals should also include courses to enable digital literacy. Existing courses should also be reviewed to include content that encourages the increased use of digital diagnostics and artificial intelligence to support the workforce in a better manner, develop high-guality task-shifting programmes, and exploit the full capability and skills of all staff.

H. Adopting Hybrid Testing Network Models that include Centralised & Point-of-Care Solution

The EU-ABC commends ASEAN for its efforts to build high-volume and point of care testing capacity for COVID-19 to meet the needs of millions of patients. This infrastructure proved strong and resilient during the pandemic and should be expanded to further strengthen not only pandemic preparedness, but responses to HIV, Hepatitis, TB, HPV and other infectious diseases to address the existing gaps in the diagnostic networks:

- coverage
- 2. Lack of clear visibility into the gaps and opportunities of the current network
- 3. Devices being over or underutilized leading to system inefficiencies
- 4. Weak empirical basis for planning the needed investments in additional capacity
- 5. Avoidable costs in procurement where new equipment might not be needed or due to expired overstocked test reagents or kits
- network management complexity
- 7. Limited reach to remote, rural, hard-to-reach areas and population

The introduction of the Diagnostics Network Optimisation (DNO) could alleviate these challenges

Since COVID-19

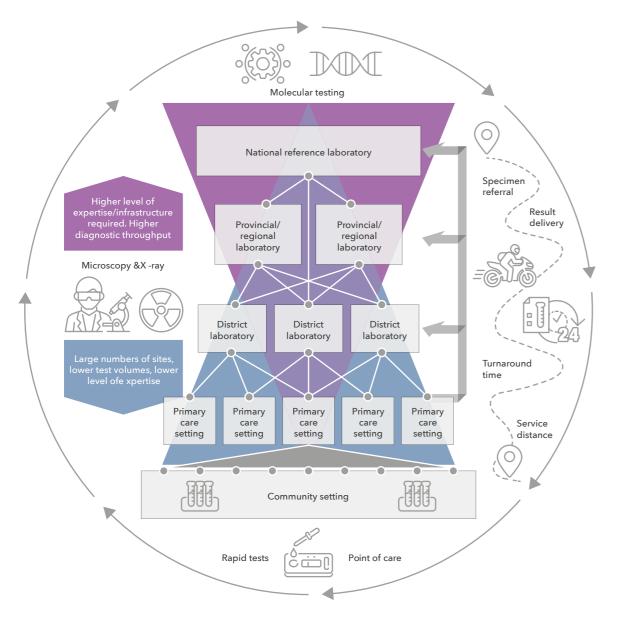
Expansion of healthcare workers by allowing other community workers can also process and interpret accurately the rapid tests.

1. Existing diagnostic networks are inconsistent with disease programme goals and aspirations for universal health

6. Sub-optimal sample transport routes over long distances can also lead to higher recurring operational costs and

What is Diagnostic Network Optimisation?

"The diagnostic network optimisation is an exercise that aims to redesign the diagnostic network set-up in order to increase access, maximise impact, and generate efficiencies"



Framework 5 Diagnostics Network Optimisation Model⁵⁷

Overall, the Diagnostic Network Optimisation (DNO) model recognises the value of diagnostics at every level of the healthcare system: from high-volume testing in reference and large hospital labs in urban and peri-urban areas; to building the backbone of a diagnostics network; even down to community-based point of care in small towns and remote areas. The EU-ABC strongly encourages ASEAN to continually evaluate country level diagnostic networks to better optimise their utility in order to plan for the future.58

ASEAN should continuously update its efforts to improve the utility of diagnostic networks in its annual report and ASEAN member states are urged to work towards building efficient laboratory and point-of-care infrastructure that can test multiple diseases and direct patients to the optimal care management.

	Community	L
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A. Education is Key

National health programmes should not be solely focused on encouraging the adoption of a healthy lifestyle, nor on the consumption of a balanced diet. Instead, there should also be advocacy to drive the awareness for the importance of early screening.

On top of this, price considerations as well as lack of awareness on the available schemes are also contributing factors resulting in the hesitancy for individuals to undergo screening. Henceforth, once the government-led initiatives on diagnostics have taken ground, there is a need to develop health campaigns to educate individuals about their benefits and eligible coverage to encourage the uptake of screening for early prevention and management. This would require NGOs and grassroot organisations to work collaboratively with the respective health ministries to ensure that the information can be shared on a wider scale to the citizens to educate them about the merits of diagnostics and the schemes available to reduce costs.

B. **Driving the Adoption of Technology**

The major development from COVID-19, was the transformation of the healthcare landscape. As individuals were more cautious about the spread of diseases, the region witnessed a common trend whereby physical visits to doctors were the less preferred option compared to telemedicine.⁵⁹

With greater adoption of technology, there is opportunity for NGOs or grassroots organisation to partner with government and private stakeholders for better management of population health. For a start, data-collection infrastructure can be developed to aid relevant stakeholders to track the medical conditions of patients, alerting individuals on when screening is needed, redirecting them to the nearest healthcare provider to undergo testing. In addition, there are four major areas wherein merits of digitalisation can be leveraged⁶⁰:

- Digital monitoring and therapeutics for early-stage patient identification
- Digital assistance through telehealth services
- Post-acute care optimisation and management through promotion of at-home wound care
- Population health management services through provision of digital testing management

ed Initiatives



Corporate-Led Initiatives

Multinational Companies (MNCs) subsidising С. cost of screening for employees

There are various means as to how employers can approach this model. One, employers can choose to sponsor in full any health screening packages opted for by their employees. To encourage the uptake of the annual screening, companies can provide health screening as part of the compensation & benefits packages of the staff.

Second, employers can opt for reimbursing only the diagnostics component to their employees. By reimbursing and sharing the cost with their staff, it will encourage employees to undergo regular screening, enabling them to take better ownership of their health, and for early detection of any medical diseases to receive treatment.

MNCs can also consider including mandatory screening for staff, especially for individuals employed in roles that are either mission critical or those that require extensive customer contact. For example, R&D Centers, Mining Operations, Oil & Gas Rigs, Call Centers etc. are some of the roles that require staff working in proximity and where infections could significantly impact operations and bottom-line. Similarly, staff working in high customer contact roles like those in banks, F&B, Gyms, Spas & Entertainment, Hospitality etc. come in regular and close contact with customers and visitors are more at risk and should be considered for periodic screening to mitigate risk of infection and impact on productivity.

D. Insurance companies to include screening as part of their packages

Singapore Occupational Screening for Employees in Select Trades

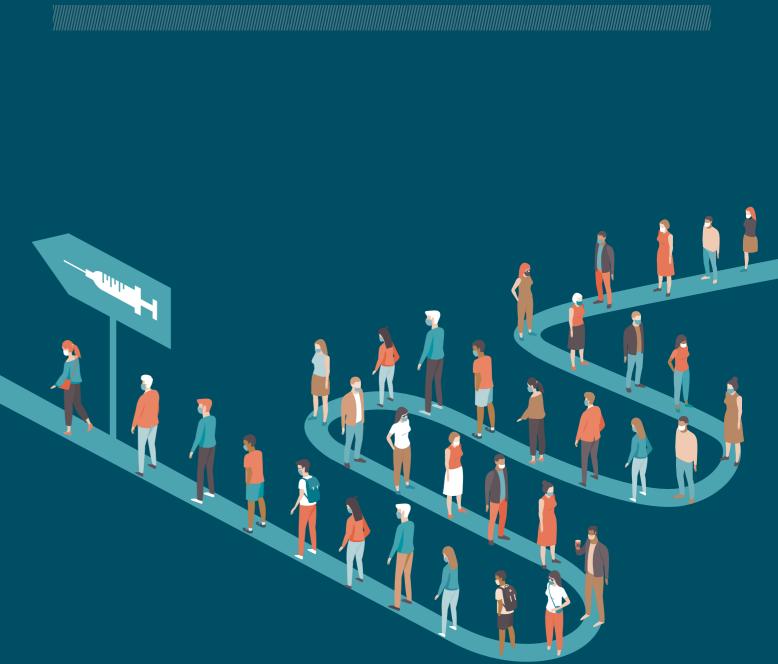
To ensure that individuals employed in workplaces with specific health hazards (exposed to noise, lead, mercury) remain physically fit, the Ministry of Manpower in Singapore mandates periodic screening employers to send these employees for screening to detect any signs of abnormalities in the early stages.

In essence, MNCs should consider diagnostic testing through two lenses - one being the need to maintain operational resilience, and the second one ensuring its employees that the company is providing a "trustworthy work environment" by looking after their health and wellbeing. These elements can be especially powerful in emerging SEA countries where the incidence of multi-generational living is higher and therefore risks to elderly staying in the same home is incremental.

