Development of health technology assessment and its decision-making process

1. Definition

"Health technology" refers to the application of science to health in the form of objects (e.g. medicines, vaccines, and medical devices), medical procedures (practices), processes or programs (course of action) used for diagnosis, treatment, prevention, and rehabilitation in order to reduce illness (1). This includes modern medicine, (Thai) traditional medicine, alternative medicine, and local innovative practice.[1]

"Health technology assessment" refers to the evaluation of health technology in terms of values and negative effects through a systematic study, analysis, and research with a well-designed framework to obtain evidence or information that shows medical, health, economic, social, ethical and/or practical impacts of health technology. The aim of these assessments is to inform policy decision-making on the choice of health technology (2, 3).

2. Importance of health technology assessment

The use of health technology inevitably has positive and negative aspects. Positive aspects include improving people's health, the economy, and social issues while negative aspects comprise financial burden, wasted time, and adverse health effects. Therefore, the decision to invest in any health technology should be based on whether the benefits outweigh the costs or whether another health technology with the same purpose is more cost-effective.

The decision to adopt health technology can occur at any level such as at an individual level (the person making the decision is responsible for the expenses and consequences which occur), the practice level (the development of guidelines by

[1]Recommendations from a stakeholder meeting on a draft of this agenda to the 7th National Health Assembly entitled "Development of system for health technology assessment in support for decision making for the universal health coverage" on 2 September 2014 at the Richmond Hotel, Nonthaburi

medical professionals), or the policy level (a decision can be made for health policy development via the utilization of public funds such as the Universal Health Coverage and Social Security Schemes.

To provide more examples, when a person is persuaded to receive new and expensive medical treatments or vaccines, it is their decision to receive and pay for such technologies. When health professionals choose treatments for their patients (for example, cancer treatments which cost several million baht to treat and have a probability of success of one in ten thousand), they should have information available for patients and their family so they can decide whether to bear the expenses. Moreover, the practice guideline should be based on health technology assessment information so that it will be the optimal choice. When the National Health Security Office (NHSO) has to decide whether cataract surgery should be included in the benefit package of the Universal Health Coverage Scheme, they need to consider the cost-effectiveness of cataract surgery and decide which target group is most suitable.

Whether the decision is made based on the individual level, practice level, or national level, it is important to have a well-informed and systematic health technology assessment to inform these decision-making processes. Moreover, this is even more significant when it concerns a large program involving a large number of the population, especially programs under health insurance, e.g. health examination involving multiple screening tests or expensive treatments or medicines. Health technology assessment for these programs requires considerable amount of knowledge and expertise. Nevertheless, the public should also have basic understanding of health technology assessment as well.

3. Health technology assessment and its decision-making process

In principal, the health technology assessment process involves setting research questions (e.g. should a diphtheria vaccine be given to adults again? At what age? What type of vaccine?), literature review regarding the advantages and disadvantages of each technology, synthesizing the evidence, analyzing the results, reaching a conclusion, making a decision, and applying the decision to real world settings. With limited financial and resources available, appropriate decisions must be made to ensure fair distribution to society.

Stakeholders involved in the health technology assessment process include those making the decisions, those affected by the decisions, and those sharing resources. This involvement should begin with setting technology assessment research questions, seeking for answers when there is information available, acknowledging the results by requesting further information, and assessing the transparency of public policy decisions, etc.

4. Situation and trend

Health technology is important to the entire population from birth until death. Some familiar or well-known examples are medicines, vaccinations, medical devices, surgery procedures, and screening tests. However, technology is like a double-edged sword in that it has both advantages and disadvantages. Its benefits can be seen in the treatment of diseases, relief, health promotion, and diagnosis, leading to a higher possibility of successfully being cured. On the other hand, the negatives are possible side effects from the use of medicines, vaccinations, or medical devices and adverse drug reactions. The use of ineffective or useless health technologies has drawbacks towards health and the economy. In addition, the use of expensive cost-ineffective technologies results in unnecessary public spending.

