



Improving the development and deployment of diagnostics in Southeast Asia

Workshop report

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Contents

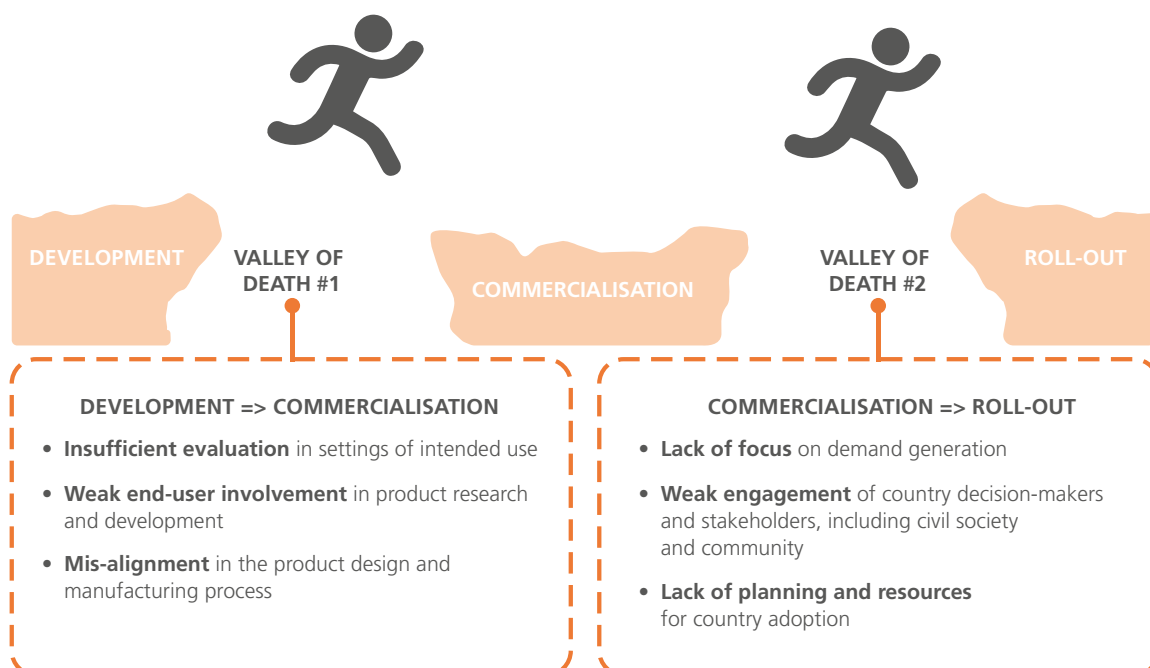
Executive summary.....	4
Introduction.....	6
Successes and challenges in diagnostics in Southeast Asia.....	8
Successes.....	8
Challenges.....	10
Priority areas to improve the development of diagnostics in the region.....	12
Scaling up development in the region.....	14
Opportunities and next steps for collaboration in the ASEAN region.....	16
Conclusion.....	19
Appendix 1: Workshop steering committee	20
Appendix 2: Participant list	21

Executive summary

Diagnostic tests wherever available guide many clinical management decisions around the world. They are key to delivering successful outcomes for both infectious and non-communicable diseases. They offer significant opportunities to improve healthcare provision in low- and middle-income countries (LMICs).

Alongside great global progress in the development of diagnostic tests, the Association of Southeast Asian Nations (ASEAN) region has also generated successes as well as highlighted challenges in this area that need to be addressed. There are strong local networks and collaborations, and some local manufacturing. There is mapping of work within the ASEAN and efforts to harmonise regulations so that the routes to delivery of products to market become smoother.

There remain bottlenecks to production and of access to products that could be improved. Better collaboration between disciplines to bring together a range of expertise is required. Researchers and developers can struggle with access to samples and with complex regulation, and tariffs can increase the cost of technology. In many cases, local solutions would be better than adapting existing tests and technology to suit a local need. Greater still is the challenge of hurdling not one, but two 'valleys of death' during the development and deployment process.



Priority areas to accelerate delivery of diagnostics have been identified as: technology and innovation; partnerships and commercialisation; quality control; and advocacy. Recommendations include a platform for collaboration across the region, and minimum standards for regulation with a harmonised environment that does not throw up additional country-by-country challenges. Biobanking can provide a source for samples and exchange agreements between and among ASEAN countries can stimulate access for the development of locally relevant diagnostic kits.

In order to improve appropriate and cost-effective use of diagnostics in clinical practice, attention must be given to tests that are on the market and available but are very poor quality, giving false results and therefore of no utility. In addition, they may be used independently of healthcare workers which leads to a dangerous precedent. Therefore the validation of tests is critical to address these challenges.

Recommendations for diagnostic development and deployment as well as collaboration are outlined in this report.