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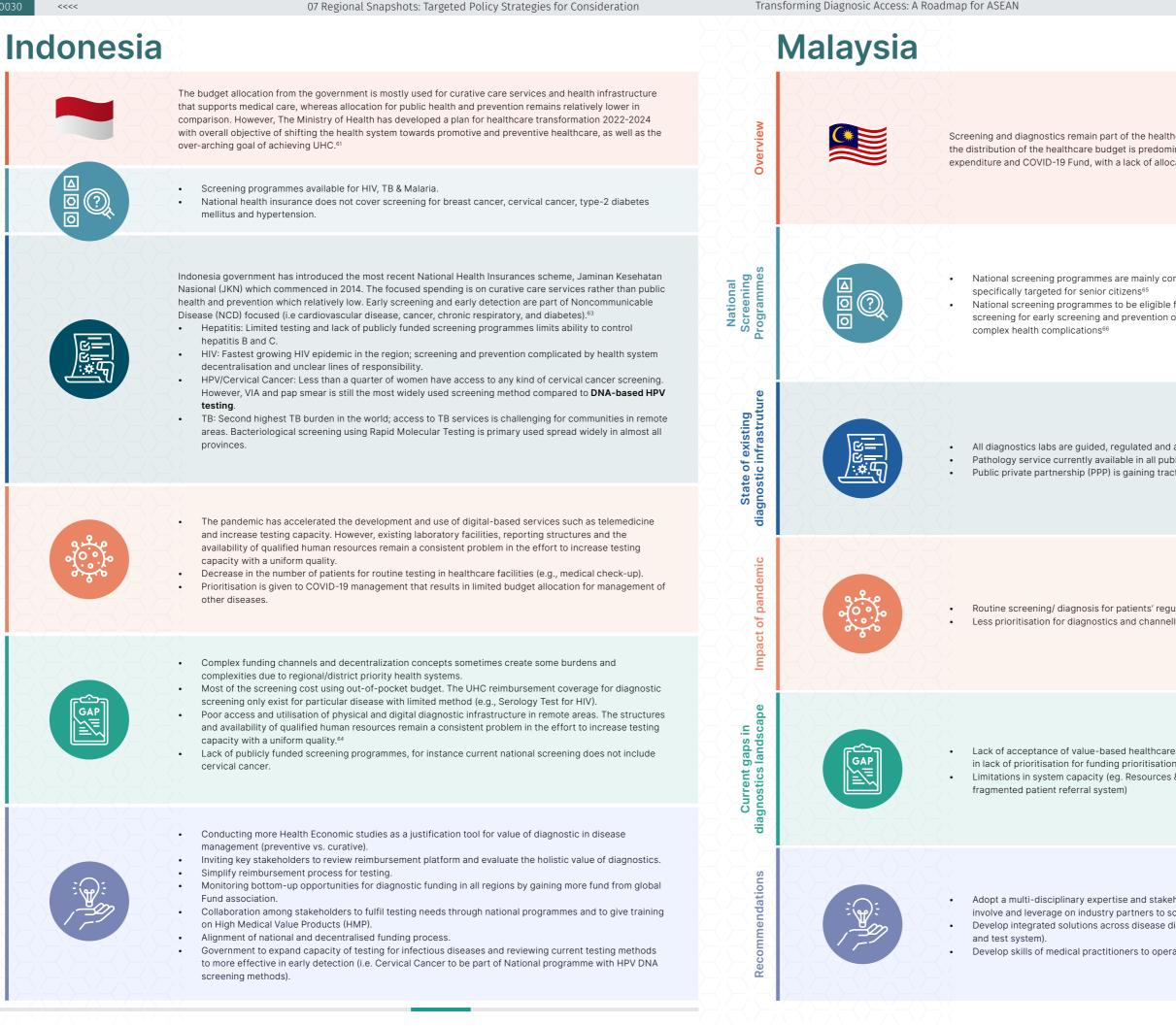
Health insurance firms can also opt to include screening as part of their products that can be segmented based on patient profile - patients with comorbidities, lifestyle behaviours. Based on the risk stratification model, insurance firms can provide screening based on the medical needs of the patients, offering necessary screening tests based on an array of criteria, including (but not limited to) age, gender, family medical history.

07 **Regional Snapshots: Targeted Policy Strategies for Consideration** [6 KEY MARKETS]



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Overview

National Screening Programmes

State of existing diagnostic infrastructure⁶²

pandemic

Impact of

Current gaps in diagnostics landscape

Recommendations

Screening and diagnostics remain part of the healthcare ecosystem however, as reflected on the Budget 2021, the distribution of the healthcare budget is predominantly allocated for operating expenditure, development expenditure and COVID-19 Fund, with a lack of allocation for diagnostics.

National screening programmes are mainly conservative and for non-innovative diagnosis technology.,

National screening programmes to be eligible for B40 group from July 2022 to encourage uptake of health screening for early screening and prevention of escalation of non-communicable diseases (NCDs) into

All diagnostics labs are guided, regulated and assessed by MOH.

Transforming Diagnosic Access: A Roadmap for ASEAN

Pathology service currently available in all public segment hospital/ healthcare (e.g., primary to tertiary) Public private partnership (PPP) is gaining traction since the end of 2021

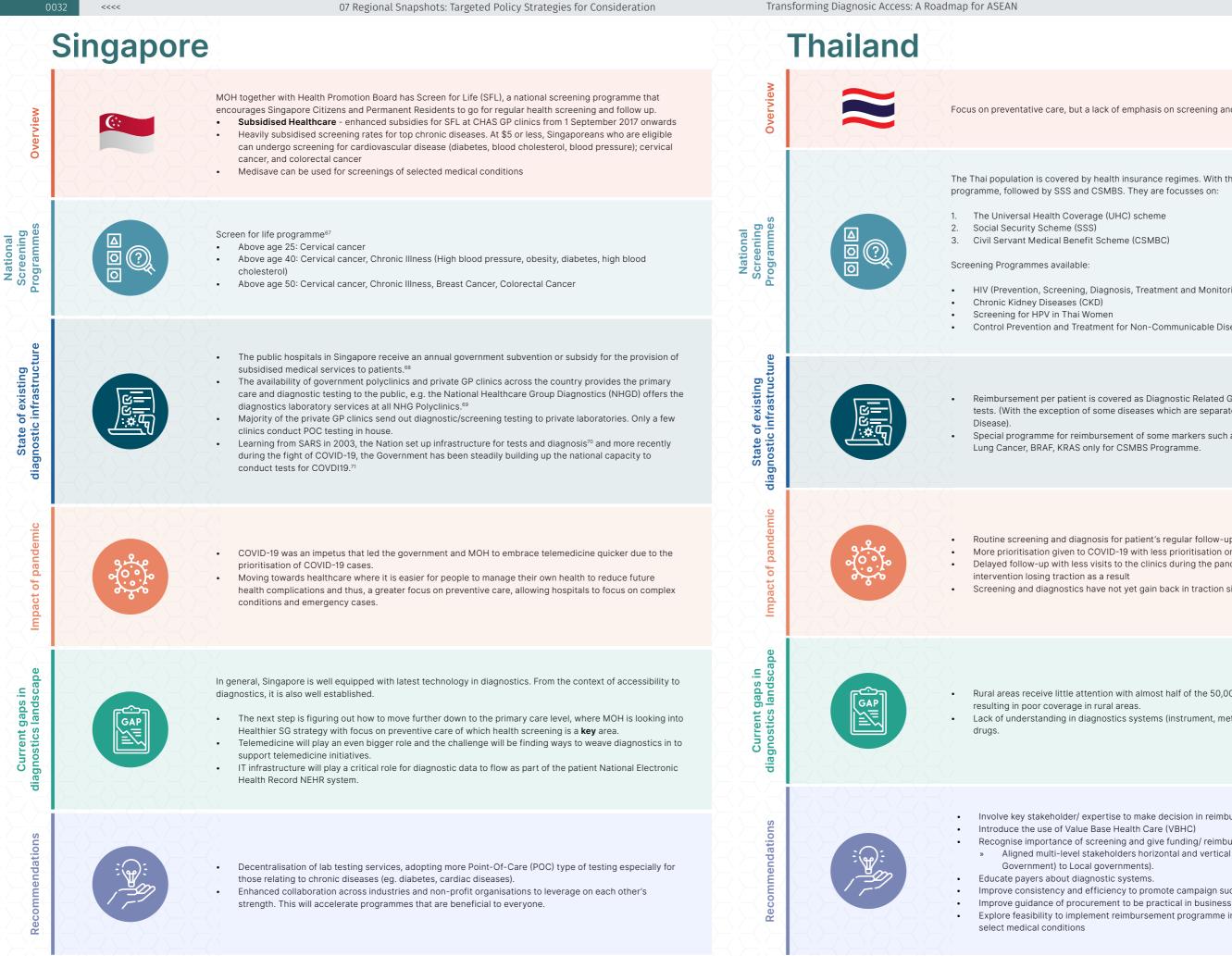
Routine screening/ diagnosis for patients' regular follow-up was disrupted Less prioritisation for diagnostics and channelling of patients to another hospital.

Lack of acceptance of value-based healthcare and lack of advocacy for the adoption of diagnostics result

Limitations in system capacity (eg. Resources & Infrastructure, lack of health technology capabilities,

Adopt a multi-disciplinary expertise and stakeholder community including for procurement. Continue to involve and leverage on industry partners to scale up national screening programmes Develop integrated solutions across disease diagnosis and treatment (e.g. joint reimbursement for drugs

Develop skills of medical practitioners to operate diagnostics equipment and analyse results



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- resulting in poor coverage in rural areas.
- intervention losing traction as a result

- Lung Cancer, BRAF, KRAS only for CSMBS Programme.

Focus on preventative care, but a lack of emphasis on screening and diagnosis.

