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Patient-centric decision making in the digital age

The importance of the patient's voice and approaches to incorporating it in healthcare decision making



Introduction

A patient's involvement in healthcare decision making is typically limited to the period between diagnosis and the initiation of the treatment pathway. The healthcare provider generally has direct control over the patient's clinical management, with payers and government agencies exerting some influence over the availability and accessibility of treatment options.

Medicine is a complex subject with multiple specialized domains of knowledge. Despite having access to a plethora of information online, there remains a gap between information that is available to healthcare professionals and patients. Furthermore, the healthcare industry is highly regulated to uphold safety standards. Consequently, regulators in most settings do not permit directto-patient promotional activities of any medical products. All information and activities involving patients are scrutinized and often require approval from health authorities. Policymakers and payers are also involved but play different roles in ensuring the provision of safe, effective, quality, affordable and value-for-money services through the healthcare delivery system. Decisions made in the deployment of an appropriate method of treatment often does not take into account the patient's perspective. The question then is, whether these decisions are truly representative of the patient voice and if patients should contribute more towards matters concerning their health and wellbeing.

Understanding the healthcare decision making journey

The healthcare system's traditional gatekeeping paradigm – experts should decide the best treatments for patients – has resulted in a largely product-centric approach to healthcare decision making, where each product or healthcare technology is assessed and discussed individually. A product is evaluated first by regulators for its safety, quality and efficacy before being granted marketing authorization. Thereafter, payers and policy makers assess the product's value for inclusion in their country's public health insurance benefit package. Finally, physicians discuss this 'available' treatment option with their patients (*Figure 1*).



Figure 1: Product-centric approach: The traditional healthcare decision making journey

Importance of involving the patient in decision making

Digital is driving change across industries and the healthcare industry is no exception. The availability of information and the accessibility to digital technologies have given rise to the 'connected patient' who now takes charge of his or her own wellbeing, enabled via online tools, the internet, peer-topeer sharing, consumer health devices, and mobile apps. The rise of digital has empowered patients to take charge of their own health, granting them greater confidence and autonomy over decisions relating to their health.

Some other advancements include the availability of telemedicine, home care and concierge care. These care delivery models offer attributes such as convenience, timeliness, value, communication and attention, which might be important to patients but sometimes overlooked by healthcare decisionmakers. A growing educated and technology-savvy population has raised the awareness of treatment options and bridged the knowledge disparity between the patient and the physician. These new technologyenabled care delivery models enable the inclusion of the patient's voice in the treatment journey in ways which might not have been possible a decade ago.

The Institute of Medicine (IOM) defines patientcentered care as: "Providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions"¹. Through digital technologies, patients now have a desire and ability to take a more active role in decisions related to their health. This alters the patient-physician relationship dynamic and enables conversations that facilitate a healthcare choice together. This is the Shared Decision Making approach. Studies have shown that patient involvement in decision making has a positive association with their health outcomes^{2,3}.

Given the complexities in health and healthcare, the other benefit of incorporating the patient voice is that it provides stakeholders and industry alike with an opportunity to re-evaluate what classifies as 'outcome' or 'quality-of-life' from the perspectives of the patient. This in turn can drive critical appreciation of existing health technology evaluation frameworks and drive the adoption of these technologies based on criteria beyond just its cost and efficacy alone, with the intention of benefitting the patient.

Therefore, insights generated through patient-centered approaches can help to shape research and policy priorities, guide the development of market access and pricing strategies of a treatment, and provide additional engagement opportunities among stakeholders.

Manufacturers share in their role in realizing this goal but may also greatly benefit from patient insights to determine research priorities, understanding the pain-points and behavior patterns of the end-user, develop market access and pricing strategies, and engagement opportunities with gatekeepers.

Ways to involve the patient in decision making

Incorporating patient-reported outcome (PRO) data into marketing authorization decision

The importance of considering PROs alongside biomarkers of health improvement in clinical drug research has increased over the past two decades in parallel to advances in patient-centric healthcare, as evidenced by the increased use of PROs as clinical endpoints in clinical trials (*Figure 2*).



Figure 2: Number of PROs used as an endpoint in clinical trials

PROs transform a qualitative endpoint into a quantifiable outcome and in the process, these add a patient's perspective on the impact of treatment on their health outcomes. In doing so, value created for the patients can be weighed against other traditional clinical outcomes. There are several available validated tools to measure a patient's health status. Health-Related Quality of Life (HRQoL) is the endpoint that assesses various dimensions such as the physical function, social function, pain severity, and mental status. HRQoL is recognized as one of key outcomes because it can measure the patients' health state and can also be translated into utility values and Quality Adjusted Life Year (QALY) which are commonly used as indicators for health care resource allocation as well as reimbursement decisions worldwide. The National Institute for Health and Care Excellence (NICE), for example, recommends the use of QALYs as a measure of health benefit for their 'reference case', to enable a standardized approach for comparing economic evaluations across different healthcare services and technologies⁶. Several countries in Asia such as Australia, South Korea, Singapore and Thailand follow the same recommendation. Hence, HRQoL has become a vital endpoint for most clinical trials.

Integrating patient preference and involvement in the HTA process

The use of PROs alone is not enough to lead the paradigm shift towards patient-centered healthcare.

PROs transform a qualitative endpoint into a quantifiable outcome

Patient preferences should complement PROs and provide a more comprehensive understanding of the needs, values and priorities of patients for their treatment and care. Patient preference elicitation methods such as conjoint analysis, time trade-off and Willingness-To-Pay (WTP) have become popular methodologies for outcomes research as they allow flexibility in addressing various research questions. For example, it can determine the total cost and value of a health intervention, evaluate how patients value an existing treatment versus a simulated one before it is really implemented, and address issues related to treatment adherence or process. WTP studies are particularly insightful as more countries move towards universal health coverage and establish their Health Technology Assessment (HTA) processes7. WTP can guide the development of threshold ranges and justify cost-effectiveness and reimbursement decision for proposed new treatments. Countries such as Thailand have developed their own threshold through WTP studies⁸. During the HTA process, the focus is often on the product's value as well as affordability due to limited government healthcare budgets. Unsurprisingly, clinical outcomes and costs often dominate these conversations but there have

Case study - Listening to the patient's voice: The reimbursement of cochlear implants in Taiwan⁹

Patients, caregivers or patient groups are invited to submit their inputs on the National Health Insurance Administration (NHIA) website up to 14 days prior to a scheduled Pharmaceutical Benefit and Reimbursement Scheme (PBRS) meeting. These inputs are collected and summarized by the HTA division. Additionally, patient representatives could be invited to the PBRS Joint Meeting to represent the patient voice and express their opinions. Other than clinical and economic evidence, patients' inputs are also considered in the reimbursement decision making process. The involvement of patients led to the reimbursement of cochlear implants for hearingimpaired patients under 18 years old in Taiwan since July 2017. Undoubtedly, the involvement of patients in the HTA process are not without limitations and barriers. Continuous efforts are still needed to refine the input collection methodology and establish an efficient patient-HTA process. And the NHIA is committed to progress along this journey.



been encouraging developments where patients' perspectives have been given greater weightage. Australia has actively pursued mechanisms to do this and started the Patient Voice Initiative in 2015¹⁰. The initiative brings together professionals from industry and academia with patient presentative groups to discuss methods and approaches to incorporate patient perspectives on value assessments. Similarly, Taiwan has started involving patients in the HTA decision making process since 2015⁹.

One framework that has been leveraged by several countries to integrate patients' perspective in reimbursement decisions is Multi-Criteria Decision Analysis (MCDA). MCDA is a structured technique that explicitly incorporates several criteria including patient perspectives into healthcare decision making. MCDA has been used for health resource allocation and policy prioritization in several European countries and has been explored in the region in countries such as Thailand and Taiwan.

