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Volume 1

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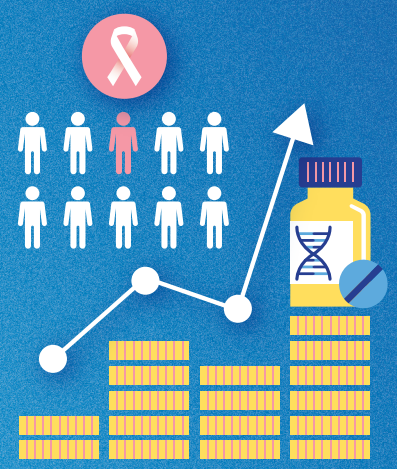

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1

DESIGNING UNIVERSAL HEALTH COVERAGE (UHC) AND HEALTHCARE SYSTEMS

Explore the essence of a successful Universal Health Coverage (UHC) design. From essential health benefits packages to effective governance, explore how robust systems can transform healthcare and learn the vital components for building and managing UHC effectively.

https://www.hitap.net/en/thaiuhc

Issue#10 November 2018

Designing the Health Benefit Package:
the essential component of a successful universal health coverage program

Yot Teerawattananon, Juliet Eames and Saudamini Dabak

policy brief

Why define a health benefit package and how to ensure its acceptability?

The 'universal health coverage (UHC) cube' conceived by the World Health Organization (WHO) identifies three key policy questions for public healthcare provision to achieve universal health coverage: what healthcare services should be covered (the depth)?; should the whole population be covered or only certain groups (the breadth)?; and what proportion of the total cost should be covered under UHC (the length)? (See Figure 1 below) The UHC cube concept recognizes that there is a finite public budget and a balance between the three dimensions must be struck. A well-defined benefits package is central to addressing these questions, outlining what healthcare services are covered, for whom, and with what degree of financial coverage.

A health benefit package may first focus on key priorities such as providing cost-effective primary care services, including health promotion and disease prevention interventions, and providing life-saving or high-impact health services to all patients who need them. High impact interventions may be provided at little or no cost to the user to ensure access for all. The package may be expanded to cover additional services once more financial resources become available.

Technologies comprise around 50% of healthcare budgets in low and middle-income countries and there are an increasing number of high-cost technologies available in the market that may or may not be cost-effective. Public financing of cost-ineffective technologies reduces resources available for provision of cost-effective health interventions. Maximized health can be ensured by a clear and carefully developed benefit package that excludes cost-ineffective treatment options in order to provide governments with good value for money.

As technologies advance, previously cost-effective interventions may be overtaken by better treatment options. For this reason, benefit packages must be consistently reviewed to ensure financial sustainability and provide the greatest level of healthcare, at the lowest cost. A systematic, transparent and participatory process for defining a health benefit package helps policy makers to make appropriate decisions and ensure accountability of decisions. Implementing these principles leads to a package that is fair and efficient and allows stakeholders to accept the legitimacy of a package even when it does not satisfy their personal priorities.

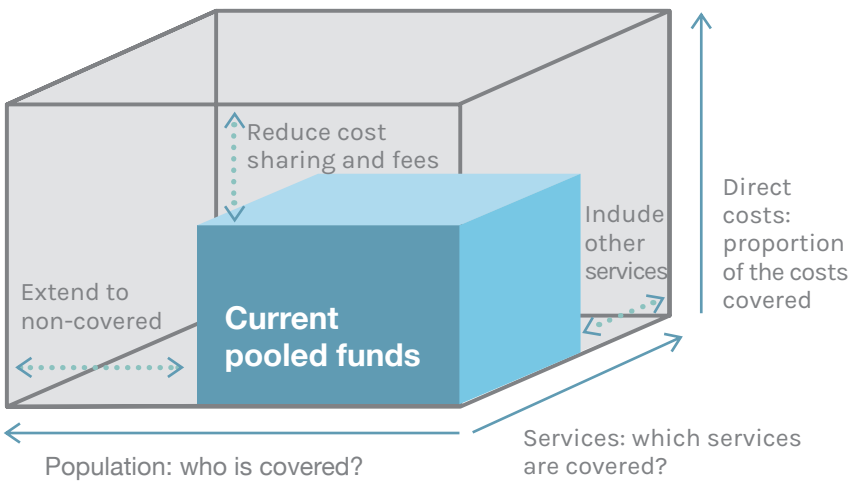

Figure 1: Universal Health Coverage Cube *(Source: World Health Organization)*

Development of the health benefit package for Universal Health Coverage in Thailand:

Until 2002, there were several public health insurance schemes in Thailand: the Civil Servant Medical Benefit Scheme (CSMBS), the Social Security Scheme (SSS) for formal employees, the Social Welfare Scheme which covered the poor, near poor, children, elderly and other deserving groups and the Voluntary Health Card scheme which subsidized low income households. These schemes covered about 70% of the population, half of which were covered by the Social Welfare Scheme. CSMBS offered the most generous benefit package, while the other schemes provided limited packages.

In April 2001, the government committed to expanding health coverage to 100% of the population and consequently, full-coverage was achieved on 1st January 2002. Full-population coverage was attained by using general taxation to expand the Social Welfare Scheme and cover the rest of the population. The initial benefit package for the new scheme, named the 'gold-card' scheme, was based on the Social Welfare Scheme benefit package and drugs list, but excluded high cost interventions such as cancer treatment, anti-retroviral treatment, organ transplant, coronary bypass surgery, as well as cosmetic care.

In 2002, the National Health Security Office (NHSO) was established as the management agency for the 'gold card' scheme and the Board, chaired by the Minister of Public Health, established a Subcommittee for the Development of the Benefit Package and Service Delivery (SCBP). The SCBP comprises stakeholder groups such as patient groups, civil society organizations, providers, relevant government agencies, and subject experts.

Initially, the SCBP considered proposals for inclusion of interventions into the benefit package from multiple groups in an ad-hoc manner, with no explicit criteria for adopting interventions. This system was inadequate as only elite groups with access to the secretariat could effectively present proposals and this process resulted in policies that did not represent the broader public interest. There was also significant variation in the quality of evidence presented to the Subcommittee.

In October 2003, the government introduced anti-retroviral treatment into the benefit package without any formal assessment. This policy put pressure on the NHSO to include other high cost interventions in the benefit package. One proposal called for the inclusion of Renal Replacement Therapy for End Stage Renal Disease (ESRD). Realizing that including expensive treatments without careful assessment would be financially unsustainable, the NHSO, which purchases health services, and the Ministry of Public Health (MoPH), which provides health services, commissioned a range of research projects that included a needs assessment, service readiness study, economic evaluation and budget impact assessment. These was completed in 2006 and treatment of ESRD became the first intervention in Thailand to be rigorously assessed before being included in the benefit package in 2008. This event paved the way for the establishment of systematic decision-making processes for health benefit package decisions in Thailand.

In 2009, the SCBP requested two academic bodies, the International Health Policy Program (IHPP) and the Health Intervention and Technology Assessment Program (HITAP), to develop rigorous mechanisms and processes for using evidence to inform decisions for the non-pharmaceutical benefits package of the Universal Coverage Scheme (UCS). The mechanisms and processes for the non-pharmaceutical benefits package are as follows (See Figure 2 below):

1

Seven groups of stakeholders nominate interventions for inclusion in the benefits package: health professionals, patients, policy-makers, academics, civil-society, industry and lay-people. Proposals can include up to three topics, one of which must focus on health promotion or disease prevention.

2

Topics are prioritized by a 'selection working-group' based on six criteria which are: burden of disease, severity of the health problem, effectiveness of intervention, variation in current practice, financial impact of the disease on households and equity and ethical dimensions including whether the disease is rare or disproportionally affects the poor. This working-group is a subset of stakeholders eligible to nominate topics and excludes industry and policy-makers to mitigate conflicts of interests. The short-listed topics are then presented to a Health Economics Working Group, which is responsible for overseeing the HTA evidence generated, before being reviewed by the Subcommittee.

3

The final list of priority topics, usually less than 10, will undergo a full Health Technology Assessment (HTA) through which information on the cost-effectiveness and budget impact are derived. The incremental cost-effectiveness ratio (ICER) of the interventions is compared with the threshold value per QALY gained. HTAs are conducted by independent research organizations including universities. IHPP and HITAP are jointly responsible for less than one-third of the proposals. The funding for most of the HTAs comes from the publicly-funded Health Systems Research Institute (HSRI).

4

All HTAs must comply with the National Methodological and Process Guidelines approved by the SCBP which ensures comparability and transparency of studies. The guidelines require HTAs to undergo a detailed external peer-review of all spread-sheets and assumptions, providing a strong quality assurance mechanism.

5

The output is presented to the SCBP for consideration which then makes recommendations to the National Health Security Board (NHSB). The NHSB makes the final decision on the inclusion of the intervention in the benefits package.

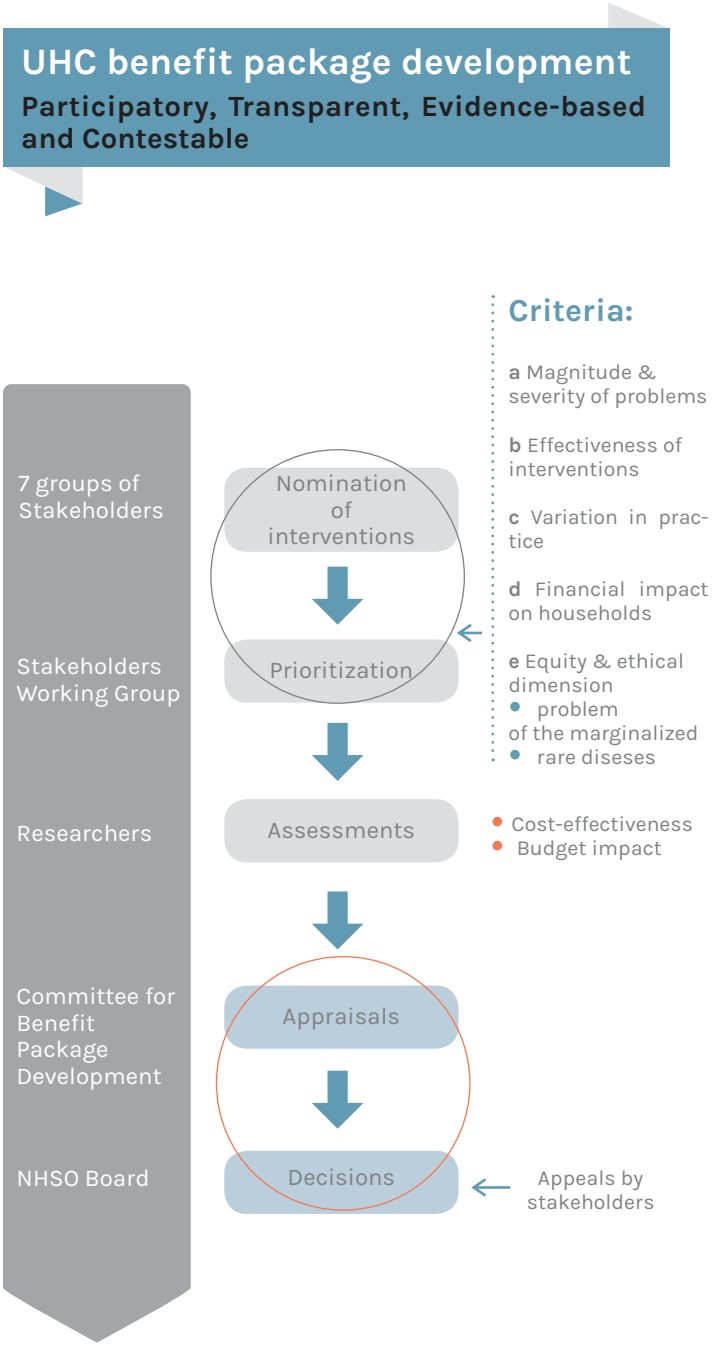

Figure 2: Process for the development of the Universal Coverage Benefits Package (UCBP). *(Source: HITAP)*

Similar processes exist for decisions made by the NLEM subcommittee regarding public provision of pharmaceuticals, including requirements that HTAs are conducted for all high-cost medicines before their inclusion in the medicines list. HTAs requested by both NHSO and NLEM subcommittee must be comprehensive, comparing across pharmaceutical and non-pharmaceutical treatment options in line with the national guidelines.

HTAs do not simply lead to the acceptance or rejection of an intervention from the health benefit package or the NLEM but can inform the method and conditions of service provision to yield good value for money for the government. For instance, manufacturers may submit price quotations to be used in HTA research. If the HTA finds that cost per QALY is above the cost-effective threshold or that the intervention has a high budget impact, then a process of price negotiation ensues to reach a price that is acceptable. When imiglucerase was not found to be cost-effective for the treatment of Type 1 Gaucher disease albeit with low budget-impact, the NLEM used the results from the HTA study to develop a cost-sharing model which allowed Imiglucerase to be included in the NLEM. Under the arrangement agreed, the government pays for the treatment of a certain number of patients, beyond which treatment costs are borne by industry.

Do's and Don'ts when defining a health benefits package:

✔ Do's

- Establish clear mechanisms and systematic processes, with 'good governance'.
- Involve relevant stakeholders in all stages of the processes.
- Formulate clear and concrete decision criteria to increase accountability at every step.
- Ensure sufficient, and sustainable public resources to support the mechanisms and processes.
- Ensure adequate investment in a committed and accountable secretariat and high-quality technical team.
- Distribute responsibility for HTA research among qualified and committed independent institutes.
- Use the results of the HTA for price negotiation and link to the financial support, procurement, and M&E aspects of the UHC system.

✖ Don'ts

- Develop a comprehensive or complicated health benefit package at the introduction of UHC rather, start with a simple and cost-effective package to ensure feasibility.
- Provide only vague descriptions of the package. General descriptions, such as 'maternal and child health services' or 'cancer treatments' leads to variations in package interpretation and differences in care provided across health facilities.
- Let anyone with clear conflict of interest be involved in the process.
- Allow HTA research and decision making to be conducted by single persons or single group of people.

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Health Management Information Systems for Universal Health Coverage

Supasit Pannarunothai

Issue#11 November 2018
policy brief

Importance of Health Management Information Systems (HMIS)

Information is the only block among the six health systems building blocks that comprehensively describes the other five blocks of health service delivery, workforce, financing, medicine and technology and governance (WHO 2007). Health management information systems (HMIS) help policy makers develop evidence-based policies and health care providers to achieve the overall health system goal of equity, efficiency and quality. Among stakeholders, few have doubts on the importance of HMIS, but many have enormous doubts on how to create an efficient HMIS architecture.

The scope of this policy brief is to highlight the important issues that need to be addressed when developing a roadmap for achieving universal health coverage (UHC) and the health-related sustainable development goals (SDGs) through strengthening primary health care (PHC) systems.

The context and historical development of HMIS in Thailand

When Thailand was formulating a UHC policy, policy makers relied on macro-level health finance data captured by the national health account (NHA) methodology that had been endorsed by the World Health Organization (WHO). The government was able to utilize cost data in the NHA to determine the need for outpatient and inpatient services at different levels of care. Once the UHC policy was declared, the significance of HMIS to manage all five building blocks of health systems for evaluating systems efficiency, equity and quality became evident.

Identification of beneficiaries is one of the key information needs for rolling-out an insurance scheme. The central computerized civil registration (CR) and the unique citizen identification (CID) number system established in the 1950s were used to identify beneficiaries covered by the Universal Coverage Scheme (UCS). In Thailand, the UCS insures the population not covered by the Civil Servant Medical Benefit Scheme (CSMBS) and the Social Security Scheme (SSS). The National Health Security Office (NHSO), which manages the UCS, took an active role to update and maintain the list of beneficiaries by working with the Ministry of Interior, which is responsible for registering and generating CID for all births, and deaths, and negotiating with the Bureau of Budget

for the capitation budget allocated to contracted providers. When integrating the CR and the unique CID systems, the World Bank (2018) recommends that the CID is issued at the time of birth registration, a practice that was applied in Thailand. This will not only uniquely identify a citizen but also facilitate the completeness of a CR system because the health insurance benefit of a baby will be automatically covered when the baby is registered and issued a CID (Pannarunothai and Kijsanayotin 2018).

Creating a standard dataset was critical in making the system of inpatient payments to hospitals based on diagnosis-related group (DRG) under a fixed global budget feasible. Hospitals were required to use the standard dataset to submit data on discharge summary for processing claims and payments. The standard dataset delineates data fields (data elements) and data coding (code sets) that are used for claim submissions. The first version of the standard dataset used for DRG claims contained 12 standard normalized files with 47 data elements, covering inpatient discharges and outpatient visits (see Figure 1). Since then, NHSO has used the World Health Organization's International Classification of Disease (ICD), a code set used for diagnosis that had been used in Thailand since 1994. This format of data submission to the national level has become the most practical and was recently extended to 43 standard files covering health activities in the community and home visit services (Health Data Center 2018).

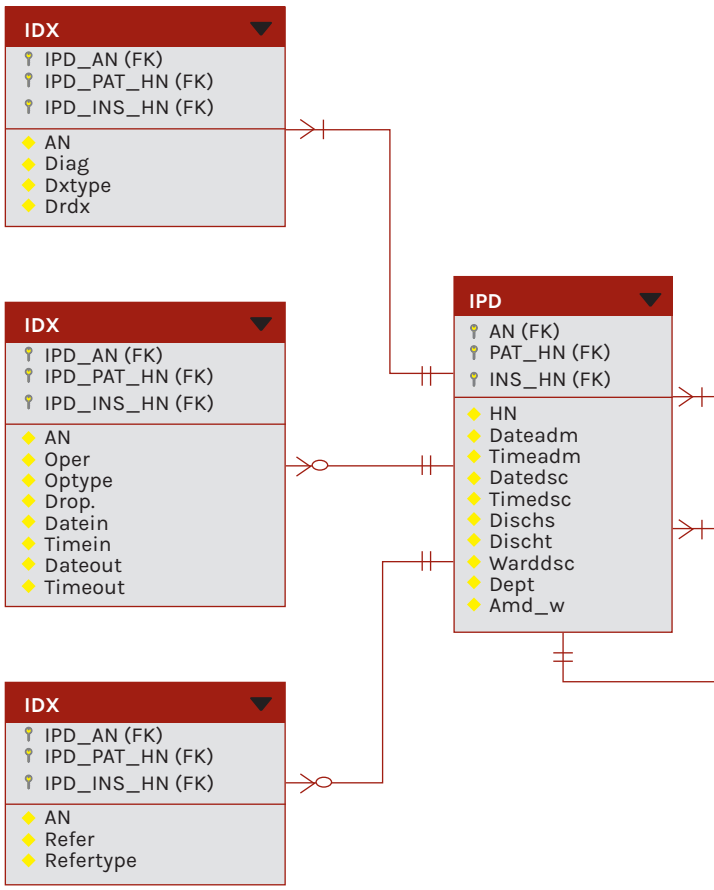
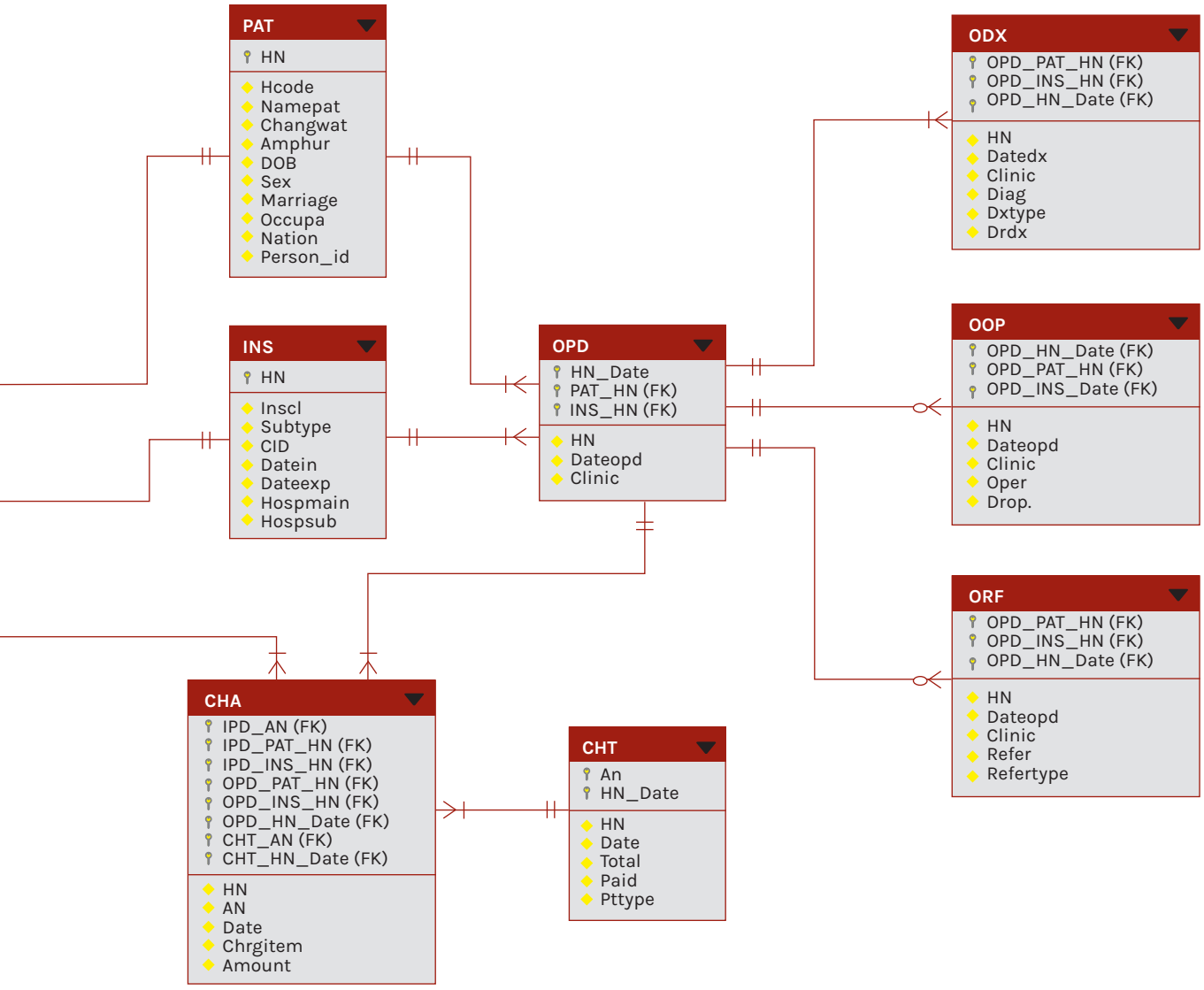


Figure 1: The first version of 12-file standard dataset for health insurance claim in Thailand (PAT = Patient demographic file, INS = Insurance scheme file, OPD = Out Patient Department file, ODX= Outpatient diagnosis file, OOP= Outpatient procedure file, ORF = Outpatient referral file, IPD = Inpatient department file, IDX = Inpatient diagnosis file, IOP= Inpatient procedure file, IRF = Inpatient referral file, CHA = Charge item file, CHT = Total Charge file)

The standard dataset approach enabled interoperability of inpatient reimbursement information systems (Kijsanayotin 2011). Hospitals are free to use an in-house or commercial vendor hospital information software that is appropriate for their work processes but are required to export data specified in the standard dataset for processing DRG claims. The Health Systems Research Institute (HSRI) has funded research activities since 1993 and has led to the development of a comprehensive information system for processing DRG claims using a locally developed software tool to handle complex inpatient clinical and treatment data into around a thousand DRGs. The software, called Thai DRG Grouper, is calibrated with cost weights (or relative weight, RW) to calculate payments to the hospital. Subsequent versions of the Thai DRG Grouper received funding from the NHSO and the software was used for managing the DRG claims processing for the UCS across all hospital providers.

Setting up this system for payments allowed for transparency in data processing at an affordable cost to the country as a propriety software was not needed.

HMIS requirements for managing capitation payment were, on the other hand, minimal. In order to use the data to evaluate the quality of the PHC system, detailed health profiles of individuals on the registration list, available to main contractors, became essential. The evaluations assessed the effectiveness of the PHC system in preventing non-communicable diseases (NCDs) and its complications, the rate of unnecessary hospitalization of ambulatory care sensitive conditions (ACSCs) such as asthma, diabetes, and hypertension by primary care providers (PCP). These analyses were made possible by linking the outpatient and inpatient data in the 12-file standard dataset and allowed NHSO to monitor and improve the quality (including equity and efficiency) of the PHC system. Moreover,



the standard dataset approach with the recent 43 standard data files could also be useful in monitoring the success of school health programs (one of the PHC activities) where there are several opportunities for improving the analysis on health service activities at the school or student levels (Kittiratchakool et al 2018).

The Health Information System Standard and Processing Administration (HISPA), currently under the HSRI, has made extensive investments in standardizing data requirements. This was required as different types of payment methods, such as, high cost medicine, investigation, high cost care medical devices, etc, that go beyond capitation and DRG were implemented. The Thai Medicines Terminology (TMT) was developed not only for claim reimbursement but also for monitoring drug purchasing by hospitals in Thailand. The TMT can also potentially be used to track accessibility to high cost drugs, auditing for fraud detection and understanding patient's adherence to drug treatment.