Development is reliant on improved biobanking, capacity building that is focused on evaluation and training, improved collaboration between industry and academia, and a clear overview of national disease priorities. New technologies are showing promise and the ASEAN region must seize the opportunities presented by technologies such as next generation sequencing (NGS), artificial intelligence (AI) and machine learning.

Deployment of diagnostics is dependent on a clearer evaluative and regulatory environment that is focused on reducing bottlenecks and fast-tracking innovative products that target unmet needs. Raising awareness of the clinical utility of diagnostics is crucial and this will require improved communication, particularly with patient networks and policymakers. Distribution chains and additional tariffs must be minimised.

Collaboration is an area to celebrate in the region, with good networks in place and knowledge of work that is already underway. A review of R&D readiness would help address variable regional capacities and increase focus on bridging the gap between translational research, clinical validation and implementation. This would improve healthcare provision and patient outcomes.

There is a great deal of work to do and the priority areas identified represent the first steps towards solutions. The collaborations that arise from this meeting should be evaluated, and solutions and knowledge shared to catalyse local development and deployment of diagnostics.

Introduction

Diagnostic tests have the capacity to transform healthcare provision for infectious and non-communicable diseases. Where they are available, clinical decisions are often guided by diagnostics; they have the power to revolutionise the way diseases are treated, focusing on appropriate treatments and helping to avoid risks of inappropriate therapies.

In LMICs rapid diagnostic tests hold enormous promise in tackling infectious diseases. Tests have been developed for many pathogens and progress has been made in implementing tests for infections such as HIV, malaria and tuberculosis.

The World Malaria Report 2018¹ shows that more than 80% of patients with suspected malaria in Sub-Saharan Africa are now tested with either rapid diagnostic tests or microscopy, up from around 40% in 2010.

For HIV, global demand for rapid diagnostic tests is expected to reach 509 million tests globally by 2021, and for viral load tests, used for monitoring and treatment of patients projected to increase to 28.5 million by the same year.

The use of a rapid test for tuberculosis has expanded since 2010 when the World Health Organization (WHO) recommended it. The test, Xpert MTB/RIF®, can give a diagnosis within two hours, and also detects resistance to the most important tuberculosis medicine.²

Diagnostics are becoming more portable. However, the development of genuinely patient-centred, point-of-care devices still remains challenging. True portability means devices need to be small; they are often required to switch between battery and mains power; they must be robust and work in challenging environments; and the sample-to-result time has to be fast or opportunities are lost because patients may leave and not return to receive their diagnosis and treatment.

There are bottlenecks in production, validation and regulation, scaling up and commercialisation of these devices. With such barriers to market entry and a lack of clarity on returns, development and commercialisation, particularly in LMICs, can be seen as too risky.

Established in 1967 as a geopolitical region, the ASEAN covers 10 countries with a combined population of 630 million. Its six largest economies make up 95% of ASEAN gross domestic product (GDP) with the smaller four among the poorest in the Asian continent.

A mapping exercise in 2009 investigated how ready each member state was to cooperate with drugs, diagnostic kits, traditional medicine and vaccines. It revealed that the region is heavily dependent on imported diagnostic kits for communicable and non-communicable diseases, including neglected tropical diseases. Most diagnosis is facility-based, in hospitals and professional laboratories, and specialised tests are usually only available in urban areas.

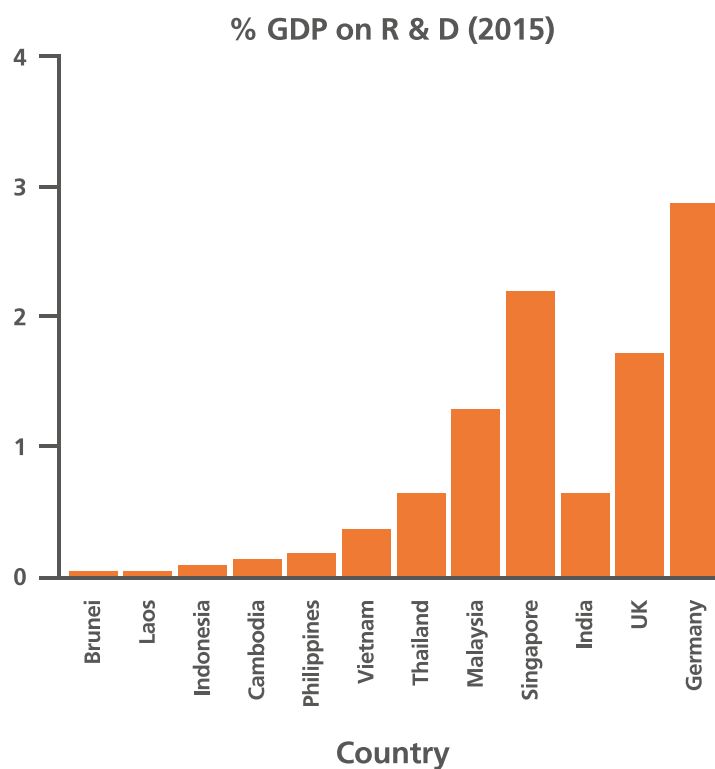
Vietnam's and Indonesia's R&D landscapes are generally focused on tropical diseases, with Cambodia, Malaysia, Myanmar, Philippines, Singapore and Thailand tending to research infectious or communicable diseases. Only Brunei Darussalam focuses on both tropical and infectious or communicable diseases. This mix in R&D priorities in the region suggests opportunities for cross-collaboration and an improved network of knowledge with more data on various diseases.

