The Economic Evaluation of Medical Devices: Challenges

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While many of the principles that guide the economic evaluation of medical devices are somewhat similar to those that guide the evaluation of other health technologies, most outline a methodology that focuses on pharmaceutical products rather providing specific guidance for medical devices. Given that medical devices use a wide range of technologies and can be used for many purposes, conducting an economic analysis for medical devices is not straight forward. The cost and effectiveness of a given technology may depend on a number of factors. The objective of this paper is to provide a summary of issues that need to be addressed before undertaking an economic evaluation of medical devices and to outline a number of suggested approaches for undertaking an economic evaluation of medical devices.

Keywords: *Technology assessment, Cost-benefit analysis, Cost, Effectiveness, Medical device*

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Medical devices are many and diverse. The World Health Organisation defines a medical device as "an article, instrument, apparatus, or machine that is used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means[1]". There are several nomenclature systems for medical devices in use around the world. The Global Medical Devices Nomenclature System (GMDN) and the Universal Medical Devices Nomenclature System (UMDNS) are the two most common[2]. In Thailand, there is no standard nomenclature system nor definition; however, the Medical Device Acts BC 2551 does give a definition of medical devices similar to that of the WHO[3].

In recent years, economic evaluations of healthcare interventions have become highly sought after by Thai decision-makers[4]. An economic analysis is one of the policy tools that can be used to justify the inclusion of a given healthcare intervention in healthcare benefit packages. According to Section 22 of the Thai Medical Device Acts BC 2551, upon the production or import of pre-defined medical devices, all manufacturers should submit a request to the licensing authority to assess the medical device in terms of effectiveness, quality, standard, safety, and efficiency. They should also assess the socioeconomic impact, value-for-money, suitability, and inclusiveness of the device introduction and examine equitable uses of the devices[3]. This legislation indicates growing concern among Thai policy-makers regarding the cost-effectiveness of medical devices.

While the evaluation of medical devices is similar to that of other health technologies, there are important distinctions. Despite this, the available guidelines are either very general or focus only on pharmaceutical products; no guidance has yet been developed that specifically addresses the evaluation of medical devices[5]. This may be due to the fact that the regulatory framework for medical devices is less rigorous than the regulatory framework for pharmaceutical products[6]. Moreover, the category of medical devices is broad, encompassing as it does prevention, diagnosis, treatment, storage, detection, measurement, and inspection. In addition, the function and duration of usage for any given medical device can also vary significantly, from single disposable devices such as pregnancy tests, HIV tests, rubber gloves, or condoms, to devices that have applications for a longer duration such as large equipment that is used for diagnostic purposes or implant devices.

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This diversity can make it difficult to formulate guidance that applies to all medical devices, a challenge that is compounded by the fact that the effectiveness of a medical device can vary significantly depending on a number of factors, including device-operator-patient interaction and device adjustment or maintenance; conducting an analysis of medical devices is not straight forward. Given these specific complexities, there are certain important aspects that should be taken into consideration when conducting a cost-effectiveness evaluation of a medical device. The objective of this paper is to provide an overview of these issues and to outline the best approach when conducting an economic analysis of medical devices, especially in limited-resource settings.

Consideration for the efficacy of medical devices

Quality of the study

In the hierarchy of research designs, the randomised control trial (RCT) is regarded as one of the most reliable sources of data. However, for medical devices, RCTs are often not feasible for a number of reasons[5,7]. For instance, concealment or blinding is often not practical for medical devices, which leads to biased results. In addition, randomization is often not possible because many devices require an invasive procedure, which requires consent from subjects, and because medical devices are used as standard practice, which makes randomization unfeasible because of ethical issues. Moreover, even when RCT is applicable to medical device evaluation, the analysis results may still be limited in terms of target population, sample size, and the time scale of monitoring and evaluation of the technologies[8]. For these reasons, effectiveness evaluations of medical devices are rarely based on experimental studies with randomization and control; instead, observational studies are usually relied upon.

Multiple applications

Medical devices that are used as screening or diagnostic tools commonly have multiple applications. For example, Positron Emission Tomography/Computed Tomography, or PET/CT, is a tool used for diagnosis and follow-up of cancers such as cervical cancer, colon cancer, oesophageal cancer, non-small cell lung cancer, lymphoma, melanoma, and ovarian and thyroid cancer[9]. Therefore, in order to fully assess the benefit of PET/CT, all of its various applications and indications need to be taken into account. Although other health technologies, including pharmaceutical products, are also subject to these difficulties, it is usually much easier to differentiate the effectiveness by indication for pharmaceuticals than it is for devices. This is, in part, because it is challenging to differentiate and quantify the benefit and cost per application for medical devices that have multiple applications, which means that the benefit of a given device may well be underestimated if all of its various benefits are not taken into account. As such, all benefits should be taken into account when conducting a cost-effectiveness analysis of medical devices with multiple applications.