In Thailand, access to health technology such as medicines, vaccines, and medical devices is based on the ability to reimburse health technology and is dependent on the health benefit schemes. The development of each health benefit scheme (Social Security Scheme, the Civil Servant Medical Benefit Scheme, and Universal Health Coverage Scheme) varies among concepts, principles, and approaches. Therefore, certain health technologies may be available only through a specific health benefit scheme, while other beneficiaries under a different scheme may not have an access to the same health technology. If the services are really needed, the inability to gain such access will affect not only patients' health but also the economic status of the family, and in some cases could lead to bankruptcy. At present, the majority of people do not know much about which health technologies are reimbursable or what steps or procedures should be followed. In addition, some people may feel frustrated about some technologies that are not listed in the benefit packages or are not reimbursable as most of these technologies are advanced and expensive.

In the view of policymakers, public funding is limited while the demand for utilizing that budget is increasing. In Thailand, health expenditure increased from 3.9% in 2012 to 5-6% of GDP in 2014 (4). Each year, the Thai government invests around 13-14% of the national budget for healthcare, while government health spending in other countries is less than 10% of the total budget. Thus, it can be seen that the Thai government has already made a considerable investment in health and it is less likely that the government will increase its investment in healthcare. Therefore, being able to use the limited resources efficiently is vital. The decision to include which technologies in the health benefit package or to be reimbursed should be based on more general considerations about the advantages and disadvantages of each technology including medical, health, economic, social, ethical and/or practical aspects. However, according to the WHO's report (5), as much as 40% of the world's health spending is wasted on practices such as prescribed drugs or medical technologies with no proven record of efficacy. This reflects wasteful investment of the countries concerned and the greater need for health technology assessment in a transparent, evidence-based decision-making manner.

Health technology assessment is the study of the impacts of health technologies concerned including medical, health, economic, social, ethical and/or practical considerations. In more simple terms, such assessments refer to attempts to answer questions such as: is a technology – medicine, medical equipment, vaccination or treatment – effective and safe? To what extent will it impact the budget? How cost-effective is it in economic terms? Does its application lead to further social/ethical problems? How practical is it in view of the country's situation?

In developed countries such as Australia, Canada, France, Germany, and the United Kingdom, a health technology assessment system has been established to provide supporting evidence and necessary information to decision-makers, health personnel, and the public for making decisions on which technologies should be included in the health package and reimbursement lists. There are agencies responsible for conducting studies and formally linking the assessment with the policymaking process via supporting laws and adequate manpower and budget. Decision-making is based on criteria and considerations acceptable to the stakeholders and general public.

Supervision and assessment are conducted under the principles of good governance. The results of health technology assessment are used in the formulation of policy in various ways, including developing standards for the quality of healthcare, designing health programs, and setting the prices of products and services.

In Thailand, there have been several attempts to establish organizations for the purpose of conducting health technology assessments. Some of the organizations are the Office for Medical Technology Assessment, the Department of Health, the Health Intervention and Technology Assessment Program (HITAP), the Bureau of Planning and Strategy, the Ministry of Public Health, as well as many university academics. At present, health technology assessment results have been utilized to ensure appropriate use of heath technology and ensure equality such as:

- In the selection of medicines to be included on the National List of Essential Medicines, where more drugs such as Pegylated interferon for Hepatitis C, and Nilotinib and Dasatinibfor myeloma - a cancer of white blood cells -have been included when they were found to be essential for the treatment of patients.
- In drug price negotiations. For instance, the National Health Security Office (NHSO) and the National List of Essential Medicines Subcommittee used health technology assessment results to allude to the appropriate prices of drugs when compared to other options used based on current cost-effectiveness standards advocated in government policy. As a result, negotiations on the prices of Tenofovir (an anti-viral drug for the treatment of HIV/AIDS infections) and Pegylated Interferon alpha 2a (for Hepatitis C) have resulted in savings in the national budget by THB 375 million and THB 600 million a year, respectively.
- In the development of benefit packages in the Universal Health Coverage Scheme, such as "The development of screening tests for visual impairment and prescription spectacles for pre-primary and primary schoolchildren in Thailand". In the past, a number of Thai children were found to have visual impairment but the symptoms were not corrected because there were not enough ophthalmologists for screening. In 2010, nearly 500,000 children between 4 and 12 years old were found to have visual impairment. Of this