The three government insurance schemes, UCS, CSMBS and SSS are managed by three different HMIS offices. The majority of the UCS data is managed by the NHSO while the CSMBS and SSS claims are managed by HISPA at the Comptroller General Department and the Social Security Office, respectively. The concept of setting up an independent and impartial National Clearing House has been proposed to manage claims data for all three public insurance systems in one office with a single preferred set of data standards. This office will be set up as an autonomous body having national coverage of good quality data for public use.

We live in the era of 'Big Data' and the private sector has demonstrated the many possibilities of utilizing transaction data for commercial use. HISPA's vision is to empower every Thai citizen through health literacy and managing personal health outcomes by accessing his or her own personal health records from reliable claim data. This presents the next frontier for leveraging the capabilities of HMIS to improve healthcare.

Key lessons for India and other countries ("do's and don'ts")

The Government of India (GoI) announced the National Health Protection Scheme (NHPS) under the "Ayushman Bharat" program in early 2018, however, data requirements for realizing this goal can be challenging. The lessons from Thailand's experiences with HMIS for UHC can be listed as do's and don'ts although their application depends on country reality and context.

✔ Do's

- Strengthen the quality and coverage of the civil registration and vital statistics (CRVS) system with the unique citizen identification (CID) system and use the integrated system as the skeleton of the national HMIS to ensure citizens' entitlement.
- Design an HMIS that utilizes (or extracts) data from the operational healthcare information systems at the point of service with most accurate data. If the transaction data are linked to payment method, the response for data collection and adherence to quality reporting are high, data audit (pre- and post audit) should be set up to ensure better data quality.
- Invest in developing interoperability of data and national health data standards that can be used by all health information applications and services.
- Review data standards used internationally and adopting the most practical/applicable data standards for compiling data for the national HMIS is essential.
- Maintain healthcare resource use data that can be used to benchmark workforce productivity and quality of service at the health facility level to project future resource needs.
- Maximize the use of transaction data with the national survey data to comprehensively describe the health systems situation of the country and develop evidence-based health and healthy public policies.
- Promote the use of HMIS by researchers and health policy practitioners for policy development and policy evaluation within a research ethics framework.

✖ Don'ts

- Develop information systems that do not comply with national health data standards.
- Delay the merging of fragmented data systems at least at the national level.
- Collect data at point of care if it is not used.
- Duplicate data collection efforts (create once, use many).

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Primary Health Care: the building block of Universal Health Coverage

Supasit Pannarunothai

Issue#12 November 2018

policy brief

The importance of Primary Health Care (PHC)

The World Health Organization in 1978 (WHO 1978) advocated for primary health care (PHC) as a strategy to achieve Health For All (HFA) by the year 2000. This abstract goal of HFA was made more concrete at the turn of the millennium when the broader set of the Millennium Development Goals (MDGs) to be achieved by 2015 were defined (UN 2000). Subsequently, the Sustainable Development Goals (SDGs) enshrined the goal of achieving universal health coverage (UHC) by 2030 (UN 2015). Various resolutions from UN General Assemblies and the WHO advocate for progressive realization of UHC by all member states as a vehicle to achieve health related SDGs.

The push for UHC has been accompanied by PHC roadmap strategies to achieve the health-related targets (WHO 2008). PHC has been tested, adjusted, and redefined by country realities as countries sought universal coverage, focusing not only on the poor or rural people but the entire population (see table 1). PHC supports the goal of 'health for all' by acting as the first point of contact for patients and by providing care that is both family and community oriented, taking into account the critical influences of both these social networks, and providing services that are well-coordinated and ensure continuity of care. An effective PHC system facilitates equitable access to quality health services with better health outcomes at a reasonable cost to the individual and the country.

Table 1: Shift in focus of primary health care

Primary health care 1978	Primary health care 2008
Extended access to a basic package of health interventions and essential drugs for the rural poor	Transformation and regulation of existing health systems, aiming for universal access and social health protection
Concentration on mother and child health	Dealing with the health of everyone in the community
PHC is cheap and requires only modest investment	PHC is not cheap: it requires considerable investment, but it provides better value for money than its alternatives

Adapted from WHO (2008)

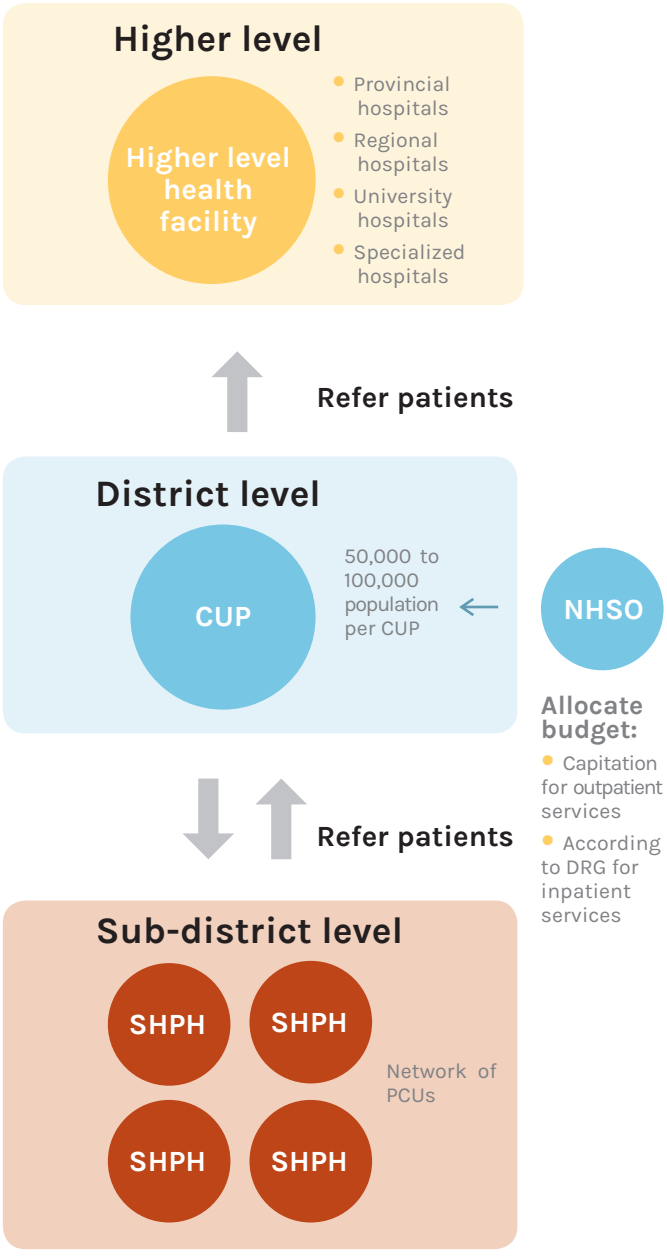
In tracking progress towards UHC, the WHO categorizes countries into three groups: the advanced, the moderate and the lagging behind. These groups are defined according to health service coverage, financial protection and health outcomes (WHO 2017). However, countries that have well-integrated PHC systems throughout the entire health care system have demonstrated effects on health outcomes and equity (Starfield et al 2008). Thailand is one such example where strengthening of the PHC system, even with limited resources and moderate progress on UHC indicators, has enabled the country to achieve UHC.

The context and historical development of PHC in Thailand

The ratio of trained human resources to population is critical in the delivery of effective PHC and may place a binding constraint on the degree of UHC that can be achieved. Thailand demonstrates exemplary records in PHC implementation as it appointed 700,000 village health volunteers for a population of 60 million (1 Village Health Volunteer per 85 persons) in order to ensure the extension of scarce health services to all Thai people, including those in rural areas (Primary Health Care Division 2014).

In 2001, three key transformations took place in the field of new health care financing, new budget allocations, and a new health care delivery model for the Universal Coverage Scheme (UCS) strengthened PHC reforms and service delivery (Nitayarumphong 2006). The UCS has since provided better access to cost-effective health packages, from basic health service items like immunization at sub-district health promoting hospital (SHPH) to high cost care like heart surgery, cancer treatment, or kidney transplantations delivered at tertiary hospitals with zero copayment at point of service, resulting in a high level of financial risk protection and preventing financial hardship from use of health services.

Financing reform started with capitation payment as a major provider payment method to the lowest health facility that can provide comprehensive primary care and public health services. The term "contracting unit of primary care" (CUP) was first used to describe an entity of service unit that covers registered populations of around 50,000 to 100,000 per main contractor at district level (usually a community or district hospital acts as CUP in rural area). The CUP plays a gatekeeper role and inhibits bypassing registration to higher levels of health facilities in the UCS. The main contractor subsequently assembles a network of primary care units (PCUs) to provide better access to health services to the registered population at the sub-district level (SHPH acts as PCU). The National Health Security Office (NHSO) was set up in 2002 as a purchaser of health services for the UCS. The NHSO allocates the capitation budget to CUPs to cover outpatient service according to registration size with age adjustment, and allocates a separate inpatient budget to hospitals according to diagnosis-related group (DRG) of hospitalized patients with the global budget (GB) or the available budget ceiling for inpatient expenditure to contain the total cost of the UCS. The Ministry of Public Health (MOPH) remains responsible for delivering public health services on disease prevention and control, and therefore, continues to manage the overall public health budget. (See Figure 1)



CUP: contracting unit of primary care
DRG: diagnosis-related group
NHSO: National Health Security Office
PCU: primary care units
SHPH: Sub-district health promoting hospital
Note: CUPs can be set up at other levels based on the management, e.g. urban district area

Figure 1: Contracting unit of primary care (CUP)

The PHC structure in urban areas including the Bangkok Metropolitan Administration (BMA) was less developed and differed from rural settings where municipalities were responsible for provision of PHC for the local communities. The government PCUs in urban cities are small and have lower capacity to respond to health needs of urban populations. This is in spite of the presence of big public hospitals (under the MOPH and other ministries, including teaching hospitals of the Ministry of Education), big private hospitals, private clinics and pharmacies in cities. In urban areas, with the NHSO's purchasing design, big public and private hospitals can act as CUPs and form the PCU networks with either public or private clinics. Under the contractual agreement, the NHSO pays a capitation budget to CUPs only, and it is up to the CUP to set specific payment arrangements and rates to its affiliated PCU network for services utilized by the population registered with the CUP. This model creates opportunity for the primary care team to reach a concentrated population in urban areas.

A survey of policy makers responsible for primary health care and primary care practitioners on primary care attributes[1] of selected services[2] found that the PHC system delivered favorable outcomes in terms of achieving equity but had questionable outcomes in terms of quality (Pongpirul et al 2012). Successive public health ministers have been advocating for improvements in the quality of primary care teams that are led by well-trained family medicine specialists. The 2017 Constitution of Thailand endorsed a "family doctor policy " whereby each Thai citizen is attached to a well-trained family practitioner with an outreach team. This policy also targeted having an appropriate family doctor to population ratio. This approach has been branded as the 'primary care cluster' (PCC) policy and recently replaced the brand of 'primary care teams' (PCTs), which emphasized the role of teams delivering services. As part of the PCC policy, a few PCUs were merged into a larger cluster in an attempt to increase capacity and quality of care within a cluster. The rapid "brand " changing has been criticized by family practitioners as too being too closely affiliated with political figures rather than fostering the spirit of PHC (Khonthaphakdi et al 2018).

The UCS health system described above covers almost 75 percent of the Thai population, which is managed by the NHSO whereas the Civil Servant Medical Benefit Scheme (CSMBS) covers 8 percent and the Social Security Scheme (SSS) insures 16 percent of the total population. This means that about 24 percent of the population covered by the CSMBS and SSS have different arrangements for PHC as compared to the UCS. The CSMBS does not apply any gatekeeping rule and incurs high outpatient expenditure due to its fee-for-service reimbursement system whereby all primary care services are provided by tertiary and university hospitals. The Social Security Office, which manages the SSS, on the other hand, contracts "big " hospitals (public or private with 100 beds or larger) as main contractors for outpatient and inpatient services (or inclusive capitation contract). The Social Security Office leaves the decision with these hospital contractors to arrange their own PHC providers through sub-contractual agreement with private clinics.

In terms of health expenditure per capita, the UCS managed by the NHSO spends the least while the CSMBS is the highest spender (at least four times per capita spending higher than UCS), driven by the fee-for-service payment system for outpatient care. With a limited budget subsidy from the government, the considerations of introducing new cost-effective interventions into the UCS benefits package applies the most explicit health technology assessment mechanism. The Health Intervention and Technology Assessment Program (HITAP) is one of the key players involved in drafting recommendations for the National Health Security Board to include new interventions in the UCS benefits package. The process of reviewing evidence takes place within the NHSO management if the UCS benefits package is being reviewed, or within the National Essential Drug Committee mechanism, if the policy decision involves the three schemes. Once accepted into the benefit package, service arrangements with PHCs and integrated health systems, including the information system to facilitate payment, are put in place.

Once the CUP and PCU receive their capitation budget from the NHSO, they have autonomy to spend the budget for the benefit of holistic health and well-being of the registered population such as self-help, patient interest group for chronic diseases. The CUPs with a larger population have the capacity to pool their risk and use the resulting surplus funds to create innovative essential services such as community rehabilitative care, long term care and palliative care. Moreover, the CUP may receive additional capitation budget when the NHSO extends benefits already included in the core package or makes changes to payment rules. A CUP or PCU may be paid on a fee-for-service basis with the aim of increasing service delivery. Examples of these type of services are home visits to offer rehabilitation for stroke patients and achieving a quality target such as high coverage of cervical cancer screening within a quality-outcome framework (QOF).

[1] Resource allocation, adequacy of resources, copayment requirements, comprehensiveness of care, first contact, longitudinality, coordination, family-centeredness, community orientation, and professional personnel.

[2] Vaccinations for children; illnesses care for children, adults and the elderly; prenatal care/safe delivery; family planning services; care of sexually transmitted diseases; treatment of tuberculosis; treatment of minor injuries; counseling about alcohol and tobacco use; minor surgery; non-major mental health problems; care for chronic illness; health education; screening/treatment of parasitic diseases; nutrition program; school-based services

Key lessons for other countries ("do's and don'ts")

The PHC experience in Thailand sheds light on the do's and don'ts for other countries as follows:

Do's

- Emphasize the importance of integration of PHC (public health plus primary care) with the country health systems. It is the role of the Ministry of Public Health to oversee effective integration for maximizing health outcomes and equitable access to quality health services.
- Set targets for the population to be covered by each PCU provider in order to achieve full coverage in rural and urban areas. The target indicators should not only include quantity of services provided but also address the quality of services such as short- and long-term outcomes.
- Design the population registration system and allow for consumers to choose a provider network.
- Apply a gatekeeper role through strategic purchasing and an effective referral system to contain cost and prevent bypassing of the PHC.
- Offer financial autonomy to PCU providers for utilizing and keeping their capitation budget, that is, exploiting decentralization of efficient management to achieve equity of health outcomes.
- Invest in an information system for catchment population enrolment through health service utilization to monitor successes and failures of the systems.

Don'ts

- Create fragmented insurance schemes to reach different target populations. Fragmentation, or sub-population targeting, is a barrier to achieving equity and ensuring an efficient system.
- Rapidly change the branding of initiatives.

Acknowledgement

This policy brief is a part of a series reflecting on Thailand's experience of implementing universal health coverage. This work has been commissioned by the Health Intervention and Technology Assessment Program (HITAP) under the auspices of the International Decision Support Initiative (iDSI) funded by the Bill & Melinda Gates Foundation, the Department for International Development, UK, and the Rockefeller Foundation.

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Supasit Pannarunothai obtained his MD from Mahidol University and PhD from London School of Hygiene and Tropical Medicine. After retired as professor and dean from Faculty of Medicine Naresuan University, he is now chair of Centre for Health Equity Monitoring Foundation continuing his areas of specialization/ expertise in health equity, health financing and casemix research.

Issue#13 November 2018

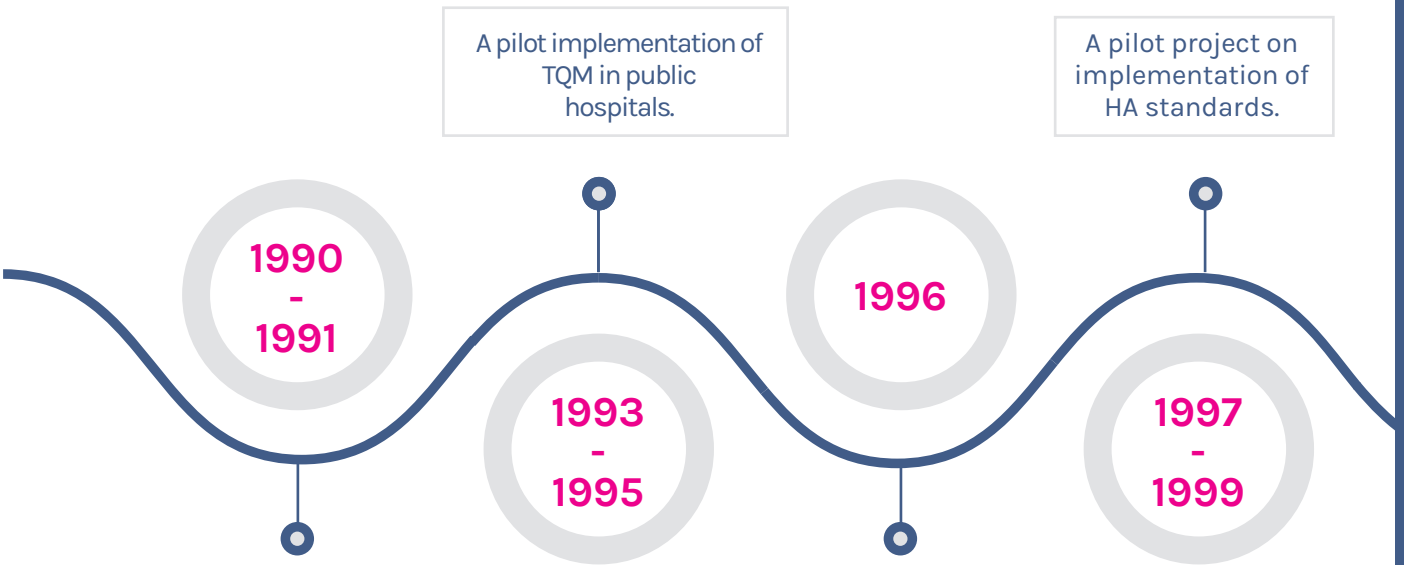
Promoting Healthcare Quality for Effective UHC: Thailand's Trajectory

Anuwat Supachutikul

The importance of addressing quality in healthcare provision

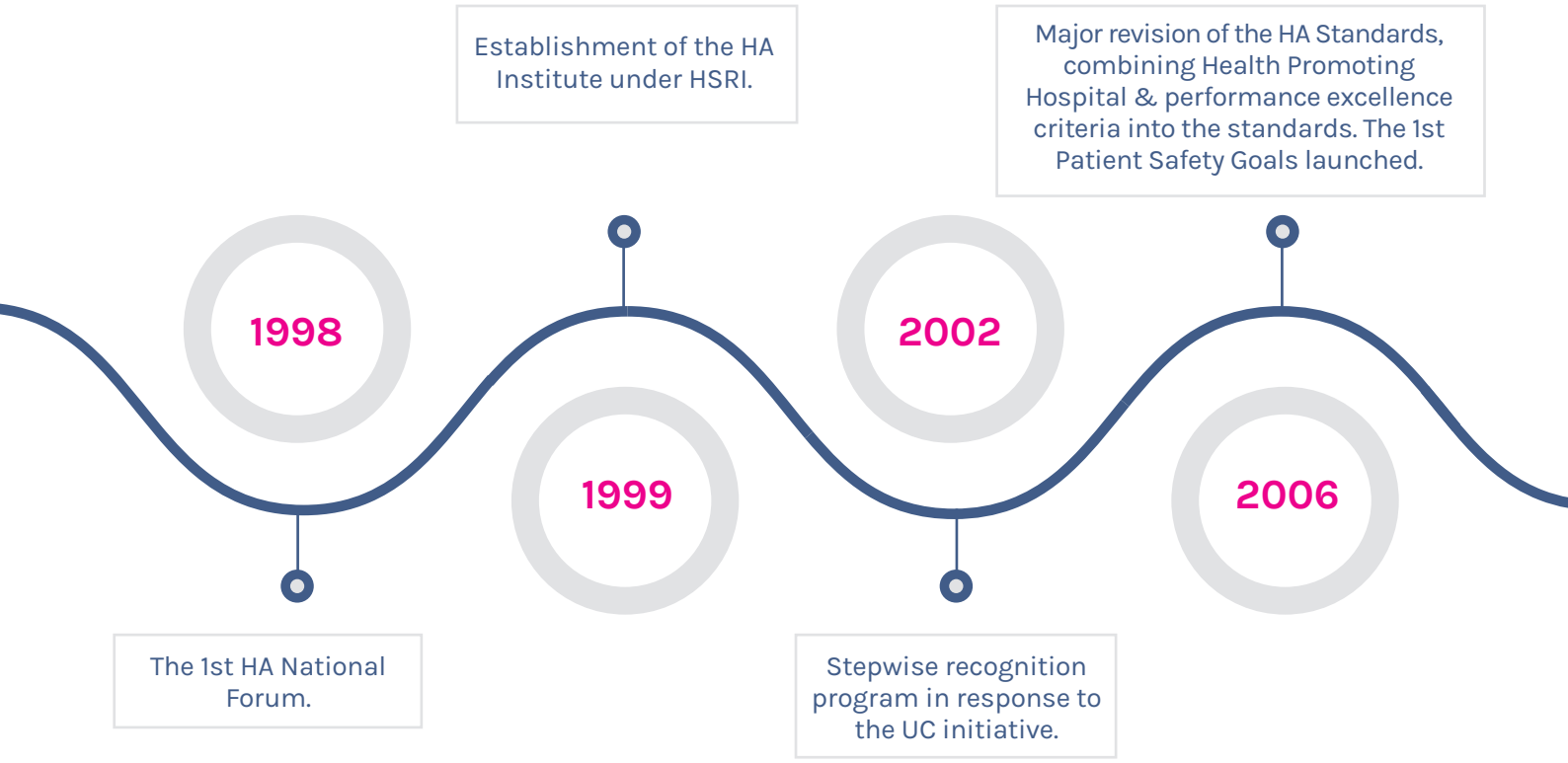
Universal health coverage (UHC) aims to "ensure that all people can use the promotive, preventive, curative, rehabilitative and palliative health services they need, and that these are of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship", according to the World Health Organization. There is an urgent need to place quality of care in the fabric of global, regional and country level action plans in order to make progress towards effective UHC. Hospital Accreditation (HA) is one of the mechanisms which encourages continuous quality improvement across levels of healthcare facilities and can address this need.