Data from the Asian Development Bank suggest that three of the Millennium Development Goals (MDGs) remain problematic in the region: reduce child mortality, improve maternal health, and combat HIV/ AIDS, malaria and other diseases.³

1. <https://www.who.int/malaria/publications/world-malaria-report-2018/en/>

2. <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>

3. Asian Development Bank (2010). *Key Indicators for Asia and the Pacific*. <http://www.adb.org/publications/key-indicators-asia-and-pacific-2010>



Source: Wolfram

There are excellent national laboratories and the ASEAN Network for Drugs, Diagnostics and Vaccines Innovation (ASEAN-NDI) has been set up to encourage the development of diagnostics. Updated mapping is currently taking place, and appropriate measures for success are under discussion. There is a sense of excitement in the region about bringing the right partners together to improve healthcare with more efficient diagnostics.

In November 2016, a two-day workshop in London was held by the Academy of Medical Sciences, UK, and the National Academy of Science and Technology, Philippines. It focused on improving the development and deployment of rapid diagnostic tests in LMICs. A key recommendation was to follow up with regional meetings to focus on priorities and perspectives.

The objective of the workshop was to consider the current and potential impact of diagnostics in the region, taking into account barriers and challenges as well as identifying opportunities. The workshop facilitated cross-border and cross-sector discussion and identified next steps for the development and deployment of diagnostics, and for collaboration in the region.

It was funded by the UK Government's Global Challenges Research Fund and is part of a series of policy workshops co-organised by the Academy of Medical Sciences that aim to:

- Enable partners (primarily National Academies) in Official Development Assistance (ODA) eligible countries to consider how scientific evidence can help address key global health challenges.
- Build capacity in ODA countries for the provision of scientific advice.

Further information and reports from the programme of workshops can be found at www.acmedsci.ac.uk/GCRF

Successes and challenges in diagnostics in Southeast Asia

The development and delivery of a diagnostic can take years, with multiple hurdles to overcome; from the initial innovation stage through to market entry, regulation and infrastructure. There is a well-known 'valley of death' for drugs, after laboratory testing and during the translational and testing phase, and this exists also for diagnostics. They face an additional valley during rollout, when manufacture, logistics and distribution add complications and additional tariffs. Included within this is also the quality of diagnostics and whether they measure what they say they are measuring and are being appropriately regulated and validated as there is no clear regulatory framework.

In the ASEAN region there are examples of best practice; groups working to deliver solutions effectively and affordably, efforts to harmonise regulation, and to reduce tariffs. There are also challenges to be met.

Successes

Local networks

The ASEAN-NDI has strengthened cooperation among member states and with regional innovation networks in health R&D. They have developed programmes and strategies to address health concerns and unmet clinical needs, and strengthen capacity and competitiveness in the region.

There are excellent national laboratories and research centres developing diagnostics in the region: notably in Indonesia, Laos, Malaysia, Myanmar, Philippines and Vietnam. Knowledge can be better exploited by cross-border approaches and these should be encouraged and incentivised.

In addition, there is a thriving network of collaboration between institutes within the region, and some collaboration with international centres outside of the ASEAN.

Cross-disciplinary collaboration

Diagnostic development requires a range of knowledge and skills. For example, where life and clinical scientists may understand the disease in question, material science researchers are able to develop better filters and membranes. True cross-disciplinary work is reaping results and bringing tests to the commercialisation stage, with more in development, though still more could be done in this area to encourage others.

Local manufacturers

Although the ASEAN region is heavily reliant on external manufacture, there are some local manufacturers in Malaysia, Indonesia and Thailand. While celebrating this as a success, it is acknowledged that these activities could be expanded.

Harmonisation of regulation

Although largely a challenge, there are areas of regulation that are being harmonised between regions and countries. There are efforts to review a global set of regulations established by five large countries, with a view to adapt these for the region. This work, done by the Asian Harmonization Working Party⁴ extends across Asia and Latin America.