number, 280,000 required spectacles but only 6% were given the appropriate spectacles. The results of this study revealed that eyesight screening conducted by teachers who received practical training from ophthalmologists was efficient and feasible for implementation (6). Afterwards, the NHSO used the findings to further investigate the matter in 2014 and conducted eyesight screening tests for Thai children in 10 provinces, where 30,000 children underwent screening conducted by class teachers. This project will be extended to cover every part of the country so that children with visual impairments will receive proper care (7).

The cases above are some of the examples that illustrate the significance of health technology assessment in Thailand's policy formulation and to maximize efficiency in health investments.

5. Limitations for implementation

Despite the fact that there are a number of institutions that have roles in conducting health technology assessment and linking with the public sector, there is no formal link established to convey the research results to policymakers; there is also no law to accommodate the work. In addition, health technology assessments are still scattered between several institutes/agencies. As the budget for health technology assessments comes from various sources, these institutes/agencies suffer from funding sustainability. Consequently, most assessments are conducted as a request from donors rather than the need of the country. The capability and number of personnel is still limited as well. Moreover, current policy decision-making mechanisms are under the Subcommittee for the Development of the National List of Essential Medicines and the Subcommittee for the Development of Benefit Package; there is no central mechanism for establishing standards and guidelines for health technology assessment under the Social Security Scheme and the Civil Servant Medical Benefit Scheme. As a result, the benefit of health technology assessment is not fully utilized and there is variation among the public health insurance schemes.

Furthermore, policymakers and stakeholders who need to utilize the results from health economic evaluations for decision-making - including those at the national level,

hospital level, practitioner level, and individual level - lack understanding about health technology assessments. Also, there is some doubt regarding the current decision-making process, some concerns regarding the un-standardized process, strict access to information, lack of participation, and lack of recognition of the importance of health technology assessments. All these threats pose an obstacle to the participatory process from various sectors in the decision to select a health technology and its application.

6. Policy, measures, and laws concerned

6.1 The Medical Device Act B.E. 2551 (2008) Section 6 (8) states that "the Minister - under the advice of the Medical Device Committee - shall have the power to determine which medical device requires technology assessment". Under Section 22, it states that "registered establishments that wish to produce or import medical devices that require technology assessment shall submit an application for assessment to ensure that such medical device is effective, meets quality standards, and is safe for use, while also including an assessment of its effect and cost-effectiveness in economic and social terms to ensure that the use of the medical device is appropriate in a comprehensive and fair manner" (8).

6.2 The Statute on National Health System B.E. 2552 (2009) gives importance to having a national mechanism to oversee the development of the health system using appropriate knowledge and technology. Chapter VI, Section 52 states that "the State shall put in place a national mechanism to oversee the direction and development of public health service systems, mechanisms to control, supervise, and develop the quality of public health services, and mechanisms to control, monitor, and develop appropriate applications of scientific knowledge and technology, as well as other necessary mechanisms."