The context and historical evolution of HA in Thailand



SSO: Social Security Office
TQM: Total Quality Management
HA: Hospital Accreditation

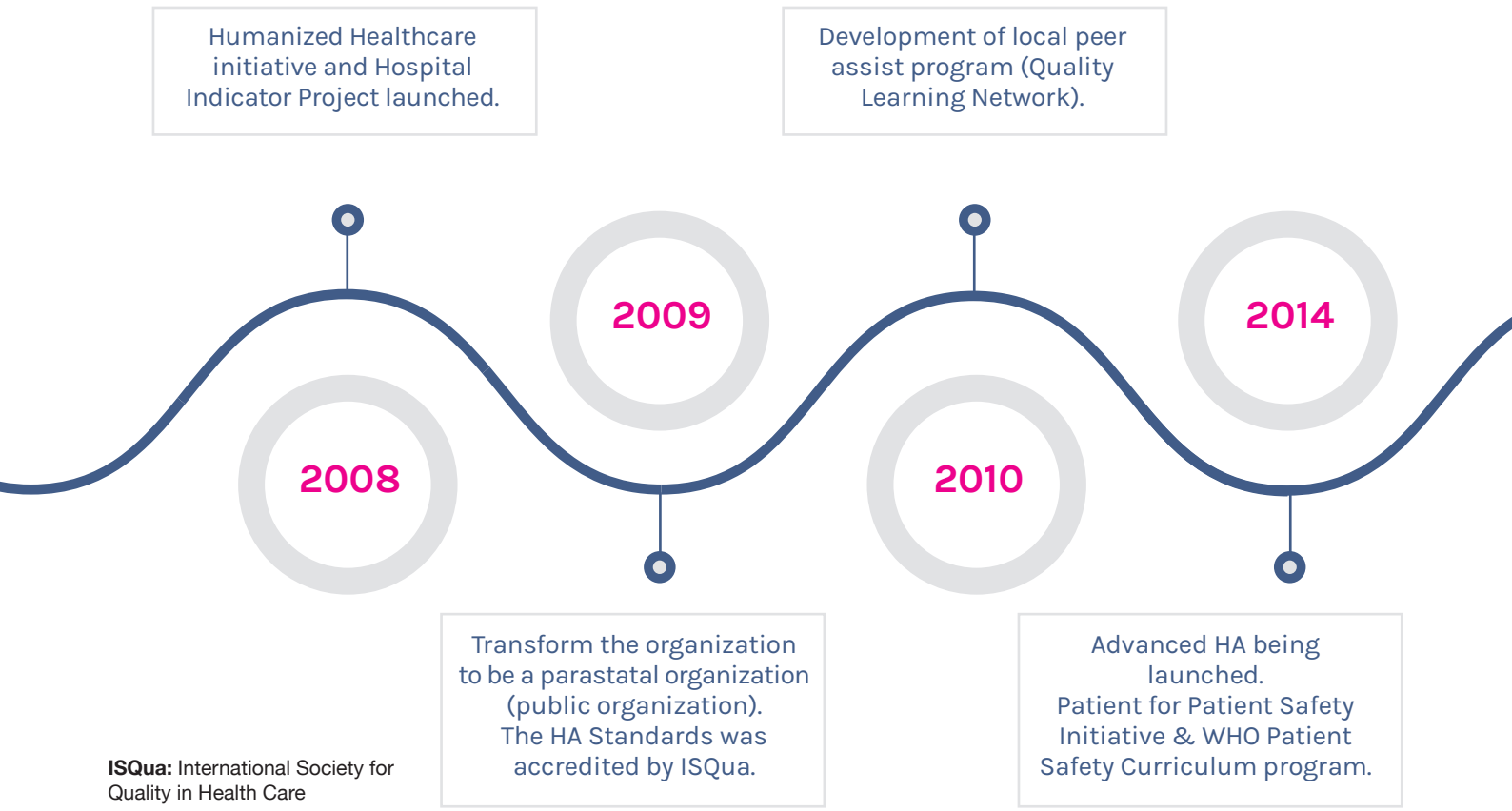
policy brief



HSRI: Health Systems Research Institute
UC: Universal Coverage

The Ministry of Public Health (MOPH) undertook several initiatives to improve quality of care in relation to infrastructure and manpower development. These included rolling out a nursing quality assurance program and assessments to recognize hospital quality by offering "stars". Most of these initiatives were either fragmented, unsustainable, and/or had a limited impact on quality of care. The implementation of the first capitation payment system in Thailand for the Social Security Scheme (SSS) in 1990 provided the impetus for the Social Security Office (SSO) to address the issue of poor or under-provision of quality care. During 1990-1991, hospital standards from many countries were reviewed to develop the standards for SSO contractor hospitals, which served SSS beneficiaries. The Australian Standards were referred to for adaptation, however, due to limited experience in assessing the process component of the standards, most of the process-related standards were omitted, with only the structure and personnel components remaining in the tool. This set of standards has been used for several years by the SSO with minimal modification since 1994. Inspired by Donald Berwick's report on the National Demonstration Project on Quality Improvement in Health Care in the USA (1990), the Health Systems Research Institute (HSRI) initiated a pilot project to implement Total Quality Management (TQM) in eight public hospitals during 1993-1995. The project served as a testing ground for applying various quality improvement tools and the TQM principles laid the foundation for the HA program development in Thailand. Additionally, in 1994, HSRI sought to establish a national mechanism for quality assurance and sponsored multiple forums with experts, reviews of literature and interviews with various stakeholders. In 1995, a Canadian consultant explained the process of carrying out an accreditation survey and emphasized its role as an educational process for all relevant stakeholders, rather than an inspection with a pass or fail assessment. This event was followed by a study visit comprising senior MOPH administrators and representatives from public and private hospitals to Canada in 1996.

The first HA standards for Thailand were finalized in 1996 by HSRI. The team spent two years reviewing standards from various countries that had successfully implemented quality standards. The Delphi technique was applied to elicit appropriate standard indicators for the Thai hospital setting. A study visit to Canada reinforced the importance of continuous quality improvement, which is one of the key elements of the Thai standards. A three-year pilot project for implementing HA standards was tested in 35 hospitals with the aim of developing capacity among hospital staff and experts to implement and institutionalize the quality standards. This voluntary pilot phase was an ideal opportunity to experiment with new concepts, such as multidisciplinary patient care teams, risk management, clinical quality improvement, were implemented without fear of failure. Further, during this pilot phase, various training programs and experience sharing forums were convened. A program for training of hospital consultants and surveyors under supervision were also arranged. At the end of the second year of the pilot project, the first National Forum on Hospital Accreditation was organized to share experiences and results. This conference continues to be held annually, indicating the usefulness of this activity.



ISQua: International Society for Quality in Health Care

The pilot implementation period showed that while the process of developing quality improvement tools encouraged teamwork and learning, the application of the standards was slow and fragmented. The HA project therefore turned its attention to setting standards with clear direction and expectations focused on systems improvement. Lastly, the project started to integrate the experience of patients which resulted in tangible improvement in activities directly affecting patients.

Given the enthusiasm shown by hospitals participating in the pilot project, the HSRI Board decided to institutionalize the HA program and an independent unit, governed by its own Board under the stewardship of HSRI, was set up. The Healthcare Accreditation Institute (HA Institute) was thus established and was responsible for both, support for improvement and accreditation of hospitals. A firewall mechanism was put in place to remove conflict of interest in the functions of quality improvement and accreditation decisions. The HA Institute generated revenue from training programs and surveying hospitals, and operated without government budget support for a decade. In 2009, HA Institute became a public organization through a Royal Decree under the Public Organization Act 2542 BE (1999) with an annual budget allocation of 50-70 million Baht (approximately US$ 1.52-2.13 million). In 2016, the Thai HA program convened by the HA Institute was accredited by the International Society for Quality in Health Care (ISQua) for its standards, organization, and surveyor training program, so increasing confidence in the accredited organizations.

In 2001, Thailand launched the Universal Coverage Scheme (UCS) and the Minister of Public Health demanded that all public and private hospitals providing care to UCS beneficiaries have quality standards accredited by the HA Institute. The HA Institute proposed a stepwise quality recognition to gain acceptance and expand coverage according to readiness of each hospital, with the aim of achieving full accreditation at the end. There are three steps for achieving progressive quality improvement: the first step focuses on risk prevention and identification of opportunities for improvement from various quality review activities; the second step focuses on quality assurance and quality improvement of each unit in the hospital, system, and patient care team; and the third step entails full accreditation which requires complete implementation of the quality standards. Between 2004 and 2005, nearly all public hospitals passed the first step.

The HA Institute has responded to the need to accredit the quality of a range of interventions. Since 2003, it has collaborated with the Department of Health of the MOPH to support health promotion initiatives in hospitals through its Health Promoting Hospital (HPH) accreditation program. In 2006, the HA Institute issued the new version of standards, combining contents from HA standards, HPH standards, and National Quality Award Criteria for Performance Excellence. The HA Institute spent two years testing the implementation of the new structure of the standards (combining three) as well as listening and responding to the hospital feedback. The HA Institute also identified core values and concepts for using together with the new standards.

Key lessons for international audiences: "do's and don'ts"

✔ Do's

- Follow the ISQua principles and standards
- Move the whole mass of healthcare organization by leaving no one behind, e.g. application of stepwise recognition, make the 1st version of standards easy to accomplish.
- Execute the principle of accreditation as an educational process or learning mode.
- Train surveyors to respect and listen to the hospitals
- Set up mechanism to ensure impartiality and transparency
- Expect learning organization towards a continuum of improvement
- Use modern model of evaluation, i.e. developmental evaluation or empowerment evaluation
- Aim at outcome and give freedom for hospitals to use any approach for improvement which are suitable to their organizational context.
- Encourage measurement for improvement, spend times to assess the process of using performance measurement
- Use multiple methods to acknowledge improvement
- Understand the adaptive challenge and use adaptive solutions
- Engage management with medical staff, e.g. witness of the process, special training
- Engage with various stakeholders, e.g. professional organizations, academic institutes, patient advocates, government agencies, 3rd party payers
- Emphasis on capacity building for hospitals at the beginning
- Use local learning network to support & spread
- Find easy and effective quality tools for hospitals
- Keep HA in the agenda and motivate interests through annual HA Forums for learning and sharing

✖ Don'ts

- Leave someone behind with the feeling of failure.
- Execute mainly as an audit mode—pass and fail.
- The surveyors behave like a judge
- Aim for perfection in one setting
- Use old paradigm of evaluation, i.e. summative evaluation
- Aim at compliance to all the detail processes
- Use measurement for judgment, assess the level of performance at the beginning
- Use superficial technical solution
- Develop accreditation as a standalone program
- Let the hospital strive for seeking assistance

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About the author

Anuwat Supachutikul has been working with the Thai Hospital Accreditation program since 1997. He also chairs the Technical Subcommittee of the Thailand Quality Award Program. His experience of working with hospitals for quality improvement ranges from quality management, hospital standard development, to a full Hospital Accreditation program. With accreditation as a driving mechanism, he encouraged patient safety movement,spirituality in healthcare, and mobilized local resources to form Quality Learning Networks for spreading of quality movement.

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Budgeting and paying for services under Thailand's Universal Coverage Scheme

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Introduction

Health financing is a component of the health system, crucial in achieving universal health coverage (UHC). Careful design of its three main functions, resource mobilisation, pooling and allocation, ensures improved access to essential health services and financial risk protection for the population. This policy brief details the use of mixed provider payment methods, an important tool for resource allocation, drawing on lessons from Thailand's largest public health insurance scheme, the Universal Coverage Scheme (UCS).

Public health insurance in Thailand: Background

Thailand achieved UHC in 2002 with the introduction of UCS. Since then, all people have been covered by one of three public health insurance schemes: Civil Servant Medical Benefit Scheme (CSMBS) for government employees; Social Health Insurance (SHI) for formal employees in the private sector and UCS for the rest. Tax-financed UCS covers nearly 72% of the population and is managed by the National Health Security Office (NHSO), an independent agency established by the National Health Security Act 2002. Unlike CSMBS and SHI, UCS is not linked to employment status and entitles all Thai citizens to essential health services.

Public health insurance in Thailand: Designing purchasing and payment mechanisms

All three public health insurance schemes apply different payment methods for outpatient (OP) and inpatient (IP) services, impacting costs and service utilisation. CSMBS applies a fee-for-service approach towards OP payments, with IP services paid through DRGs under open-ended budget. SHI applies capitation (a fixed per capita payment to the health provider) for both OP and IP services, although more resource-intensive treatments are paid using DRG under a global budget. This contrasts with UCS, which applies capitation for OP services, and uses DRG under global budget for all IP services. UCS also allocates a small portion of the total budget via fixed fee schedule for select high-cost items. Details of each are further explained in Table 1.

policy brief

Table 1: Pros and cons of different financing methods

Payment methods	Description	Pros	Cons
Fee-for-service	• Health provider sets per patient charges for each resource used, or service provided during treatment	• Increases utilisation rate • No incentive to under-provide care • Increased access to high-cost medicines	• Inefficient service delivery • Increased provision of unnecessary care • Greatest scope for cost escalation
Fixed fee schedule	• Payment for health services based on a list of fixed fees for different services and items.	• Guaranteed rate for health providers • Increases utilisation rate	• Increased provision of unnecessary and low-quality care if fixed fee is higher than cost • Decreased provision of necessary care or incentive to provide low quality care if fixed fee is lower than cost • Cost-escalation and inefficiency, although less than fee-for-service
Capitation	• Healthcare provider receives a fixed per capita payment for registered population	• Incentivises efficient service provision • Flexibility of budget management	• Under-provision of necessary care affecting overall quality of care • Incentive to turn away high-cost demographics • Financial risk for hospitals with few registered patients, as budget received may be less than average costs
Age-adjusted capitation	• Capitation payment levels adjusted for age composition of registered population, with higher cost demographics receiving higher capitation payments	• Reduces risk of discrepancy between payments received and costs incurred, reducing financial risk for providers	• More complex to develop, requiring strong technical capacity and demographic information
Diagnostic Related Groups (DRG)	• Hospital cases are classified by resource use and payment levels are adjusted by classification [based on factors such as patient characteristics (principal diagnosis, co-morbidities, etc.) and services required (procedures involved etc.)]. Degree of payment adjustment is determined by the 'Relative Weight' or 'Adjusted Relative Weight'	• May increase admission rate • Cost control through incentive to reduce cost per admission • Incentivises provision of the appropriate care option • Designed to ensure fair repayments to providers that align with required resource use	• Some providers might incur a loss if their facility is less efficient than the average and it incurs higher than average costs when providing treatment • Quality of service may be lower as providers attempt to reduce costs • Incentive to discharge patients early • Risk of financial loss to providers if DRG weights are not accurately set and payments do not cover resources required to deliver treatment

Payment methods	Description	Pros	Cons
Open-ended budget	• No upper limit on payments to providers	• No financial risk to providers	• Financial unsustainability and inefficiency as no limit on total cost of services, encouraging unnecessary use of expensive drugs
Close-ended budget or global budget	• Payments to providers only up to the level of the fixed budget	• Cost containment • Financial sustainabilty and efficiency	• Some providers might incur a loss if their costs exceed maximum reimbursement

Evidence shows that fee-for-service used by CSMBS results in per capita government payments of around four times that of UCS, largely attributable to fewer limits on using branded medicines under CSMBS. Data shows that these drugs were reimbursed at full cost plus a 20-25% margin by the Comptroller General's Department.

In contrast, SHI has adopted a capitation contract model since its inception in 1991, whereby an agreement on the services to be provided is made between the insurance scheme manager and public and private health providers. The capitation contract model pays a pre-defined amount per patient, under global budget, incentivising more efficient care and effective control of the total annual budget. NHSO, learning from SHI, now uses the capitation contract model under a global budget for OP services under UCS. For IP services, UCS, from conception, pursued cost containment using DRGs under global budget, rather than capitation, as the scheme covered a heterogeneous population in comparison to SHI, which was limited to the working age population.

There are other sources of efficiency in the system. NHSO exerts monopsonist purchasing power (a single large buyer purchasing from multiple, competitive sellers) and cost savings from price negotiations provide additional resources, offering higher benefits to UCS members. Additionally, the UCS primary care gate-keeping system requires that patients first visit their registered, contracted primary provider in all non-emergency cases, enhancing appropriate and efficient provisioning of care.

Payment to health care providers under UCS

The annual UCS budget is a full-cost subsidy, covering all expenses associated with service delivery, including cost of labour, material and capital depreciation; providers should not require any additional co-payment from the patient. Originally, UCS required a co-payment of 30 baht (approximately 1 USD) for each patient at the point of service, although exemptions were made for various groups. In practice, very few patient contributions were received, resulting in policy discontinuation. Chief features of payment methods used by NHSO are outlined below:

- **OP services:** Per capita budget for OP care is estimated through the "Price and Quantity (PQ)" approach which combines data on unit cost of a comprehensive benefits package (OP, IP, high-cost care, prevention and health promotion services) with their respective utilisation rates from a routine administrative dataset. OP capitation rate is paid based on population size for which a primary healthcare provider network has been contracted. However, total payment is then adjusted by age group, given different utilisation patterns. These age adjustments, conducted every three or four years, aim to reduce incentives to turn away higher-cost population groups.

- **IP admissions:** DRGs under a global budget are applied to payments for IP admissions, using a DRG base rate with adjusted relative weight. The global budget, fixed for the year, is the portion of total capitation budget allowed for use towards IP care.

- **High-cost services:** To ensure better access, NHSO pays health facilities for high-cost services such as renal replacement therapy or antiretroviral treatment through a central reimbursement system from an extra budget, currently not included in the capitation or DRG budget. UCS provides both cash and non-cash (in kind) payments for distribution of dialysis solutions, medical devices, and medicines.

- **Monitoring, auditing and complaint management systems:** NHSO utilises monitoring, auditing, and complaint management systems for UCS to collect data on a routine basis and provide feedback. This helps NHSO ensure fair payment mechanisms which improve health system efficiency and patient access to healthcare, without a price barrier. This data can also be used by NHSO to adjust and improve the scheme, as necessary.

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Key lessons for other countries ("do's and don'ts")

Payment methods adopted by NHSO for UCS offer good examples to other low- and middle-income countries in their journeys towards UHC.

✔ Do's

Provider payments
- Design a system balancing benefits and limitations of different payment mechanisms. For example, paying preventive, OP and health promotion services by capitation based on registered UCS members in the catchment area and disbursing funds prospectively can guarantee revenue to providers. IP admissions can be paid by DRGs retrospectively to ensure payments align with real admissions. Cash as determined in the fixed fee schedule or non-cash support can facilitate high-cost interventions, as necessary.

Budgetary decisions
- Ensure fiscal sustainability by using an annual global budget.
- Apply global budgets and audit systems for DRGs to prevent false reporting of additional comorbidities and complications by providers to receive higher payments associated with higher DRG relative weights.
- Apply other non-financial measures for primary healthcare and OP services with proper referral mechanisms to ensure needs-based allocation of resources.
- Use monopsonist purchasing power to negotiate the lowest price with assured quality for drugs and services, expanding efficiency and service coverage.

General principles
- Offer free or lowest cost-sharing care to patients at points of service.
- Continuously strengthen individual and institutional capacity in health financing. Adequately invest in data, especially unit cost data, and ensure regular updates. Design corrective measures through monitoring, auditing, and complaint management systems.

✖ Don'ts

Provider payments
- Apply only one type of payment system such as fee-for-service or capitation. Alone, these methods may lead to uncontrollable health spending and an inefficient system.

Budgetary decisions
- Design incoherent systems such as applying a global budget with an open-ended provider payment method (like fee-for-service). This causes a full use of the budget with facilities unable to provide care to all patients. The fixed fee schedule system is preferable to the normal fee-for-service if it needs to be used.

General principles
- Create incoherent policies and practices on price-setting, purchasing and regulation across many schemes.
- Underestimate need for strong regulatory and auditing systems.
- Be discouraged by incomplete data; it is not essential for moving towards UHC.

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This policy brief can be downloaded from www.globalhitap.net

Issue#18 September 2020

Good Governance for Universal Health Coverage

Dr. Somsak Chunharas and Ms. Juliet Eames

Achieving universal health coverage (UHC) requires policy initiatives supported by long-term system reform and an accountable governance structure that can sustainably deliver all three dimensions of UHC, population coverage, breadth of benefits package, and degree of financial coverage. A good governance structure must match policies with available financial and infrastructural capacity, and incentivise all actors to work towards UHC goals. It must also ensure effective implementation and feedback use to consistently improve delivery on UHC dimensions.

There is no single structure of UHC governance and functions can be assigned to one or more administrative bodies. Available literature identifies some central attributes, outlined below:

- clearly defined goals, well understood by all actors,
- support to act synergistically, but with a degree of autonomy and financial capability,
- staff (or partners) with technical skills to design evidence-based policies,
- mechanisms to influence actors to implement pre-decided policies, and
- information capacity to monitor the scheme.

Transparency and accountability can ensure good governance, with stakeholders personally invested in monitoring their interests and influencing necessary changes in a participatory manner; a delicate balance must be struck between promoting transparency and accountability, while ensuring speedy action. Building strong systems takes time and countries may initially aim for governance that is 'good enough' to meet priorities and mitigate the greatest risks to the scheme's success, while enhancing capacity for improved governance over time.

This policy brief draws on theories of governance for UHC and describes practical aspects of Thailand's UHC governance, to enable other countries to learn from these successes and mistakes.

Governance for UHC in Thailand

Before 2002, Thailand's health insurance system comprised two major schemes: Social Health Insurance Scheme (SHI) and Civil Servant Medical Benefit Scheme (CSMBS) which covered only 30% of the population, who were either civil servants or formal sector employees. The country then implemented the Universal Coverage Scheme (UCS), expanding coverage to the remaining 70% that was previously uninsured. The UCS governance structures are limited to this scheme alone and do not cover SHI and CSMBS. However, since UCS covers most of the population, its design and operation reflect an attempt to build governance for UHC in Thailand. UCS governance was influenced by important contextual factors associated with the Ministry of Public Health's interest in improving their patient services, addressing rising out-of-pocket payments even at public facilities, increased demand for services and insufficient funds. In addition, previous health insurance schemes (SHI and CSMBS) had left a majority uninsured and vulnerable to catastrophic expenditures.

policy brief

Systems for good policy making

The National Health Security Act (NHSA) was promulgated to outline the UHC governance system. The Act established the National Health Security Office (NHSO) and a Board (the National Health Security Board) to govern UCS, with a mandate over all aspects, including defining the benefits package, purchasing care and monitoring outcomes. As an 'autonomous public organisation', NHSO has the freedom to design evidence-informed policies. The multi-stakeholder governing Board, which includes government officials, civil society, technical experts, professional councils, and private health providers, is chaired by the Minister of Public Health, ensuring strong accountability to stakeholders, further enhanced by having a Board comprising multiple stakeholders that appoints the Secretary General who is responsible for implementing Board decisions. This balance between freedom and accountability indicates that policymaking is based on stakeholder interests and meets the political mandate. Thirteen similar "regional boards" operate at the local level to ensure that policy is tailored to context.

Participatory structure in Thai UHC board

Source: National Health Security Act 2002

The UCS system has been designed based on Thailand's past experiences, such as unaffordability of care by the poor due to user fees, unreliability and high resource-requirement for means testing of potential recipients. This led UCS to evolve into a tax-financed scheme, providing a uniform benefit package to all citizens uninsured by either pre-existing scheme. Provider payment systems were also built based on SHI which had been effective in controlling costs, improving access, and providing fairer reimbursements for patients with severe conditions. Availability of improved evidence on impacts of payment mechanisms has led to updates in these mechanisms and made them more complex.

Defining an affordable benefit package at inception was crucial due to limited funding and the need to avoid patient co-pay. Initially, the package excluded high-cost items but as the capacity for Health Technology Assessment (HTA) developed, it could be expanded in a sustainable, consistent and fair manner (see policy brief "Designing the Health Benefit Package: the essential component of a successful UHC program").

The NHSO Board estimates resource requirements from data submitted by providers during the scheme's reimbursement and performance assessment processes. Since UCS is fully tax-funded, NHSO uses this evidence to negotiate with the Bureau of the Budget, Ministry of Finance and senior political leaders to secure funds required to meet its commitments. Robust evidence has allowed the Board to negotiate a sustained increase in funding over 15 years and gradually expand the benefits package. If UCS funding sources are diversified in future, NHSO will need to ensure that commitments and resources continue to align.

Ensuring effective policy execution

Primary care is central to UHC and UCS implemented a system of 'Contracted Units for Primary Care' (CUP) to ensure entitlements extend beyond curative services. Under this system, patients must first visit primary providers and facilities which deliver disease prevention and health promotion activities for non-emergency cases (see policy brief "Primary health care: the building block of Universal Health Coverage"). The financing design, capacity, and coordination of CUPs continues to evolve and the changes will test UCS governance. NHSO uses its position as a purchaser to manage incentives, refine procurement arrangements, effectively balance supply and demand, and leverage its purchasing power to negotiate prices with manufacturers; this has saved USD 188 million in recent years.

NHSO must not abuse this power, ensuring payments are evidence-based and financially feasible and acceptable, as unfair prices undermine providers' ability to deliver quality care and support the scheme. When possible, NHSO selects a contractor through a competitive process incentivising efficiency and quality. However, since a choice is not always available, NHSO also requires that UCS empaneled facilities receive formal quality accreditation and supports facilities in meeting quality standards.

The importance of information systems for UCS implementation cannot be emphasised enough. Computerised systems for providers to submit data for reimbursements eased claims processing, increased transparency (which earlier systems lacked) and supported development of fair and

effective payment mechanisms. Linking UCS to the registration system enabled accurate allocation of populations to CUP networks and improved communication about entitlements and service networks from NHSO to citizens (before individuals had registered themselves). Continuous efforts are being made to make population and patient data interoperable, enhancing integrated and continuous care processes.

Tracking outcomes

NHSO aims to track outcomes through a 24-hour patient complaint hotline, financial and clinical audits of service providers, analysis of routine data, annual public surveys, and National Health Accounts. Performance is scrutinised at an annual public hearing where providers and beneficiaries provide feedback to the Board, which is then used to identify and redress scheme limitations. To date, indicators have shown high rates of satisfaction with UCS and significant financial protection, especially for the lowest income groups. However, increasing demand and utilisation of UCS will challenge the governing body to design policies that can maintain scheme outcomes, requiring concerted efforts from various stakeholder groups.

Building trust among stakeholders

Stakeholders must support UHC for effective implementation; they must trust that systems are fair, transparent, evidence-led, based on patient interests, and aligned to policy makers' targets with aims for equity, financial protection, and affordability for all. Though far from comprehensive, UCS has been designed to be responsive, transparent, and accountable through documentation of audits and audit appeals, public access to performance reports, annual public hearing, and through the multi-stakeholder Board. Despite these information dissemination channels and engendered trust, NHSO still faces criticism for not being transparent enough in terms of checks on claims processing and subsequent reimbursement as well as limited knowledge of inputs and resulting actions from the annual public hearing. NHSO must redress these shortcomings to maintain stakeholder support.

Building capacity and continuous learning

NSHO has worked to consistently review and strengthen its systems over the past 15 years, with investments made to improve information systems capacity, participation and communication channels, audit processes, assess benefit package inclusions and conduct regular reviews of payment systems and reported outcomes to inform the scheme.

NHSO's data requirements may need further improvements to reduce the time taken for data submissions, provide data in a form that is more useful for providers (see policy brief on "Health management information systems for universal health coverage"), and to expand data use for purposes beyond management, such as better population health planning, patient care coordination, and purchasing modifications.

Governance beyond UCS

NHSO's governance mandate does not extend beyond UCS and there is no harmonisation between the three public health insurance schemes. Different payment mechanisms for hospitals result in varied outcomes in terms of efficiency and quality of care; patients have different freedoms of choice regarding providers across schemes, and schemes cover different benefits, exacerbating inefficiencies and inequalities in healthcare provision. NHSA mentions scheme harmonisation without specific details on supporting such governance structures. Overarching governance by NHSO, or a national committee for UHC, with participation from all three schemes has been discussed as a potential option. However, different scheme structures, governance, and vested interests have meant that harmonisation has not gained traction. The mandate for defining this system is beyond NHSO and requires a body such as the Ministry of Public Health to take it forward. Having achieved the priority of UHC through UCS, Thailand must now turn toward addressing these challenges.