Getting more 'value' out of the value proposition

A value dossier is one of the most important tools in market access. A compelling value proposition clearly demonstrates the evidence-based benefits a product has to offer as compared to its cost, and against its competitors. Essentially, people buy when they see value. Perception of value, however, is subjective. Traditionally, healthcare professionals and payers were the primary focus of product value messaging. This is due to the established healthcare paradigm, where manufacturers serve patients through these stakeholders with limited or no direct interaction with the patient. However, what matters to a healthcare professional or a payer might differ from what matters to a patient. This difference in value perception stems from the difference in needs and perspectives. By incorporating evidence generated from patient's voice, a solid value proposition which is relevant across all stakeholders can be achieved.

Empowering patients through decision aids

Decision aids are tools which can help patients make informed decisions regarding their own health. These tools are helpful in the context of Shared Decision Making where physicians work together with patients to decide on interventions based on evidence as well as patient's preference. It has been shown that initiating treatments based on patients' preferences improves treatment adherence and satisfaction with care¹¹. Leveraging the advancement in technology, a web-based decision aid can now be developed with minimal cost. Studies have shown that a web-based format performs similarly to conventional printed or video materials in terms of decision-quality outcomes¹². The web-based approach increases patient access to decision aids as it is readily available and maintains the anonymity of patients. Web-based decision aids are increasingly used across different therapeutic areas such as oncology and immunology^{13,14,15}.

Future outlook

The evolution of digital health has transformed traditional healthcare. Tools can now readily be leveraged to connect the dots between patients and various other stakeholders, in order to support patientcentric healthcare decision making.

Gathering patient insights from AI and big data

Powered by technology, data related to patient preferences and treatment outcomes are increasingly becoming cheaper and faster to obtain. Technologies such as Artificial Intelligence (AI) have transformed patients' lives and healthcare experience. Wearables can be used to pick up events, outcomes and behaviors of interest. Patient preference could be elucidated from app usage, search histories, and medical records. AI may in future be able to infer hidden priorities and criteria that patients and clinicians themselves might have been unaware of. The possibilities are endless.

In China, tech giants are transforming the healthcare system with AI. AI is increasingly being used to support clinical management in many areas such as medical imaging and diagnosis. Faster and more effective options are available to cope with the increasing demand for healthcare services and providing accessibility to quality services in the remote rural areas. Insights generated from AI would also help in bringing the patient's perspective which truly reflects specific needs from patients and support a more patient-centric healthcare decision making.

Case study - Artificial-Intelligence (AI) at its best in China: The Ping An Good Doctor¹⁶

The Ping An Good Doctor portal provides a link between patients, healthcare providers and payers. It connects 265 million users with healthcare providers from thousands of clinics and pharmacy outlets across China. The app provides a one-stop solution to cater for all healthcare needs. Patients can utilize the app to access the healthcare system and request for online consultations. The artificial intelligence (AI) assisted online consultation collects relevant information from patients. A preliminary report will be generated and sent to a doctor for further consultation. The doctor's decisions are captured and entered into a machine learning system. This enables the AI model to continuously improve its diagnoses and predictions with the goal of being able to treat patients completely independently of human input. Patients can also fill their prescriptions and purchase drug through the app. The costs of treatment are borne by payers which are linked on the same portal.

Transforming PROs data collection with electronic platform

PRO methodologies have wholeheartedly embraced digital technologies to effortlessly collect information on patient's outcomes in a seamless workflow from recruitment to analysis. There are many standardized PROs that have been validated and integrated into electronic data collection templates. While this reduces the errors and manpower requirements inherent in any manual data entry and improve administrative and data management processes for researchers, the accuracy of self-reported data is still dependent on the patient and biases still remain. A technology-driven era of high connectivity has led to the high penetration of smart devices further encouraging and enabling the facilitation of PRO studies.

The concept of Bring Your Own Device (BYOD) is taking root and is a viable alternative for PROs data collection. Patients or subjects can use their own devices, to complete the survey via a web-based portal or through a downloaded mobile app. BYOD allows patients to self-administer the questionnaire remotely and conveniently while at the same time, allowing the Principal Investigator access to a wider pool of patients or subjects. Although BYOD has clear advantages, some challenges in its execution remain to be addressed, especially in emerging markets in Asia, where literacy and penetration of smart devices may not be as high as the European counterparts.

Conclusion

Adoption of mechanisms that incorporate the patient's voice in healthcare decision making processes in Asia Pacific

With Australia and Taiwan taking steps towards incorporating patient perspectives in their healthcare decision making process, the trend is likely to continue to countries within the region regardless of the maturity of the healthcare system. In a heavily regulated industry such as healthcare, patient's voice provides a way to connect with the end-users of our industry and ensures that they are able to reap the benefits of healthcare innovations (Table 1).

Table 1: Some methods that add value to the decision making process through patient-centric approaches

METHODS	BENEFITS		
Patient Reported Outcomes	 Better alignment of research efforts and resource allocation to the demands of the market Richer data to showcase improvements in clinical outcome Clear identification and prioritization of research gaps to complete the value story of products and services Structured explicit approach to demonstrate value of products for 		
atient Preferences	appraisal committees, clinicians and private patients		

Keeping the human touch at the core of digital health

While technology is used to expand the access to quality care, it should not come at the cost of humanity. The idea is to understand the patient in order to improve patient outcomes, while the challenge is to leverage the convenience which technology brings bearing in mind the 'human' at the center of care. With patients being the vulnerable consumers in healthcare, empathy is the key element to a good patient experience. After all, the goal of healthcare is to improve patients' health-related quality of life. And it is imperative to preserve the human touch in our efforts moving forward.

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INNOVATIVE FUNDING MODELS FOR TREATMENT OF CANCER AND OTHER HIGH-COST CHRONIC NONCOMMUNICABLE DISEASES

In a global landscape study, 105 innovative funding solutions were identified as potential solutions to addressing the funding gap challenge. Results highlighted collaboration and knowledge sharing as the key success factors.

GLOBAL LANDSCAPE

Globally, noncommunicable diseases (NCDs) are rising in prevalence, particularly in low and middle income countries (LMICs). NCDs can be categorized into cardiovascular diseases, diabetes, respiratory diseases and cancers.

Management of NCDs requires long term and ongoing therapy, and in the case of cancer—expensive interventions, posing an increasingly high burden of disease to achieve optimal patient outcomes.

Particularly in LMICs, lack of sufficient funding often leaves patients with the choice between abandoning treatment or facing financial hardship. Despite meaningful efforts within the health system, current traditional funding models will struggle to close the gap.



EXISTING CHALLENGES

The funding gap between optimal treatment and available funding continues to widen—a gap notable in LMICs as patient numbers increase. Within this funding gap, key challenges are:



Ageing populations and increase of chronic disease prevalence compared to acute diseases



High demand on traditional funding

Pools of funding are stretched and patients are exposed to high out-of-pocket costs



Limited access to standard of care

Resources (equipment, specialists, infrastructure...) are supporting a higher caseload



Reach of typical financing platforms

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Difficulty delivering funding to a
demographic that is unable to
set up bank accounts/
traditional insurance
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INNOVATIVE FUNDING MODELS



Innovative funding models can be leveraged as part of the solution to address these challenges through new means of raising funds and providing alternative financing delivery options. In collaboration, Roche and IQVIA conducted an in-depth analysis of innovative funding models in a global landscape study compromised of:

Coverage of **5 regions around the world** (Africa, Asia, Europe, Latin America, Middle East) as well as **highlighted cases from 17 countries** Identification of **105 innovative funding models**, from research analysis supported by **32 expert interviews** from government, NGO and industry sector **36 showcased examples** to enable readers to better **understand** different possibilities for innovative funding models. Models were found to focus on **unlocking new funds, pooling resources** or **to target distribution and delivery** of said funds –or a combination

TYPES OF INNOVATIVE FUNDING MODELS

Globally, diverse and innovative approaches are successfully being used to address funding challenges. Below are 4 examples from the landscape study report:



IMPLEMENTATION OF INNOVATIVE FUNDING MODELS

The report analysis of different models identified common key factors that support the long-term success and sustainability of an implemented innovative funding model.