Diagnostic development by disease

According to the ASEAN-NDI, diagnostics are being developed and used for the diseases and in the countries set out in the table:

Disease	ASEAN member states
Dengue	Philippines, Indonesia, Malaysia, Thailand
Tuberculosis	Philippines, Malaysia, Thailand
Hepatitis B	Indonesia
Hepatitis C	Indonesia
Leptospirosis	Philippines, Malaysia
Malaria	Indonesia
Thalassaemia	Thailand
Arboviral diseases	Singapore

4. <http://www.ahwp.info/>

Challenges

Bottlenecks

Diagnostics often lag behind the development of new clinical approaches to disease management or are required for protection of novel conditions. In order to better keep up with healthcare requirements, there are several bottlenecks on the journey to market that could be tackled, from regulation and production, to scalability and commercialisation. Work should be done to identify each obstruction, and the relevant groups or experts brought together to address them and propose workable solutions.

Cross-disciplinary collaboration

There can be a disconnect between life scientists and engineers, and these disciplines need to work together for the benefit of diagnostics development. More effort should be made to bridge gaps between fields and to encourage and incentivise different communities to effectively share knowledge.

Sampling

Researchers working on neglected diseases that are out of the limelight can struggle to get enough samples to test. Others are coming under increasing scrutiny for the samples they already possess. Biobanking could serve as a source for samples that comply with ethical requirements. The community needs to speak out and raise awareness of the issues they face and make the case for greater access to ethically obtained samples.

Diagnostic quality

In order to improve appropriate and cost-effective use of diagnostics in clinical practice, attention must be given to tests that are on the market and available but are very poor quality, giving false results and therefore of no utility. In addition, they may be used independently of healthcare workers which leads to a dangerous precedent. Therefore the validation of tests is critical to address these challenges.

Tariffs

A device that costs only a small amount to produce can accrue several separate distribution and import tariffs, increasing the price of each test. Addressing this through increasing local manufacture and potentially reducing the number of distributors in an end-to-end chain will take time and requires government and industry collaboration.

Affordability and accessibility

In order to deliver a diagnostic or solution effectively and efficiently, affordability and accessibility are crucial. Many companies take solutions from elsewhere and adapt them to fit a local requirement by reducing features that do not work in that environment. It is better to start from the bottom up, using local knowledge and understanding of needs, and design an appropriate device for the region.

Speed of development

In contrast to the pace at which management of diseases emerge and develop, the development of diagnostics is desperately slow. As well as tackling bottlenecks, increased surveillance will help the research community keep up with evolving disease emergence in the Southeast Asia region. Understanding the ability to treat diseases is changing but we don't have good diagnostics for all diseases that can be used at point of care for example.

Complex regulatory environment

Among the four main categories of products regulated by the Food and Drug Administration Philippines, medical devices are the most complex. For most categories only one field of expertise is needed but in the regulation of medical devices, different professionals must be engaged. Regulatory devices are accepted with recognition of tests done by global labs, but those used in vitro require local performance testing. Addressing this and agreeing a regional rather than country-by-country approach could help.

Addressing 'the valleys' through collaboration

The non-profit health organisation PATH partners with other organisations to de-risk the main stages of development and market entry. Working with the National Institutes of Health subsidiaries to show proof of principal on a device and then with teams of researchers in Africa to demonstrate field testing, they have demonstrated the value of a technology and supported R&D over the first valley of death. With Bill & Melinda Gates Foundation they agreed a 'pull' mechanism to jump-start the market and address the second valley. These initiatives have worked successfully elsewhere and could be replicated in the ASEAN region.

Priority areas to improve the development of diagnostics in the region

Participants broke into four areas to workshop the priorities for action and change to improve the development of emerging and next generation diagnostics. Discussions were based on the morning's presentations, in particular the panel discussion on successes and challenges, but participants' knowledge and experience in their own areas enriched the session.

The groups focused on four areas: technology and innovation; partnerships and commercialisation; quality control; and advocacy. Five or six key priorities were developed in each, and groups' priorities overlapped, with several proposing the same solutions. Advocacy, for example, appeared in each presentation during the feedback.

- Advocacy is key to improving the funding environment for diagnostics development. The community must get onto the political agenda to improve regulatory development and implementation, and must work with funders, investors, clinicians and patient communities to increase understanding of diagnostics. A culture of research and entrepreneurship can be shaped in this way.
- A platform for collaboration across the ASEAN region would strengthen diagnostics efforts. The recognition of the key strengths of each partner and how to leverage them could boost development and help avoid the two valleys of death. Sharing expertise in manufacturing and access to raw materials, and understanding in-country needs, would complement the network of laboratories that already exists.
- Creating a united access market where recognition is shared and evaluation and approval can be fast-tracked would increase the speed of reimbursement for funders and investors.
- To lower costs, effort should be put into reducing import tariffs. There are examples of countries reducing the number of distributors in a chain, which diminishes possibilities of multiple tariffs.
- The market and incentives for diagnostic tests are limited at present, and financial gaps can be off-putting for investors. Creating push-and-pull mechanisms to guarantee volume and pre-ordering before manufacture would encourage investors who are nervous about a lack of return. It is also important that the market is developed on addressing clinical need.
- Scant regulation can be a challenge and advocating better clinical evaluation and regulation diagnostic kits quality would support reputable companies and ensure only reliable devices are available. A quality control mark or mechanism could ensure that kits have been appropriately validated rather than simply published and marketed.
- A minimum level of standards that are documented in a comprehensive manual of procedures is recommended. The manual would include validation procedures for equipment and kits, along with standards for staff competence.
- Decisions around the adoption of tests should consider a balance of the sensitivity specificity and performance of the test and the buying power of the patient or the government. Better performing tests and those that are easier and quicker to use may be too expensive and inaccessible so a balance need to be struck in cost effectiveness that can be used to benefit more patients.