Key lessons for other countries ("do's and don'ts")

NHSO's experience of managing UCS can provide some lessons on good governance for UHC.

Do's

- Design a governing structure with clearly defined roles and functions for all relevant stakeholders with scope to evolve, based on short-term goals and long-term requirements of feasibility and sustainability.
- Ensure the governing mechanism is autonomous enough to mobilise competent and dynamic leadership at the executive level, workforce, and partners at an operational level, and have built-in capacity for improvements.
- Develop a model where policy is grounded in evidence and the governing body can utilise external evidence to maximise quality and quantity of healthcare.
- Monitor outcomes and executive performance through strong information systems and have an ability to respond to findings.
- Build trust through transparency and accountability against policy goals and principles of good UHC governance, with platforms to address feedback from various stakeholders.

Don'ts

- Make the governing structure overly bureaucratic. If possible, limit the ties between recruitment and compensation to public civil services rules, as it may limit ability to recruit and mobilise talented workforce at all levels.
- Limit roles and functions only to financing and expect others to do the rest at their best. Achieving desirable outcomes of UHC is complex and requires active partnership.
- Allow governance to be over-populist or introduce a benefit package that is not evidence-based or financially viable which results in ad-hoc rationing and detrimental health outcomes.
- Neglect to set up effective communication channels to regularly inform stakeholder groups on all aspects of scheme policy, deliberations, and developments etc.

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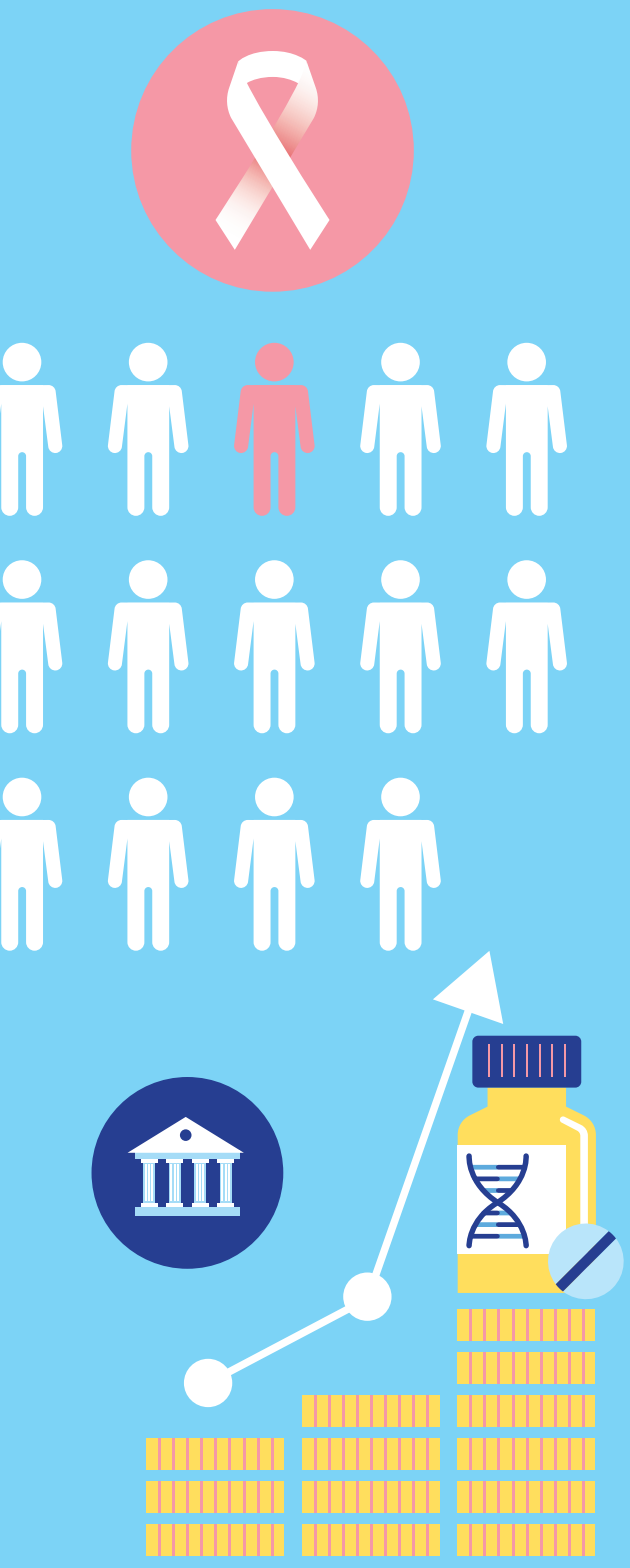

CHAPTER

2

MANAGING RARE DISEASES AND HIGH-COST MEDICINES

Navigating rare diseases and high-cost medicines are essential as well as a great challenge for every health system. Discover global strategies for sustainable access, innovative assessments, and reimbursement to expand coverage and improve patient outcomes.

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HTAP
Health Intervention and Technology Assessment Program

Rare diseases: talk of the town for some time but what's next?

Introduction

Rare diseases are defined as those whose incidence or rate of occurrence are so rare that they barely affect the common populace [1]. The incidence of disease is sometimes quite small compared to the luck-possibility of lottery drawing. However, it's a lottery that no one wants to win. Once it accidentally occurs to you, the disease may not lead to a long life, because of the frequent lack of treatment to support one's symptoms.

Because of their rarity, it is often treated with what the industry refers to as, 'orphan drugs'. The phrase "orphan drug" is frequently used to describe medical technology used to treat rare disorders [2]. These group of drugs are quite expensive because of the fewer number of people suffering from such sickness and usually provide low profit to manufacturer compared to other common drug for non-communicable diseases (NCD) as example. These characteristics might affect future investments in such drugs. Therefore, to aid in the funding of these drugs, legislative strategies are continuously being debated as to what criteria should be applied to the orphan drug policy in several countries.

This piece explores the different prioritisation criteria used for these orphan drugs in different countries. The objective of this piece is not to argue that severity must be considered as a priority setting criteria for rare disease, but rather to present the ethical underpinning of funding rare diseases and to facilitate the conversation among the decision makers to make orphan drugs more accessible as highlighted in the publication by Monica Magalhaes[3].

The remainder of this piece is structured as follows: first we highlight the different accepted definitions of rare diseases from different countries, which is followed by the challenges in prioritisation of rarity and the suggestion of a potential criteria for priority setting for rare diseases. Case studies from other countries are presented thereafter. Lastly, we present the ethical arguments for the reimbursement options for rare diseases and a proposal to investigate the potential of using severity as a priority setting criteria for rare disease in Thailand.

What are "rare" diseases?

Nowadays, there is no universal definition of rare disease [1, 2, 4]. In most countries the definition of rare diseases is based on the number of cases per total population or prevalence thresholds. For example, in the United Kingdom, rare disease is a condition which affects less than 1 in 2,000 people [5]. Meanwhile, in Japan, it is described as disease with fewer than 50,000 prevalent cases [6].

In Thailand, the definition of rare disease has never been defined by law. The current data provided by National Health Security Office (NHSO) in Thailand in 2019 mentions rare disease as the disease which occur one with fewer than 10,000 cases, whereas an ultra-rare disease is defined as a disease with fewer than 1,000 cases [7].

Challenges with prioritising rarity

The problem of prioritising rarity or judging which disease is more deserving of attention is a difficult issue. Since treating rare illnesses usually requires exorbitant sums of money, they do not often qualify for public funding under the standard cost-effectiveness parameters. The fundamental principle of these parameters is to obtain maximum health benefits, regardless of who gets it [3]. Thus, paying an elevated price for the treatment of rare diseases does not agree with the maximising approach cost-effectiveness parameters [3]. However, cost-effectiveness alone does not capture all the elements of disease and illness [8]. In addition, prioritising rarity as a category will always be mired in social controversy. Equality will be a formidable challenge for any authority or system dealing with such cases to support this group of people [3]. The injustice in the allocation of large portions of the health care budget to minority people instead of others with common diseases makes it more challenging to prioritise rarity. Therefore, an alternative criterion is required for decision-makers.

If not rarity, what else?

Another approach that can be employed is to prioritise severity over rarity. The importance of shifting the focus to severity is well established in Norway, Finland, France and Germany. Simply put, severity matters because there is a moral reason to treat the ones that are worse off than others [8]. However, there are not well-defined internationally accepted criteria for defining severity. One example of a severity scale that can be employed in decision making was proposed by Nord E [9]. The following figure depicts the adapted proposed severity scale with the arrows representing the health gain from treatment for three hypothetical individuals. Upon prioritising severity rather than rarity, the health gain acquired by individual A would be valued more than the health gain acquired by individual B [10].

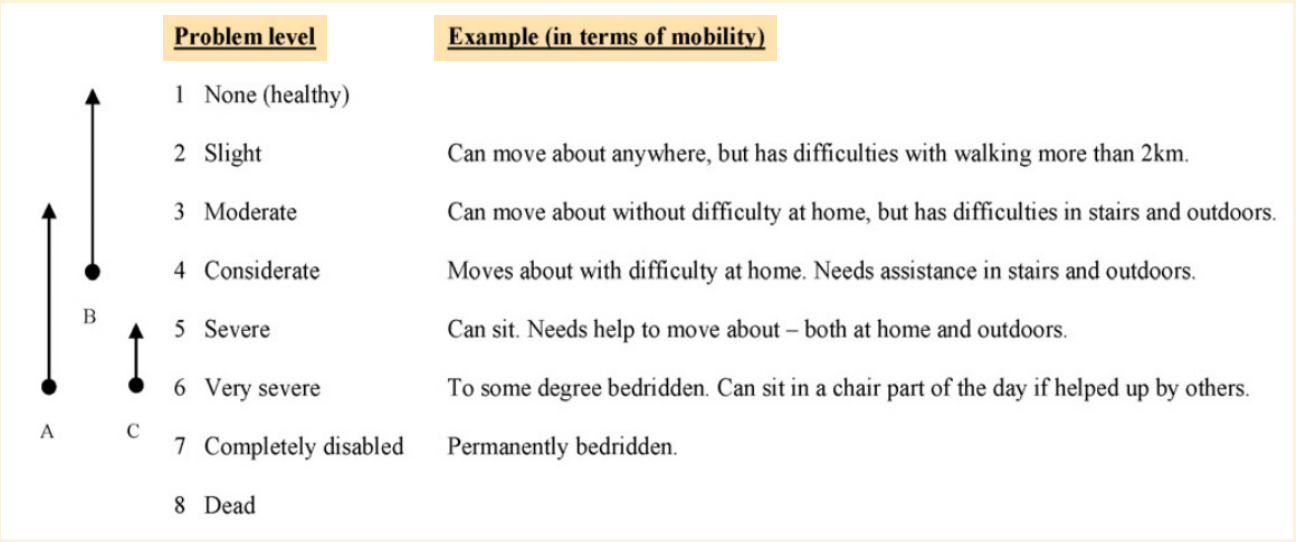

Figure 1. Severity scale proposed by Nord E [9].

Examples of prioritising severity over rarity

Successful examples from different countries prioritising severity over rarity are a testament to the possibility of a cost-effective implementation of such a strategy. One such example is Norway, where the severity of the disease is a component in drug coverage decisions [11].

In the context of rare disease, health inequalities can widen when heath maximisation is the only criteria for drug coverage decisions. To tackle this unfair distribution of health, Norway developed a system which considers the disease severity into the coverage decision of new drugs. Thus, in Norway, the following three priority setting criteria plays a key role in drug appraisal:

1. Health benefit
2. Resource use
3. Disease severity

In such a system, patients with very severe conditions have a stronger claim for treatment. Therefore, when all the other factors are equal, the ones with severe diseases often get higher priority.

In addition to Norway, the United Kingdom's National Institute for Health and Clinical Excellence (NICE) is an organisation that incorporates severity of the illness in the decision-making process [12]. For instance, during the appraisal of a drug, riluzole, used for the treatment of motor neuron diseases, the Technical Appraisal Committee (TAC) of NICE considered the "severity and relativity short lifespan" of affected individuals and subsequently recommend the use of this drug. Interestingly, this drug was approved despite its cost being higher than NICE's approved price range [13]. Similar examples of the NICE approving drugs and technology following considerations of severity has been reported. While, the severity of illness is not an explicit criterion in the decision-making process in the UK, there are examples where the TAC used severity as a criterion for drug appraisal. Although there are only a few countries in the world that have systematically incorporated concerns of severity into health technology appraisal, evidence from these countries points towards the feasibility of the approach.

Discussion

With a small potential market for such orphan drugs and no incentive for profit, such drugs often are very expensive when they find their way into the market. This high cost often makes these drugs non-ideal for public funding. The tension between the desire to yield maximum benefits from the finite resources and the rule of rescue makes the reimbursement of orphan drugs are subject of debate.

The utilitarian principle upon which cost-effectiveness heavily relies focuses on maximising the benefits for a fixed amount of money spent. Thus, funding these drugs goes against the utilitarian ethical view. On the other hand, the egalitarian ethical standpoint highlights the need for everyone to be treated equally and consequently posing an ethical imperative for the funding of rare diseases [14]. Additionally, some ethicists even agree that sometimes certain compensations are required, especially by the disadvantaged, in order to achieve equality [15]. However, this can lead to the using up of a significant amount of a finite public funds, thus leaving out another larger group of the population without access to healthcare. Therefore, the decision to choose rarity or severity as a parameter for public funding of drugs is not as black and white as it may seem.

In conclusion, considering the various ethical and moral trade-offs that are bound to occur, incorporating severity as an additional parameter in the decision-making process could be worth considering. The appropriateness of using this severity criteria can be witnessed from its successful incorporation into priority-setting by countries such as Norway and the United Kingdom. With Health Technology Assessment (HTA) at the heart of discussion around rare diseases, additional research is needed to access the effectiveness of using severity criterion in Thailand. However, undoubtedly it is time that we jump on the wagon to explore new and innovative policy changes that can make healthcare accessible to everyone. We hope that this piece promotes the much-needed discussion and collaboration between policy makers and researchers to enhanceaccess to rare and sever drugs.

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Experience in using HTA for expanding UHC benefit package to cover rare diseases and high-cost drugs among seven middle and high-income countries: A targeted literature review.

Dian Faradiba
Kumaree Pachanee

Key messages

- Treatment for rare diseases is typically more expensive than medications for common diseases given high cost of research and development and small patient population from whom to recoup costs.
- The term "high-cost drugs" and "rare diseases" are closely associated and often used interchangeably. In general, however, while countries have a clear definition of rare diseases, the definition of what constitutes high-cost drugs is still debated.
- Among seven countries reviewed, most countries have similar definition of rare diseases, and only one country, England, explicitly define high-cost
- Australia, Republic of Korea, and England, have special pathway for reimbursing high-cost rare disease drugs with certain requirements that must be met and the requirements must be met. The pathway must be reviewed, its cost-effectiveness assessed, and approved by the decision-making authority.

Background

A rare disease is a chronic disease that can cause disability or can lead to premature mortality in patients. For drug companies, recouping research and development costs from a small patient population is harder compared to drugs developed for common conditions. As a result, treatments for rare diseases are typically more expensive than medications for common diseases.[1] The term "high-cost drugs" and "rare diseases" are closely associated and often used interchangeably. In general, however, while countries have a clear definition of rare diseases, the definition of what constitutes high-cost drugs is still debated.

Health Technology Assessment (HTA) is a multi-disciplinary tool to help inform decisions around the development of the health benefits package for the population of the country and is being increasingly adopted by many countries seeking to achieve or sustain Universal Health Coverage (UHC). However, for rare diseases, the use of HTA to support decision-making for developing the benefits package poses challenges in terms of them not being cost-effective.[2] Therefore, treatment of rare diseases is rarely included in the benefits package of many countries.

This policy brief provides a summary of a recent review of the definition of rare diseases, high cost and how HTA has been used in the case of rare diseases in seven countries. The countries were purposively selected based on them having established HTA policies and availability of resources in the public domain. This review will give readers a better understanding of the current situation of rare diseases in the healthcare system, as well as the potential role of HTA in providing support, allowing them to adapt these processes to their own context.

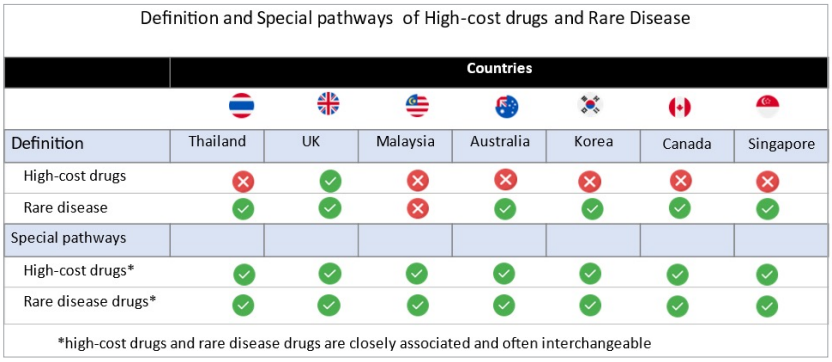
Definition of rare disease and high-cost drugs.

Based on a targeted review of seven countries, namely Thailand, England, Malaysia, Australia, the Republic of Korea, Canada, and Singapore, it was found that all countries, except Malaysia, have explicitly defined rare diseases. Six countries reported a definition of rare diseases: Thailand, England, Australia, Republic of Korea, Canada and Singapore. In Thailand, a rare disease is defined as one with fewer than 10,000 cases per year, whereas ultra-rare disease is defined as a disease with fewer than 1,000 cases per year. The topic of rare diseases is important for health policy development in Thailand because Thailand aligns with and prioritizes the Sustainable Development Goals (SDGs) principle of 'Leaving no one behind,' and the goal of its UHC policy is to provide equitable access to essential health services for everyone, as well as to protect households from bankruptcy due to high health care costs.

The definition of high-cost was only discussed in the England where a drug is considered high cost if (*i*) the drug and its expected associated costs of care are disproportionately high compared to the other expected costs of care within the Health Resource Group (HRG), a standard grouping of clinically similar treatments which use comparable levels of healthcare resource (ICD-10 and OPCS), which would affect fair reimbursement, and (*ii*) there are, or expect to be, more than a £1.5 million spend or 600 cases in England per annum. All countries reviewed have a special pathway and /or consideration to reimburse drugs for rare diseases (Figure 1).

policy brief

Figure 1.
Definition and special pathways of high-cost and rare disease



Special pathway for accessing rare diseases and/or high-cost drugs and its criteria.

Given the scarcity of literature describing rare disease pathways, we selected three countries as case studies (the Republic of Korea, Australia, and England) to elaborate on these processes in the section below.

Australia

Starting in 1995, the Australian government has provided a special pathway to increase access to rare disease drugs through the Life Saving Drug Program (LSDP) which applies the "Rule of Rescue" (ROR) principle. Australia has set up a "Rare Disease Benefit Review Policy Framework", adding to the existing general benefits review process. When any new drugs are being considered by the Pharmaceutical Benefits Advisory Committee (PBAC) and are found to be "clinically effective but not cost-effective", they will be considered further under the LSDP. [3]

To meet the ROR claim, a few factors must be considered: there is no alternative treatments exist in Australia, it is a life-threatening disease (a severe, progressive disease that can lead to premature death), it is a rare disease (affecting a very small number of people), and the proposed drugs provides a worthwhile clinical improvement sufficient to qualify as a rescue from the medical condition.[4] See **Table 1** for specific criteria for inclusion in the LSDP.

Table 1. Decision-making criteria for LSDP (adapted from procedure guidelines).[3]

	Criterion	Notes
A1	The drug is a proven therapy for a rare but clinically definable disease	• ≤1 per 50,000 • High lifelong cost burden
A2	The disease is identifiable with reasonable diagnostic precision	
A3	Evidence of significant reduction in age-specific life expectancy due to the disease	• Data for disease progression without treatment • Life extension can be represented by disability reduction
A4	Evidence of significant life extension due to the drug	• Or significant disability reduction • Surrogate outcomes data is acceptable if there is no survival data
A5	The drug is clinically effective but rejected for PBS listing due to the lack of cost-effectiveness	
A6	No lifesaving alternatives on the PBS listing or available through public hospitals	
A7	No suitable and cost-effective non-drug therapy	Such as surgery or radiotherapy
A8	The cost of the drug is required per year is an unreasonable financial burden for the patient	
B1	The proposed confidential price of the drug compared with effective price in comparable oversea markets	
B2	The proposed cost of the drug compared with the cost of comparable drugs already funded through the LSDP	

Source: Policy Brief, The Life Saving Drug Program: Australia's pathway for high-cost drugs, available at https://www.hitap.net/documents/185668

Republic of Korea

In the Republic of Korea, the task of HTA is now being conducted by the National Evidence-based Healthcare Collaborating Agency (NECA) under the Medical Service Act.[5] Since for newer therapeutics targeting rare diseases or diseases for cancers, there is difficulty in providing pharmacoeconomic evaluation (PE) evidence and usually lack alternatives treatment, pathways such as: a) listing as essential drugs b) Risk Sharing Agreement (RSA) and c) PE exemption and d) price negotiation waivers that are different from there traditional route as shown in Table 2 have been adopted by the Republic of Korea's government. The process of pricing and reimbursement for any new drug is heavily influenced by the presence or absence of available alternatives. Alternatives are drugs that are currently being used for an equivalent therapeutic indication on the regulatory label.[6]

Table 2. Criteria for P&R pathways for drugs with no alternatives

Pathway	Criteria	Notes
When no alternatives		
Essential Drug	• No alternatives • Treat life threatening conditions • Treat small patient groups • Significant improvement in clinical efficacy or patient survival	*Life threatening*- 2 years or less of life expectancy Unclear definition of small groups
Risk Sharing Agreement	• No alternatives • Anticancer agent or serious life-threatening diseases • Should be approved via drug review committee on severity, social and ethical influences	*Refund based* RSA most used (mandatory PE evidence) *Contract term*- 4 years can't be extended if alternatives exist. *No expansion* of indications for P&R
Pharmacoeconomic evaluation exemption	• Rare disease and rare cancers • Clinically effective proven by single arm RCT or phase -II trial. • Drugs to be listed in at least three of A7 countries	*Expenditure cap RSA*- with the pharmaceutical sector *Price*- based on lowest adjusted list price from A7 countries.
Price negotiation waiver	• If pharmaceutical companies accept the weighted average price, it is allowed to pass the negotiation period of 60 days	-

PE, Pharmacoeconomic evaluation; RCT, Randomized controlled; RSA, Risk-sharing agreement; trials.
Source: Lee JH. Pricing and Reimbursement Pathways of New Orphan Drugs in South Korea: A Longitudinal Comparison. Healthcare (Basel). 2021 Mar 8;9(3):296. doi: 10.3390/healthcare9030296. PMID: 33800373; PMCID: PMC8000795.

England

The National Institute for Health and Care Excellence (NICE) in in England has a special guidance to consider reimbursement for high-cost rare disease drugs known as Highly Specialized Technologies (HST). This evaluation is based on factors such as 1) the nature of the condition, 2) clinical efficacy, 3) value for money and 4) the technology's impact beyond immediate health benefits.[7]

Decisions are made based on the findings of an economic evaluation study for HSTs, which are benchmarked against an Incremental Cost-effectiveness Ratio (ICER) of £100,000 per quality adjusted life years (QALYs) gained. The Evaluation Committee will apply a weight between 1 and 3, which corresponds to the incremental QALYs gained per patient over a lifetime horizon of 10 to 30. For example, if incremental QALYs gained (per patient, using lifetime horizon) is 10, then the weight applied is equal to 1. For QALYs gained in the range of 11 to 29 and greater than or equal to 30, weights applied are between 1-3 and 3, respectively.

See **Table 3** for summary of special pathways from three countries.

Table 3. Summary of the special pathway for rare diseases and/or high-cost drugs

	Countries		
	England	**Australia**	**Republic of Korea**
1. Definition			
1.1 Rare Disease	Number of cases less than 1 in 2,000	Number of cases less than 5 in 10,000	< 20,000 patients, or for which the prevalence is unknown owing to difficulties in diagnosing the disease
1.2 High-cost drug	There is, or is expected to be, more than a £1.5 million spend or 600 cases in England per annum	-	-
2. Pathways	Highly Specialized Technologies (HST)	Life-Saving Drug Program (LSDP)	1. Essential drug 2. Risk sharing agreement 3. Pharmacoeconomic evaluation exemption 4. Price negotiation waiver
2.1 Criteria	1) Nature of the condition, 2) clinical efficacy, 3) Value for money 4) Technology's impact beyond immediate health benefits.	**Criteria for LSDP** • **A1** The drug is a proven therapy for a rare but clinically definable disease • **A2** The disease is identifiable with reasonable diagnostic-precision • **A3** Evidence of a significant reduction in age-specific life expectancy due to the disease • **A4** Evidence of significant life extension due to the drug • **A5** The drug is clinically effective but rejected for PBS listing • **A6** No lifesaving alternatives on the PBS listing • **A7** No suitable and cost-effective non-drug therapy • **B1** The proposed confidential price of the drug compared with the effective price in comparable oversea markets • **B2** The proposed cost of the drug compared with the cost of comparable drugs already funded through the LSDP	**Criteria for Essential drug :** • No alternatives • Treat life threatening conditions • Treat small patient groups • Significant improvement in clinical efficacy or patient survival **Risk sharing agreement:** • No alternatives • Anticancer agent or serious life-threatening diseases • Should be approved via drug review committee on severity, social and ethical influences **Pharmacoeconomic evaluation exemption:** • Rare disease and rare cancers • Clinically effective proven by single arm RCT or phase -II trial. • Drugs to be listed in at least three of A7 countries **Price negotiation waiver :** • If pharmaceutical companies accept the weighted average price, it is allowed to pass the negotiation period of 60 days
2.2 Agency	National Institute for Health and Care Excellence (NICE)	Pharmaceutical Benefits Advisory Committee (PBAC)	National Evidence-based Healthcare Collaborating Agency (NECA)

Case study: Topic prioritization for high-cost drugs in England

The overall flow of topic prioritization for high-cost drugs can be seen in Figure 2.