CALL TO ACTION



CONCLUSION



The funding gap for cancer and NCDs is significant and, without action, will grow. Approaching health financing in new and innovative ways can help countries address this challenge, ensuring patients benefit from new scientific and technological advances.

For further details, and more examples of real world case studies, please see the full white paper report at <u>www.iqvia.com</u> or scan the QR code.



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EIOVIA'

Bringing quality and affordable medicines to populations

Improving population health outcomes while achieving universal healthcare coverage



Universal Healthcare Coverage (UHC) in Southeast Asia: An overview and progress

Since early 2001, the implementation of the full Universal Coverage Scheme (UCS) in Thailand has provided effective and affordable interventions to its citizens with little or low insurance coverage and has expanded access to primary healthcare. This was a culmination of 30 years of social insurance system transformation, facilitated by gradually expanding coverage for the poor*, then near-poor, formal sector employees**, the children and elderly. By 2011, the program covered 48 million Thais, or 98% of the population, and cost just US\$80 per person annually, primarily funded by the general income tax. While there have been improvements in health outcomes (e.g. reduced infant mortality and decreased worker sick days), the public health system has had to address increased workload for providers and higher administrative and financial burdens.

Still, given the positive changes as a result of UCS, other countries are following suit. Between 2014 and 2018, Indonesia, Vietnam, and the Philippines have enrolled over 40 million people in their respective national health insurance schemes. *Table 1* and *Figure 1*

Figure 1: National Health Insurance coverage trends in 2014 and 2018

Population coverage of national health insurance scheme (in millions)



^{*}Note that Vietnam's latest available data is as of 2017

Source: IQVIA Analysis

show the shifts in national health insurance coverage over the last few years in these countries.

As a result of efforts to implement Universal Healthcare Coverage (UHC) initiatives, we now have better data to understand the health system of these countries.

	POPULATION (2014)	% POPULATION COVERED IN 2014	COVERAGE IN 2014	% POPULATION COVERED IN LATEST YEAR	COVERAGE IN LATEST YEAR
INDONESIA	255,129,000	70%	178,590,300	75% (2018)	208,054,199 (2018)
PHILIPPINES	100,513,140	91%	91,466,957	91% (2018)	100,000,000 (2018)
VIETNAM	91,714,600	81%	74,288,826	84% (2017)	81,000,000 (2017)
TOTAL			344,346,083		389,054,199

Table 1: Summary of national health insurance population coverage across Indonesia, Philippines and Vietnam

* The starting population coverage was 30%, but the service coverage, although comprehensive, was not deep. In 1985, there was gradual coverage of the near-poor, based on a voluntary, publicly subsidised healthcare scheme.

** Since 1984, government employees were covered by the tax-financed Civil Servant Medical Benefit Scheme, and the informal sector by a voluntary public-subsidized insurance scheme.

The introduction of Social Health Insurance (SHI) administrative databases provides a means of access to national healthcare claims data for epidemiological and health economics research and a source of evidence for policymaking decisions in Indonesia, Vietnam and the Philippines. Some of the key data capture information in the respective national insurance for each of these countries are summarized in *Table 2* below.

While we should celebrate that national health insurance efforts are broadening access to healthcare, we must also recognize the political pressure on government budgets to provide high quality care at affordable costs.

Yet this effort can be actively undermined if these medicines do not work as they are intended to, mostly because they are either substandard or falsified***. Such products exist in all regions. Thus, more evidencebased estimates of the volume and distribution of poorquality medicines across all markets is needed.

Furthermore, recent evidence shows that governments may not be able to afford the package of care they have promised. BPJS Kesehatan, Indonesia's government agency that oversees and administers the national health insurance program, has suffered deficits in five of the six years since the system was introduced in 2014. This year, the shortfall between spending and premium income is set to balloon to 28 trillion Rupiah (or nearly US\$2 billion), more than double the gap in 2018, as shown in *Figure 2*. In response, BPJS has planned to raise its premiums by at least 65% starting September 2019 in an effort to plug the deficit, which will result in a big impact for the lower income populations¹.

	JKN	VHIS	PHILHEALTH
HEALTH FACILITIES COVERAGE (YEAR)	2017	2015	2017
NUMBER OF PROVIDERS	25,391	13,508	6118
OUTPATIENT	22,975	12,143	8127
CLINICS	20,300	345	1541ª
PRIVATE (%)	51	0	0
RURAL HEALTH UNITS	NA	11,798	2606
RETAIL PHARMACIES	2675	None	None
OTHERS (INFIRMARIES AND BIRTHING HOMES)	NA	NA	2067
HOSPITALS	2416	1365	1913
PRIVATE (%)	60	13	60
CONTINUOUS AND CONSISTENT DATA CAPTURE	Yes, only for specialist outpatients and inpatients	Yes	Yes, only for inpatients
RECORD DURATION OF COMPLETE DATA, AS OF FEBRUARY 2019	3 years (2014–2016)	2 years (2017–2018)	2 years (2016–2017)
DATA LATENCY	2 months to 1 year, depending on how prompt hospitals are with filing of claims	2–4 months	2 months
NUMBER OF CLAIMS (YEAR)	~ 50 million (2015)	~ 200 million (2017)	~ 10 million (2016)
IN-HOUSE DATABASE EXPERTISE	Yes	Yes	Yes

Table 2: Description of the JKN, VHIS and PhilHealth databases²

JKN Jaminan Kesehatan Nasional

VHIS Vietnam Health Insurance Scheme

PhilHealth Philippine Health Insurance Corporation, NA not applicable

^aOnly includes facilities accredited to provide primary care benefits

*** According to the WHO definitions, substandard medicines are authorized medical products that fail to meet either their quality standards or specifications, or both; Falsified medical products are those that deliberately/fraudulently misrepresent their identity, composition or source.



Figure 2: Indonesia's widening health insurance deficit³

Indonesia's widening health insurance deficit

(in trillions of rupiah)

Source: BPJS Kesehatan

In many countries that have implemented UHC, there are signs that service delivery is not high. For instance, in Thailand, there has been reported long waiting times and overuse of health systems. Doctors may have less incentive to provide quality care and spend less time per patient to keep their costs down. These evidences suggest that increased government spending on healthcare workers and service delivery is still required to fully deliver on the promise of UHC in developing countries.

Moreover, UHC efforts are expected to focus on the basic care provision, and still involve out-of-pocket costs. For example, a recent study of the rotavirus vaccine in Indonesia reveals that the majority of local communities would be willing to pay 10,000 to 50,000 Rupiah (US\$ 0.80 to US\$ 4.00) per immunization, which is close to the price offered to GAVI through the UNICEF multi-year supply agreement prices of between US\$1.88 to US\$3.20 per dose. The actual cost of the vaccine is US\$84 to US\$120 per dose in the Indonesian private market, which may be prohibitive to the consumer as it is not covered within the governmentfunded insurance program, JKN.

Challenges in ensuring access to quality and affordable medicines

The key challenge for many developing countries implementing UHC is how to ensure that patients who visit a healthcare facility can have access to quality medical services at an affordable price.