- Governments must oversee a quality assurance system for all laboratories, including those who process emerging and next generation diagnostics. If such a system is not available in a given country, participation in international programmes is encouraged.
- Biobanking could serve as a source of samples for the validation of diagnostic kits in compliance with ethical requirements on the use of samples. There could also be the option of commercial companies paying a fee for access.
- Research communities should advocate the sharing of biological samples through exchange agreements between and among ASEAN countries for the development of locally relevant diagnostic kits. These needs to be compliant with international regulations on data sharing.
- Next generation sequencing (NGS) presents opportunities for diagnostics, in epidemiology and in optimisation of therapy and control programs. There is currently no consensus in standardising molecular data, resulting in difficulty comparing results, and the technology is expensive and not yet amenable to rapid tests. Ironing out these issues could bring NGS closer to benefitting patients, but only if it becomes more patient-centred, and is linked to the delivery of treatment. It is recommended that the region considers setting a price structure for these technologies.
- There is a rising threat of non-communicable diseases in the ASEAN region, as elsewhere in the world. A comprehensive early detection programme could reduce healthcare costs and increase patient treatment. There are examples to watch and learn from. These include Healthy Communities⁵ which was launched in 2017 to improve hypertension diagnosis and management in Myanmar and Vietnam, and the FamilyDOC⁶ in the Philippines which brings together public and private sectors in diagnosing diseases in semi-rural communities.
- Flexible diagnostics and biosensor technologies – for example the use of mobile phones to diagnose disease from remote settings or the miniaturisation of sensor sets – offer great potential but become more feasible when used in combination with more conventional screening tests.

5. <https://accessaccelerated.org/initiative/healthy-communities/>

6. <https://www.familydoc.com.ph/>

Scaling up development in the region

Four presentations explored positive examples of the scaling up of diagnostics within Southeast Asia and in other LMIC settings. Discussions followed to explore how initiatives and technologies like those presented could benefit people in the region quickly and efficiently.

CRADLE Vital Signs Alert (VSA)

Around the world each day, 830 women die during childbirth, and although this has reduced significantly since the adoption of MDG 5 to improve maternal health, more can be done. The variety in quality and accuracy of the blood pressure devices available means pre-eclampsia is often undiagnosed which puts mothers and babies at risk.

The CRADLE Vital Signs Alert monitors blood pressure and heart rate and unlike many other devices, has been tested on pregnant women. The device meets the WHO criteria for use in low-resource settings: it is accurate, affordable, easy to use, robust and has a low power requirement. The simple traffic light system gives a reading according to well established thresholds of hypertension and for a shock index that is used in diagnosis and management.

Early trials confirmed that healthcare workers adopted and continued to use the devices,⁷ with an increase in monitoring and use. A trial in Ethiopia, India and Zimbabwe⁸ also looked at use in 10 further locations. It showed high adoption and use of the device and started to report on how training and intervention could be adapted to different settings.

i-sense

Many researchers are working to exploit the potential of smartphone adoption and capability. Working in alignment with the UN Sustainable Development Goals and the Global Challenges Research Fund, i-sense was initiated in the UK 2013 and has funding from EPSRC until 2022 to build a new generation of digital sensing systems to identify and prevent outbreaks of infectious disease.

i-sense is feeding into a raft of developments that use smartphones for diagnostic tests. Their mobile phone connected diagnostic tools can widen access to GPs, and the team has looked at cellular network coverage, populations and access to healthcare to map where opportunities and challenges may lie. In areas with network coverage but limited healthcare they hope to have the most impact.

The team can also monitor platforms like Google search and Twitter, in order to identify searches and conversations that could indicate disease outbreaks before people attend clinics.⁹