The Thai population is covered by health insurance regimes. With the UHC taking the lead for screening programme, followed by SSS and CSMBS. They are focusses on:

HIV (Prevention, Screening, Diagnosis, Treatment and Monitoring) Control Prevention and Treatment for Non-Communicable Diseases (NCDs)

Reimbursement per patient is covered as Diagnostic Related Group (DRG) includes drug and diagnostics tests. (With the exception of some diseases which are separate from DRG program such as Cancer, Renal

Special programme for reimbursement of some markers such as HPV, EGFR, Her2-DISH, BRCA. ALK for

Routine screening and diagnosis for patient's regular follow-up decreased

More prioritisation given to COVID-19 with less prioritisation on diagnostics and screening

Delayed follow-up with less visits to the clinics during the pandemic, resulting in essential patients' disease

Screening and diagnostics have not yet gain back in traction since COVID-19

Rural areas receive little attention with almost half of the 50,000 doctors in the country working in Bangkok,

Lack of understanding in diagnostics systems (instrument, method, maintenance) that are different from

Involve key stakeholder/ expertise to make decision in reimbursement programme

Introduce the use of Value Base Health Care (VBHC)

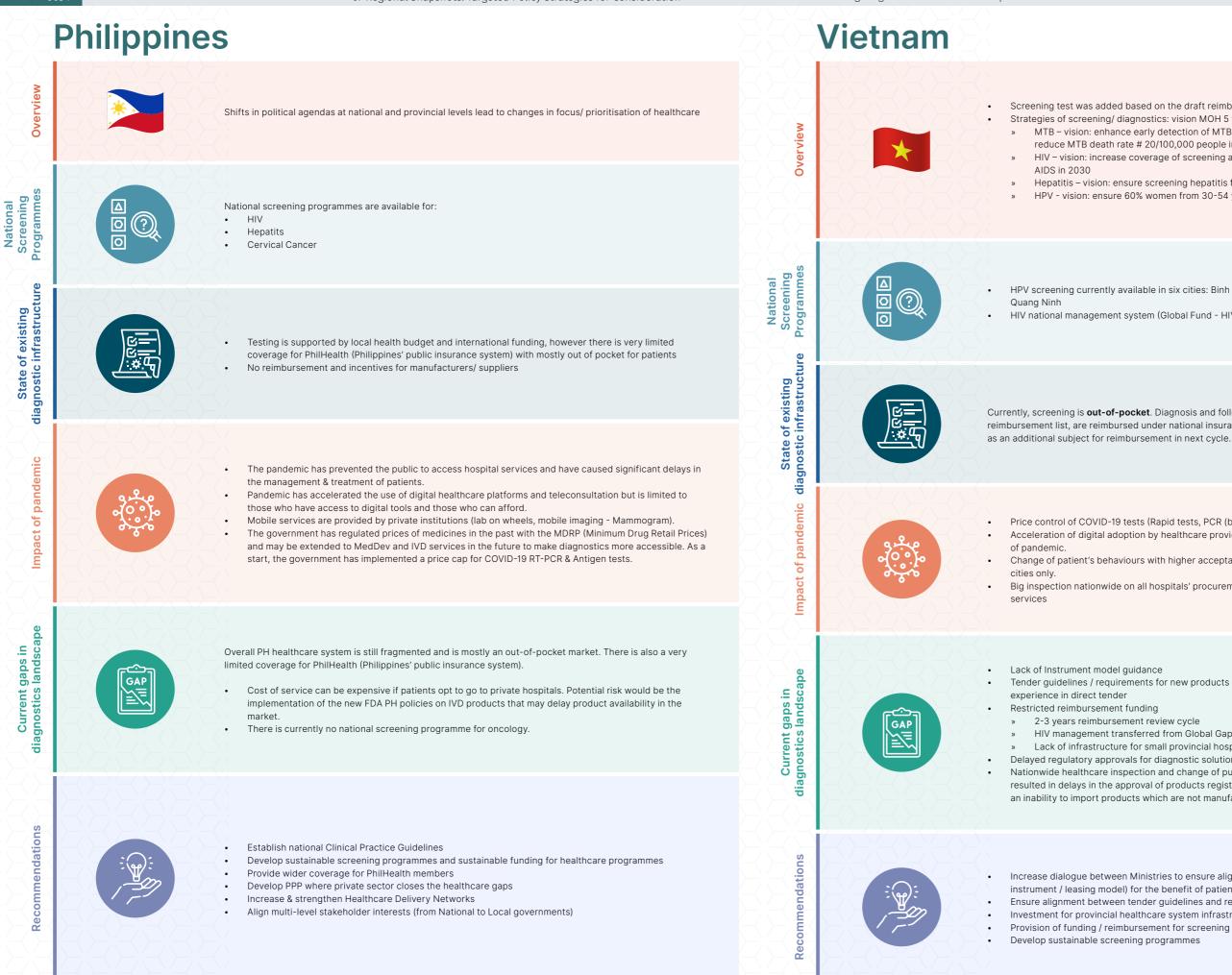
Recognise importance of screening and give funding/ reimbursement for screening diagnostics

Aligned multi-level stakeholders horizontal and vertical lines (from National (Government to

Improve consistency and efficiency to promote campaign such as HPV Screening in target group.

Explore feasibility to implement reimbursement programme in the country for screening and testing of

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- Screening test was added based on the draft reimbursement circular
- Strategies of screening/ diagnostics: vision MOH 5 years 10 years
- » MTB vision: enhance early detection of MTB by investment in innovative Diagnostics solution to reduce MTB death rate # 20/100,000 people in 2030
 - HIV vision: increase coverage of screening and follow-up treatment to all ward level hospitals to stop

Hepatitis - vision: ensure screening hepatitis for all high-risk group to reduce 90% hepatitis rate in 2030 HPV - vision: ensure 60% women from 30-54 years old get cervical cancer screening in 2025

HPV screening currently available in six cities: Binh Duong, Long An, Dong Nai, Thanh Hoa, Hai Phong,

HIV national management system (Global Fund - HIV -AIDS Department of MOH)

Currently, screening is out-of-pocket. Diagnosis and follow-up treatment which are enlisted in National reimbursement list, are reimbursed under national insurance. New reimbursement law has listed screening test

 Price control of COVID-19 tests (Rapid tests, PCR (by government). Acceleration of digital adoption by healthcare providers and patients & increasing home sampling because

Change of patient's behaviours with higher acceptance decentralised hospitals rather than going to big

Big inspection nationwide on all hospitals' procurement especially COVID-19-related tests/ medicine/

Tender guidelines / requirements for new products creates limitations for foreign companies due to request of

- HIV management transferred from Global Gap to local reimbursement
- Lack of infrastructure for small provincial hospitals to succeed in decentralised model
- Delayed regulatory approvals for diagnostic solutions; published timelines are not adhered to by regulators Nationwide healthcare inspection and change of public management board of hospitals / MOH in 2021 - 2022 resulted in delays in the approval of products registered under Circular 30 and 47 since 2020/2021, creating an inability to import products which are not manufactured domestically, resulting in disruption of supply

Increase dialogue between Ministries to ensure alignment and adoption of model (placement model of instrument / leasing model) for the benefit of patients

- Ensure alignment between tender guidelines and requirements for new products
- Investment for provincial healthcare system infrastructure.
- Provision of funding / reimbursement for screening and diagnostics.

08 Conclusion

Conclusion **80**

The lessons to learn from COVID-19 are plenty. Of those, the importance of diagnostics stands out. By enabling individuals to obtain ease of access to diagnostics, it will enable patients to be more empowered about their health. Since the onset of the pandemic, most, if not all (as shown in the regional snapshots) national governments have implemented the inclusion of diagnostics as a strategy to overcome the battle with COVID-19. The rationale was to ensure that the early detection of symptoms can enable isolation to contain the virus. This rationale should not be restricted to COVID-19 but should ideally be applied as a strategy to contain the spread of a broad range of diseases, both communicable and non-communicable alike.

Technology and learnings inherited from COVID-19 should be leveraged, and ASEAN as a region should look towards the adoption of diagnostics to further strengthen their healthcare systems. By reallocating funds to encourage enhancements of testing capability and investing in diagnostics pertinent to the prioritised medical conditions around the region, ASEAN can reduce the mortality rate and increase the DALYs averted, thereby availing the workforce to continue driving the economic vibrancy of the region.

Diagnostics should not be adopted as a "reactive" solution. It must be incorporated in existing health systems as a proactive strategy to curtail the burden of diseases. To reiterate the view by the WHO, diagnostics are part of the health ecosystem. The adoption of which should come in tandem with the utilisation of treatment to deliver quality care to patients and benefit stakeholders within the patient pathway.

Diagnostics and self-testing have been key in the containment of the COVID-19 disease. Also, it brings about clear positive outcomes for patient health and possesses the potential to stimulate national economies. Ultimately a tool needed by the region to address the current pandemic as well as other diseases, screening and diagnostics is required to create a healthy, caring, and sustainable ASEAN community.

09

WHO country cooperation strategic agenda for select ASEAN Member States

Indonesia⁷² Malaysia⁷³ Facilitate multisectoral 1. Address the challenges of communicable diseases and collaboration and support reach the 'Post2015 Agenda' coordination for health 2. Strengthen policies and targets 2. Address the challenge of capacities to build a more noncommunicable diseases resilient, sustainable and and their modifiable risk responsive health system that factors moves even further towards 3. Improve maternal, neonatal, universal health coverage child and adolescent health 3. Strengthen policies and through increasing access to capacities for assessing, quality services preventing, managing, Ensure Indonesia achieves mitigating and monitoring universal health coverage health risks and chronic (UHC) conditions Enable capacity for 4 preparedness and response expertise and sharing of to public health emergencies experiences in regional or and disasters. to provide expert advice to other countries Singapore⁷⁵ Thailand⁷⁶ Healthier SG Strategy Mobilisation of a Network of Family Physicians Migrant Health Healthcare Plans for

5.

Road Safety **Preventive Care**

Forging Community

Partnerships with agencies

Board, Agency for Integrated Care, People's Association,

such as Health Promotion

SportSG, National Parks

Board, and community partners that oversee various

social services

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Annex [Annex 1] Health Priorities of Select ASEAN Member States

Facilitate the use of Malaysian global settings and events and

Noncommunicable Diseases

Philippines⁷⁴

1.	Save lives: ensure full
	access to immediate-impact
	interventions
2	Dramata wall baing ampawa

- people to lead healthy lives and enjoy responsive health services
- 3. Protect health: anticipate and mitigate disasters, and environmental and emerging health threats
- Optimize health architecture: overcome fragmentation to achieve universal health
- 5. Use platforms for health: support health in all settings, policies and sectors

Vietnam⁷⁷

- Strengthening key health towards universal health
- Building sustainable national capacities and partnerships to ensure public health security
- Managing effectively communicable and

09 Annex

09 Annex [Annex 2] Benefits of Diagnostics – Use Cases

Creating a Success Story: The Value of Diagnostics

As a timely reminder, the global COVID-19 pandemic has profoundly raised awareness about the role diagnostics plays in disease prevention and management, providing the prime opportunity to showcase the merits of screening and diagnostics in enabling ASEAN to respond timely to all hazards and emerging threats.