Rising pressure on costs

The downward pressure on prices in countries that are implementing UHC has also led to some manufacturers making a tough choice between their commitment to patients versus maintaining their profit margins. For example, some key essential medicines, such as the antibiotic penicillin or methotrexate for cancer, are disappearing from the market globally due, in part, to prices that have become so low that it seems no longer commercially viable for manufacturers to supply them⁴.

Overall, there are many factors that contribute to the challenge of ensuring guality and affordable medicines in many countries ranging from type of financing of medicines to monitoring capacities.

Finding the balance in financing medicines

A large part of medicine spend today is out-of-pocket - especially in lower- and middle-income countries where pharmaceuticals spend accounts for a moderate proportion of total healthcare expenditures. Vietnam, Philippines and Indonesia are examples of countries that fall in this category (Figure 3). Consequently, these countries also have a significantly higher private sector share than public sector share of financing pharmaceutical expenditure compared to their uppermiddle income counterparts (Figure 4).

Figure 3: Pharma expenditure as a % of current health expenditure across 3 markets⁵



Source: IQVIA MIDAS National Sales Audit and WHO Global Health Observatory 2016, OECD Health Statistic



Figure 4: Government share of pharmaceuticals expenditure, 2010-2014 (%)

Source: WHO Global Health Observatory 2016, OECD Health Statistic

Medicines are fundamental and require appropriate and carefully planned financing across both the public and private sectors, in order to ensure that people can receive the necessary treatment at the right time. As governments further implement UHC initiatives, the planning and purchasing decisions that governments make will have an increased influence on pharmaceutical markets and access for patients.

Need for stakeholder education and capacity building

At the same time, we know that amidst the complex healthcare systems, patients and consumers are most concerned with having high quality medicines reach them through the last mile. All countries have guidelines and initiatives in place to improve local drug standards and to ensure that these standards are compliant with international guidelines. This helps make sure that consumers are getting the legitimate pill to treat their symptoms.

However, many developing countries with limited resources still face difficulties in monitoring the quality of medicines e.g. conduct effective product testing, pharmacovigilance (PV) and safety surveillance, capacity building and technical training for regulators to keep up to date on guidelines, technology and innovations in healthcare.



Figure 5: Pharmaceutical Rx sales in Southeast Asia by Manufacturer Country (MAT Q3 2013-2018 sales, US\$ Bn)

Source: IQVIA Analysis

Dominance of generic products among local manufacturers

In Southeast Asia, while the prescription sales are mainly driven by multi-national companies, most of the generic medicines are manufactured in the region with strong growth of local players from Indonesia, Philippines and Vietnam (*Figure 5*).

As more manufacturers are entering the market, particularly for low-cost generic products, there will be an increased need to monitor quality risks.

A generics-dominated market also reduces the appetite and incentive for pharmaceutical innovation. This can detrimental to the development and accessibility of timely and quality care for patients.

Within the OTC market of medicines, non-retailing (i.e. direct sales and online channels) form substantial share in Malaysia, Vietnam and Thailand. However, quality risk is likely to be the highest in these channels given difficulties in regulating them.

There are various indicators for countries to predict what quality of medicines is being delivered to consumers:

 The source of product distribution where regulation may prove to be difficult, resulting in consumers receiving falsified or substandard medicines e.g. unregulated websites, illegal street markets, non-store retailing, other direct sales channels

- 2. The significant presence of independent or nonchain pharmacies topped with low penetration of pharmacies in Southeast Asia allow for unregistered drug stores to dispense falsified or substandard medicines to patients (Figure 6). In case of the former, it is difficult for authorities to monitor and regulate the distribution of quality drugs; while for the latter, lower access to pharmacies has in turn led people to turn to convenient channels to purchase medicines which they believe to be the most reliable, affordable and best-known quality. As noted, some of these channels may be unlicensed and the origins of their medicines may be questionable. For instance, in the e-commerce sector in Indonesia, 361 violations were found for pharmaceutical products in 2018 (or a total of 50% of reported violations in of intellectual property rights)6
- 3. The high level of domestic manufacturing in some local markets increases the risks of quality gaps, necessitating contemplation of types of intervention. Furthermore, for many of the middle-income Southeast Asia markets, domestic consumption and production of medicines may be outpacing their regulatory maturation. Potential weaknesses in domestic manufacture and export will impact global patient safety because of both the legitimate pharmaceutical trade and potential for production of falsified and substandard medicine for the illicit unregulated supply chain⁷



Figure 6: Pharmacy penetration and share of independent pharmacies

4. Government policies in favor of local manufacturers may deter or limit access to novel drugs which could potentially improve the lives of patients. Furthermore, in lowering costs of production, some manufacturers will inevitably be forced to compromise on quality in order to fulfil the government's push to drive down pharmaceutical prices as part of being able to afford UHC. This may in turn result in patients receiving the lowest denominator treatment drug for their diseases.

Importance of providing access to affordable and quality medicines for UHC

The current and future risks of patients consuming falsified and substandard medicine are tremendous and pose huge global public health risks without proper detection and harmonized reporting. Some examples are⁸:

- Treatment failure in malaria, TB and HIV/AIDS: These diseases are more common, widespread and destructive in resource-poor settings of Africa and Asia. Treatment failures put patients at risk for disease progression and favor the selection of resistant virus strains⁹. As their viral loads increase, these patients are also more likely to transmit the infection, impeding efforts to control the virus¹⁰.
- 2. Growth of resistance to existing anti-infectives from use of sub-par treatments: The cost of health care for patients with resistant infections is higher than care for patients with non-resistant infections because of longer duration of illness, additional tests and the need for more expensive medicines¹¹.
- Spread of drug resistant pandemics, including HIV and influenza: The rise in resistance not only impedes our ability to treat infections, but has broader societal and economic effects.
- 4. Use of illegal funds to finance further illegal manufacture of medicines: Drug markets remain the largest criminal markets in the world and generate multi-billion dollars in profits for groups involved in this criminal activity. The UNODC estimates that the

largest income for transnational organized crime comes from illicit drugs, which account for some 20% (17%-25%) of all crime proceeds, or about half of transnational organized crime proceeds and 0.6% to 0.9% of global GDP. In turn, drug-related proceeds available for money-laundering through the financial system is equivalent to between 0.4% and 0.6% of global GDP¹².

For affordable and quality medicines to reach patients, coordination between various actors will need to improve, healthcare systems will need to be strengthened, and financing barriers will need to be addressed. Given the globalization of health-care delivery, securing the integrity and safety of the global medicines supply chain is important for patients to receive safe and efficacious treatments.

While governments aim to improve access to essential medicines and ensure effective spending on healthcare, it is also critical that the private sector commit and contribute to improving global health and ensure that their products continuously meet quality requirements for safe and high-quality treatments to be delivered to populations.

In this regard, many initiatives have been in place to strengthen local capacity, particularly in better monitoring and detection of substandard and falsified medicines and educating healthcare professionals to promote quality use of medicines. These initiatives will help provide patients with the much-needed assurance that they are receiving medicines that work.

Furthermore, many large pharmaceutical companies are committed to licensing their technologies to quality generic manufacturers. Some are also expanding their production and distribution capacities to meet patients' needs, while others are conducting R&D to develop missing essential medicines. The end goal is for patients to receive the best available and affordable treatment for their illnesses.

Future horizons: Improving population health outcomes for UHC

Improving access to quality-assured essential medicines is not an end in itself. It is a means to improving health status, promoting well-being and achieving equity across populations.

Going forward, shifting UHC interventions from curative care (i.e. providing quality medicines) to preventive care can help the health system to efficiently deliver the expected standard of care.

Today, people are taking a more proactive role in managing their own health, with the influx of telehealth and self-monitoring devices and apps. Better educated patients and health professionals are also demanding change in diagnosis and treatment approach.