7. Nathan HL, et al. (2018). *The CRADLE vital signs alert: qualitative evaluation of a novel device designed for use in pregnancy by healthcare workers in low-resource settings*. *Reprod Health* **15(1)**: 5. <https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-017-0450-y>
8. Vousden N, et al. (2018). *Evaluation of a novel vital sign device to reduce maternal mortality and morbidity in low-resource settings: a mixed method feasibility study for the CRADLE-3 trial*. *BMC Pregnancy and Childbirth* **18**:115. <https://doi.org/10.1186/s12884-018-1737-x> <http://cradletrial.com/wp-content/uploads/2018/07/Evaluation-of-a-novel-vital-sign-device-to-reduce-maternal-mortality-and-morbidity-in-low-resource-settings.pdf>
9. Wagner M, et al. (2018). *The added value of online user-generated content in traditional methods for influenza surveillance*. *Scientific Reports* **8(13963)**. <https://www.nature.com/articles/s41598-018-32029-6>

diaTROPIX

Based in Dakar, Senegal, diaTROPIX provides diagnostic tests to meet patient needs. It is a patient-centred alliance for the local manufacture and affordable supply of tests for neglected tropical diseases that affect over a billion people worldwide. Dakar is close to these patients, is in the heart of Africa and is an economic hub that provides critical mass and a public health ecosystem involving WHO, UNICEF, Centers for Disease Control and Prevention (CDC) and others.

diaTROPIX's approach is collaborative but has the aim of creating a disruptive production and supply model. The organisation's intention is to develop diagnostic interventions that incorporate what is important for the end user, while incentivising breakthroughs in the barriers that exist to marketing these diagnostics.

GEMS@UM

As global health improves and the average life span increases, there are new challenges to face. There are changing disease patterns and the rise of non-communicable diseases. Approaches to healthcare are also evolving, and in the 21st century there is a greater emphasis on precision medicine and targeted therapy – in particular but not limited to cancer treatments.

Precision medicine is useful for rapid diagnosis as well as treatment, but reagents and infrastructure are costly and expertise can be lacking. These challenges prevent LMICs from benefitting from the rapid advances in other parts of the world.

GEMS@UM is a public-private partnership between the University of Malaya and Pathomics Health in Singapore. The university provides space, professional expertise and access to patients. Pathomics Health has precision medicine capability and funding. They work with tests for targeted therapy with a high chance of pharma investment, and their approach allows for training for scientists as well as enhancing research; it also enables access to the Beijing Genomics Institute and US company Tempus. Ultimately it gives patients access to precision medicine via a low- or no-cost route.

From training and capacity building to encouraging the flow of ideas between academics and commercial companies, these four case studies demonstrate how isolating and analysing barriers allows them to be tackled. Above all, each shows that raised awareness and education deliver results, and that the involvement of patients and patient groups is crucial for success.

Opportunities and next steps for collaboration in the ASEAN region

When great minds come together to share expertise and ideas, great concepts arise and work can begin to truly create impact. The collaboration and discussion that arose in the workshop is a testament to the engagement and knowledge of the participants and there is huge promise for the future.

During a breakout session, there were three groups who discussed the opportunities and next steps under three headlines: diagnostic development; diagnostic deployment; and better collaboration. The result of the discussions was new ideas to take forward along with excellent examples from elsewhere that could be adapted for the ASEAN region.

Diagnostic development

we should not make perfect the enemy of good. Instead of striving for the perfect test, development can be iterative; beginning with a usable minimum viable product that can be improved.

The assessment of user and market needs must be included in early feasibility studies as this reduces the time spent on diagnostics that disappear into one of the two valleys of death.

DxD Hub in Singapore focuses on public sector R&D, looking to the market and opinion leaders to find a user case and collaborate towards an end result. In this way both the risks and the upsides are shared. The goal is to ensure that expertise is transferred and companies become self-sustaining. With more and more entities able to do that, development within the region will gain critical mass.

New technologies such as machine learning and artificial intelligence AI can improve the accuracy and speed of diagnostics and could be built to learn to reduce problems such as false positives and negatives. Machine learning is not reliant on large corporations; Individuals can achieve results. Within Southeast Asia, AI and machine learning approaches could provide differentiation for simple diagnoses, be used for surveillance and reporting on a national, regional and global level.

Biobanking of samples is absolutely necessary. The creation of a virtual network of biobanks with an inventory of samples available at individual institutions for development and evaluation is needed. This virtual setting is cheaper and easier to manage compared to a physical biobank and should have minimal standards required for storage, maintenance, clinical and patient details. An overarching governance protocol and ethics agreements would be put in place.

Capacity building should centre on how to evaluate tests for clinical validity and how to develop assays, with workshops on how to evaluate different test types and a blend of online and wet lab training.

There needs to be better collaboration between academia and industry with increased professionalisation and respect for intellectual property.

Finally, disease priorities by country should be mapped to give a clearer than ever picture of the region's challenges, and to help focus collaboration efforts and diagnostic development.

Diagnostic deployment

The regional WHO, or another convener, is to be identified to call for the creation of a clinical network for different diseases and to be driven by key opinion leaders. Once established, such a network would aim to achieve greater alignment across the region.

The approval of new tests onto the market that are not equal or better than existing ones does not benefit the market or patients. The focus needs to be on minimum viable products, or where one exists already, on improvements, and on tests that can provide differential diagnosis. Accessibility and machine learning need to be taken into account for newer devices.