6.3 Health technology was listed on the agenda of the 60th World Health Assembly in 2007 and Resolution WHA60.29 concerning multiple problems with health technologies, especially medical devices was adopted. It was mentioned how resources were wasted as a result of inappropriate health technology investment and how they did not meet the needs, infrastructure, and manpower of the country. As a result, the resolution urged member states "to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and

management of health technologies in collaboration with personnel involved in health-technology assessment and biomedical engineering" (1). Later on, the 67th World Health Assembly in 2014 passed Resolution WHA67.23 on "Health intervention and technology assessment in support of universal health coverage", recognizing the importance of evidence-based policy development and decision-making in health systems and urging member states to take actions, among others, to consider establishing national systems of health intervention and technology assessment to inform policy decisions, to strengthen the link between health technology assessment and its application, to develop national methodological and process guidelines for health technology assessment to ensure transparency and quality, and to develop and improve the collection of data on health intervention and assessment, training relevant professionals so as to improve assessment capacity (9).

6.4 Section 6.2 of the policy statement of the current (2014) Public Health Minister (Professor Dr. Rajata Rajatanavin) mentions the strengthening of effective mechanisms for drug systems development and assessment of health intervention and technology to promote rational use of technologies and local industries, revision of legal provisions to promote an appropriate and cost-effective use of vaccines and medical technology. This reflects how the government attaches importance to the issue as part of the country's sustainable development of the drug systems and technologies.

7. Role of organizations and stakeholders

7.1 The Subcommittee for the Development of the National List of Essential Medicines has a role to select and review medicines to be included in the National List of Essential Medicines. They are the ones who utilize the cost-effectiveness information (which is a part of health technology assessment) for the National List of Essential Medicines' development which includes value-for-money of the medicine, budgetary impacts, and drug price negotiations.

7.2 The Subcommittee for the Development of Benefit Package is the one who uses health technology assessments for the consideration of provision of necessary and appropriate health service systems to be included in the benefit package of the Universal Health Coverage Scheme. They also have a duty to develop service systems and ensure equality among the three health insurance systems.

7.3 The National Health Security Office, the Comptroller-General's Department, and the Social Security Office are the main agencies responsible for the Universal Health Coverage Scheme, Civil Servant Medical Benefit Scheme, and Social Security Scheme, respectively. They use health technology assessments to decide on the inclusion of technologies into their benefit packages, ensuring equitable and appropriate budget allocation.

7.4 Agencies undertaking health technology assessments such as the Office for Medical Technology Assessment, the Department of Health, the Health Intervention and Technology Assessment Program (HITAP), and academics in various universities.

7.5 The Pharmaceutical Research and Manufacturers Association, the Thai Pharmaceutical Manufacturers Association, and the Thai Medical Device Technology Industry Association are non-profit organizations comprising companies conducting research and development of imported medicines and producing locally manufactured drugs and medical devices. Health technology assessment has an impact on their work such as drug prices, new drug research and development, and marketing activities.

7.6 Health personnel and professionals, such as physicians, nurses, and pharmacists, including medical royal colleges, conduct health technology assessments; the findings of which are used to improve medical practice, drug prescription behavior, or technologies used by health professionals.

7.7 Non-profit NGOs, such as Consumer Protection Foundation and patient groups, benefit from health technology assessment. The population is able to obtain verifiable evidence-based information, thus ensuring fair health services andbeing less exposed to dangerous use of technologies.

8. Issue for consideration by the National Health Assembly

To ensure that there are mechanisms to efficiently develop the country's health technology assessment systems on a regular basis, with a participatory management and evidence-based approach, it is proposed that a central mechanism be established as a body responsible for the task. A feasibility study conducted in 2011 on the development of the health technology assessment organization's structure (10) recommended that the format should be a "public organization" due to its autonomy and flexibility to undertake greater variety of actions, including greater security and

financial flexibility due to support from the government budget. It is recommended that a decree be issued for such establishment to develop health technology assessment in the form of a public company acting as a non-civil-service state mechanism with freedom to act in a continuous and sustainable manner, with its own budget, and ability to attract competent and knowledgeable persons to work effectively in the same manner in which the Healthcare Accreditation Institute was established.

Requesting the National Health Assembly to consider Document National Health Assembly 7/Draft Resolution 3, "Development of health technology assessment and its decision-making process".

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