According to the IQVIA Institute¹³, the proliferation of digital health tools will hold great promises for populations, with the potential to improve outcomes for patients, sometimes at near zero, incremental costs. Among the over 318,000 health apps available worldwide today, there are now established leaders among apps for consumers to use. Over 55% of the most downloaded health apps now use sensor data, with significant adoption of consumer wearables like Fitbit and Jawbone for wellness management being a key driver of this phenomenon. The next wave of innovation being applied to sensor technologies — including smartphone sensors, wearables and vital-sign-specific sensors — brings significant possibility to improve health by supporting condition management. Telehealth usage is also expected to double in the next 5 years.

Looking at Singapore, we have witnessed how the Health Promotion Board (HPB) has made efforts to empower citizens to live a healthy lifestyle enabled by technology and analytics. The National Steps Challenge, launched in 2015, provides a rewards system for Singaporeans to engage in sustained physical activities.

In August this year, the HPB also announced an initiative in collaboration with Fitbit called the "Live Healthy SG" initiative to incentivize Singaporeans to subscribe with the Fitbit Premium programme and encourage them to change their habits and adopt healthier habits.

At the same time, the HPB will study and analyze the data obtained from the initiative to identify trends for the formulation of more focused and enriched health intervention and promotional programmes and generate efficiencies in the healthcare system in the long run. This should be a lesson for countries which endeavor to have successful population health management – the marriage of technology and patient data and engagement.

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Delivering patient-centric care with digitalization in MedTech

How digital health is adding value to MedTech companies' approach towards patient-centric care

As the healthcare landscape continues to evolve against the backdrop of an ageing population and rising chronic diseases, greater constraints on government spending is expected. Public policy is expected to focus on costeffective ways to provide greater quality of care and shift towards preventive care, in a bid to minimize the impact on national healthcare budgets. In parallel, the advent of big data, technology and the firepower of analytical computing, has ushered in an era of increased connectivity, making it possible for organizations to achieve operational efficiencies and increase productivity which might have been unthinkable previously. Not only is digital disruption impacting workflow efficiency and processes but it is also bridging the gap between the industry and patients by providing innovative solutions to engage, educate and encourage, thereby driving improved patient outcomes.

The introduction of digital services will be among the most important factors in transforming healthcare over the next decade. Healthcare is one of the few industries that has the potential to be impacted profoundly by digital technology. However, many challenges still lie ahead for early adopters. Regulatory barriers, economic hurdles and difficulties in effectively digitizing and utilizing data derived from patients data are among the hurdles awaiting those who wish to launch pioneering services powered by digital technologies, or in other words, digital health.

In this article, we demonstrate the added value that technologies enabled by digital health will bring to the healthcare industry. The paper also examines the pressing need for the adoption of digital health and associated technologies by MedTech companies.

Digital health is already delivering patient-centric care

Healthcare has been a traditionally risk- averse sector, lagging behind when it comes to the adoption of digital tools due to considerations such as regulations and data sensitivity. However, factors such as rapidly ageing population, rising chronic disease burden and downward pressure on healthcare costs are compelling the industry to open up to disruption of the traditional processes via adoption of digital tools. There is an urgent need to increase productivity, optimize efficiencies and reduce waste through job re-design, automation and right-siting of care. In the coming years, digital health and related technologies will play an even larger role in facilitating this transformation process.

At the same time, the advent of the digital age has given rise to a crop of 'connected patient', presenting the industry with the opportunity to engage patients appropriately so that the latter can actively take ownership of their own health, thereby driving improved patient outcomes. Health activation is a critical factor in enhancing patient outcomes and care experience through upstream prevention, early disease detection and prediction. This gives care-givers the opportunity to take better care of their own health as they can now cope with the burden of care more confidently.

Recognizing this opportunity, early adopters have already started piloting and deploying programmes that leverage digital tools to either optimize existing workflow inefficiencies or to engage patients in order to improve their quality of life.

Case study: US Centers for Disease Control and Prevention (CDC) deploys a digital health platform for diabetes prevention

Diabetes is one of the most common and costly chronic diseases with an estimated 23.1 million people in the United States who are diagnosed at a cost of more than US\$245 billion per year¹. In 2017, the global diabetes prevalence was 8.8% of the world population and is expected to further increase to 9.9% (95% confidence interval 7.5-12.7%) by the year 2045².

Furthermore, a large percentage of the population either remains undiagnosed or is disposed towards prediabetes.

Diabetes is also often associated with a number of co-morbidities and is known to be a major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation³. Given this, Diabetes remains one of the most challenging chronic diseases to deal with for a country's healthcare system.

In order to delay in the onset of diabetes and promote a preventive, healthy lifestyle, the CDC

established the Diabetes Prevention Recognition Program (DPRP) standards to accredit digital Diabetes Prevention Program (DPP) translations that deliver an approved curriculum, provide health coaching and group support, and equip participants with skills and self-monitoring tools to support behavior change. The study's objective was to examine clinical outcomes up to 3 years postbaseline and the relationship between program engagement and clinical outcomes in a digital DPP. Participants who completed 4 or more lessons and 9 or more lessons achieved significant weight loss and A1c reduction. Patient engagement (website login, group participation, lesson completion) and consistent health behavior tracking are key success factors to the program⁴ (*Figure 1*).

Omada Health, the digital DPP provider, is one of the first digital health companies to receive reimbursement from the U.S. federal government for its online diabetes prevention program.

Figure 1: Overview of Digital Diabetes Prevention Program

DPRP delivers an approved curriculum, provide **health coaching** and **group support**, and **equip participants with skills** and **selfmonitoring tools** to support behavior change

Ĵ,

The Omada Health Program is a digital translation intervention that is accessible via **internet-enabled desktop or mobile devices.** The program consisted of:

- 1. One year of a behavior change curriculum
- 2. Technology-enabled tools to track nutritional intake, physical actitivity, and body weight
- 3. Personalized health coaching
- 4. Small group support

Significant outcomes: Weight loss and A1c reduction maintained from baseline to 3 years

- This program engagement revealed that website logins and group participants (patient engagement) were significantly associated with weight loss at 16 weeks and 1 year
- This research validates the longterm efficacy of a digital DPP, supporting its expanded use in standard clinical practice & reimbursement

This programme clearly demonstrates the shift in the payer mindset towards increasing healthcare spend towards preventive care. Furthermore, it emphasizes the importance of leveraging digital tools for engaging and educating patients to help them strive for better quality of life.

Digital health is rapidly gaining traction in MedTech

As digital health continues to disrupt an essentially traditional healthcare ecosystem, MedTech companies will need to keep pace in order to remain relevant and successful in this dynamic market. Early movers have identified the need to transform their existing processes to provide better value to patients, physicians and payers. When considering deployment of digital health or technology-driven solutions, two broad trends stand out in terms of business and operating models: collaboration and acquisition.

Case study – Collaboration: Cloud-based oncology care and workflow tool to foster collaboration on patient management and inform physician decision making via dashboard

Tumor boards often share a series of inefficiencies related to workflow challenges, with many practitioners investigating the role and efficacy of tumor boards in hospitals, health systems and academic medical centers⁵.

In order to improve workflow efficiency, Roche Diagnostics and GE Healthcare have partnered up to launch the innovative NAVIFY Tumour Board, which enables a more personalized approach to cancer care. The NAVIFY Tumour Board leverages medical imaging and patient data together with its Clinical Decision Support apps portfolio, enabling multi-disciplinary teams who determine treatment plans for cancer patients to have a more comprehensive view of each patient in one place and enable efficient, more informed decision making. The partnership provides an ecosystem of workflow solutions and apps on an industry-first shared integrated diagnostics platform. Both companies are aiming to seamlessly integrate and enable analysis of comprehensive lab and medical imaging data, patient records, medical best practice, real time monitoring and the latest research outcomes. The aim of the platform is to instill confidence in clinicians so that they can make the best possible treatment decision for each patient.