Since the onset of the pandemic, billions of lives have been disrupted. According to the Organisation for Economic Co-operation and Development (OECD), "the pandemic has triggered the deepest economic recession in nearly a century." Due to the pandemic, people have lost jobs, become unable to visit loved ones, and even face the risk of becoming homeless. In addition to the socio-economic impacts, COVID-19 has also claimed the lives of millions. As of mid-September 2021, there have been more than 519 million confirmed cases of COVID-19 and nearly 15 million deaths from the virus. Every continent except Antarctica has been affected.

The rapid spread of the SARS-CoV-2 virus created an urgent need for millions of tests – and quickly. Tests were needed not just to detect active infections but also to measure a person's immune response to the virus. In addition, diagnostics also helped vaccine manufacturers measure the effectiveness of their vaccines in development. Countries with strong diagnostics and digital health infrastructure were better able to cope with the pandemic and continue to meet the other health needs of their patients.

However, SARS-CoV-2 (and its variants) is far from the only dangerous infectious disease. Hepatitis B and C, tuberculosis, HIV, and insect-borne diseases like Zika are serious infectious diseases – 354 million people worldwide live with chronic hepatitis and over 8,000 new infections of Hepatitis B and C occur every day. Diagnosing an infectious disease early and starting treatment as soon as possible are essential to reducing the spread of the disease. Despite the wide range of tests developed to detect and monitor these diseases, they remain among the top 10 causes of death in low-income countries.

Equally critical is the role of diagnostics in battling noncommunicable diseases such as cancer – the leading cause of death amongst individuals aged between 30 to 69 years in ASEAN.⁷⁸

	Cancer F	ank as Leadi	ng Cause of D	eath Among	30 – 69 yea	rs ⁷⁹		
Brunei	15	t	c	Cambodia		2nd		
Indonesia	21	nd	L	.aos		2nd		
Malaysia	21	nd	N	lyanmar		2nd		
Philippines	21	nd	S	Singapore		1st		
Thailand	15	t	١	/ietnam		1st		
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Per the classification by the World Bank, the ten ASEAN countries can be classified based on their social, political, and economic conditions as follows:⁸⁰

Brunei	Cambodia	Indonesia	Loas	Malaysia	Myanmar	Philippines	Singapore	Thailand	Vietnam
High	Low	Lower- middle	Lower- middle	Upper- middle	Low	Lower- middle	High	Upper- middle	Lower- middle

ASEAN Countries Classification Based on Income

Based on this tiering, the Economist Intelligence Unit (EIU) conducted a study to analyse the level of preparedness of select ASEAN countries. As findings from the study revealed, taking Malaysia and Thailand – the upper-middle-income countries – as a baseline for the level of cancer preparedness, the overall score of Indonesia and Vietnam (both lower-middle income countries) falls well below the global average. Meaning, for low-income economies like Myanmar, cancer preparedness levels will fall below that of Indonesia and Vietnam.

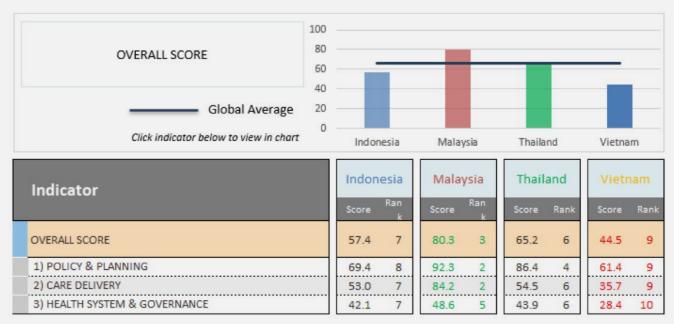


Table 2 EIU Findings on Cancer Preparedness

	Brunei	Cambodia	Indonesia	Loas	Malaysia	Myanmar	Philippines	Singapore	Thailand	Vietnam
Incidence Rate (per 100,000)	413	12,861	494,629	5,728	30,190	66,723	69,218	12,916	112,666	111,581
Mortality Rate (per 100,000)	233	8,882	215,626	4,191	20,130	45,628	52,124	6,106	70,334	82,006

With 500,000 deaths arising from cancer in 2008, and countries of "lower-middle" and "low" income status attributing to more than half of those deaths, the adoption of diagnostics and screening is one of the ways that can help these countries reduce mortality rate by enabling cancer preparedness. Especially where cancer treatment capacity is lacking, ASEAN must tap into the value of diagnostics to detect symptoms and start intervention early. Testing should be made available at the primary care levels to ensure that medical conditions do not escalate into the terminal stages which majority of the healthcare systems in LMICs are not equipped for.

To illustrate its importance for the ASEAN region, four use-cases that reflect how diagnostics battle both communicable and non-communicable diseases alike – Human Papillomavirus, Cardiovascular diseases, as well as Infectious Diseases such as HIV and Hepatitis (leading to Liver Cancer) and COVID-19 – have been engaged.

Secondary

Despite being almost preventable with vaccination and screening, cervical cancer resulting from Human Papillomavirus (HPV) continues to claim the lives of approximately 300,000 women every year, making it one of the main causes of death in women.82



Across ASEAN (except for Vietnam in which no data was recorded), only Singapore and Thailand scored favourably under the WHO recommendations for HPV secondary prevention:

	Primary Invention	Secondary Prevention*
Brunei	8 in 10 received final dose of HPV vaccine by age 15	3 in 10
Cambodia	HPV Vaccination not included in national vaccination schedule	1 in 10
Indonesia	Fewer than 1 in 10 girls in the primary target cohort have received the final HPV vaccination dose	<1 in 10
Loas	7 in 10 girls in the primary target cohort have received first HPV vaccine	<1 in 10
Malaysia	8 in 10 received final dose of HPV vaccine by age 15	4 in 10

	Invention	Prevention*
Myanmar	9 in 10 girls in the primary target cohort have received the first HPV vaccination dose	<1 in 10
Philippines	Fewer than 1 in 10 girls in the primary target cohort have received the final HPV vaccination dose	<1 in 10
Singapore	Among girls turning 15, fewer than 1 in 10 received their final HPV vaccination dose	6 in 10
Thailand	HPV included in national vaccination programme but data N.A	6 in 10
Vietnam	N.A	N.A

Table 3 ASEAN Cervical Cancer Prevention Overview⁸⁴

Receiving HPV vaccines and encouraging regular screening for early detection of the virus has remained a priority for the WHO. In 2020, WHO launched the Global Strategy to Accelerate the Elimination of Cervical Cancer. The three goals of the strategy are, by 2030:

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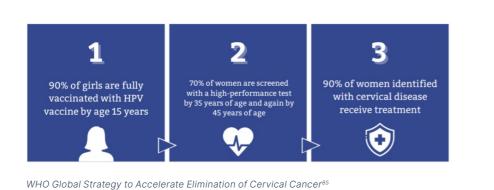
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*How many women have been screening for cervical cancer in the last 5 years

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Primary

To achieve the three goals, the WHO has recommended three preventative methods at the primary, secondary, and tertiary levels respectively. The role of diagnostics is especially critical under "secondary prevention", with WHO recommending women aged 30 and above (and 25 for those living with HIV) to get screened to detect traces of cervical cancer early.86

	Types of Screer
Cytology (Pap Smear)	Examination of a cervical c microscope in a laboratory
Visual Inspection with Acetic Acid (VIA)	Visual screening of the cer application of 3 – 5% acetic
HPV DNA Testing	Molecular biology techniqı vaginal cells

Whereas cytology-based testing has been the norm for the mode of detection, it is now recommended for individuals to get tested via DNA-based HPV testing as a first choice given its higher efficacy and accuracy in screening and detecting cervical cancer.⁸⁷ As the WHO announced, it is "more cost-efficient and is suitable for all settings, areas, and countries".⁸⁸ This is especially so primarily for two reasons: (1) DNA-based testing has higher sensitivity than the traditional pap smear in detecting the HPV; (2) given the higher accuracy of results, there can be longer intervals between screenings, meaning individuals would require less frequent testing as a result.

Many countries are therefore pivoting to HPV DNA testing to help prevent cervical cancer or to catch it in its early, curable stages. One such country is Thailand. Cervical cancer is the most common cancer in Thai women since 1989.89 Thailand has adopted the recommendations put forth by WHO to combat cervical cancer. Initially, Thailand opted for a dual-track cervical screening policy and allowed provinces to choose either cytology-based testing or VIA screening as the primary screening method for women aged 35 to 60 years, all the while following the screening intervals recommended by the WHO which is set as every five years.⁹⁰ This has been the case up until the "costeffectiveness analysis study of HPV testing as a primary cervical cancer screening in Thailand" was published in the gynaecologic oncology reports of Elsevier in 2017.

Results of the study revealed the following:

- 1. Most cost-effectiveness strategy with higher accuracy
- 2. Decrease cost by 46,950,840 THB (1,394,441 USD) per 100,000 women screened when compared to VIA

The study aimed to compare the cost and benefits of the different cervical cancer screening strategies for detecting the HPV virus. Overall, the results from the model predictions were in favour of DNA-based testing, as opposed to the other two forms of testing. The considerations were (1) cost; and (2) accuracy. Recognizing that DNA based testing generated better results on both spectrums, Thailand has since introduced HPV DNA testing as a primary screening method in nationwide cervical cancer programs back in 2020.

ning for HPV ell smear stained with Pap technique under a to detect early dysplastic or cancerous cells vix for acetowhite lesions 1 minute after the acid le for the detection of HPV in cervical and

3. Decrease cost by 51,279,781 THB (1,523,011 USD) and detected 506 more cases than cytology-based testing

NT-proBN

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2. Managing Cardiovascular Diseases (CVDs)

As the WHO has stated, CVDs are not only the leading cause of death globally, but it also places a heavy economic burden on individuals from LMIC households who are unable to afford the cost of treatment. While one solution proposed by the WHO is for governments to encourage their citizens to adopt and sustain a healthy lifestyle, another suggestion leverages on diagnostics to ensure that patients can detect heart failure (HF) in the early stages to enable treatment to start as soon as signs of HF are detected.