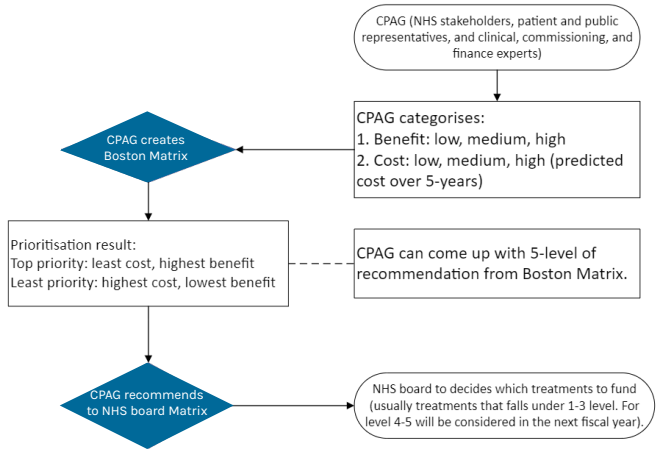
To determine which high-cost drugs to fund, the NHS consults with a committee known as the Clinical Priorities Advisory Group (CPAG). This committee oversees reviewing drugs and therapies including those used to treat expensive and/or rare diseases. Members of the CPAG represent a diverse range of expertise and include NHS stakeholders, patient, and public representatives, and clinical, commissioning, and finance experts. The CPAG is not a decision-making body, but it plays a significant role in developing recommendations.

CPAG creates a "Boston Matrix" to aid in determining which drugs should be prioritized when they are all more expensive but provide greater clinical benefit than current practice (i.e., drugs which falls in top-right quadrant of cost-effectiveness plane). This matrix divides the top-right quadrant of the cost-effectiveness plane into nine additional compartments, dividing the benefit (x axis) into three categories (low, medium, and high benefit) and the cost (y axis) into three categories (low, medium, and high cost). See figure 3 for Boston Matrix example by NHS.

CPAG will classify the clinical benefit and cost of drugs into three categories (low, medium, and high). There will be clinical and economic experts who will forecast and provide input, particularly on drugs costs over a 5-year period. CPAG will summarise the drugs into the Boston Matrix and forward the recommendation to NHS England once all information has been gathered. NHS England will then decide which drugs they could commit to funding. See figure 3b for 5-level of priority by NHS.

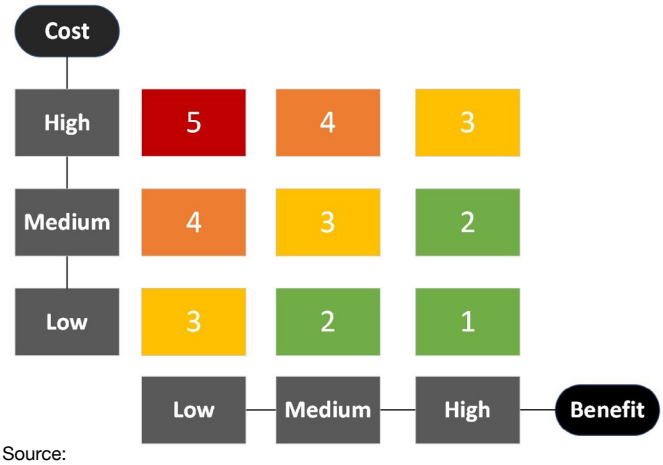
If some drugs are not considered to be funded in the next fiscal year, CPAG will review those treatments within six months, and these drugs can be considered up to three times. The final decision is made by NHS England, which must be approved by the NHS Board.

Figure 2. England topic prioritization for rare disease and/or high-cost drugs



CPAG, Clinical Priorities Advisory Group; NHS, National Health Services
Source: Simplified and/or adapted flowchart prepared by authors based on information available in NHS website[8]

Figure 3. Example of Boston Matrix



Source:
NHS website[8]

Figure 3b. 5-level of priority from Boston Matrix

Source: NHS website[8]
Note: CPAG forwards the recommendation to NHS. Due to resource constraints NHS cannot commit to all 5-level priority, therefore they will commit to fund drugs which fall in level 1-3. However, there is possibility to fund drugs in level 4-5. These drugs will be reconsidered (up to three times) in the next CPAG meeting in 6 months period.

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HTAP Health Intervention and Technology Assessment Program
policy brief

SOUTH KOREA's EXPERIENCE OF REIMBURSING HIGH-COST MEDICINES

Dimple Butani

Key messages

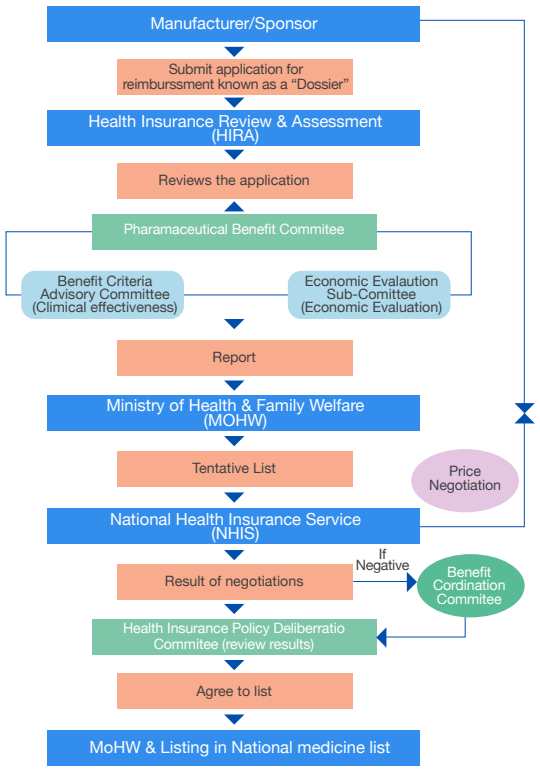
- Cost-effectiveness and availability of alternative treatment options play a crucial role in the listing of new medicines in South Korea. However, high-cost medicines with **no alternative treatment options**, particularly those for treating **cancer and rare diseases,** were not reimbursed under the traditional route.
- To address this issue, the government of South Korea introduced several reforms to facilitate the reimbursement of high-cost medicines, including the **listing of essential medicines, RSA, price negotiation waivers, and PE exemptions.**
- These mechanisms have enabled increased access to high-cost medicines and reduced the time between market approval and reimbursement decisions. However, there is potential for improvement and issues around confidentiality of agreements and transparency of price raised by stakeholders that need to be addressed.

South Korea's approach to expanding access to high-cost medicines

System for reimbursing new medicines

South Korea implemented the National Health Insurance (NHI) programme in 1963 and gradually expanded its scope to achieve Universal Health Coverage (UHC) (1). It is mandatory for all citizens to participate in the national insurance system and a co-pay of 5-60% of the medical cost is often applicable to patients. In order to manage the health budget more efficiently, the NHI introduced the Positive Listing system (PLS) in 2007 to rationalise the distribution of medicines and therapeutics and curtail the medicine expenditure (2). After the implementation of PLS, only clinically and economically viable medicines that were cost effective were reimbursed, and prices were set through price-negotiations between the National Health Insurance Service (NHIS), the insurer, and pharmaceutical companies, in collaboration with the Health Insurance Review and Assessment (HIRA) and the Ministry of Health and Family Welfare (MoHFW)[3]. Figure 1, adapted from Young Bae[4], explains the governance structure of different agencies responsible for pricing and listing of new medicines under the NHI.

Figure 1. Governance structure for listing and pricing of new medicines in South Korea



HIRA, Health Insurance Review and Assessment Service; MOHW, Ministry of Health and Welfare; NHIs, National Health Insurance service

[Adapted from] Bae E-Y. Role of Health Technology Assessment in Drug Policies: Korea. Value in Health Regional Issues. 2019;18:24-9]

Challenges and reform

Although South Korea was the first country in the Asian region to adopt economic evaluation to inform the reimbursement of new medicines, it has been observed that high-priced medicines with uncertain cost-effectiveness are often unavailable to patients due to their cost-ineffectiveness. Consequently, the reimbursement acceptance rate for reimbursement for oncology and rare disease medicines was as low as 39% and 42% respectively [5, 6]. For example, XOLAIR (omalizumab), an orphan medicine for treating severe allergic asthma, remained non-reimbursable due to uncertainty in its cost-effectiveness evidence, with the longest waiting period of 11 years for reimbursement [7].

However, high-cost medicines became available after the introduction of yet another policy reform in 2013 known as the "Introduction of the Benefit Enhancement Plan" (IBEP) which covers four major conditions namely, cancers, cardiovascular diseases, cerebrovascular diseases, and rare diseases [8]. This scheme applies a higher incremental cost-effectiveness ratio (ICER) threshold for medicines with no alternative forms of treatment for these four conditions.

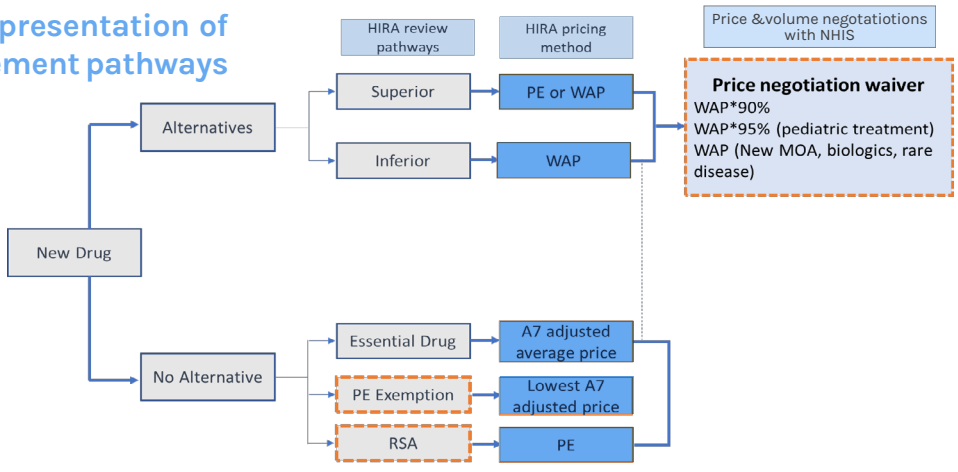
The government of South Korea introduced the IBEP reform in consultation with HIRA, which establishes guidelines for economic evaluation[9]. In addition to implementing a higher ICER threshold for medicines that meet the pre-defined criteria (Table 1), high-cost medicines may be reimbursed through other **alternative pricing and reimbursement (P&R) pathways** including; a) listing as essential medicines; b) risk-sharing agreements (RSA) for high priced medicines with no alternatives (primarily cancer medicines); c) pharmacoeconomic evaluation (PE) exemption for medicines with limited clinical evidence, indicated for life threatening conditions, with no alternative treatments and d) price negotiation waivers to expediate the launching of new medicines [3], as detailed below.

Pricing and reimbursement pathways for the high-cost medicines

The P&R process for any new medicine is typically determined by comparing it with available alternative treatments. Alternatives are defined as medicines currently used for an equivalent therapeutic indication[3, 10]. **For a medicine with therapeutic alternatives,** there are typically two pathways for reimbursement based on comparative effectiveness evidence: a) PE evaluation; and b) negotiation with the NHIS based on weighted average price (WAP) of alternative medicines. The medicine with proven clinical superiority is first evaluated for its cost effectiveness evidence and later an acceptable price is recommended by HIRA through the PE pathway. For clinically non-inferior medicines, an adjusted price is determined by comparing the medicine acquisition costs and recommending the WAP of alternative medicines, based on market share data from reimbursement claims.

However, as noted earlier, providing evidence for PE can be difficult, and there are often limited alternative treatment options for high-cost medicines, particularly those targeting rare diseases or cancers. Hence a series of "alternative P&R pathways", that are different from the traditional route, have been adopted by the South Korean government, as shown in Figure 2 and described below.

Figure 2. Schematic presentation of pricing and reimbursement pathways for new medicines



Adapted from [Lee JH. Pricing and Reimbursement Pathways of New Orphan Drugs in South Korea: A Longitudinal Comparison. Healthcare. 2021; 9(3):296.]

Alternative Pricing & Reimbursement (P & R) pathways

Essential Medicines list

For new medicines that do not have alternative treatments available and for which cost-effectiveness evidence cannot be submitted, the Drug Evaluation Expert Committee (DREC) of HIRA, can list them as essential medicines if they meet the criteria (see Table 1), and it then becomes exempt from requiring a cost-effectiveness evaluation. The price is determined by negotiating with the NHIS based on the adjusted price from seven countries known as A7 countries - US, UK, Italy, Germany, Japan, Switzerland and France.

Risk-Sharing Agreement System (RSA)

RSAs were introduced in 2013 to alleviate the financial burden of accessing high-cost medicines. There are four types of RSAs: 1) **condition treatment continuation and money back guarantee,** which is reimbursed by the payer (NHIS) if the response of a medicine meets a pre-defined goal; if it does not meet the goal, company refunds the full cost to NHIS; 2) **an expenditure cap,** wherein the total expenditure of medicine is set in advance and the company pays back the exceeding amount to NHIS; 3) **a refund** approach, wherein the company refunds a certain percent of the nominal price to the NHIS; and 4) a **utilisation cap,** wherein a fixed cost per patient is agreed upon and the company covers the cost of the medicine beyond the pre-agreed level of utilisation [11].

Pharmaco-economic waiver

Evidence generation for medicines to treat rare and ultra-rare diseases is difficult. To counter this limitation, the PE waiver was introduced in 2015, and only those medicines that satisfy all criteria such as the medicine being used to treat a rare disease (see full list in Table 1) were eligible for this scheme. Later, it was mandated that every medicine for which economic evidence was not generated needed to share the risk in the form of an expenditure cap RSA between the manufacturer and insurer/payer.

Price negotiation waivers

Price negotiation waivers accelerate the process of listing new medicines. If a pharmaceutical company accepts the weighted average price of an alternative medicine (90 or 100 % as in figure 2), it can skip the negotiation process that usually takes 60 days with the NHIS.

For medicines with no alternatives, the average price of the same medicine from the A7 countries is used as a reference price. In this case, an RSA may be applied to spread financial risk related to uncertain clinical usefulness and budget impact. For this reason, these medicines can be listed at high prices through a comparatively simple process [12].

Table 1. Criteria for P&R pathways for medicines with no alternatives

Pathway	Criteria	Comments
Without alternatives		
Essential Medicines	• No alternatives • Treat life threatening conditions • Treat small patient groups • Significant improvement in clinical efficacy or patient survival	• *Life threatening* refers 2 years or less of life expectancy • Unclear definition of *small groups*
Risk Sharing Agreement	• No alternatives • Anti-cancer agent or serious life-threatening diseases • Should be approved via drug review committee on severity, social and ethical influences	• Refund based RSA most used (mandatory PE evidence) • Contract term of 4 years cannot be extended if alternatives exist • No expansion of indications for P&R
Pharmacoeconomic evaluation exemption	• Rare disease and rare cancers • Clinically effective, as proven by single arm RCT or phase II trial. • Medicines to be listed in at least three of A7 countries	• Expenditure cap RSA - with the pharmaceutical sector • Price is based on lowest adjusted list price from A7 countries.
Price negotiation waiver	• If pharmaceutical companies accept the weighted average price, the medicine is exempt from the negotiation process (which can take 60 days)	

Monitoring and Evaluation

Although the mechanism for the Monitoring and Evaluation (M&E) of these schemes has not been reported, the South Korean government has conducted frequent audits for medicines that have been approved under the new alternative pathways programme [13]. As rule of thumb, any medicine approved through

the RSA needs to submit the effectiveness evidence (i.e. no alternative treatment available, improves survival and/or quality of life) every four years in order to be eligible for extension of exemption.

In terms of impact, at HIRA, the Pharmaceutical Benefit Coverage Assessment Committee (PBCAC) meets monthly to review company submissions for medicine reimbursement. PBCAC assesses the suitability of medically essential medicines, RSA, the waiver of PE data submission, and the new mode of action, along with clinical usefulness and cost-effectiveness. Application of new modes of access have shown a positive impact [14] on both listing for reimbursement and time to listing: more than 50% of medicines listed post alternative pathway introduction were cancer and rare disease medicines and the time to listing reduced by approximately 8 months [15]. As of 2019, 39 medicines had been reimbursed under RSAs and PE exemptions had been applied to 19 of these medicines. The impact of alternative pathways on patients was reported in an early analysis of reduced out of pocket expenditure by USD 299.8 million[16]. However, this costed the government approximately USD 75.8 million, with the largest amount for medicines listed under the RSA system followed by PE waiver system, respectively[17].

For the list of essential medicines, since the criteria for listing medicines in the essential category are very specific, the system has so far proven to not be effective when it comes to patient access and as of year 2017, only 10 medicines evaluated by HIRA have been designated as "essential medicines"[17].

Introduction of such schemes have led to increased possibility of listing in the benefit package. Also, a study by Kim S. et al found that the lead time i.e., time taken from market authorisation to an HTA reimbursement decision, was reduced after the introduction of new alternative pathways from median 21 months to 10.9 months. This difference is mainly attributable to pathways such as the price negotiation waiver and PE exemption. However, when RSA individually were evaluated, it took 29.1 months for medicines to be listed and reason reported was additional time to review economic evidence[15, 18].

Conclusion

In conclusion, the introduction of alternative P&R pathways in South Korea has allowed for increased access to high-priced medicines for rare diseases and life-threatening conditions. This has been achieved through risk-sharing agreements and other non-traditional pathways, which waive the need for cost-effectiveness evidence.

However, the increased access to such medicines has led to higher government expenditure and raised concerns around price transparency. Additionally, generating cost-effectiveness evidence for medicines under the refund scheme remains challenging and stakeholders have expressed concerns about producing such evidence (15, 19). Other issues such as high administrative cost, generation of cost-effectiveness evidence for the refund type of evidence continue to pose challenges for both, the payer and the pharmaceutical company(20).

These challenges highlight the need for continued efforts towards finding a balance between access to innovative therapies and cost containment while ensuring transparency and sustainability of the healthcare system.

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The Life Saving Drug Program: Australia's pathway to high-cost drugs

Evan Huang-Ku & Dr. Tracey Laba

Issue#21 October 2022

policy brief

Australia's approach to expanding high-cost drug access

Australia developed the Life-Saving Drugs Program (LSDP) in 1995 to complement the Pharmaceutical Benefits Scheme (PBS), expanding access to high-cost drugs for rare diseases (DRD). This program, funded and administered by the Department of Health and Aged Care, permitted sponsors (often pharmaceutical companies) to apply for listing when their clinically effective DRD is rejected for PBS listing on the grounds of cost-effectiveness.[1] At the time of writing (2022), sixteen medicines were subsidised via the LSDP.[2]

The Pharmaceutical Benefits Scheme contains a list of medicines the Australian government subsidises to reduce the out-of-pocket costs that beneficiaries pay to access medicines. The Pharmaceutical Benefits Advisory Committee (PBAC), a government-appointed independent expert body, uses a set of criteria, including cost-effectiveness, to evaluate whether a medicine should be included in the PBS.[3] Although cost-effectiveness analysis is a legislative requirement, the PBAC does not use a defined Incremental Cost-effectiveness Ratio (ICER) threshold. Nevertheless, past studies have shown that medicines with lower cost-effectiveness ratios have a higher chance of listing.[4]

The consideration of cost-effectiveness is crucial for budgetary control, but it poses a challenge when assessing DRDs. This is because DRDs have a weaker evidence base for their effectiveness and higher prices due to higher research costs and fewer competitors in smaller-sized markets.[5]

Table 1: Drugs reimbursed through LSDP in 2022 (adapted from the LSDP website)

Medicine(s)	Condition
Agalsidase alfa (Replagal®) Agalsidase beta (Fabrazyme®) Migalastat (Galafold®)	Fabry disease
Imiglucerase (Cerezyme®) Velaglucerase (VPRIV®) Taliglucerase (Elelyso®)	Gaucher disease (type 1)
Nitisinone (Orfadin® and Nityr™)	Hereditary tyrosinaemia type 1 (HT1)
Cerliponase alfa (Brineura®)	Late-infantile onset Batten disease (CLN2)

Medicine(s)	Condition
Laronidase (Aldurazyme®)	Mucopolysaccharidosis type I (MPS I)
Idursulfase (Elaprase®)	Mucopolysaccharidosis type II (MPS II)
Elosulfase alfa (Vimizim®)	Mucopolysaccharidosis type IVA (MPSIVA)
Galsulfase (Naglazyme®)	Mucopolysaccharidosis type VI (MPS VI)
Asfotase alfa (Strensiq®)	Perinatal- and infantile-onset hypophosphatasia (HPP)

The Life Saving Drug Program at a glance

After a medicine is rejected by PBAC, the sponsor applies for an LSDP listing with the required information. The LSDP Expert Panel then reviews the application, the LSDP secretariat's assessment of the application, additional stakeholder input from the public, presentations made to the panel, and materials from the PBAC's consideration to advise the Chief Medical Officer.[6] Within two to six weeks, the Chief Medical Officer makes a recommendation on whether the medicine should be funded through the LSDP, pending approval from the Minister for Health.[4] *See Figure 1 for the LSDP process.*

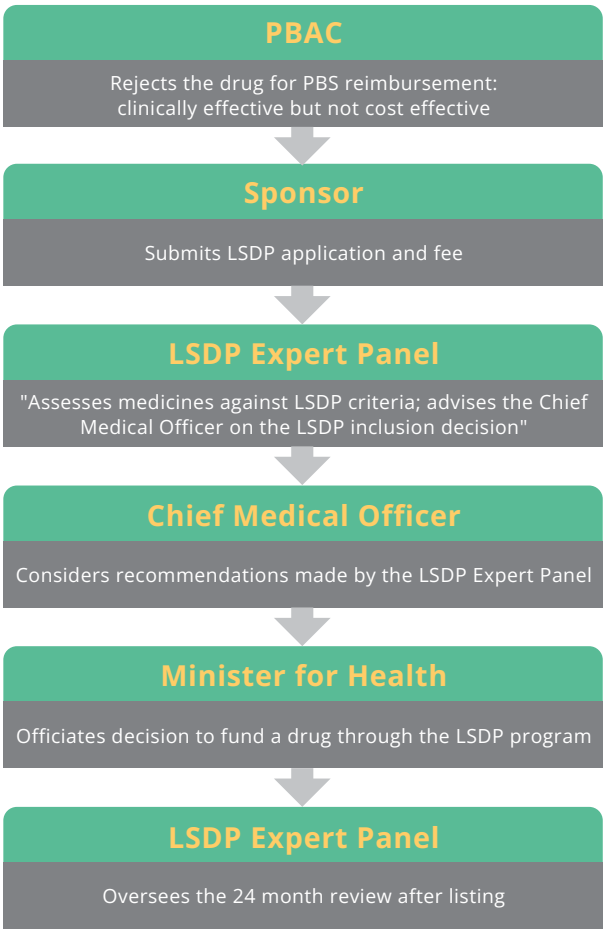

Figure 1: A simplified flowchart of the LSDP governance structure adapted from the procedure guidance.[4]

This section describes a simplified overview of the LSDP decision process. In practice, there is communication between the sponsor and the LSDP Expert Panel, where the sponsor supplies additional evidence upon request to support the decision-making. During the process, stakeholders such as patients, their caregivers, and physicians are welcome to directly provide written input to the LSDP Secretariat to be considered by the Expert Panel.[1] *The main stakeholders are depicted in Figure [2].*

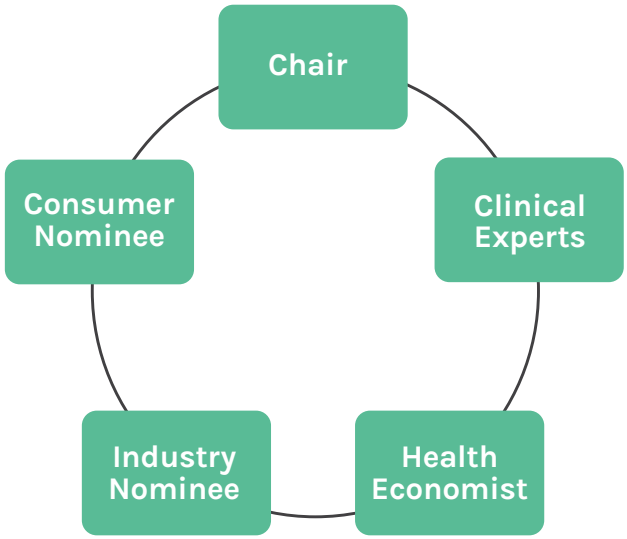

Figure 2: Key people on the LSDP Expert Panel [6]

Reimbursement Process

For a medicine to be recommended for LSDP listing, the LSDP Expert Panel assesses the application to ensure it meets the ten LSDP criteria. The requirements include disease rarity, defined as less than 1 in 50,000 people, as the LSDP is intended to supplement the PBS to expand access to DRD.[1] In addition, there must be evidence that the medicine can extend life or reduce disability in someone who would otherwise have a significant life reduction or have a significant disability due to the disease.[1] Although demonstrating the medicine is cost-effective is not required for listing, the sponsors are still needed to supply medicine prices in comparable overseas markets to provide the context of medicine pricing.[1] *See Table 2 for the complete list of criteria.*

Table 2: Decision-making criteria for LSDP drugs (adapted from procedure guidelines)

	Criterion	Notes
A1	The drug is a proven therapy for a rare but clinically definable disease	• ≤1 per 50,000 • High lifelong cost burden
A2	The disease is identifiable with reasonable diagnostic precision	
A3	Evidence of significant reduction in age-specific life expectancy due to the disease	• Data for disease progression without treatment • Life extension can be represented by disability reduction
A4	Evidence of significant life extension due to the drug	• Or significant disability reduction • Surrogate outcomes data is acceptable if there is no survival data
A5	The drug is clinically effective but rejected for PBS listing due to the lack of cost-effectiveness	
A6	No lifesaving alternatives on the PBS listing or available through public hospitals	
A7	No suitable and cost-effective non-drug therapy	Such as surgery or radiotherapy
A8	The cost of the drug is required per year is an unreasonable financial burden for the patient	
B1	The proposed confidential price of the drug compared with effective price in comparable oversea markets	
B2	The proposed cost of the drug compared with the cost of comparable drugs already funded through the LSDP	

It is important to note that despite the criteria that exist, they, by design, allow for flexibility, subject to the LSDP Expert Panel's discretion.