New diagnostics face regulatory bottlenecks and then policy approval. To bring policymakers and regulators to the same table to assess acceptable risks and clinical benefits would accelerate the process and bring public health advantages.

Opening up laboratories and specimens to private companies to do late-stage tests to ensure development is on the right track is recommended. Preparing the pathway in this manner would stop poor tests entering the market.

The WHO and other NGOs have a role in achieving approval for new devices, and the question of efficiency needs to be addressed, specifically for innovative new products. This does not mean replacing regulatory requirements but expediting them to reduce the time taken for the benefit of patients.

For innovative products that target unmet needs, a fast-track mechanism is needed. This could take the form of a 'green lane', or a shared recognition scheme so evidence can be shared rather than replicated in each country. The framework could be agreed and applied across borders.

The analysis and isolation of barriers such as pricing add-ons is recommended. Distribution chains should be kept to a minimum, while avoiding the monopolisation of one distributor. Identifying appropriate incentives would help in this arena.

One of the underpinnings of deployment is creating demand and this requires better advocacy. Raising awareness and education are key. Identifying and working with champions can be a springboard to public support. In order to succeed with this education and advocacy, forward planning is required, including communications strategies for different stakeholder groups, taking into account user needs. Crisis communication plans during outbreaks are needed wherever broad communication is planned, to ensure the appropriate steps are taken if messaging goes off-track, or if miscommunication arises, as sometimes happens with external communications.

If faster, cheaper, better and safer tests are required to diagnose diseases in LMICs, then early preparation ahead of regulation and approval is crucial, and this involves collaboration.

Better collaboration

There are two ASEAN frameworks for the integration of R&D activities in the region: APASTI, the ASEAN Plan of Action on Science, Technology and Innovation, a roadmap of science and technology work across the region; and ASEAN-NDI, which supports APASTI.

The APASTI 2016–25 Implementation Plan was adopted by ASEAN Ministers for Science and Technology in 2016 and outlines key actions, components and priorities, as well as targets, activities, timelines and indicators. ASEAN-NDI was founded in 2009 and supports partnerships for capacity building and the establishment of strategic research networks to facilitate coordination of stakeholders.

There remain challenges in terms of the readiness of different countries to engage in collaborative work. Mechanisms of interaction are limited by a lack of opportunities for researchers, and in some cases a lack of awareness that opportunities are available. There are a disproportionate number of researchers to population ratio per country, and the GDP allocation to research can be low.

There is no one-size-fits-all solution, but the key objective would be to find the solution that works for each country or each challenge.

A mapping exercise is taking place at present via ASEAN-NDI to outline what is being done in the region. The creation of a network of reference laboratories and clinical sites across the region would support diagnostics as well as aid surveillance and rapid detection. It could build on an existing network for animal surveillance and diagnostics, taking a one-health approach. Along with this mapping, an inventory of scalable work in the region is recommended.

Encouraging collaboration between policymakers, scientists, clinicians, regulators and patients by bringing them together would support the understanding of bottlenecks, and go some way in easing these. A review of R&D readiness in the region is suggested to improve variable capacity and increase sharing of knowledge and skills.

There is good will and collaboration already, as well as work with NGOs who can be intermediaries between public and private organisations. This can be further capitalised upon.

It is important to consider the problems that need to be solved in primary, secondary and tertiary settings, and develop appropriate diagnostic solutions for each of these levels.

Supporting the capabilities that are building in ASEAN member states, with a focus on bridging the translational gap to implementation, will improve human health and grow healthcare industries in the region.

Conclusion

We are on the threshold of a digital and diagnostic revolution that will change how medicine is practised around the world. With this come huge opportunities but also challenges that need to be tackled head on.

Solving common problems such as bottlenecks related to pathways, regulation, clinical validation, production, scalability and commercialisation can be achieved only with collaboration. And although different problems are faced in different countries, there are common issues and methods that can be shared and scaled to improve the picture and prospects for the future.

Discussions about networks across the ASEAN region are healthy and there is a clear impetus to work together. Although there is no single solution, there is a lot that can be achieved through solution sharing. This workshop is just the beginning of increased capacity and lasting change for diagnostics development, deployment and collaboration in the region.

The two-day workshop benefited greatly from excellent inputs from attendees with promise for future collaborations.