ASEAN is a region that should target to enhance their diagnostics capacity to detect HF given that it has been identified by the WHO, in the 2014 global status report, as the region with a high probability of premature deaths arising from cardiovascular diseases:



Probability of Premature Death from NCD⁹²

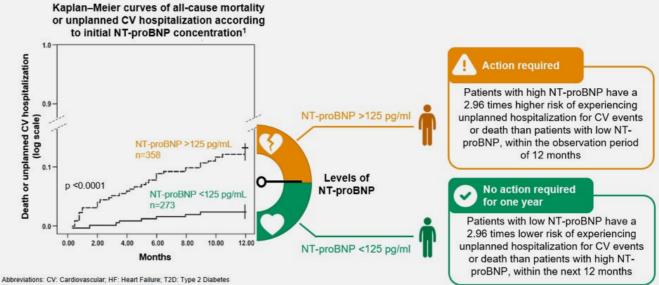
On this note, the introduction of biomarkers such as the N-terminal pro-brain natriuretic peptide test (NT-proBNP) plays a critical role in improving the diagnosis and averting premature deaths as a result of HF. Although NT-proBNP is considered useful both in the diagnosis and prognosis of heart failure and is considered to be a gold standard biomarker in heart failure, however, it was found that it is not well adopted as the standard of care in some ASEAN countries during a HF Gap Survey done by the Asian Pacific Society of Cardiology. In Singapore, NT-proBNP is well adopted compared to BNP as it is more stable and is not influenced by the new HF drug Angiotensin Receptor Neprilysin inhibitor (ARNi)I. On the contrary, BNP or NT-proBNP are not widely used in Indonesia, Philippines and Malaysia due to limited availability and cost concerns. The benefit of biomarkers should be reviewed and weighed against its cost as NT-proBNP has also a strong prognostic value of death in acute and chronic heart failure and also predicts short- and long-term mortality in patients with suspected or confirmed unstable CVD. This is especially beneficial for patients who suffer from CVDs and chronic diseases such as Type 2 Diabetes (T2D). The benefits are highlighted in three primary ways:

1	2
IP levels	Prioritised inte
entify Type2	CV manageme
patients -	may help to pe
natic for Heart	or delay the o
IF)	heart failure
nose who are high	NT-proBNP can ide
CV complication,	with type2 Diabete
eart Failure, and	asymptomatic for
ould (not) benefit	but identified to be
assessment.	Heart Failure.

Benefits of NT-proBNP testing for Patients with T2D⁹⁴

With the adoption of NT-proBNP biomarker testing, doctors can create personalised treatment plans to help reduce mortality and morbidity. The inclusion of the Troponin T-high sensitivity test (hs TnT) also enables doctors to detect HF more quickly and accurately so that patients diagnosed with symptoms can start treatments sooner – helping save lives and reduce complications.

NT-proBNP levels help to identify T2D patients asymptomatic for HF who are at high [*low*] risk of CV complication, especially HF, and who would [*not*] benefit from further assessment



Abbreviations: CV: Cardiovascular; HF: Heart Failure; T2D: Type 2 Diabetes For more information, please see <u>Huelsmann 2008</u> publication summary slides References: **1.** Huelsmann, M. et al., *Eur Heart J.*, 2008; Vol. 29, pp. 2259-2264

Higher Sensitivity of NT-proBNP to Detect Symptoms of Heart Failure95

Overall, cardiac biomarkers which are specific to the condition (such as the NT-proBNP) plays a role in bridging the current gaps within the existing HP patient pathway and creates value for all stakeholders within the healthcare system (for the exhaustive list of benefits of NT-proBNP in bridging the HP Patient Pathway, please refer Annex 2). A brief illustration is reflected below in which the diagnostics tool provides benefits at each stage of the patient pathway.

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ensified net which revent nset of

entify patients es who are Heart Failure e high-risk of

Prioritisation of healthcare resources

3

NT-proBNP testing can be used as a powerful tool to exclude T2D patients who are not at risk of Heart Failure within the next year. <<<<

Value of Diagnostics (NT-proBNP) in bridging gap in Existing gaps in the HP Patient Pathway the HP Patient Pathway Value to patients Value to patients Value to healthcare systems Patients with chronic HF are typically under-High rates of misdiagnosis & Lack of close monitoring often dosed, with multiple therapies applied missed diagnosis as symptoms leads to patient non-adherence are not HF specific incrementally and suboptimal doses that results in fatal outcomes Aid in the correct identification of HE NT-proBNP is a stronger predictor that enables Switching long-term care to primary which can help patients adapt lifestyle to dentification of patients at risk of adverse events setting to enable cost-effective better manage condition of disease allowing for optimisation of treatment continuous monitoring 1 Diagnosis / Referral CHRONIC PHASE PATIENT PATHWAY 2 Treatment / Stabilise 3 3 Discharge (2) Acute Treatment / Monitoring 노 ACUTE PHASE Value to healthcare professionals Value to healthcare systems Value to patients Patients leaving hospital after acute HF Hospitalisation costs, room and boarding fees are the greatest cost drives in HF following a test. When presenting in Emergency epartment (ED), Point of Care Testing (POCT) has the episodes remain at high risk of death and hospital readmission for up to 3 months potential to speed up the diagnosis 1. Reduce hospital costs related to length of stay, time of staff, clinical examination and imaging procedures Information provided by a cardiac biomarker POCT for HF is a tool for healthcare providers (HCPs) 2. Allows to predict the length of stay of a patient in the specific to HF reduces the risk of re-hospitalisation to make timely decision that can be critical to hospital, aiding the planning of an efficient strategy & and its associated costs discharge patients

Diagnostics Value Adds to the Patient Pathway for Individuals with Symptoms of Heart Failure

Such targeted diagnostics capability can support timely diagnosis and person-centred management of the syndrome, thereby improving outcomes, reducing the need for hospitalisations, and protecting healthcare resources. Hence, the adoption of which will ultimately create a more resilient healthcare system that is better prepared to serve the needs of the populace battling HF.

3. Dealing with Infectious Diseases

A. Human Immunodeficiency Virus (HIV)

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Despite global and national efforts to battle the virus, Human Immunodeficiency Virus (HIV) remains a major public health issue. Overall, suboptimal testing rates of HIV remains a prevailing gap before the world can attain the WHO 95-95-95 Goal for HIV Elimination by 2030 - diagnose 95% of all HIV-positive individuals, provide antiretroviral therapy for 95% of those diagnosed and achieve viral suppression for 95% of those treated.⁹⁶

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Overview of HIV97

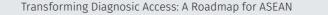
HIV reside in the ASEAN region, of which close a third are female99

Across select ASEAN countries, namely Cambodia, Indonesia, Malaysia, Myanmar, Singapore, and Thailand, the biggest barrier to HIV diagnosis remain the social stigma against HIV/AIDS. Individuals choose not to get tested for fear of discrimination from testing positive.¹⁰⁰ Therefore, to close the gap in achieving the 95-95-95 targets and to encourage testing, the conventional methods of testing needs to be improved. To broaden access and reach to key populations, the WHO has identified HIV Self-Testing (HIVST) as a critical component in its strategy to eliminate HIV and have recommended it as an approach to HIV testing services.¹⁰¹

Primarily, since it can be done privately, HIVST removes the barriers to testing by ensuring confidentiality and mitigating anticipated HIV stigma among key populations who are disproportionally affected by HIV.¹⁰² This enables HIVST to increase testing uptake, thereby providing opportunities for reducing HIV-related morbidity and mortality and preventing new transmission. In Vietnam, for example, identified as one of the top countries that account for 89 percent of all new HIV infections, self-testing has been introduced since 2016 to battle the HIV epidemic in the country.¹⁰³ In 2019, recognising the preference of individuals to self-test, Vietnam have registered the first HIVST product since July that same year.¹⁰⁴

Why testing for HIV is important¹⁰⁵ whenever start treatment early to manage the disease 3. Testing is the gateway to HIV prevention and treatment strategies treatment of their HIV status prevention of mother-to-child transmission 7. Early diagnosis enhances the quality of life of patients, lowers the cost of treatment and the risk of potential transmission

In adopting a phased approach since the pilot programme in Vietnam in 2016, HIVST have resulted in a high HIVpositive yield. There are also high rates of linkages from self-testing to diagnosis and care. Of the 8,699 people who were tested for HIV between May 2016 and May 2018, 6.8 percent received a positive result and were referred for confirmatory testing. Of those individuals, 86.5 percent received an HIV confirmation and 94.5 percent of those diagnosed with HIV were enrolled in antiretroviral therapy.¹⁰⁶



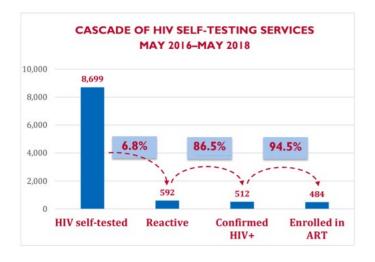
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WHO Recommends⁹⁸

- There is no cure for HIV infection. However, by increasing access to diagnosis, HIV infection can be a manageable chronic health condition Current HIV testing can be done through rapid
- diagnostic tests that provide same-day results and thus immediate initiation of antiretroviral treatment (ART) as required after confirmation Self-testing facilitates early diagnosis and
- enables patients to receive treatment and care

- 1. HIV self-testing empowers people to find out their HIV status wherever and
- 2. Easy, quick and private testing can encourage individuals to test for HIV and
- 4. Lack of knowledge on HIV serostatus could delay the initiation of antiretroviral
- 5. Transmission rate can be reduced by 3 to 3.5 times when individuals are aware
- 6. Awareness of HIV status is an important factor in HIV prevention, including





As the case with Vietnam, safe and effective models of HIVST implementations have been piloted successfully. Nonetheless, government support is needed to scale-up these efforts to leap over the "last mile" for HIV Elimination and extend their reach beyond select provinces. Even in regions such as Vietnam where HIVST has been trialled, policies and funding need to fuel the momentum to ensure uptake and affordability to encourage individuals to undergo regular testing. National governments must identify the hard-to-reach key populations and develop guidelines and implementation programs for self-testing of HIV to remain on course to end the AIDS epidemic by 2030.