Price negotiation begins once the sponsor is notified that the Chief Medical Officer intends to advise the Minister for Health to fund the medicine through LSDP. Although details of the pricing arrangement are strictly confidential between the sponsor and Australia, the procedural guidance for LSDP listing has referenced using outcome-based risk-sharing agreements as a pathway to reimbursement.[1]

An outcome-based risk-sharing agreement can be used to determine the future price of a medicine. This type of agreement permits the medicine to be funded with the condition that further data on disease stability and improvement must be collected to evaluate the appropriateness of the price. The price of a medicine is then reduced if new evidence suggests it is less effective than previously assumed.

However, due to the disease rarity, data collected from the small sample size often lack statistical significance, posing a challenge to their implementation.

The LSDP only funds medicine costs but may also cover the cost of importation and transportation to some extent when the manufacturer directly delivers the medicine to the place of administration.

In addition to using risk-sharing to manage medicine prices, LSDP also adopted a price reduction policy to control medicine prices similar to that of PBS.[4] For example, the medicine price was to be reduced by 5% on the 5th anniversary, another 5% on the 10th anniversary, and finally by 26.1% on the 15th anniversary of listing.[7] However, this policy has been discontinued for LSDP since June 2022.[8]

Implementation

Before funding the medicine, the LSDP Secretariat must finalise the treatment guideline based on the Expert Panel advice and by working with the sponsor and clinical experts.[1] This will include directions for initiation and continuing the treatment. Once the medicine is approved for funding, a patient must meet the eligibility criteria to access the medicine. This includes satisfying treatment criteria and consenting to data collection for medicine evaluation. In addition, the patient must show clinical improvement or at least stabilisation of the condition for continued access to the medicine.

Patient access to LSDP medicine is carefully managed. The treating physician must apply to the LSDP to initiate access to the medicine and nominate a dispensing pharmacy.[9] The LSDP medicine will be delivered to the pharmacy in the quantity of a one-month supply only at a time, ordered by the LSDP directly, due to the high-cost nature of these medicines.[9] Differing from PBS medicines, patients do not co-pay to access LSDP medicines.[10]

Monitoring and Evaluation (M&E)

To ensure the use and effectiveness of the medicine meet the expectations at the time of listing, medicines on the LSDP are reviewed for their usage, clinical benefits, and financial cost 24 months after listing.[1] Patient-level data is collected and submitted by the treating physician to the Department of Health and Aged Care following their website instructions annually to understand the real-world use.[1,11] The scope of the review is drafted based on issues identified by PBAC and LSDP Expert Panel when the medicine was considered for listing. In addition to patient-level data collected by the Department, sponsors can also submit additional data, including international evidence, to support the review.[1]

Upon completion of the review, the recommendations are made to the Minister, which may include changing the eligibility criteria or treatment guidelines, amendments to risk-sharing arrangements or the scope of data collection, referral to PBAC for PBS listing considerations, or the removal of such medicine from the LSDP listing.[6]

Lessons Learned

- Establishing a new reimbursement programme such as the LSDP for clinically effective but high-cost medicines can facilitate the decision-making process by easing the criteria for cost-effectiveness when the medicine is lifesaving (or disability-reducing), and there are no alternative treatment options.
- Payers can control prescribing volumes and expenditures by requiring approval for individual-patient use from the funding authority *before* the medicine is dispensed and granting continued medicine access conditional on demonstrated improvement or stabilization of the patient's condition.
- Risk-sharing agreements may be explored to facilitate patient access to lifesaving medicines with a higher level of uncertainty in clinical benefit and minimise the payer's financial risk, while being mindful of implementation barriers such as higher transaction and administrative costs.[12]
- A two-tier evaluation system (PBAC evaluation followed by LSDP expert panel evaluation), while appearing time-consuming, may be more efficient as a baseline evaluation has already been performed, i.e., clinical data has already been assessed by PBAC, and the LSDP expert panel does not repeat the process completely from the beginning.

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Horizon Scanning in the European Union

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policy brief

Key messages

- Horizon Scanning (HS) is the process of identifying new and emerging technologies before uptake into practice to evaluate the potential impact to inform decision-making.
- In the European Union (EU), the EuroScan International Network was established in 1997 and over time, given its expanded geographic scope, was renamed as the International HealthTechScan (i-HTS).
- The HS process in the EU generally consists of identification, filtration, prioritization, assessment, dissemination and monitoring. HS is mostly used for pharmaceutical products.
- Cross-country collaboration through an HS network reduces resources required to develop an HS system and offers opportunities to learn from other countries' experiences.
- HS agencies, including publicly funded agencies, need to work hand-in-hand with government bodies to ensure use of the outputs of the HS process.

What is Horizon Scanning (HS)?

Advancement of new technologies fosters significant benefits for the healthcare system, resulting in improved clinical outcomes of patients.[1] Majority of new technologies tend to have a high price point due to their complexity and substantial production costs.[2] This presents challenges for sustainable and fair access to medicines and health interventions even in high-income countries (HICs).[3,4] In addition, some innovations may not be effective or may not lead to additional health benefits compared to established practices.[5] Therefore, an innovative mechanism is required to identify and evaluate the potential outcomes and healthcare costs of such new technologies before widely used. To fill this gap, Horizon Scanning (HS) has been developed to inform policy-makers to use evidence to make strategic decisions and prioritize efforts before such high-cost medicines enter into the market.[4,6] HS is recommended as the first step of Health Technology Assessment (HTA) for countries in the European Union (EU) where HTA systems have been well established for over 20 years.[7]

What is the definition and objective of horizon scanning?

HS is defined as identification of new and emerging technologies before uptake into practice to evaluate potential impact for inform decision-making.[8] It is intended to assess the extent of potential impact of new and emerging technologies including their economic impact, safety and efficacy, social and ethical considerations and any changes that may be needed at the system level in order to be recommended for use.

Which countries use Horizon Scanning in the European Union (EU)?

According to a survey conducted in 2019, 10 out of 27 countries in the EU had already established their own national HS system.[9] Among them, six countries systematically use HS (Iceland, Italy, the Netherlands, Norway, Sweden and the United Kingdom), and a further four countries (Austria, Denmark, France and Ireland) have established ongoing HS activities.[9] The HS system in Italy was established in 2006 and is the oldest HS system in the EU region.[10]

Who are collaborating on Horizon Scanning in the EU?

In 1997, a network comprising representatives from Denmark, the Netherlands, Spain, Sweden, the United Kingdom (UK), Canada, and Switzerland was established with the aim of facilitating cross-country collaboration. The objectives of this network are to foster knowledge sharing and exchange of skills and experiences related to the identification and evaluation of emerging technologies, as well as to develop methodologies for early awareness and alert activities. Furthermore, the network serves as a platform for exchanging information on the safety and efficacy of new technologies.[9] Two years later, it was set-up as the EuroScan International Network and expanded into a collaboration of 12 countries.[11]

The network has since become a global one and renamed as the "International HealthTechScan (i-HTS)". This network includes regional groups, such as Africa (AfroScan), America (ScanAmericas), Asia (AsiaScan) and Europe (EuroScan).

In addition, other cross-national collaborations have emerged in the EU region such as the Valletta Declaration, Nordic Pharmaceutical Forum and International Horizon Scanning Initiative. Countries without national HS systems such as Croatia, Cyprus, Finland, Greece, Malta, Portugal, Romania, Slovenia and Spain have joined at least one of these networks with plans to establish an HS system in the near future.[12]

What is the process for Horizon Scanning in the EU?

HS in EU countries is used to identify pharmaceutical products, technologies for diagnosis and health interventions, public health interventions, and treatment delivery systems.[13] However, based on a survey conducted in 2019, it was found that only Italy, Norway and the UK had HS systems in place to identify any type of health technologies, while other countries focused on identifying pharmaceutical products exclusively.[9] In 2017, more than one-third of the requests for HS to the European Medicine Agency were related to anti-cancer and immunomodulating agents.[14] Generally, there are six steps in the HS system in the EU, namely, identification, filtration, prioritization, assessment, dissemination and monitoring as shown in Figure 1.

Identification
Scanning sources to identify new or emerging health technologies

Filtration
Initial selection of potentially relevant drugs or interventions to include in the prioritization process

Prioritization
Prioritized new and emerging technologies for investment based on the scope of interest as per national healthcare priorities

Assessment
Predicting potential impact of technologies prioritized depends on stakeholders' interests and needs

Dissemination
Deliver the output of Horizon Scanning to target audience in timely manner

Monitoring and updating
Identify any new information is carried out and evaluate key performance indicators such as time dedicated to activities, potential obstacles to activities, and workloads

Figure 1 Steps in the HS System in the EU

Identification

Identification, the first step of HS, is the process of scanning sources to identify new or emerging health technologies. [10,13,15–20] Majority of agencies involved in the EuroScan network, started the identification process from the "experimental" phase (phase II - III) of technologies or within two years before roll out into the market.[21] Generally, sources for identification can be divided into four types as shown in Table 1.

Type of source	Country
Primary: The manufacturer, company websites, including press releases and investor report	EU-countries[13], Sweden[16], Italy[10], UK[18], Austria[19]
Secondary: Regulatory agencies like FDA, scientific journals, internet news releases, conference proceedings, and health technology media outlets	EU-countries[13], Sweden[16], Austria[19], Italy[10], UK[18,22], Norway[17]
Tertiary: Other EAA systems or registries of clinical studies	EU-countries[13], Sweden[16], Italy[10], Austria[19]
Consultation with stakeholders including clinical experts and technical developers	Italy[10], UK[18],
Open call to stakeholders for submission of new and emerging technologies by using structured notification form	Italy[10]
Patients' suggestion	Netherlands[27], UK[18]

Table 1. Type of sources involved in identification process

Primary sources include direct information from manufacturers or investors.[8,10,13,16,19] Secondary sources such as the media or other channels as well as published articles.[8,10,13,16,17,19,22.] Tertiary sources include information from other organizations engaged in identifying new healthcare technologies.[10,13,16]

Identification is usually conducted by staff from HS agencies[20] and stakeholders representing government bodies, clinical experts, medical associations and patient associations.[10,15]

Filtration

Filtration refers to identifying an initial list of potentially relevant drugs or interventions to include in the prioritization process.[23] There are three criteria to filter new and emerging technologies: 1) early phase of development (phase II – III) or early post-marketing stage[16,19,23,2] the targeted technology of interest[15] (for instance, pharmaceutical products or surgical procedures), and 3) completeness of information available in sources.[15]

Prioritization

Following the filtration process, new and emerging technologies are prioritized for investment based on the scope of interest as per national healthcare priorities.[13] Generally, it is based on criteria related to patient, disease, health systems and technology perspectives, as shown in Table 2. Prioritization is usually conducted through stakeholder consultations or focus group discussions.[17] During the consultation, individual stakeholders provide scores to products based on the four criteria and products are prioritized based on the total score received.[10]

Assessment

Assessment is the process of determining the potential impact of technologies prioritized depends on stakeholders' interests and needs.[10,23] It involves developing HTA model or having focus group discussions with relevant experts.[17]

Prioritization criteria	Country
Patient perspective • Number of patients eligible for the drug under considerations; Applicable to a small proportion of the population but with obvious and far-reaching benefits; Intended use of the new therapy; Anticipated clinical benefit; Ethical issue; Risk; Cost	Austria[23], EU-countries[13], Italy[15], Sweden[16], Norway[17], UK[18]
Disease perspective • Burden of disease	Sweden[16]
Health system perspective • Level of resource utilization	Austria[23], EU-countries[13], Sweden[16], Norway[17], UK[18]
Technology perspective • Novelty; Level of interest from media; Anticipated sub-optimal market uptake	Sweden[16], Norway[17], UK[18]

Table 2. Prioritization Criteria for new and emerging technologies

The assessment criteria take three perspectives: patient, economic evaluation and type of new drug or technology. The patient perspective considers the potential impact at the patient, in terms of level of satisfaction, level of effectiveness, and level of utility.[10,17,18] The economic evaluation perspective focuses on estimating accurate economic impact following the uptake.[10,18] Lastly, the level of innovation and probability of implementation in the near future are taken into account from the technology perspective.[17]

Internal peer-review is conducted to check for accuracy and consistency of the assessment report before being published.[10] The assessment report is distributed to experts from the medical advisory committees such as Medical Services Advisory Committee or other dedicated organizations assessing the safety and efficacy of new drugs or interventions .[16]

Dissemination

Dissemination is the process of delivering the output of HS to the target audience in a timely manner.[23] Fundamentally, dissemination reports provide information on: target population, description of the procedure and technology, clinical importance and epidemiological data of the disease, current development stage, potential benefit of the technology over current alternatives, safety, effectiveness, cost-effectiveness, social, ethical and organizational impact.

The reports are disseminated in the forms of alert report, brief, early assessment report or newsletters to the target audience from government bodies, pharmaceutical and technology industries, medical and patient associations.[15] For members of the EuroScan network, the HS reports are uploaded on EuroScan database for an international audience.[15] However, some of the reports like internal reports are confidential and distributed only to decision-makers, the HTA department, and other internal stakeholders for peer review.[10]

Monitoring and updating

It is important to periodically monitor key performance indicators such as time dedicated to activities, potential obstacles to activities, and the workload of conducting HS.[10] It is also important to keep abreast and update the information. This is because of the nature of uncertainty of the information in early assessment which can change or be updated frequently before the technology is implemented. It may be necessary to consider re-assessment in some cases.[10,19,23]

How is Horizon Scanning used as a policy tool?

Countries with national systems with systematic use of HS such as Italy, the Netherlands, Norway and the UK have fully integrated the HS system into their pharmaceutical policy frameworks and is used in the decision-making process.[9] The HS system is widely used to assess new technologies in the area of oncology, preventing infectious diseases such as vaccines, immunological and rare diseases due to their nature of rapidly evolving and limited treatment options.[14,24,25]

What are the challenges of Horizon Scanning in the EU?

The HS system in the EU is one of the most established system that is established since 1985. [26] However, it is not a system without challenges.

First, there are limited resources available for short-term and long-term operations in terms of finances, appropriate expertise and logistical constraints.[10] In some instances, there is low participation of stakeholders, possibly due to limited interest and knowledge especially of new technologies such as Advanced Therapy Medicinal Products (ATMPs).[10,13,15,18] This is reflected in that fact that only 10 out of 27 of the EU countries have established an HS system to date.[9]

Second, accuracy of prediction in assessing possible implications of new and emerging technologies might be insufficient because of limited knowledge of drugs and technologies at the early development stage.[8,10,18,23]

Third, the ultimate goal of HS is to support the managed entry of new technologies into the health system and it is crucial that this information reaches policy makers. Nevertheless, there are some challenges in coordination and communication between technical experts and government bodies.[9] For instance, some of the internal reports on HS results are only delivered within HTA agency and without being distributed to decision makers.[10] There is also a risk that the findings may not be used by policy -makers if the HS process is conducted by organizations that are not directly connected with the government health system.[9]

What are the strengths of international collaboration and networking for Horizon Scanning?

International collaboration and networking can alleviate many of the limitations of the national HS process. The i-HTS network is one of the best examples of an HS network where working groups among members in the network are set up for HS of specific technologies such as ATMPs, and by collaborating together, can reduce the extent of resources required and expand the availability of expertise.[9] Additionally, it creates opportunities to develop an effective HS system by taking lessons learnt from HS experiences of other countries. Last but not least, sharing HS information in the network is time-saving, avoids duplication and enhances learning best-practices of HS methodologies and activities across the system.[10,15]

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Strategies for Sustainable Access: Unpacking Managed Entry Agreements (MEAs) and Innovative Medicine Access

In recent years, significant advancements in science and technology including novel pharmaceuticals, have emerged (1). These innovative medicines not only extend life expectancy but also hold the potential to **improve the quality of life and save lives.** However, the soaring prices of these groundbreaking medications, coupled with the increasing prevalence of non-communicable diseases (NCDs), such as cancer, and rare diseases, have become a cause for global concern. Governments worldwide are grappling with the financial burden of funding these high-cost medicines (2). Additionally, reimbursing them has several challenges with traditional funding and pricing models (1,3). This predicament becomes even more pronounced for low and middle-income countries (LMICs), where healthcare resources are limited and prioritizing healthcare expenditure is paramount to achieve affordable, equitable, and sustainable access to these life-changing medicines (4).

The high cost of innovation places significant budget constraints within the healthcare systems. Challenges such as higher rates of inflation, increasing prices and limited initial evidence of new therapeutic benefit, present daunting hurdles for both payers and manufacturers. For countries with commitment to Universal Health Coverage (UHC) (5), reimbursement decisions are based on value which is a function of clinical and cost effectiveness. However, the high cost makes it difficult for the payer to prioritize. This challenge has led to many developed high income countries exploring alternative funding models and one such mechanism to facilitate reimbursement is through **Managed Entry Agreements (MEAs)** (6,7,8).

MEAs aim at early access to high-cost innovative medicines at pre-determined terms that can ensure the financial sustainability of healthcare systems. However, their successful adoption hinges on a consideration of various factors to address the unique challenges faced by different nations.

The aim of this document is to explore the concept of MEAs, understanding insights from existing literature regarding their benefits and challenges. Additionally, it seeks to formulate overarching recommendations for the implementation of MEAs in LMICs.

Understanding Managed Entry Agreements (MEAs):

The concept of MEAs is relatively new and therefore subject to varying interpretations in terms of both concept and terminology. Broadly defined as "Conditional agreements between the producer/manufacturer and the payer/provider," MEAs facilitate access through coverage or reimbursement of health technologies under predefined conditions (9).

Depending on the nature of the agreement, several mechanisms exist to manage uncertainties related to cost-effectiveness/or clinical effectiveness in a real-world setting leading to uncertainty in adoption, or its impact on the overall health system budget.

policy brief

MEAs can be broadly categorized into two main types:

Financial-Based Agreements (FBAs): These primarily focus on cost containment, considering factors such as the cost of the medicinal product or the overall cost of treatment. In FBA, the financing of a product falls on both the manufacturer and the payer. For example, a payer may agree to pay for a specified amount of the population over a given period of time, with the remainder of the treatment required to be paid for by the manufacturer.

Performance-Based Agreements (PBAs): PBAs are centered on the effectiveness of a product. When a novel, innovative product is under contract for a PBA, evidence is often limited, and payers' concerns focus on uncertainty as to whether the product will perform as beneficial in the real world. In these agreements, usually, a pact is established between the payer and the pharmaceutical company, enabling the collection of real-world data to determine payment based on observed clinical results.

In addition to these two primary types, a newer model of MEAs known as service-based agreements (SBAs) has gained prominence and importance although it has not been extensively studied.

For a comprehensive understanding of MEAs, Kanavos et al. proposed a taxonomy framework. This framework classifies MEAs based on a) The objectives they aim to achieve; b) The subject matter being monitored; c) The instruments used for their implementation; and d) The impact they can potentially bring about. **Figure 1,** adapted from Ferrario and Kanavos (2013) (9), provides a visual representation of this taxonomy framework, aiming to classify and analyze the impact of MEA. The most frequent types of FBAs and PBAs are detailed in **Table 1.**

Figure 1 MEA Taxonomy

(as adapted from Ferrario and Kanavos)

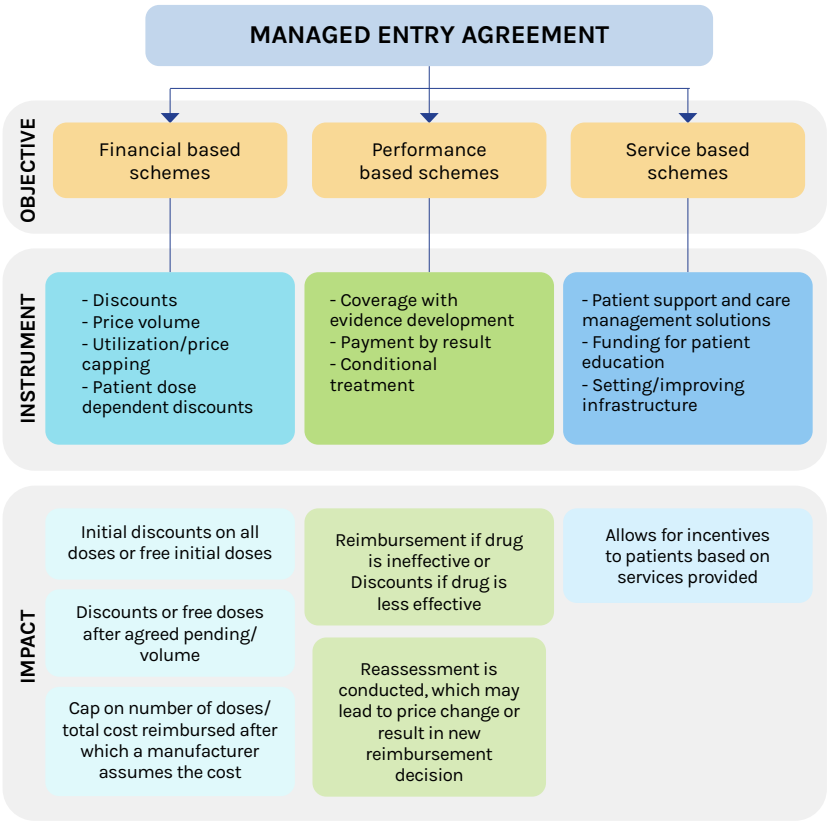

Table 1: Detailed description of different types of Finance and Performance-based agreements

Finance-Based Agreements	Rebates	Payments refunded by the manufacturer to the payer driven by incremental cost-effectiveness ratio (ICER) or simply determined during negotiations.
	Discounts	Price reductions granted to payers to improve market access, usually confidential, without affecting the drug list price. Discounts may also be agreed on manufacturer's portfolio in exchange for better price/access for another product.
	Price-volume agreement	Price drugs are reduced based on sales volume. Alternatively, depending on the total sales volume, the price will be discounted for all units sold, according to a predefined scheme.
	Utilization cap	At patient level, it aims at capping the yearly price/ yearly treatment course reimbursed. Additional treatment courses are provided by the manufacturer for free. At population level, beyond the cap, manufacturers may have to reimburse the full/ part retail price/ex-factory price, depending on the agreement.
	Fund-based payment	Such as national silo fund for specific conditions (e.g., the Cancer Drugs Fund in the UK that pays for new cancer drugs rejected by the NICE).
	Cost-Sharing	Manufacturers share in the cost with Payers of introducing a product on to the market on an agreed upon basis, amount, rate, duration, etc.
	Free Initiation Treatment	Manufacturers will provide free initiation of treatment to share the financing of a product with the payer. After an agreed upon duration or number of treatments, payers assume responsibility of financing the products.
Performance -Based Agreements	Payment by result	Manufacturer pays rebate / refund to the payer if pre-determined clinical goals are not met during actual usage (Pay-for-performance, P4P).
	Conditional treatment / Discounted treatment initiation	Treatment initiation is provided for free or at a discount for all patients; payers pay full price of further therapy for responders.
	Coverage with evidence development	Product reimbursed for set period. After that time, additional evidence gathered will determine whether coverage should be expanded, withdrawn, or continued as is. A rebate may also be required if evidence is unfavourable.

Source: Dabbous M, Chachoua L, Caban A, Toumi M. Managed Entry Agreements: Policy Analysis From the European Perspective. Value in Health. 2020;23(4):425-33.