Appendix 1: Steering committee

- Co-chair: Academician Dr Jaime Montoya, Professor in Infectious Disease, University of the Philippines College of Medicine and Executive Director of the Philippine Council for Health Research and Development
- Co-chair: Professor Sanjeev Krishna FMedSci, Professor of Molecular Parasitology and Medicine, St George's University of London
- Dr Catharina Boehme, Chief Executive Officer, Foundation for Innovative New Diagnostics (FIND)
- Mr Zoltan Bozoky, CEO and Co-founder, Biosensors Beyond Borders at the London School of Hygiene & Tropical Medicine
- Professor Emeritus Dr Soottiporn Chittmittrapap, Chulalongkorn University and King Chulalongkorn Memorial Hospital, Thailand
- Academician Distinguished Professor Datuk Dr Looi Lai-Meng FASc, Distinguished Professor and Senior Consultant Histopathologist, University of Malaya, Malaysia

Appendix 2: Participant list

Name	Organisation
Dr Rocelle Maria Agero	FHI 360, Philippines
Dr Htin Aung	Otago University, New Zealand
Dr Maria Christina Batac	University of the Philippines Manila, Philippines
Professor Stuart Blacksell	Mahidol-Oxford Tropical Medicine Research Unit, Thailand
Ms Abigail Bloy	Academy of Medical Sciences, UK
Ms Liz Bohm	Academy of Medical Sciences, UK
Mr Zoltan Bozoky	London School of Hygiene & Tropical Medicine, UK
Mr Bugi Ratno Budiarto	Indonesian Institute of Sciences, Indonesia
Dr Youlet By	Fondation Mérieux, Cambodia
Dr Arjun Chandna	Mahidol-Oxford Tropical Medicine Research Unit, Thailand
Professor Ren Ee Chee	A*STAR's Singapore Immunology Network, Singapore
Dr Khampheng Chomlasak	National Center for Laboratory and Epidemiology, Lao PDR
Dr Fresthel Climacosa	University of the Philippines Manila, Philippines
Ms Micaela Dato	University of the Philippines Manila, Philippines
Mr Leonidas Eleftheriou	London School of Hygiene & Tropical Medicine, UK
Ms Ruth Francis	Freelance Science Writer, UK
Ms Kristine Garcia	National Academy of Science and Technology, Philippines
Dr Soliman Guirgis	FHI 360, Philippines
Dr Anasufiza Binti Habib	Ministry of Health, Malaysia
Ms Darla Mae Hasan	National Academy of Science and Technology, Philippines
Dr Le Nguyen Minh Hoa	National Hospital of Infectious Diseases, Vietnam
Mr Alex Hulme	Academy of Medical Sciences, UK
Dr Tran Thi Thanh Huyen	Vietnam Academy of Science and Technology, Vietnam
Professor Dame Anne Johnson FMedSci	Academy of Medical Sciences, UK
Dr Grace Kahenya	FHI 360, Philippines
Professor Sanjeev Krishna FMedSci	St George's University of London, UK
Academician Distinguished Professor Datuk Dr Looi Lai-Meng FASc	University of Malaya, Malaysia
Dr Pornsawan Leungwutiwong	Mahidol University, Thailand
Ms Emma Leister	Department for International Trade, UK
Professor Dr Yvonne Lim Ai Lian	University of Malaya, Malaysia
Dr Santi Maneewatcharangsri	Mahidol University, Thailand
Engr. Maria Cecilia M. Matienzo	Food and Drug Administration, Philippines
Professor Myra Mistica	University of the Philippines Manila, Philippines
Academician Dr Jaime Montoya	University of the Philippines, Philippines

Name	Organisation
Dr Khin Mar Mya	Biotechnology Research Department, Ministry of Education, Myanmar
Mr Hector Thomas A. Navasero	PHILAB, Philippines
Professor Rahmah Noordin	Universiti Sains Malaysia, Malaysia
Mr Jonathan O'Halloran	QuantuMDx, UK
Dr Carmencita Padilla	University of the Philippines Manila, Philippines
Professor Rosanna Peeling	London School of Hygiene & Tropical Medicine, UK
Professor Fortunato T. Dela Peña	Department of Science and Technology, Philippines
Dr Chau Dara Pheak	Ministry of Health, Cambodia
Dr Vanhnaseng Phouthapane	Lao PDR
Dr Prasit Phowthongkum	Chulalongkorn University, Thailand
Ms Guada B. Ramos-Dimaya	National Academy of Science and Technology, Philippines
Dr Tanya Robbins	King's College London, UK
Dr Matthew Robinson	Mahidol-Oxford Tropical Medicine Research Unit, Thailand
Ms Holly Rogers	Academy of Medical Sciences, UK
Dr Amadou Sall	Institut Pasteur de Dakar, Senegal
Ms Luningning E. Samarita-Domingo	National Academy of Science and Technology, Philippines
Ms Camille D. Santos	National Academy of Science and Technology, Philippines
Dr Tala de los Santos	PATH, USA
Professor Tan Sura	Ramathibodi Hospital, Thailand
Dr Valerian Turbe	University College London, UK
Dr Sharon Villanueva	University of the Philippines Manila, Philippines
Dr Manivanh Vongsouvath	Mahosot Hospital, Lao PDR
Dr Kosonh Xayphakatsa	Ministry of Science and Technology, Lao PDR
Dr Sidney Yee	Diagnostics Development Hub and ETPL, Singapore
Dr Li Yongfeng	Diagnostics Development Hub and ETPL, Singapore



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