Figure 5 Cascade of HIV Self-Testing Services from May 2016 to May 2018¹⁰⁷

"There are key reasons why key populations do not go for testing, even at facilities with established HIV testing services. Some of them include:

- 1. Misconceptions that downplays the need to get tested (no time to do it, or I don't feel any symptoms, why should I get tested?);
- 2. Morality as a factor not to test (idea of testing is embarrassing, especially when my friends/peers see it, I might be tagged as "immoral");
- 3. Worries in confidentiality and privacy (others might know I am positive, or see I might be positive because I had additional steps);
- 4. Fear of what happens when one tests positive, among others

Similar models of HIVST initiatives in Philippines - LoveYourself.inc

A similar initiative of self-testing - with a mission to empower individuals and spreading the message of the value of self-worth and the critical importance of loving oneself - has also been rolled out in the Philippines by LoveYourself.

LoveYourself therefore allows individuals to overcome these challenges by providing self-testing as an alternative option for individuals to know their HIV status as part of a differentiated service delivery. We have been successful in drawing people to opt for self-testing as an alternative means of testing to know their HIV status. Since the start of this programme, LoveYourself has provided around 5,800 tests to individuals, with around 75% of individuals linked to confirmatory testing opting to receive treatment.

HIVST is therefore valuable in our aim to reach the 95-95-95 targets, and diagnosis is critical as it allows the community to gain access to testing as one of the preventive options, regardless of one's HIV status: If one is negative, they need to be enrolled to pre-exposure prophylaxis (PrEP). If they are positive, they need to be linked to ART. Testing everyone and employing a status neutral approach will ensure that everyone - regardless of their lifestyle - will be taken care of. This will help us test everyone who needs to be tested, hence bringing us closer to reaching the 95-95-95 targets."

Interview with DANVIC ROSADIÑO, DIH, Program and Innovations Director, LoveYourself Inc.

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B. Liver Case: A Patient Journey from Hepatitis to Liver Cancer

Hepatitis 1.

Labelled as "a silent killer" by the WHO, the hepatitis B and C virus are major causes of acute and chronic liver diseases which can be deadly if left undetected.¹⁰⁹ Given that approximately 80% of individuals contracted with hepatitis B and C virus do not exhibit any symptoms, infected individuals remain unaware of their condition.¹¹⁰ Therefore, for years, even decades, the virus can slowly and silently damage the liver, leading to hepatocellular carcinoma and other serious health consequences for patients.

Snapshot of Disease Overview¹¹¹

Overview¹¹²

- Hepatitis B disproportionately affect Asians and Pacific Islanders, who are historically also the ethnic group most affected by liver cancer¹¹³
- Viral hepatitis is the seventh leading cause of mortality worldwide claiming the lives of 1.4 million per year¹¹⁴
- 81% of deaths due to viral hepatitis in the • Southeast Asian region are attributed to Chronic complications of Hepatitis B and C¹¹⁵
- 410,000 people die due to viral hepatitis each year in the Southeast Asian region

WHO recommends all expectant mothers to be routinely screened for HBV early in early pregnancy, and all infants receive the hepatitis B vaccine as soon as possible after birth to reduce by 90% the risk of virus transmission. Those living with hepatitis B are advised to take lifelong oral medication to suppress the virus. Whereas vaccination is a preventative measure for hepatitis B (similar to the WHO's recommendation of adopting a healthy lifestyle to prevent Heart Failure); and medication aids in disease management, a monitoring element is missing within the liver disease continuum to prevent the escalation of hepatitis B and C from developing into hepatocellular carcinoma.

A prevailing gap exists for diagnosis of hepatitis, even though screening of the disease is:

- 1. the most critical component in preventing hepatitis infection transmission; and
- 2. enables patients to receive treatment that can cure more than 95% of persons with hepatitis C infection

WHO Recommends

- WHO recommends facility- and communitybased testing approaches for viral hepatitis (2017) to scale-up patient screening and reach WHO Goal to eliminate viral hepatitis as a major public health problem by 2030, recommending "that all adults have access to and be offered HCV testing with linkage to prevention, care and treatment services".
- Receive vaccination for prevention of contracting hepatitis; and antiviral treatment management of the disease

Where we are now - scale up (with risks) and simplifications

Transforming Diagnosic Access: A Roadmap for ASEAN

As the WHO recently acknowledged

in June 2022¹²³, "[e]arly diagnosis

can prevent health problems that

may result from infection and prevent transmission of the virus".¹²⁴ Critically,

testing and diagnosis of hepatitis B and

C are key to prevention and treatment.

Early identification of persons with

chronic hepatitis infection will not only

contain the spread of the virus, but it

Disease Journey





- transmission to others 2
 - Lack of testing means higher risk of escalation of HBV/HCV infection into HCC
- 3
- Late-stage HCC management lowers quality of life for patients with HCC 4.

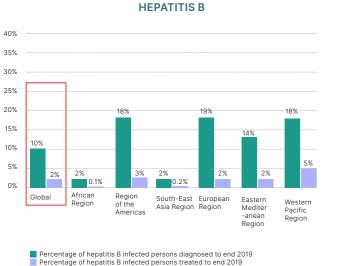
EGYPT - Case Study

Such was the case for Egypt which was faced with one of the world's largest hepatitis C epidemic prior to 2019. In 2016, Egypt had about 5.6 million hepatitis C infections. In 2018, Egypt launched a massive countrywide effort to screen 62.5 million people – aged 18 years and older – within one year and to provide treatment provided by the state for all infected individuals. By mid-2019, nearly 50 million adults have been screened.¹²⁶

Through a range of initiatives and national campaigns rolled out by the government, in partnership with private stakeholders, Egypt was able to administer treatment for hepatitis C to 2.2 million of the infected population,¹²⁷ successfully reducing the prevalence of hepatitis C in the community from 7% in 2016 to less than 1% by the end of 2019.128

VIETNAM - Case Study

In Southeast Asia, viral hepatitis is the third cause of death in Vietnam.¹²⁹ With an estimated population of 8.8 million people living with chronic HBV and HCV infection and 40,000 deaths annually, Vietnam continues to witness 80 -90% of the infected people remaining undiagnosed, with 95% of treatment eligible patients remaining untreated. To increase awareness of, and subsequently treatment for, viral hepatitis, HepLINK - a model of decentralised and integrated viral hepatitis service delivery - was launched with the aim of availing testing services for viral hepatitis at Primary Healthcare levels.



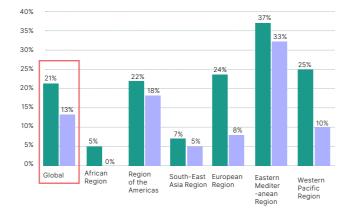
10% of estimated 296 million people

with chronic HBV were diagnosed in 2019

21% of estimated 58 million people with chronic HCV were diagnosed in 2019

HEPATITIS C

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Percentage of hepatitis C infected persons diagnosed to end 2019 Percentage of hepatitis C infected persons treated to end 2019

Figure 6 Viral Hepatitis Service Cascade by WHO Region, 2019¹¹⁸

As witnessed in the statistics from the 2021 Global Hepatitis Report, the gap in screening for hepatitis is a common phenomenon worldwide. ASEAN is no exception, with challenges still remaining for the adoption of screening and diagnostics for hepatitis B and C still remaining.¹¹⁹

Impedime	ents to Combatting Hepatitis in Select ASEAN Member States
Indonesia ¹²⁰	Limited testing and lack of publicly funded screening prorammes creates a constraint on the ability of the country in controlling hepatitis B and C.
Cambodia ¹²¹	257,000 people is estimated to be living with hepatitis C in Cambodia. Despite this, access to hepatitis C testing and treatment is currently limited due to the lack of a public programme and high private sector costs.
Philippines ¹²²	A national screening programme for hepatitis does not exist in the Philippines. Many of the estimated 10.6 million Filipinos infected with hepatitis B, and the 614,000 Filipinos with hepatitis C do not know they have the disease until it is too late and they develop symptoms of severe liver damage or liver cancer.

As illustrated in the Liver Disease Continuum, inadequacies exist when hepatitis testing is not included within the continuum. When individuals remain undiagnosed in the initial stages (Stage 1), it enhances the risk of infection to other persons within the community. Further, non-diagnosis that leads to non-treatment (Stage 2 and Stage 3) will, in the worst-case scenario, develop into hepatocellular carcinoma that will drastically reduce the quality of life for patients living with hepatitis B and C (Stage 4).