NAVIFY Tumor Board was launched in several APAC countries including Singapore starting in April 2019 and demonstrates how MedTech companies are already harnessing digital tools to optimize the hospital workflow processes and improve patient outcomes.

Case study – Acquisition: Development of a fully integrated digital surgery platform across continuum of care

Smith & Nephew and Brainlab have entered into a strategic collaboration for future development of technology for digital surgery in orthopaedic joint reconstruction business. This partnership will offer Smith & Nephew access to a broad range of Brainlab technologies in cloud computing, tracking, augmented reality, robotics, AI, machine learning, image fusion, and anatomical segmentation. The combined competencies are expected to result in a powerful digital ecosystem from which ground-breaking clinical solutions can emerge, bolstering Smith & Nephew's technology base for robotics.

Digital health is here to stay: Adapt or be left behind

Digital health is no longer a buzzword, it is nearly a norm. MedTech companies have already started investing in solutions that leverage digital health in order to meet specific objectives.

In order to understand how crucial digital health is to MedTech companies, IQVIA surveyed 33 senior executives representing mid-to-large MedTech. Survey respondents included executives across multiple functions from medical device, diagnostics, and imaging companies.

When asked if digital health and associated technologies were a priority for their organizations, recognising the urgency, 100% of the survey respondents acknowledged that these were indeed a top priority for them and that their adoption is crucial for these companies to stay competitive in the market.

All survey respondents also agreed that these technologies could provide a new way to bridge the existing unmet needs and identify new market opportunities. Above 60% of the senior executives surveyed, indicated that the adoption of digital technologies is critical for their companies (*Figure 2*).

SURVEY METHODOLOGY

IQVIA surveyed 33 respondents, from midto-large MedTech companies. The survey was conducted to understand the reception of digital health technologies by the MedTech industry.

Survey respondents included senior executives across multiple functions of medical device, diagnostics, and imaging companies.

Figure 2: Level of criticality for the adoption of digital technologies for MedTech companies



Source: IQVIA Analysis, Data from IQVIA Survey, n = 33

Figure 3: Key technology adoption priorities for MedTech companies



Source: IQVIA Analysis, Data from IQVIA Survey, n = 33

When asked about their organization's key technology adoption priorities, 61% senior executives indicated data analytics, while 33% have already deployed artificial intelligence (AI)/ Machine learning (ML) related initiatives and remaining 33% have deployed cloud-based technology related initiatives within their organizations (*Figure 3*).

These findings show that digital technologies are increasingly being adopted in MedTech companies in order to reduce cost, improve quality and access. Between 2016-2018, Healthtech funding in APAC increased significantly, at 40% p.a., closing at US\$6.3 billion in 2018. Asia Pacific Healthtech funding value is highly concentrated in China with the highest average deal size, which contributes to 80-90% consistently over past three years⁶ (*Figure 4*). Most MedTech executives show a strong inclination towards investing in smart devices powered by AI followed by digital therapeutics and analytics platforms (*Figure 5*). About 90% of the survey respondents were open to investing in or collaborating with digital Healthtech startups.

Figure 4: Asia Pacific digital health technology funding

	CAGR	Avg. deal size (US\$ Mn), 2018
🛑 China	+38%	39
🛑 India	+71%	7
RoA ¹	+38%	5

Total Asia Pacific funding value by region (Bn US\$, 2016-2018)⁶



Source: 2018 Asia Health Tech Investment Landscape report. Galen Growth Asia, 2018

High

Medium

Low

Figure 5: Investment appetite of MedTech companies for different digital health technologies

Medical diagnostics (e.g. AI diagnostics/imaging)

Data analytics platform (e.g. flatiron: software to accelerate cancer research and improve treatment)

Remote disease monitoring/management (e.g. interactive app that allows users to access help)

Digital therapeutics (e.g. software programs to prevent, manage, or threat a medical disorder)

Smart devices powered by AI

Source: IQVIA Analysis, Data from IQVIA Survey, n = 33

Figure 6: Rise of digital therapeutics: Technological evolution and its impact on healthcare



The next generation of care

Digital is disrupting healthcare just like how it has already disrupted the way we hail our cab and the way we shop.

It has already revolutionized conventional pharmaceuticals by introducing a new drug classification – 'digital therapeutics' (*Figure 6*), which rely on an AI-enabled software to treat a disease, which may also include ancillary components such as connected hardware device(s), adjunctive pharmacotherapy, or live clinical support, but the software component could still drive meaningful outcomes as an independent contributor to treatment.

Furthermore, in home and community care for instance, digital health is already leveraging technology akin to the application of IOT and wearables in order to collect new and real-time data, develop predictive and actionable health-related insights through AI / ML and translate these into automated actions such as automated diagnostic for X-ray image and robotic surgery guided by AI to increase precision and reduce turnaround time (*Figure 7*). Figure 7: The patient-centric model as supported by digital healthtech deployment



In addition, novel digital technologies, continuous data collection and analytics could lead to novel ways of collecting scientific evidence which can help improve patient care through more accurate clinical decisions and improve the decision making for value-based healthcare where positive outcomes are the standard for reimbursement.

Companies that embrace digital and leverage digital health tools in order to deliver high-quality, cost-effective care, will undoubtedly lead the pack in the coming years.

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Claims substantiation in Southeast Asia Generating claims that inform Consumer 2.0

Significant needs, vast opportunities

The importance of data-driven, scientifically valid claims to gain consumer understanding and trust in the crowded me-too field of consumer health has never been greater. Gone are the days when endorsement by popular media personalities and well-made massmedia ads boasting of "Smoother skin!" "Whiter teeth!" etc. were enough to boost product uptake. Today's consumer is self-focused and digitally empowered. They want trustworthy information to compare and choose products for their individual needs to maintain wellness, prevent disease and treat illness.

The challenge is to uncover the secrets to the consumer's trust, such as:

- What do consumers really think about a product vs. its competitors? New technology is unlocking consumer secrets hidden in Big Data and social media

 secrets they may be reluctant to otherwise reveal in surveys and focus-groups
- How are consumers really using your product? Read on to learn how the discovery of unexpected uses have yielded entirely new benefits that are then backed by scientific substantiation, creating lucrative new products
- What are consumers really looking for when buying? Not just a product. They want a solution to their specific problem; it must fit their lifestyle and deliver meaningful benefits

Unearthing these secrets is key to increasing value share and product innovation. The product must tell a story that consumers trust. The good news is that there are powerful new tools available to help select the right claims to substantiate – those that optimize trust – and to gather the evidence needed to secure regulatory approval. These tools include deep consumer insights, real-world evidence, and secondary data from wearables and smartphones. Together these are transforming deep consumer insights generation, making it faster, more efficient, more accurate. These are truth detectors to uncover secrets buried in consumer data.

The foundation of excellent claims selection and substantiation, however, rests on two pillars:

- First is to approach claims strategically. Consumer Insights, Marketing, Medical, Regulatory, R&D and Legal must work as one to maximize the likelihood of success and avoid pitfalls.
- Second is to use a proven methodology that begins with a white space analysis – all possibilities explored and step-by-step claim concepts that resonate with consumers, clearly differentiate the product, can be substantiated at a cost commensurate with the value delivered and can pass regulatory approval.

Southeast Asia's fragmented regulatory framework makes it especially important to tap into marketby-market knowledge of claims substantiation requirements. Thinking strategically, leveraging new technology, deep knowledge of markets and consumers: this is the magic elixir to success in the region.