Use, Adoption, and Trends in MEA

There has been a notable surge in the implementation of MEAs over the years, particularly in high-income countries (more than 95% of all MEAs are in HICs) (4). Specifically, MEAs have been implemented mainly in European countries, while such utilization remains less common in low-income nations. Among the various types of MEAs, experience with financial-based agreements is extensive, whereas experience with outcome-based agreements remains relatively limited. Among financial schemes, price/volume agreements and discounts stand out as the most frequently employed instruments (4).

LMICs that have documented the use of MEAs have predominantly reported utilizing financial MEAs, primarily in the form of discounts. The diseases that are commonly covered under either type of MEA are NCDs, particularly cancers, chronic melogenic leukemias, osteoporosis, diabetes, and rare diseases such as multiple sclerosis (4).

To understand the situation of MEA in high-income countries we purposively looked at selecting three countries with developed Health Technology Assessment (HTA) systems. Table 2 below provides an overview of different types of MEA implemented in Australia, England and South Korea.

Table 2: Summary of types of MEAs implemented in select countries.

Country	MEA used	Medicines reimbursed
Australia	The risk sharing arrangement is captured through a legal deed of agreement ('deed') that is negotiated between the sponsor and the government. Some financial risk share arrangements can be class deeds where sponsors share the risk based on market share.	A financial risk share was mentioned for 24 medicines in the most recent public summary documents.
England	National Health Service (payer) and manufacturers have an agreement and one of the functions of Cancer Drug Fund (CDF) is managed access fund providing conditional funding for cancer drugs where uncertainty is addressed through data collection. Dominantly financial MEAs in form of discounts are used, but outcome-based MEAs are also used.	England has approved 42 medicines since introduction of CDF.
South Korea	Four types of MEAs: i) Coverage with additional evidence; ii) expenditure cap refund; iii) Utilization cap per patient; and iv) Refund/expenditure cap	As of 2019, 39 medicines had been reimbursed under RSA.

Source: Authors Analysis

Advantages and limitations of MEAs as an effective risk management tool

MEAs offer numerous benefits including reducing budget impact while ensuring early access to innovative technologies by minimizing uncertainty in clinical and cost-effectiveness data thus potentially lowering payer risks. Financial MEAs i.e., FBAs aim to enhance the financial stability of health plans and equitably allocate resources within finite budgets, achieving cost control and ensuring broader patient coverage plans (10,11,12). Payers consider that the FBAs are a resource rationing tool. Reducing the cost pressure in terms of price reduction allows coverage of a maximum number of patients and certainty of medicine budget. For outcome-based or PBAs are crucial in areas with high clinical unmet needs, small patient populations, challenging data collection, and market access uncertainty. PBAs enable both payers and patients to gain valuable experience with the medication and address clinical data uncertainty through real-world data collection, aiding collaboration between pharmaceutical companies and payers. Manufacturers employ to differentiate their products and demonstrate effectiveness against competitors (13).

Despite these advantages, MEA's implementation poses challenges, necessitating careful consideration by policymakers. A primary challenge with FBAs is the inclination of manufacturers to establish them with payers from larger market shares and higher purchasing power, thereby placing a disproportionate burden on smaller, less affluent markets. Moreover, the confidentiality of discounts and rebates to payers often obscures the actual list price of medicines, affecting External Reference Pricing (ERP), because prices are set based on official listed prices rather than on the actual net ones (14, 15). Additionally, a central issue revolves around defining the objectives of MEAs and assessing the sufficiency of evidence for informed decision-making.

For PBAs, although designed to collect real-world clinical outcome data, establishing the infrastructure for such data collection is resource-intensive and costly. Payers face challenges related to administrative burdens, resource demands, execution costs, and the complexity of implementing and executing these agreements. The intricate nature of such agreements and the associated costs can slow down access.

A case study from Italy, which has one of the oldest PBA systems, revealed that the return to payer accounted for 5% of the total expenditure in setting up the PBA scheme (16, 17). Another significant criticism is related to the outcome uncertainty in clinicaltrials, either because of theirshort duration orthe use of surrogate endpoints that may not accurately represent true endpoints, thereby undermining the very purpose of outcome-based agreements, which is to address uncertainty (18, 19, 20). Critics express concerns that MEAs may become quick fixes or ad hoc solutions. Predictability for manufacturers concerning listing and future rewards imposes constraints. For Coverage with Evidence Development (CED)-based MEAs, reversing reimbursement coverage decisions is typically challenging, further contributing to payer resistance towards conditional coverage. Lastly, from the patient's perspective, there is a fear of premature withdrawal of effective treatments if predefined criteria are not met (8, 14, 21).

Policy Implications

MEAs hold a great potential in facilitating early access to innovative medicines while addressing financial challenges.The policy recommendations outlined in this brief aim to guide healthcare policymakers from LMICs towards informed decision-making, fostering a sustainable and equitable healthcare system that meets the evolving needs of its population.

1. MEA not a quick fix - MEA should only be used when the traditional reimbursement model like health technology assessment identifies issues to coverage decisions and requires further evidence on either clinical effectiveness or cost. MEA should be seen as a last resort and particularly as a mechanism for price negotiation.

2. Establishment of a National MEA Framework: Countries may consider establishing clear and coherent guidance for MEAs, outlining the roles and responsibilities of all stakeholders, including government agencies, pharmaceutical companies, and healthcare providers.

3. Robust Evaluation an dMonitoring Mechanism: It is crucial to develop a robust evaluation and monitoring mechanism for MEA's to assess their impact on patient outcomes, healthcare costs, and overall healthcare system sustainability. Regular assessments will enable evidence-based adjustments and improvements to the agreement terms.

4. Stakeholder Collaboration: Collaboration among all stakeholders is essential for the successful implementation of MEAs. Engaging healthcare experts, patient advocacy groups, and pharmaceutical industry representatives in the decision-making process will lead to fair and transparent agreements that prioritize patient welfare.

5. Continued knowledge exchange and Capacity Building: Initiating knowledge exchange programs and capacity-building initiatives for healthcare professionals, policymakers, and stakeholders will foster a better understanding of MEAs and their potential benefits. This will help build expertise and ensure effective negotiation and implementation of agreements.

Acknoweledgement

This policy brief is a part of the research project titled "Development of policy options to support reimbursement decisions on high-cost health interventions in Thailand's public healthcare system". HITAP was commissioned by the National Health Security Office (NHSO) in Thailand to conduct this study with funding from the Health Systems Research Institute (HRSI). This policy biref was written in consultation and reviewed by Saudamini Dabak & Assoc. Prof. Wanrudee Isaranuwatchai from HITAP.

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For the list of references, please visit
https://www.hitap.net/en/research/188013

CHAPTER

3

INNOVATION AND DIGITAL HEALTH

Discover cutting-edge innovations transforming healthcare. Explore how technology and digital health enhances patient care and drives global advancements in health policy and services.

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November 2023

HITAP
Health Intervention and Technology Assessment Program

Unveiling Thailand's Path to Open Data for Health Policy

Highlight of the study

- Open data is widely recognized as valuable, especially during the COVID-19 pandemic, highlighting the need for up-to-date information systems, leading all sectors to acknowledge its significance in enhancing efficiency, fairness, and societal development.
- These open data movements observed during the pandemic raise important policy questions regarding how to leverage and sustain these movements for long-term improvements of the health system
- This policy brief provides a concise overview of perspectives gathered from the data custodian, data users, case studies, and experts, highlighting the potential of open data systems and addressing the future trajectory of Thailand's health sector through the implementation of an open data policy.

Open Data for Health Policy Research

The Thai government, along with the Ministry of Public Health and other relevant agencies, collaboratively supports research on Thailand's health policy by utilizing open data. They aim to promote information disclosure, facilitate data exchange, and link databases through platforms like www.data.go.th, managed by the Digital Government Development Agency (Public Organization). Additionally, the private sector and civil society have created software and applications to collect health data and offer various health services, which proved crucial during the COVID-19 outbreak. This concerted effort has garnered significant attention in Thailand and led to the advancement of big data management and the establishment of a health information management system.

The multitude of agencies in Thailand possess the necessary expertise and capabilities to handle open data; however, the captivating challenges lie in fostering collaboration among these agencies, determining the path for health information disclosure cooperation, and ensuring data privacy protection while facilitating information transparency, demanding a collective effort from all sectors to uncover solutions.

This Policy Brief presents key perspectives from data custodians, data users, case studies, and experts on open data systems, synthesized from the knowledge exchange forum, " Open Data Movement to Support the Development of Research and Thai Health Policy" held on March 3, 2023, featuring a panel discussion led by Dr. Piya Hanvoravongchai, Secretary-General of the Thailand's National Health Foundation, and the research team from the Open Data Catalytic Initiative for Research and Policy Support in Thailand under Open Data Catalytic Initiative for Research and Policy Support in Thailand, WHO-Royal Thai Government Country Cooperation Strategy (CCS). The discussion also invited presentations by Dr. Lalitya Kongkham, Deputy Secretary-General of the National Health Security Office; Prof. Dr. Weerasak Jongsoowiwatwong, Faculty of Medicine Prince of Songkhla University; Ms. Nongnuch Tantitham, Deputy Director of the Injury Prevention Division, Department of Disease Control; and Dr. Boonchai Kitsa Nayothin, M.D., founder and president of Asia eHealth Information Network (AeHIN).

policy brief

Importance of open data for better health: perspective from data custodian

The National Health Security Office (NHSO) recognizes the significance of data utilization during a COVID-19 outbreak, integrating COVID data from various departments such as the Ministry of Public Health and the Department of Medical Sciences. The Health Link platform facilitates cooperation, connecting beds and patients, while collaborating with organizations like the WHO for analysis and preparedness. However, the challenge lies in obtaining comprehensive data from all service units and ensuring open access for researchers and those interested in advancing the country's public health and insurance systems.

Open data utilization: perspective from data user

Researchers emphasize that the key to utilizing open data for health lies in questioning and asking relevant queries. This approach not only provides users with insights into the purpose and format of the data they seek but also aids in the development of a valuable open data system and database for future research. Although numerous databases are currently open for access, their usefulness is limited since no one delves deeper by posing questions to utilize the information effectively. Accessing a database does not guarantee its usability as certain datasets may contain confidential and personally identifiable information.

Therefore, individuals intending to use such data must be aware of ethical considerations and take appropriate actions. Thailand has taken significant steps in this regard by developing and supporting an open access system for health data through collaboration between the NHSO and the National Science and Technology Development Agency (NSTDA).

Furthermore, during the data analysis process, it is crucial to examine and comprehend the data thoroughly to avoid extracting or analyzing inaccurate information. Effective visualization of the data analysis results facilitates understanding and enables users to apply further inquiries.

Open Data Governance and Ecosystem: perspective from expert

Initially, in accordance with the WHO mandate for the governance of open health information systems, five main characteristics were identified. Firstly, data quality is crucial, emphasizing the need for accurate and reliable information. Secondly, data integrity ensures that the owners' information remains secure and undisclosed without authorization. Thirdly, transparency is vital, promoting openness and accessibility of health data. Fourthly, accountability is emphasized through the ability to audit and examine the system. Lastly, innovation is encouraged, enabling further advancements in the field.

The Thai Health Information Standards Development Center and Asia eHealth Information Network play a significant role in developing and establishing consensus on the key principles of open data governance in health across Asia. Experts in open data systems concluded that health-related open data should consider three aspects. Firstly, data privacy is paramount, ensuring the safeguarding of personal information and fostering trust among information providers. Secondly, generating benefits for the health system by establishing standards and promoting collaboration among agencies to facilitate information sharing. Finally, prioritizing equality by not only focusing on government benefits but also considering the interests of the people. This involves granting the public rights and ownership over their data, requiring permission for data usage.

Case study:
3 databases of road traffic mortality rates to open data

The integration of road traffic mortality data is a result of a cabinet resolution that authorized the Ministry of Public Health to oversee the integration process involving three key agencies: the Department of Disease Control, The Royal Thai Police, and the Central Motor Vehicle Accident Victims Protection Co., Ltd. This integration aimed to consolidate data from the years 2011 to 2021. Once the integration was completed, it became apparent that government agencies, interested individuals, and academics had a high demand for accessing this comprehensive dataset. The website www.data.go.th was established to showcase the recorded data from 2011 to 2022, including information from the Injury Surveillance (IS). It is important to note that the privacy of the data owners was taken into consideration during this process. However, a challenge arises with the disclosure of such data, as users often lack the necessary knowledge and skills to analyze and interpret raw data. This includes a lack of understanding of variables' meanings and data management, hindering the development of effective accident prevention policies at the provincial or local level.

Summary and Discussion

In Thailand, one of the key challenges in the realm of health open data is the lack of a public campaign to raise awareness and inform interested parties about this open data movement. Currently, individuals resort to using information from unknown sources or employing unconventional methods to access health data, despite the existence of databases. Thus, there is a pressing need for policy support to disseminate information and establish a public relations platform dedicated to open information for those who are interested. This support should extend beyond research applications and include the integration of open information into educational curricula for students. Presently, Thailand has made progress by creating various databases and expanding access to open health data at district, provincial, and national levels, thereby facilitating accessibility. However, looking ahead, the utilization of open data is expected to increase further. Therefore, Thailand should develop a robust system that promotes and facilitates easy access to information while also ensuring appropriate safeguards are in place to protect personal health data. This can be achieved through the implementation of processes for recording and storing de-identified data, allowing for academic use and research that tackles complex and diverse health issues, ultimately driving the advancement and utilization of open data analysis in the country.

This document is one of the deliverables under the "Open data catalytic initiative for research and policy support in Thailand" project.
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IMPLEMENTATION OF A VIRTUAL CONSULTATION PLATFORM (VCP) FOR HEALTHCARE PROVIDERS INTEGRATED WITH A PATIENT-FACING MOBILE APPLICATION

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Key Messages

- NUHS telemedicine service was developed to improve patients' and caregivers' convenience in accessing patient care and to prepare for future crises that hinder in-person clinical consultation
- The key enablers of the telemedicine service were mainly due to strong cross-collaboration between the cross-functional delivery teams in NUHS and Synapxe Pte. Ltd. that supports technical development of the service and Covid-19 that increased the uptake
- An automated scheduling process, namely the Virtual Consultation Platform, has helped to alleviate the burden of healthcare providers' staff due to the additional work process of telemedicine provision
- NUHS is exploring the use of telemedicine that will be expanded beyond existing outpatient appointments

Background

Telemedicine is an intervention used as an innovative solution to tackle the challenge of equitable access to health services. Thailand is currently actively working to establish a nationwide telemedicine system. Nevertheless, the widespread implementation of telemedicine across the country has encountered many challenges. To effectively identify these challenges, a qualitative study was conducted to identify the key gaps in the provision of telemedicine services in Thailand. To supplement the findings of this study, an international case study was subsequently undertaken to gain a broader perspective on the challenges faced in telemedicine. The objective of this case study was to identify and assess the ways in which other countries are addressing the gaps similar to those seen in Thailand. As a part of this case study, telemedicine services from India and Singapore were closely examined.

This policy brief aims to provide an overview of the National Health University System (NUHS), Singapore's telemedicine service. The document will delve into the origins of the service, its implementation process, and the factors contributing to its successful execution.

Methods

An open call for telemedicine case study was widely promoted through the Health Intervention and Technology Assessment Program's (HITAP) existing networks. This was an opportunity to identify case studies of telemedicine service delivery beyond those present in academic literature and engage with the telemedicine implementers. Following this call, submitted case studies were presented to relevant stakeholders in Thailand, who subsequently selected two specific cases, namely OneNUHS and eSanjeevani, for an in-depth study. Following the identification of the case studies, semi-structured interviews with the case study authors were carried out. The transcripts were coded by HITAP researchers and triangulated with document reviews. Cases were described narratively and validated with the corresponding telemedicine implementers.

policy brief

About the National University Health System, Singapore

The National University Health System (NUHS) Singapore is one of three public healthcare clusters in Singapore that covers about 1 million residents of West Singapore [1]. Under 21 healthcare providers, consisting of three tertiary hospitals, three acute hospitals, two community hospitals, three national specialty centers, seven polyclinics, three family medicine clinics, and three primary care networks.

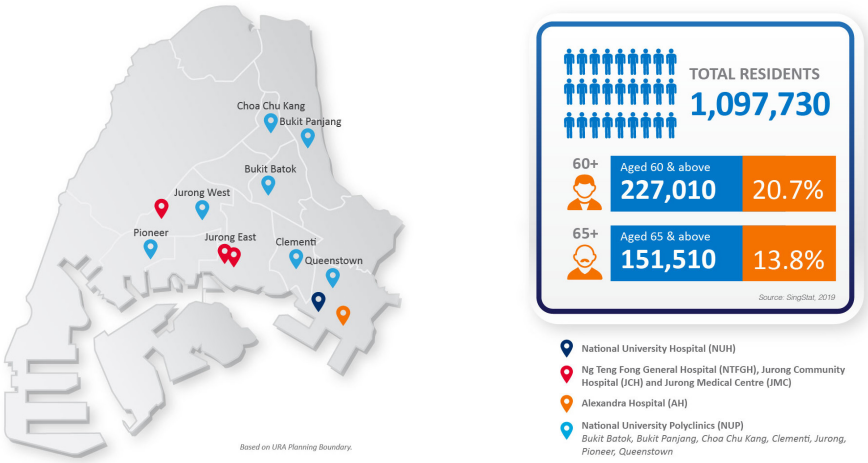

Figure 1. NUHS institutions and catchment area (West Singapore) [1]

Inception of the telemedicine service

Before the COVID-19 pandemic, NUHS institutions had already started using telemedicine to enhance patient care. However, implementation was fragmented with each institution taking individual initiatives. NUHS group realised the future potential use of telemedicine in patient care; thus, made a concerted effort to adopt telemedicine across all institutions.

The main objectives for developing the telemedicine service were to:

- **Convenience** – facilitates access to care for patients with low mobility while reducing the need for caregivers to take leave from work to accompany the patient on a physical visit.
- **Future Proof** – be prepared for future crises that disallow patients to have an in-person consultation and ensure continuation of care.

An initial step was to understand the size of the demand, capacity and capability of the staff and digital infrastructure in each institution. A team was formed at the NUHS group to develop a telemedicine feature, with technical support from Synapxe Pte. Ltd., a national health technology agency supporting government institutions in developing digital technologies [2]. This service was piloted in Alexandra Hospital in August 2021 – a first for public healthcare in Singapore and was subsequently scaled up across all the hospitals and polyclinics in NUHS.

Overview of the telemedicine service

The telemedicine service was developed as a feature in the OneNUHS App, a mobile application available to patients across all institutions under NUHS [3]. The service allows patients to have online consultations with their physicians and order their prescriptions, if applicable.

From the patients' perspective

Through OneNUHS, patients and caregivers can manage their appointments (Figure 2) after logging in with their Singpass [4], a trusted digital identity of Singapore residents providing convenient and secure access to government and private sector services online. On the day of their consultation, patients will receive a notification, view the estimated waiting time and their queue status. After the consultation, patients will be asked to confirm the purchase of prescribed medication and select whether they would like the medication delivered or be made available for self-pickup before being directed to the payment page.

From the providers' perspective

NUHS found that online consultations created an extra burden on the healthcare providers' staff, as it involved a separate process from in-person consultations. This process included setting up a virtual meeting link, sending the link to patients, sending reminders, and preparing a device for the physicians to conduct the consultation. Moreover, without a proper system, this process was susceptible to human errors.

NUHS introduced a Virtual Consultation Platform (VCP) with technical assistance from Synapxe Pte. Ltd. This platform streamlines the process of providing online consultations and reduces the workload of providers' staff (Figure 3). The VCP interfaces with the NUHS electronic medical records system, Epic, to extract a list of upcoming video consultation appointments. VCP then automatically schedules a corresponding Zoom meeting and sends this information to the patient via the OneNUHS App. On the consultation day, clinicians can launch the video consultation directly from the VCP platform.

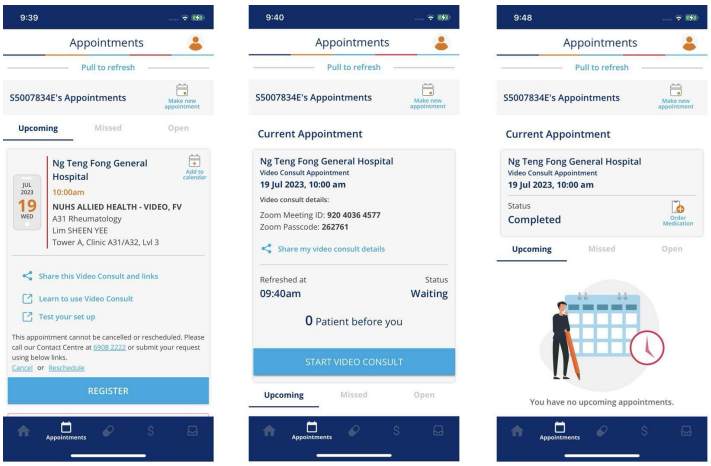

Figure 2. OneNUHS interface on the appointment page (source: OneNUHS application)

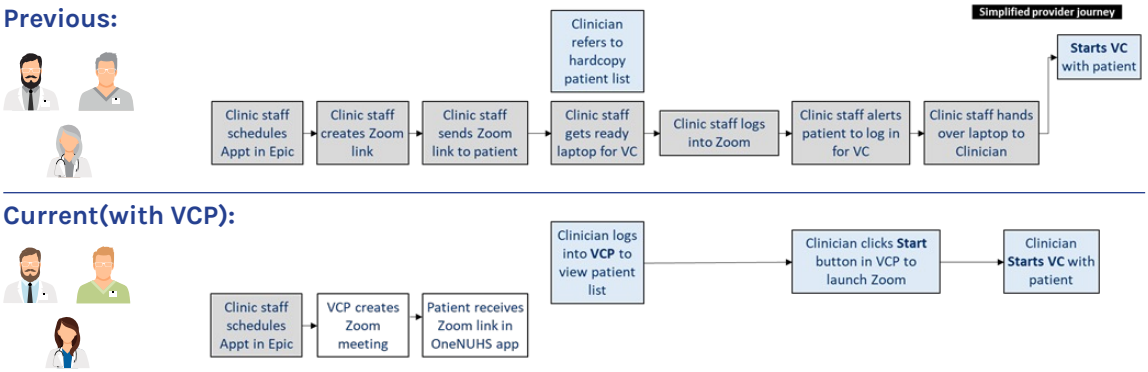

Figure 3. Workflow comparison before and after the implementation of VCP

Evolution of the telemedicine service

COVID-19 elevated digital initiatives from a "nice-to-have" to the new normal in healthcare, which escalated the service uptake. NUHS leveraged this burning platform to transform patient experience and care by using telemedicine to provide patients with repeat visits and ongoing care remotely via video-conferencing tools where in-person clinical consultations are not necessary or not possible.

The patient and provider experiences for conducting telemedicine through NUHS digital platforms have been continuously improved. NUHS focused on reducing the barriers to adoption by:

- Addressing usability concerns
- Focusing on education for staff and users.

Some notable improvements include increasing the default session timeout length to reduce the need for repeated sign-ins by providers and developing the ability for providers to trigger pre-defined messages to patients to provide them with timely updates while waiting for their consultation.

Monitoring and impact evaluation of the telemedicine service

With the aforementioned objectives of the service, NUHS focuses on evaluating the impact on the uptake of the service, user experience and satisfaction. Additionally, on-boarding the telemedicine service to the OneNUHS application and adding the VCP feature were intended to:

- Minimize the amount of manual processing required by the staff when scheduling video consultations,
- Present healthcare providers with a single consolidated view of their patient lists for the clinic session,
- Provide patients with support throughout the entire video consultation session, from registration, consultation, ordering of medication and payment, and
- Develop a user interface (UI) that enables users with basic tech literacy to adopt the service.

NUHS monitors the number of teleconsultations per specialty in each institution and the polyclinics monthly. This also includes the proportion of video teleconsultations that were carried out through the OneNUHS App. In addition, the project team meets with the clinical operations teams monthly to review processes and to plan future improvements.

User experience and satisfaction are monitored via feedback from various channels such as the Apple Store, Google Play Store, support email and contact centre.

Barriers and mitigation of impediments to use of the telemedicine service

Variation in operational workflows between institutions

To address this issue, a cluster work group was formed, comprised of Telemedicine Operations Lead appointed by each institution to understand the differences and user needs to establish a viable common solution.

Singpass as an on-boarding requirement

Access to the OneNUHS app is secured with Singpass to ensure the safety of user authentication before allowing access to patient information. However, this requirement creates barriers for certain segments of patients who do not have Singpass credentials. To address this issue, manual workflows have been implemented to ensure that teleconsultation services are still available to these groups (e.g., sending links for teleconsultations or medication orders via email).

Way forward

Going forward, NUHS is exploring how the platforms can be expanded beyond existing outpatient appointments to deliver care across a wider spectrum (e.g. right siting of care and post-discharge support).