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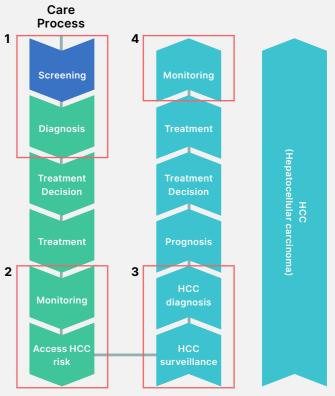
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will also enable patients to receive the necessary care and treatment to prevent or delay the progression of liver disease.125



Model 2 Diagnostics Gap in Liver Disease Continuum

Low rate of hepatitis testing means people who are infected with HBV/HCV remain unaware of their infection & increases the risk of

Screening only at the advanced stages when HCC symptoms arise translates to higher cost & poor 5-year survival

<1% prevalance of hepatitis C by . end 2019



What is HEPLINK?¹³¹

- An initiative by PATH and The Hepatitis Fund in collaboration with Vietnam's MOH to demonstrate communitybased (CBT) and facility-based testing (FBT) for viral hepatitis
- 2. A cost-effective model of decentralised and integrated viral hepatitis service delivery—that effectively engages populations at risk of viral hepatitis in prevention, awareness raising, case detection and treatment—to improve viral hepatitis outcomes and provide evidence for scaling and financing interventions that are integral to the elimination of hepatitis B and C by 2030
- 3. Targeted to accelerate testing uptake and treatment access for key populations in Hanoi and Ho Chi Minh City

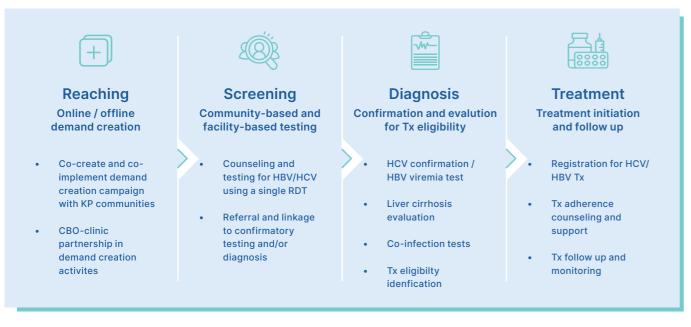


Figure 7 Model of Community-based and Facility Based HBV/HCV Screening and Linkage to Care¹³²

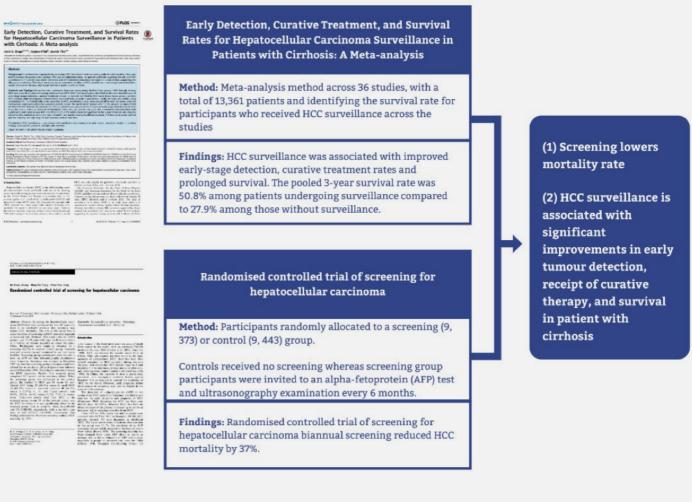
Overall, HepLINK revealed that community-based testing is an effective approach to reach, test and identify people at high risk of HBV/HCV infection. By extending the reach of the campaign through the decentralised model, it increases the rate of referral and diagnosis and allows for individuals diagnosed with viral hepatitis to undergo treatment. Nonetheless, for the country to get closer to eliminating hepatitis as the case of Egypt, there needs to be a consistent effort to sustain and intensify screening, translating initiatives into long-term sustainable programmes, thereby edging Vietnam closer to realising their goal of eliminating hepatitis by 2030.¹³³

B. Liver Case: A Patient Journey from Hepatitis to Liver Cancer

2. Hepatocellular Carcinoma

If left undetected in the initial stages, Viral Hepatitis will progress in the liver into full-fledged cancer, otherwise known as Hepatocellular Carcinoma (HCC), accounting for 90% of liver cancers globally. As the sixth most common type of cancer, over 750,000 people are diagnosed with HCC annually, most often in the late stages of the diseases. Despite the availability of testing technologies - from HBV and HCV screening (e.g. HBsAg, anti-HBs, anti-HCV serology tests), to diagnosis, treatment decision-making and monitoring, to more advanced procedures such as ultrasound imaging or, increasingly, AFP and PIVKA-II surveillance tests as a biomarker to catch the oncogenesis progression much earlier and as a more precise means to determine tumour stage – diagnostics remain undervalued, resulting in more than half of HCC cases being diagnosed in the later stages of the diseases, causing the five-year survival rate to be less than 10%.

Diagnostics significantly benefit individuals who are diagnosed with HCC, with studies showing that early diagnosis before the development of symptoms can result in significant improvements for the overall survival of patients.¹³⁴



As findings from both studies revealed, the screening for hepatitis B and C (and subsequently hepatocellular carcinoma, if needed) in adults is as important as infants receiving vaccinations for the prevention of the viruses. HCC mortality rates were shown to decrease by as much as 37% through earlier and more advanced diagnostics; while survival rates jumped to over 50%, as compared to 27% using more limited protocols. Through screening, surveillance and other preventative testing, patients who are identified early were able to benefit from curative care with prolonged survival.

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Timeline validating the importance of screening for HCC

Although studies have shown that in the Asia Pacific, closer to 80% of HCC cases are diagnosed in the later stages. Fortunately, discussions are underway to evolve how biomarkers and other diagnostic technologies are adopted in the region to improve early detection:

2019	Incorporation by the European Association for the Study of the Liver (EASL) in 2019 of Hepatitis B and C screening as standard of care for primary HCC prevention
2021	Japanese Society of Hepatology (JSH), with its expert panel on HCC, updated their clinical practice manual in 2021 to include the PIVKA-II biomarker screening approach in its fourth edition revision. By incorporating these biomarkers such as PIVKA-II into health screening programmes, it will enable earlier detection of HCC.

In essence, there are three prongs of effective liver disease progression management:

- 1. tackling the risk factors (through HBV/HCV management),
- 2. earlier identification of those patients with chronic issues, and, ultimately,
- 3. the surveillance therein in order to pick up early-stage HCC that could potentially benefit from curative therapy.

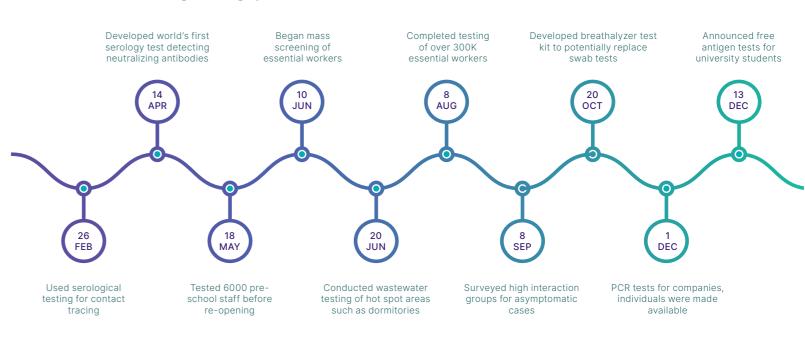
all of which would require greater access to diagnostic technologies in order to detect conditions early to lower the mortality rate of hepatitis B and C, especially granting patients who are diagnosed with hepatocellular carcinoma a 5-year survival through timely intervention and early treatment. The importance of diagnostics in addressing the issue of HCC is paramount.

4. Containing COVID-19

The delivery of the message pertaining to the importance of diagnostics would not be complete without giving due recognition to the COVID-19 pandemic. Pre-COVID-19, years of neglect in the field of diagnostics had initially left global healthcare systems scrambling to cope with testing to contain COVID-19.¹³⁵ The urgency to mitigate the spread of COVID-19, paired with the need to compensate for the negligence in the field translated to rapid innovation in diagnostics and testing.

Singapore, for example, has responded timely to combat COVID-19. "As soon as information about the disease emerged ... Singapore began preparing by ramping up laboratory capacity for mass testing and developing its own test kits. This was seen as instrumental to containing infections and not overwhelming hospitals".¹³⁶ Further, Singapore also rapidly adopted testing as a strategy to minimise the transmission of COVID-19 whilst ensuring early re-opening of workplaces and educational institutions once asymptomatic transmission of the virus was first reported on 4th February 2020.

Timeline of Testing in Singapore¹³⁷



*First local transmission cluster reported on 4 Feb 2020

Testing for COVID-19 targeted primarily three communities: (1) persons vulnerable to infection; (2) individuals with high risk of exposure such as migrant workers in marine and construction sectors and front-line health workers; and (3) persons with a high frequency of interaction with other people such as drivers, food and beverage vendors, and delivery personnel.¹³⁸ The whole of society, ranging from ministers, physicians, medical practitioners, businesses, as well as patients were receptive to testing given its convenience, affordability, efficiency, and accuracy:

- 1. Point-of-Care tests can be conducted in the hospital setting under the presence of healthcare professionals, or in the patient's home
- 2. Results are guick, immediate, instant, and in real time. In some cases, antigen tests are even accurate enough to replace RT-PCR which can be most useful to identify outbreaks¹³⁹
- 3. Rapid tests are crucial in emergency situations (such as COVID-19); or in monitoring chronic diseases (diabetes)¹⁴⁰ 4. Rapid testing kits cost less than a PCR test, enabling patients to undergo frequent testing at low cost¹⁴¹

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Given its rapid uptake and the reduction in time to receive results, Singapore was able to keep to a minimum its casualty rate. Of the 1.34 million COVID-19 cases, the casualty rate was 0.1% with a total of 1,398 deaths since 2021, allowing Singapore to ensure safe reopening of workplaces and educational institutions starting April 2022.

WHO has acknowledged the importance of self-testing kits for both diagnostics and screening purposes.¹⁴² WHO has even gone the extra mile to recommend that COVID-19 self-testing be adapted to national priorities, enabling patients to be empowered and in control of their own health.