Claim selection and substantiation

The rise of 'Consumer 2.0', in other words, consumers who are information-savvy and digitally empowered, represents changes in demographics and lifestyles worldwide. They are seeking prevention instead of treatment; they want improved product offerings and reliable data. In addition to the traditional claims derived via primary market research methodologies, consumer health brands are increasingly leveraging scientific claims[#] to educate and get buy-in from this new breed of consumer.

[#] A scientific claim is a statement released by the manufacturer on functional benefits of the product backed by scientific evidence. Brands with clinical evidence can potentially "consumerize" a scientific claim for relevance.



Every claim, regardless of the type, must be substantiated. Some regions of the world have adopted harmonized regulations governing claim substantiation; others have not, like here in Southeast Asia (the exception being cosmetics claims, where progress is being made in ASEAN guidelines harmonization). This makes local knowledge especially important to avoid costly re-working of substantiation research to meet local requirements. Do it once, do it right.

Figure 1: Testing consumer claim concepts



Having an overarching strategy is critical. Best practice is to have a company-wide claims strategy that crosses product categories and product lines. This creates a consistent methodology to choosing the best approach for each claim. Claims have multiple purposes and must satisfy scrutiny from distinct audiences, hence the need for a cross-functional team to oversee the process:

- For consumer health companies: differentiate the product, gain value share. Typically led by brand managers.
- For consumers: buy products that do the job. Typically led by Marketing & Insights.
- For regulators: empower consumers with credible claims appropriate for mass-media advertising, protect them from false and misleading claims, and prevent unfair trade practices. Typically led by R&D, Medical / Regulatory Affairs and Legal.

Claims substantiation approaches vary depending on the product and type of claim. *Table 1* shows examples suitable to clinical research the most scientifically rigorous and expensive approach and real-world evidence* and those suitable for market research (focus groups, surveys, etc.).

Claims generated through clinical and Real-world studies

Clinical trials generating scientifically robust data or evidence from literature are needed to support most health claims related to disease risk reduction. Real-world evidence (RWE) can be used support or complement clinical efficacy and safety in subpopulations and incorporating patient experience. Efficacy claims are carefully reviewed by regulatory authorities and therefore, it is important to carefully design the clinical trial or RWE end-points to obtain supporting evidence for substantiation.

Factors to consider include:

- Who is the target audience?
- Is the claim meaningful to consumers?
- Are you most interested in demonstrating efficacy, safety or effectiveness and quality of life?
- Is a pilot study the best way to go for an initial hypothesis or should you start with a large, definitive trial?
- What is the best study design? Open label? Randomized double blind? Others?

Real-world evidence provides another avenue to gain the validation needed. Data from consumer reported outcomes in the real world can complement clinical findings in a meaningful way as well integrate consumer insights gathered through traditional market research.

APPROACHED VIA MARKET RESEARCH	APPROACHED VIA CLINICAL AND RWE
Consumer Testimonial Claims	Comparative Efficacy & Effectiveness
Expert Endorsement Claims	Health Improvement Claims
Perceived Performance	Overall Health and Wellbeing
Satisfaction Claims	Safety and Tolerance Claims
Sensory Claims	Structure/Function Claims

Table 1: Claims substantiation approaches

* Section 505F(b) of the FD&C Act defines RWE as "data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials" (21 U.S.C. 355g(b)).¹

Claims generated through primary market research approaches

Claims appropriate for market research include consumer preference and satisfaction, e.g. "Mothers prefer..."; sensory claims, e.g. "less greasy", "improved taste" etc.; and consumer-claimed performance, e.g. "firmer skin", "less puffiness" etc. For market research the priority is to make sure there is a robust, geographically representative sample size in order to achieve a 95% confidence level, the usual target.

Regardless of the approach taken, it is vital that a crossfunctional, company-wide team oversees the process, said GlaxoSmithKline's Sunitha Shanmugam, Regulatory Affairs Director, Consumer Healthcare Southeast Asia.

"For multinationals like GSK it's important for key messages to be consistent globally," Sunitha said. "You can't promote Panadol[®] in the UK for pain and say it's for fever elsewhere. Central control by a multidisciplinary team ensures that every part of a claim is tight, especially for claims involving efficacy, health, function and safety. It's a sanity check."

Dr. Sheryl Tan, Head of Medical, ASEAN Consumer Health, Bayer, said that understanding the patient or consumer journey before and after they use the product is key. "Central control by a multidisciplinary team ensures that every part of a claim is tight, especially for claims involving efficacy, health, function and safety. It's a sanity check."

– Sunitha Shanmugam, Regulatory Affairs Director, Consumer Healthcare Southeast Asia, GlaxoSmithKline

In Bayer, said headquarter-generated strategy and consumer insights are augmented by market-level research, locally. Sheryl gave the example of how consumer market research in Vietnam resulted in Bayer enhancing its local advertising tagline for Berocca[®], a B-vitamins rich multivitamin supplement.

Robust scientific evidence substantiates Berocca's benefits in mental alertness and physical energy, and this aligned with a consumer insight of a 2 p.m. power nap commonly practiced in Vietnam.

Utilizing this insight, Bayer enhanced the local tagline in Vietnam to "Have Your Berocca at 2 p.m." – positioning it as an alternative to daily power naps. "This campaign positively resonated with our Vietnam consumers", Sheryl said.



Figure 2: When to opt for scientific claims substantiation approach over primary market research

Publications in medical or scientific journal
 Sensitive populations (e.g. no product placement is allowed in infant population via PMR,

claims can only be 'parent reported outcomes')

Claims derived

from data collection

involving any of the

below are treated

as Interventional studies. As a

prerequisite ethics

approval is sought

before initiating such studies

Food & nutrition claims

Let's take a deeper dive into claims selection and substantiation in the food and nutrition category. There are no harmonized nutritional labeling and claims in Southeast Asia (whether harmonized or country-by-country, food and nutrition labeling regulations are informed by global Codex^{\$} guidelines). Here regulations vary at a country-level, making the process complex – trade barrier.

Nutrition labels convey information about the food's nutrition content and are designed to help today's health-conscious consumers make better choices. This creates opportunities for companies to introduce healthier alternatives to meet consumer demand – and to make nutrition and health claims that capture the consumers' attention and wallet.

The rise of Consumer 2.0 is creating opportunities for consumer health companies to develop and promote healthier products. However, there also are barriers. Nutrition labeling is expensive, especially if done incorrectly. It is complex and there is a lack of high-quality labs to provide analytical services, to name a few.

In Southeast Asia only Malaysia requires labeling for general foods at this point. There is, however, mandatory labeling for special dietary use foods, foods enriched or fortified, and foods making nutrient claims (Thailand requires labels for some snack foods, e.g. potato chips, popcorn, etc.). Voluntary labeling, if it follows a prescribed format, is allowed in some countries within Southeast Asia.

The region's regulatory agencies also face challenges. For example, some beneficial nutrients such as iron run the risk of being overused. Consumed in proper amounts iron is essential to preventing anemia. However, when overused or overfortified in food, it can cause hemochromatosis and other health problems².

Regulatory bodies and advertising councils in Southeast Asia put consumer safety and understanding first. They review evidence to ensure that claims are valid. Adding to the importance of advertising councils in the region, is the rise of digital promotion, with consumer health ads appearing on consumers' web browsers across multiple countries.

Despite the overall lack of regulatory rigor and consistency, health and nutrition claims are already common in Southeast Asia. The next step is to develop clear, consistent regulations at the regional level on labels and claims. IQVIA is joining industry associations and other organizations to facilitate discussion with governments and regulators to achieve that.