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This policy brief can be downloaded from www.hitap.net

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eSanjeevani, the National Telemedicine service: Bridging healthcare gaps in India

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Key messages

- eSanjeevani was developed primarily to tackle the challenges of inequitable healthcare access and the shortage of healthcare professionals in India
- The 'one application' approach ensured that only one application is used for the national telemedicine service delivery, thus ensuring interoperability among different healthcare systems
- Provider-to-provider types of teleconsultations, involving healthcare workers at primary healthcare facilities and doctors at tertiary healthcare facilities, allows eSanjeevani to address the digital literacy challenges prevalent in rural India
- One key enabling factor for the implementation of eSanjeevani was the establishment of dedicated workforce solely for digital service delivery, thereby preventing an undue burden on the existing workforce

Background

Telemedicine is an intervention used as an innovative solution to tackle the challenge of equitable access to health services. Thailand is currently actively working to establish a nationwide telemedicine system. Nevertheless, the widespread implementation of telemedicine across the country has encountered many challenges. To effectively identify these challenges, a qualitative study was conducted to identify the key gaps in the provision of telemedicine services in Thailand. To supplement the findings of this study and to gain a broader perspective on the challenges faced in telemedicine, an international case study was subsequently undertaken. The objective of this case study was to identify and assess the ways in which other countries are addressing the gaps similar to that seen in Thailand. As a part of this case study, telemedicine services from India and Singapore were looked into closely.

This policy brief aims to provide an overview of India's national telemedicine service, eSanjeevani. The document will delve into the origins of the service, its implementation process, and the factors contributing to its successful execution.

Methods

An open call for telemedicine case study was widely promoted through the Health Intervention and Technology Assessment Program's (HITAP) existing networks. This was an opportunity to identify case studies of telemedicine service delivery beyond those present in academic literature and engage with the telemedicine implementers. Following this call, all received case studies were presented to relevant stakeholders in Thailand, who subsequently selected two specific cases, namely OneNUHS and eSanjeevani, for an in-depth study. Following the identification of the case studies, semi-structured interviews with the case study authors were carried out. The transcripts were coded by HITAP researchers and triangulated with document reviews. Cases were described narratively and validated with the corresponding telemedicine implementers.

Rationale for the development of eSanjeevani

India, as the world's most populous nation with over a billion people, faces significant challenges in ensuring the equitable distribution of healthcare services. The concentration of healthcare facilities in urban areas, coupled with nearly 70% of the national population residing in rural India is often cited as a major challenge is healthcare access in India [1]. Adding to this challenge is the shortage of healthcare professionals. Studies indicate that India requires an additional 1.8 million healthcare workers to meet the World Health Organization's recommended standard of a 1:1000 doctor-to-population ratio [2]. Furthermore, tertiary and secondary healthcare facilities often bear the burden of tasks that could have been efficiently managed at primary healthcare centres, thus compromising the qualit of care provided [3]. These factors undeniably impact India's healthcare delivery system.

To tackle these multifaceted challenges, the Government of India introduced the Ayushman Bharat scheme in 2018 with the overarching goal of achieving Universal Health Coverage (UHC) [4]. Within this scheme, eSanjeevani – the National Telemedicine Service of India emerged as a telemedicine solution aimed at providing comprehensive primary healthcare and specialist consultations. eSanjeevani allows easy access to healthcare through its smart phones applications or by visiting the nearest healthcare centre for a provider-to-provider remote consultation.

Genesis of eSanjeevani from Sanjeevani

The origins of the present-day eSanjeevani platform can be traced back to a pilot project titled 'Development of Telemedicine Technology' initiated by the Ministry of Communications and Information Technology in collaboration with the Ministry of Health and Family Welfare (MoHFW) in the year 1999 in India [6]. The objective of this pilot initiative was not only to enhance the national healthcare delivery system but also to optimise the utilisation of medical resources.

The implementation of the telemedicine system under this pilot project at three tertiary hospitals in the country, was achieved by creating an indigenous telemedicine platform developed by the Centre for Development of Advanced Computing (C-DAC), Mohali [5, 6], an autonomous scientific body operating under the Ministry of Electronics and Information Technology.

At the core of the then telemedicine solution was the integrated software named 'Sanjeevani', that provided **doctor-to-doctor teleconsultations** by consolidating patient information into Electronic Patient Records (EPRs). Sanjeevani also offered imaging capabilities for digitised radiographic images and ensured efficient data transfer and real-time hardware-based video conferencing.

Subsequently, after the decision to establish a nationwide telemedicine service under the Ayushma Bharat scheme, a survey was conducted to identify and assess all telemedicine applications that were currently in use across the country. The objective of this survey was to pinpoint a single telemedicine service suitable for nationwide implementation. The goal of this **"One Application"** approach was to eliminate the silos in telemedicine projects and establish interoperability among various healthcare systems. As a result of this assessment, C-DAC's Sanjeevani was selected for a nationwide rollout by the MoHFW as 'eSanjeevani'. Several reasons supported the selection of eSanjeevani as the national telemedicine platform:

1. User-Friendly and Intuitive Interface: eSanjeevani was designed with input from medical experts, resulting in a user-friendly and intuitive interface.

2. Proven Track Record: eSanjeevani had a track record of being used in India from 1999. Additionally, it had been implemented in four other countries, namely Myanmar, Tanzania, Armenia, and Kyrgyzstan, through bilateral arrangements.

3. Government Compliance: As a Government institution, C-DAC ensured that the service it developed complied with the data privacy and confidentiality standards of the Government of India.

Implementing eSanjeevani: A closer look

eSanjaaveni started its operations in November 2019 by providing population level doctor-to-doctor teleconsultations, under a variant called eSanjeevani Ayushman Bharat Health and Wellness Centers (eSanjeevani AB-HWC). eSanjeevani was designated for implementation following a 'Hub and Spoke Model' architecture to provide this doctor-to-doctor consultation. **Figure 1** illustrates the 'Hub and Spoke Model' of telemedicine service delivery.

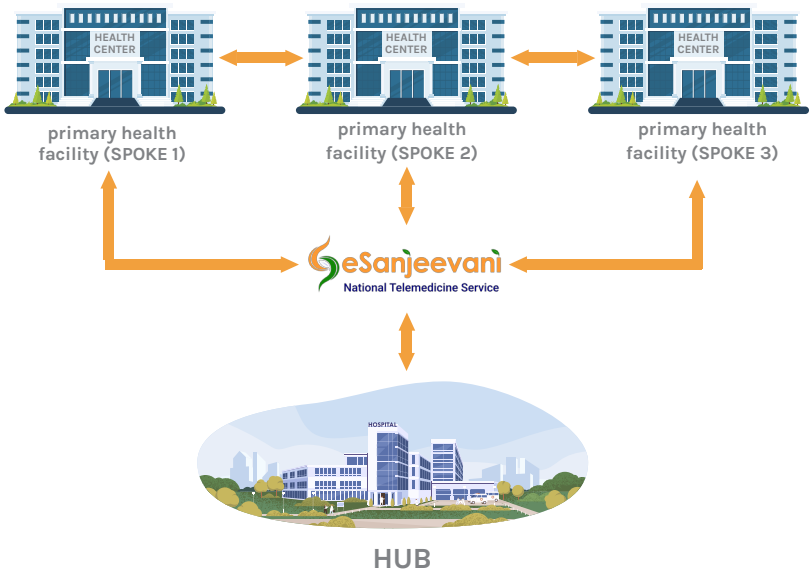

Figure 1: Schematic representation of the 'Hub and Spoke model' of telemedicine service deliverry.

The tertiary or secondary level hospitals in the country act as Hubs of telemedicine service provision. These Hubs are equipped with dedicated telemedicine departments or centres which can deliver remote consultation and prescription to the Spokes. These dedicated telemedicine centres ensure that the newly introduced telemedicine service does not cause added workload to the already overburdened healthcare workforce. The Spokes are typically the primary level hospitals. **Figure 2** illustrates the patient's journey when they seek medical assistance at a primary care centre, where the healthcare practitioner conducts a remote consultation with a specialist at the hub.

Subsequently, the 2020 COVID-19 pandemic induced lockdown led to the regular Outpatient Departments (OPDs) being closed, necessitating the introduction of a patient-to-doctor teleconsultation service alongside the previously established doctor-to-doctor variant of eSanjeevani. In response to this demand, eSanjeevani OPD, a patient-to-doctor teleconsultation service, was introduced in April 2020.

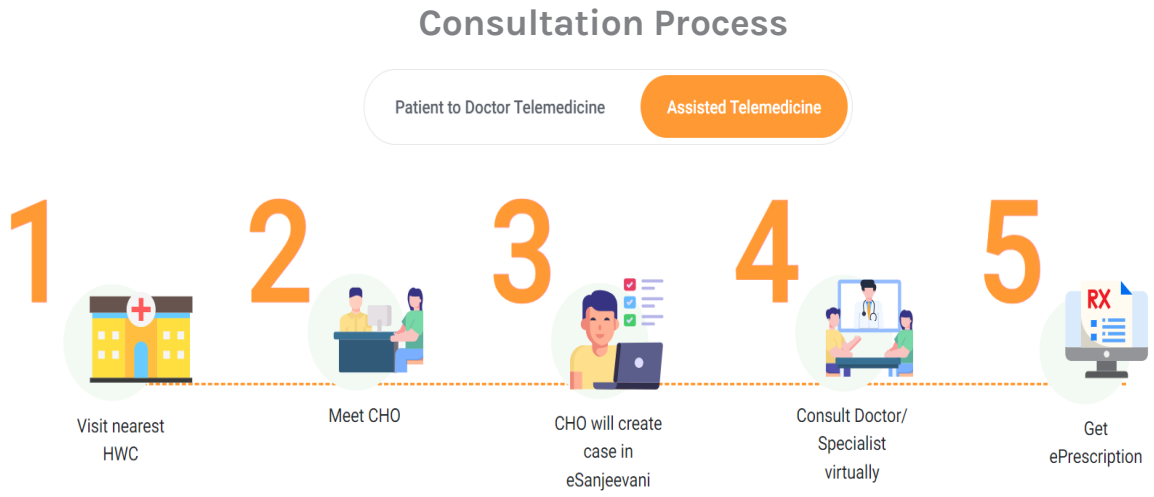

Figure 1: Patient journey from their visit to HWC to e-prescription. Adopted from eSanjeevani's official website. CHO: Chief Health Officer, HWC: Health and Wellness Centre

eSanjeevani is available as a web-application as well as in the form of Android and iOS mobile applications. Users in the doctor-to-doctor variant access eSanjeevani on laptops, desktops and tablets even, whereas majority of the beneficiaries/patients of patient-to-doctor variant of eSanjeevani use eSanjeevani through mobile devices/smartphones.

The entire process and data uploaded on eSanjeevani is secured by its developers. All stakeholders have their login IDs and passwords to access their data and provide consultations. System monitoring is conducted by administrators at the district, state, and national levels. C-DAC, Mohali, has full access to nationwide data. Monitoring administrators at each level can check user attendance, the number of consultations, average consultation times, consultation summaries, and dormant summaries through a dashboard module. This allows for continuous monitoring, thus providing a pathway to address the anticipated and unanticipated challenges in service delivery.

Impact of eSanjeevani

With its very large volume of teleconsultations, eSanjeevani has evolved into the world's largest telemedicine implementation platform in primary healthcare. Reports suggests that the number of consultations facilitated by eSanjeevani has grown exponentially since its inception in 2019, with COVID-19 serving as a catalyst for this increase in uptake. Currently, eSanjeevani operates through 131,538 Health and Wellness Centres (HWCs) as spokes and over 16,000 as hubs. eSanjeevani boasts over 235,000 doctors, specialists, and health workers as telemedicine practitioners, operating in all states and union territories of India. It serves approximately 450,000 patients daily, with the capacity to handle up to 1 million patients per day.

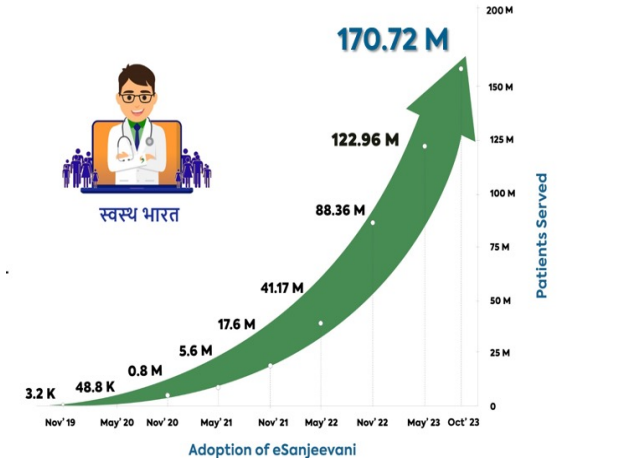

Figure 2: Number of teleconsultations facilitated by eSanjeevani from November 2019 to October 2023

Enablers and barriers

The driving force behind the initiation of digital health services in the country was the escalating demand for healthcare services in proportion to the increasing population, especially in the rural areas. During the COVID-19 pandemic, when in-person healthcare services were disrupted, digital health services became imperative, leading to the widespread adoption of e-Sanjeevani nationwide. Notably, the establishment of dedicated telemedicine departments or centres, staffed by specialists and super-specialists hired explicitly for the purpose of delivering teleconsultations, has been mentioned as a facilitator in expanding the service's reach without overloading the existing service providers.

Barriers to the inception of telemedicine services included providing reliable internet connectivity to every healthcare centre, especially in rural settings, and creating user-friendly software. In India, healthcare is a state subject, so the states took on these challenges by providing internet connectivity, necessary hardware, and other facilities required for teleconsultations. e-Sanjeevani developers made the platform user-friendly to ensure that both patients and doctors can easily fill out electronic health records to initiate consultations.

Way forward

Going forward, eSanjeevani is planning to integrate Artificial Intelligence models into the platform with the aim of enhancing data collection, elevating the quality of care, and ensuring quality assurance of the teleconsultations.

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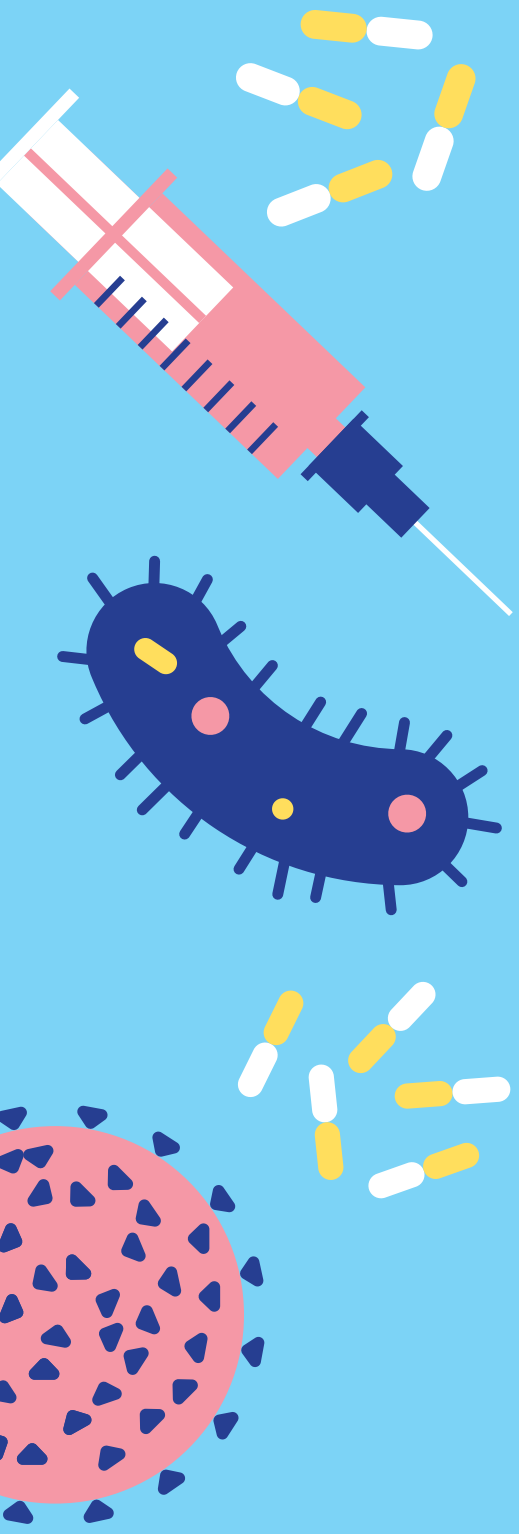

CHAPTER

4

ANTIMICROBIAL RESISTANCE (AMR)

Explore Thailand's policies to combat antimicrobial resistance, a crucial public health challenge.

Issue#19 April 2021

Addressing Antimicrobial Resistance in Thailand: A Policy overview

Antimicrobial Resistance (AMR) occurs when pathogens (bacteria, viruses, fungi, and parasites) develop a resistance or tolerance to the medicines that are used to combat these microorganisms, such that these treatments are no longer effective. AMR has been increasing in low-, middle- and high-income countries around the world in recent years, including in Thailand where a 2011 study estimated that there were 87,000 new AMR infections, an additional 3 million days of hospital stay, and 38,000 deaths of patients with AMR infections per year.[15, 16]

Thailand produced its first national strategic plan on AMR (NSP-AMR) which was the product of The Coordination and Integration Committee on Antimicrobial Resistance, set-up in May 2015, with 5 sub-committees dealing with different components aligned with the One Health approach[1] and a working group to coordinate the progress. Figure 1 shows the framework guiding the implementation of the NSP-AMR.

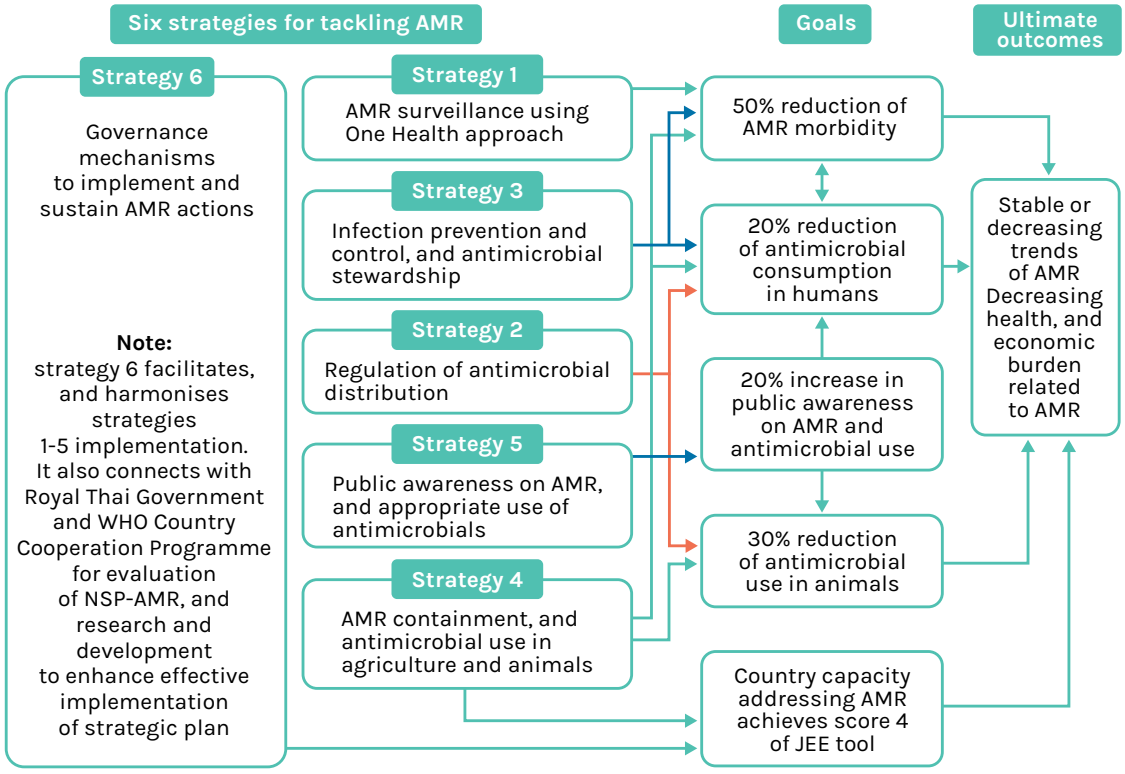

Figure 1. Six Strategies to Tackle AMR and achieve NSP goals – from Sumpradit N, Wongkongkathep S, Poonpolsup S, et al. New chapter in tackling antimicrobial resistance in Thailand. BMJ.

1 What is One Health?

'One Health' is an approach from the collaboration between multiple health science to obtain optimal health of human, animals, plants, and the shared environment. The main causes of AMR can be attributed to antimicrobial overuse and misuse in human, animal, and environmental sectors. A One Health approach is crucial for tackling AMR as it captures the interconnectedness across these sectors and uses a holistic framework for addressing this problem.

Policy Brief

• Steps taken to tackle AMR in Thailand so far

Goals 1, 2 and 3: 50% reduction in AMR morbidity, 20% reduction in antimicrobial consumption in humans and 30% reduction in antimicrobial use in animals [18-23]

Surveillance is vital for evidence-informed decision making and developing comprehensive awareness of AMR. Information sources include the National Integrated AMR Surveillance System (Thai-SAC) which provides data on antimicrobial consumption, and Thailand's Food and Drug Administration (Thai-FDA) annually reports on the value and volume of all pharmaceutical products (including antimicrobials) used in humans and animals. Thailand has also set up a National Antimicrobial Surveillance Research Center (NARST) for monitoring AMR infections which helps differentiate between AMR rates and patterns across individual health districts.

Surveillance

• Infection prevention and control (IPC)

As per the World Health Organization (WHO), IPCs are made up of 6 core components - programmes, guidelines, education and training, surveillance, multimodal strategies and monitoring and feedback of IPC practices. Thailand has incorporated many of these components but the approach remains fragmented since it only involves successful local or sub-national and facility-level interventions and lacks a comprehensive national program on hospital-acquired infections.

• Antimicrobial Stewardship Programmes (ASPs)

ASPs are coordinated activities to measure and improve optimal antimicrobial use (AMU). Some examples of these are outlined below:

20% reduction in antimicrobial consumption in humans

- The Antibiotic Smart Use Program to encourage the rational use of medicines found that community pharmacists are the most important stakeholders as they dispense medications and are the first points of contact in the health system for people seeking care.

30% reduction in antimicrobial use in animals

- Research on AMU trends in companion animals in 2021 as the first step in launching a routine monitoring mechanism for these animals in 2022.
- Progress towards controlling distribution of antimicrobials, with a drive for reclassification of drugs.
- Regulations to ban the use of antimicrobials as growth promoters in the animal husbandry sector.
- Advocacy to improve awareness, establish standards and provide recommendations to all stakeholders across the continuum of antimicrobial consumption in animals, especially noting the role of veterinarians.

Goal 4: 20% increase in public knowledge of AMR and awareness of appropriate use of antimicrobials

Thai Health was mandated to partner with civil society organisations and the media to create public awareness campaigns on the appropriate use of antibiotics. Furthermore, Thailand has encouraged researchers to generate and disseminate evidence on AMR through academic channels, to improve the public's understanding.

To evaluate this goal, an AMR module was added to the Health and Welfare Survey (HWS) that is carried out in Thailand every 2 years; results of the 2017 HWS AMR module were used as the baseline for monitoring progress of Goal 4, with subsequent updates every two years.

Comparing the result of HWS between 2017 and 2019 by indicators

Needs improvement	Let's see! [1]	Success
The percentage of Thai adults who provided correct answers about appropriate antibiotic use and AMR more than 60.0%	The mean score of the awareness of the importance of appropriate antibiotic use and awareness of AMR	Information on AMR and appropriate antibiotic use reached people sufficiently.

1 This dimension wasn't recorded in 2017, hence there is no baseline

Goal 5: An increase in the capacity of the national AMR management system to level 4, as measured by the WHO's Joint External Evaluation Tool (JEE) for International Health Regulations (2005)

The JEE Tool for the International Health Regulations serves as an implementation guide to address AMR in both humans and animals, including in the agricultural sector. The tool employs four indicators (each indicator has five scores or levels)

In recognition of Thailand's progress, in the 2019 Global Health Security Index Report, Thailand was ranked 22nd out of 195 countries in the world for prevention of AMR, which explicitly considered the capacity of countries to conduct effective AMR surveillance, detection, reporting and control.

Indicators	Thailand's Score
Detection of antimicrobial resistant bacteria by designated laboratories	4
Surveillance of infections caused by AMR pathogens at designated sentinel sites	3
Healthcare associated infection prevention and control programs at designated facilities	2
Antimicrobial stewardship activities at designated centers	2

• Conclusion

Thailand's commitment to the issue of AMR as evidenced by the NSP-AMR goals and strategies offers promise as a good blueprint for other low- and middle-income countries navigating the challenges of AMR. However, like many others, this plan too will need to ensure that the most significant challenges of implementation and multi-stakeholder collaboration are addressed. As has been documented, the One Health approach will require technical capacities to be strengthened across these sectors and their efforts united, towards combating the burdens of AMR in Thailand.

Recommendations

- Develop a comprehensive National Action Plan for AMR: The WHO recommends establishment of a national action plan for AMR and offers support on how to build out its components including implementation and monitoring and evaluation
- Follow a One Health approach: Recognise the interdisciplinary, multi-sectoral nature of AMR and ensure that human, animal and environmental sectors work together. Also unite a multitude of stakeholders from different government, non-government and civil society sectors such as finance, and infectious diseases to work together
- Human resources for AMR: Provide additional routine training on AMR for healthcare professionals, pharmacists and community health workers to increase awareness, improve prescribing practices, and optimise antimicrobial use. Introduce measures to improve hygiene and sanitation procedures within healthcare settings to reduce avoidable infections
- Implement or adjust regulations to restrict availability of antimicrobials without a prescription, particularly antibiotics of strategic importance
- Conduct public information campaigns to improve the understanding of AMR in the general population

References

References for this policy brief are in the full report, please **click here.**

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