Centralisation and Decentralisation: A Complementary Approach¹⁴³



Critically, rapid testing kits also complements the healthcare system. As a decentralised testing solution, POC testing can reduce the likelihood of transmission by enabling individuals to test from home. Not to mention, POC testing frees up capacity of centralised labs to improve the turnaround times and ensure earlier diagnosis "by decongesting the RT-PCR laboratory to help cater to more patients" with other medical conditions.¹⁴⁴

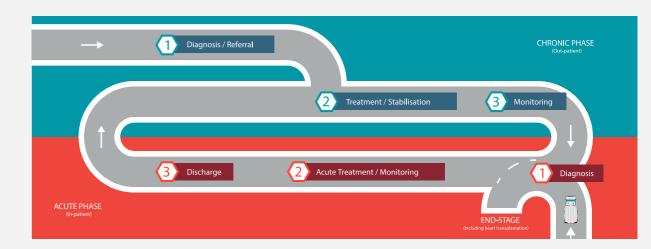


Annex

Current Gaps in HF **Patient Pathway & the** Value of Diagnostics in **Bridging the Gap**

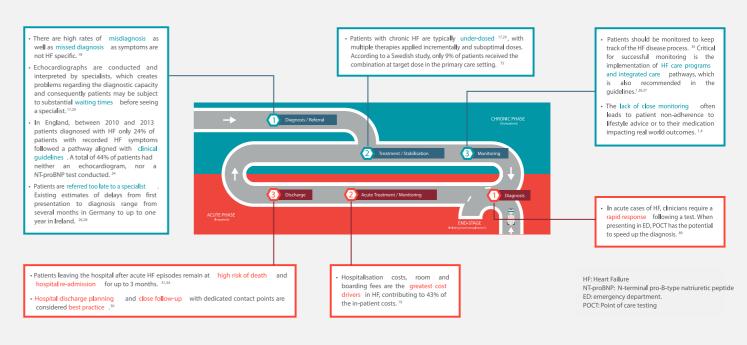
The Heart Failure patient pathway is complex as patients may experience both chronic and acute (requiring hospital admission) stages of the condition

Timely diagnosis, treatment and effective monitoring are crucial



CHALLENGE

Untapped opportunities along the patient pathway lead to suboptimal Heart Failure care



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[Annex 3] Current Gaps in HF Patient Pathway & the Value of Diagnostics in Bridging the Gap

OPPORTUNITY

The use of information provided via cardiac biomarkers may address current shortcomings in Heart Failure* care

Value creation at each step of the patient pathway and to all stakeholders in the healthcare system

The information provided by a cardiac biomarker cific to HF The information provided by a cardiac biomarker can be cost-effective as it reduces the specific to HF: 🔿 Dia specialist care (monitoring and operator-needed techniques). 28,42-44,46 allows the prediction of short-and long-term mortality as well as the re-admission rates reduces the risk of re-hospitalisation (troponin).9 allows to switch long-term care to the it / Stabilisation can aid in the correct identification of HF , which can help patients adapt their lifestyle and have a Treatm 🔨 Mo setting and reinforce integrated, ho between all stakeholders involved (GPs, sense of control over their own body or disease. can support the correct triaging and drive the appropriate use of imagining in more complex patients.^{17,58} tan support continuous monitoring , to predict acute events such decompensation.⁴⁹ The information p ovided by a cardiac biomarker specific to HF: can contribute to an increase of the diagnost allows for early identification of sig symptoms and therefore represent information on the therapy needed, enables the identification of patients at risk of adverse events , allowing for intensified care of the patient (treatment optimization). capacity and therefore reduce the waiting list for specialist referral and care. ⁴¹ reduces the risk of missed diagnosis as further confidence is provided that HF will not be missed. ⁵⁰³ presents valuable information to t is the strongest predictor of cardiovascular events in patients with Type-2-Diabetes, allowing for early diagnosis ⁴⁴ and guides the decision on more invasive treatment with consequent improvement in outcomes. ession and notential imp ndition as well as the risk of unp Value of information to patients events such as pump failure. Value of information to hospitals *A cardiac biomarker specific to HF is a measurable biochemical indicator of the condition of the heart and The information provided by early scre refers to NT-proBNP. can save 40% to 45% in number of echocardiogram if all patients with suspected HF are screened. ^{17,58} Value of information to healthcare system symptomatic patients combined with collaboration between GP and special GP: General practition HF: Heart Failure reduce the severity of HF overall. 66

The information provided by In-Vitro Diagnostics such as cardiac biomarkers specific to Heart Failure* can be a valuable solution to the challenges in managing this disease

Diagnostic Information brings multidimensional value from healthcare pathway to health path ¹²

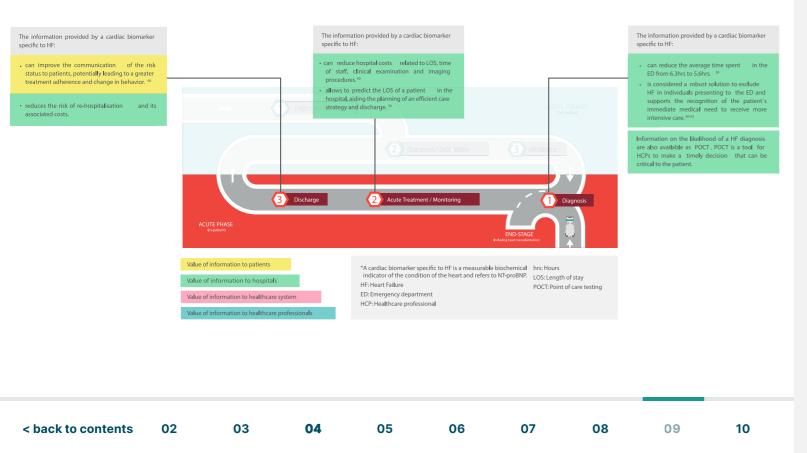
ne costs of expensive, and its	Value of diagnostic information to healthcare systems Improve patient triage Avoid cost of disease progression Decrease waiting time Avoid adverse events Reduce the rate of (re-ihospitalisation Allow a shift to community care	
primary olistic care HF nurses, which allows us cardiac	Value of diagnostic information to patients - Enhance patient empowerment - Improve the satisfaction - Improve the value of knowing and deciding	Current shortcomin along the Heart Fa patient pathway: • Missed or late diagnosis
ns and s valuable if multiple the patient wement of redictable	Value of diagnostic information to healthcare providers (Hospitals) • Improve the turnaround time • Reduce operational cost • Improve the quality delivered (reliability, reproducibility)	Re-hospitalisation Inefficient use of healthcare resourd Poor patient involvement
reening of h a tight allists may	Value of diagnostic information to healthcare professionals - Enable a rapid, appropriate clinical response - Avoid unnecessary, ineffective testing	

cific to HF is a me rable biochemical indicator of the ndition of the heart and refers to NT-proBN

OPPORTUNITY

The use of information provided via cardiac biomarkers may address current shortcomings in Heart Failure* care

Value creation at each step of the patient pathway and to all stakeholders in the healthcare system



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Healthcare systems need to recognise and fully leverage the value of information provided by In-Vitro Diagnostics in Heart Failure for patients, healthcare professionals and society by:

- Removing barriers to timely diagnosis, optimal treatment and guideline-based care through an efficient and appropriate use of In-Vitro Diagnostic information at an early disease stage to provide high value care. A redistribution of resources creates improved outcomes, care, well-being for patients who can become more active members of society. It also allows for sustainable cost savings for healthcare systems.
- · Improving education of healthcare professionals, be it nurses, general practitioners or specialists, to raise awareness of the value of diagnostic information along the Heart Failure patient pathway.
- Establishing a reliable source of Heart Failure patient data at European level (e.g. as is the case for diabetes) that allows to collect, analyse and compare real-world data to further leverage the value of diagnostic information and improve Heart Failure care in Europe (via the European Health Data Space, for example).

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12 About the EU-ASEAN Business Council



The EU-ASEAN Business Council (EU-ABC) is the primary voice for European business within the ASEAN region. It is formally recognised by the European Commission and accredited under Annex 2 of the ASEAN Charter as an entity associated with ASEAN.

Independent of both bodies, the Council has been established to help promote the interests of European businesses operating within ASEAN and to advocate for changes in policies and regulations which would help promote trade and investment between Europe and the ASEAN region. As such, the Council works on a sectorial and cross-industry basis to help improve the investment and trading conditions for European businesses in the ASEAN region through influencing policy and decision makers throughout the region and in the EU, as well as acting as a platform for the exchange of information and ideas amongst its members and regional players within the ASEAN region.

The EU-ABC conducts its activities through a series of advocacy groups focused on particular industry sectors and cross-industry issues. These groups, usually chaired by a multi-national corporation, draw on the views of the entire membership of the EU-ABC as well as the relevant committees from our European Chamber of Commerce membership, allowing the EU-ABC to reflect the views and concerns of European business in general. Groups cover, amongst other areas, Insurance, Automotive, Agri-Food & FMCG, IPR & Illicit Trade, Market Access & Non- Tariff Barriers to Trade, Customs & Trade Facilitation and Pharmaceuticals.

Membership

The EU-ABC's membership consists of large European Multi-National Corporations and the nine European Chambers of Commerce from around South-East Asia. As such, the EU-ABC represents a diverse range of European industries cutting across almost every commercial sphere from car manufacturing through to financial services and including Fast Moving Consumer Goods and high-end electronics and communications. Our members all have a common interest in enhancing trade, commerce and investment between Europe and ASEAN.

Current Membership



Executive Board

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The EU-ABC is overseen by an elected Executive Board consisting of corporate leaders representing a range of important industry sectors and representatives of the European Chambers of Commerce in South East Asia.

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EU-ABC Healthcare Advocacy Group

The EU-ABC's Healthcare Advocacy Group consists of: Bayer; Boehringer Ingelheim; Haleon; KPMG; Novartis; Novo Nordisk; RB Health; Philips; Prudential; PwC; Roche; Sanofi; Zuellig Pharma.

To find out more about the benefits of Membership and how to join the EU-ASEAN Business Council, please either visit <u>www.eu-asean.eu</u> or write in to <u>info@eu-asean.eu</u>