Table 2: Global view on nutritional and health claims

These claims refer to statements or suggest that a food or product has certain properties

ТҮРЕ	SUB-TYPES	EXAMPLES
	Nutrient content	"Source of", "High in", "Free of"
Nutritional	Nutrient comparative	"Less than …", "Reduced …", "More than …"
Health	Nutrient function	"Calcium helps build strong bones and teeth." Note: "Milk helps build strong bones and teeth" is unacceptable; claims can only be made for a nutrient (calcium) in a food, not the food itself.
	Disease risk reduction	"Three grams of soluble fiber from oatmeal may reduce the risk of heart disease."

\$ The Codex Alimentarius, or "Food Code" is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission. The Commission, also known as CAC, is the central part of the Joint FAO/WHO Food Standards Programme and was established by FAO and WHO to protect consumer health and promote fair practices in food trade. ASEAN guidelines on health supplements³ call for different levels of evidence for three types of health supplements:

- **General or nutritional claims** require general evidence from at least one authoritative text, scientific journal, scientific opinion from regulatory authorities, etc.
- **Functional claims** require a medium level of evidence, e.g. at least one piece of compulsory evidence from human studies, scientific papers etc. and an additional piece of evidence from scientific animal studies or documented history of use, etc.
- **Disease risk reduction claims** require the highest level of evidence: compulsory scientific evidence from human intervention study and additional evidence from authoritative papers, monographs etc.

Big Data & the big picture: Innovation in claims

In his book "Everybody Lies"⁴, author Seth Stevens-Davidowitz writes about how data can unveil hidden truths about consumers. He cites Peter Theil, an early investor in Facebook, who says that great businesses are built on secrets – either secrets about nature or people.

Blockbuster drugs are built on unlocking the nature's secrets to better therapies (imagine the value of understanding the biological pathway of Alzheimer's disease); the same holds true for discovering the hidden needs of consumers in nutrition, supplements, over-the-counter (OTC) products, cosmetics, etc.

Some of the biggest consumer-product success stories in recent years have arisen from discovering that consumers were using a product in unintended ways. For example, it was found that some consumers were taking the long-established cold remedy from Vicks, NyQuil[™], to help them sleep, even when they weren't sick. That led to ZzzQuil[™], a formula clinically tested for occasional sleeplessness, offering consumers a restful night's sleep without the other active ingredients in the cold formula⁵. "Marketers and product developers focus too much on customer profiles and correlations unearthed in data, and not enough on what customers are trying to achieve in a particular circumstance."

— "Know Your Customers' 'Jobs to Be Done", Harvard Business Review, September 2016.

It's vital to focus on what consumers are trying to do when they purchase a product ("the job to be done") vs. just the product itself. For example, a mother packing her daughter's school lunches may buy boxed drink "A" because of its nutritional claims. Instead of just looking at why she purchased "A" vs. competing products, researchers should look at what the mother was really trying to accomplish – pack a healthy lunch for her daughter. That opens a rich new field for exploration.

Dr. Volker Spitzer, Global Principal R&D at IQVIA Consumer Health, gives a vivid example of what McDonald's discovered by looking at the job to be done vs. the product alone. McDonald's wanted to learn why drive-in customers were purchasing milkshakes vs. other types of drinks to take on long commutes. What they found was that it was not the taste of milkshakes, but rather the drivers' desire for a longer-lasting drink that wouldn't slosh out of the cup. The result: McDonald's focused on making thicker milkshakes to satisfy the commuters' real need.

It's not just about the function of the product; there are powerful social and emotional dimensions to customer preferences, and hence claims that resonate with them, as well. That is where starting with a "white space" analysis at the start of claims research can lead to big discoveries.

When claims go wrong: Consumer apathy, regulatory enforcement

How can claims go wrong? Several ways. Dr. Spitzer gives an example of FruitFlow[®], the first European Food Safety Authority-approved natural cardio-protective functional ingredient. Despite strong scientific evidence supporting its claim "Clinically proven to promote healthy blood flow", products containing FruitFlow are still not very well known by consumers.

FruitFlow remains a niche ingredient after more than a decade on the market. Most consumers probably don't understand the link between blood flow and heart-health benefits, unlike claims for cholesterol-lowering ingredients, for example, which are well established and understood. In short, even world-class scientific evidence accepted by regulators is not always enough, on its own, to gain consumer trust⁶.

Another way is by picking the right claim but doing the wrong type of research, resulting in substantiation that doesn't pass regulatory muster or ends up costing more than an alternative method that would have been cheaper and/or better.

And the most highly publicized and expensive way things can go wrong is by making and promoting claims that result in regulatory action and penalties. For example, in early 2019, the U.S. FDA accused 17 nutritional-supplement makers of selling more than 58 products with improper claims that they can prevent, treat or cure serious diseases, including Alzheimer's. The companies involved often marketed their products via websites and social media.

The future

The future of claims success lies in stronger scientific evidence that translates to meaningful and relevant claims mirroring Consumer 2.0's needs. The former can be developed by new technologies and techniques, especially through data and decoding derived from social media, personal devices and health apps.

In addition, claims and billing data and product and disease registries are important sources of evidence

for Rx-to-OTC switches. Because real-world data is consumer-generated, it is de facto consumer-centric. It delivers insights essential to answering the vital question: "What claim should I focus on?"

The future is undoubtedly digital. Recognizing this, IQVIA has formed an exclusive partnership with ObvioHealth's proprietary platform to conduct clinical, real-world evidence, and market research studies digitally. Virtually any smart device can be linked to the IQVIA virtual research platform – smart watches; activity and sleep trackers; Bluetooth-enabled scales, blood pressure monitors, etc.

Recently IQVIA used a web-based quantitative survey in Thailand to help one of its clients extend the benefits of a baby skin-care product from "treatment" to "prevention." About half of the 300 participating mothers used the product after every diaper change, whereas the other half only used it to treat their baby's skin rash. The result: an enhanced understanding from consumers that regular usage offered better protection.

Social listening is providing valuable consumer insights unfiltered by research intervention. Monitoring what's being said online by regular consumers can reveal candid consumer insights in near real-time. The data can be used in multiple ways – competitive intelligence, the consumers' decision journey, brand perception, and influencer identification to name a few.

Keys to success

Best practice in claim substantiation begins with a "white space" analysis - the strategy, needs and resources. A full examination would include the competitive landscape evaluation - what are the competing products and their claims, regulatory approvals needed in each market, access to market-by-market consumer insights and need for additional research.

Both GSK's Sunitha Shanmugam and Bayer's Sheryl Tan said that understanding the consumers' needs is always the priority. Sunitha cautioned against the old-school approach of taking a product's key attribute



and trying to "retrofit" it to meet a consumer need. Deeply understanding your consumers – their lifestyles and social, cultural and economic factors in addition to health needs – is essential. Sunitha also emphasized the importance of "consumerizing the language" used in a claim – taking the language of science and medicine and converting it to statements that consumers can easily understand and relate to. Sheryl described it as "giving the consumer a reason to believe" in your product.

New technologies can help companies quickly and efficiently gather the scientific and real-world evidence needed to gain regulatory approval and the consumer behavior and perception research to craft claims that resonate in the marketplace. The trick is to choose the right approaches from among many options. Another key to success is to understand "how to talk" to regulatory authorities in each country. Sunitha said this goes beyond the dry guidelines about what authorities require. Practical experience in how to present substantiation research to authorities can significantly improve the odds of claim substantiation approval.

And finally, after all the work has been done and the product launched using the new claim(s), a new round of listening must begin – how are the claims impacting sales? What is being said on social media? What are the changes in consumer perception?

Listening...the key to uncovering secrets that lead to success.

Continue the conversation with: Swapna Kondapuram, swapna.kondapuram@iqvia.com Airene Valencia, airene.valencia@iqvia.com Volker Spitzer, volker.spitzer@iqvia.com

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