Intermediate and final outcomes

Since a cost-utility analysis is one of the standard tools typically recommended when making coverage decisions for benefit packages in tax-based national health insurances, it is important that data on the outcomes of the technology under consideration, given in terms of quality-adjusted life year (QALY) or disability-adjusted life year (DALY) be available[10]. However, for medical devices, this can be somewhat complicated, given that, in most cases, the efficacy or effectiveness of a medical device is reported in the form of intermediate outcomes, such as success rate, complication rate, procedure duration, diagnostic performance, and level of measurement. In this case, a cost-utility analysis can only be performed where a strong causal link between the intermediate and final outcome can be demonstrated, which is not very common. For instance, with medical devices that are used for screening or diagnosis, the outcome of the device will vary depending on the episode of care of the patient, which will be determined by the diagnosis following use of the device. Consequently, to evaluate the real costs and benefits of medical devices, the entire pathway of care should be taken into account for all true positive cases, false positive cases (which can result in unnecessary worry for patients and their families), and false negative cases (which can result in a delay treatment or care).

Device-operator interaction

For medical devices that require personnel for operation or interpretation, the performance of the device to prevent, diagnose or treat a condition depends not only on the device itself, but also to a significant degree on the operator's skill and experience-known as "device-operator interaction". The higher the skill or experience of the operator, the greater the benefits of the device will be; this is known as a "learning curve"[11]. This was demonstrated, for instance, in one multicentre study involving the USA

and several European countries, which proved that the benefits of laparoscopic radical prostatectomy improved significantly in line with operator experience and skill[12]. The present study found that the positive surgical margin, which represents the efficacy of the surgical procedure, improved with the number of surgeries the operator had conducted, reaching a plateau at approximately 200 to 250 surgeries. Researchers conducting analyses of medical devices that rely on device-operator interaction should take into consideration the stage of development of the technology. For instance, a technology that is assessed in the early stages of development may well generate less positive results that it would if assessed at a later stage, as the operators are likely to have become more experienced.

Incremental innovation

While research and development of pharmaceutical products usually takes a decade or more, this is not the case for medical devices. Many devices have a short product life-cycle, approximately 1-3 years[13], usually undergoing only minor incremental innovations such as those that result in a longer battery life or improved interactive functions that render the device easier to use. A good example of medical device evolution can be seen in the self-monitoring blood glucose meter which, after many iterations, now requires a smaller blood sample size, has reduced pain and test times, improved error detection routines and portability, and contains software integration to monitor blood glucose levels for physician facilitation. Hearing aids have also undergone frequent modification so that now there are many designs that can be adapted according to the user's preference. These modifications have included the development of various different styles (behind-the-ear, in-the-ear, in-the-canal, completely in-the-canal, and body-worn hearing aids), different sound-amplifying systems (analogue or digital hearing aids), and certain special features such as a directional microphone and telephone switching. As these medical devices demonstrate, medical devices tend to develop incrementally, with small but frequent stages of innovation. This means there is less incentive for the industry to invest in effectiveness studies of newer iterations unless there are significant changes that result from the modification.

Factors affecting the efficacy of medical devices ("real world" factors)

There are numerous factors that may contribute to the effectiveness of a given technology, including the training that is available for proper use and care or evaluation and monitoring. For individuals who have undergone a cochlear implantation, for instance, auditory/speech rehabilitation is required for users to be able to take full advantage of all the benefits of the technology; this means that it is not only the success rate of transplantation that affects how effective the cochlear implant can be said to be[14]. This can also be seen with hearing aids, where the effectiveness depends not only on the aid itself but also whether the patient regularly attends hearing aid fittings with their audiologist, and with self-monitoring blood glucose meters, where the effectiveness depends in part on the patient's knowledge and ability to properly calibrate the device (an improperly adjusted device may generate incorrect glucose readings, resulting in hypoglycemic events).

Moreover, the effectiveness of the medical device will also depend on the context of analysis. While primary data are usually preferable, it is often unavailable or partial. For example, when the cost-effectiveness analysis of cochlear implantation was conducted, there were no data available regarding the successrate of the operation, so retrospective data collection of the rate was conducted instead[14]. In cases where an along-side clinical trial is implemented, the factors associated with the outcome may be controlled[15]. However, when evaluating the effectiveness of medical devices, researchers should try, as far as possible, to collect data from a context similar to that within which the real decision will be made. Where this is not possible, researchers should include real world factors (such as acceptance rate) when constructing models for the economic analysis of medical devices.

Consideration for costing medical devices

Cost information and economy of scale

Calculating the cost of a medical device can be relatively straightforward, for instance in the case of disposable devices. In contrast, evaluating the cost of medical devices that can be used numerous times or for various indications can be more challenging. In the context of an analysis where a device with a high level of technology is to be introduced into the health system, calculating the costs of start-up will be necessary. Two noteworthy examples of this are the magnetic resonance imaging (MRI) or positron emission tomography (PET) systems, which both require significant start-up costs, whether for screening or

diagnostic options. This is because the proportion of the systems' fixed costs is much higher than their variable costs. In this case, calculating fixed costs–where the cost of input for each unit of output stays the same in the short run–and variable costs–where the cost of input increases with each unit of output produced–are useful for determining the break even point. One recent study found that current PET and CT services were under utilised. On average, they found that PET and CT machines were used less frequently than they would need to be to break even (eight times per location per week), meaning that, at the current usage, providers needed to pay higher fix costs, resulting in a deficit. They calculated the fixed and variable costs of providing PET and CT services to be 14,773,376 baht per year and 20,714 baht per year, respectively, and suggested that this under utilization reflected patients' unwillingness to use these services due to their expense. Clearly then, the calculation of fixed and variable costs of very expensive medical devices is an important part of ensuring that policies are developed in an integrated and informed way that ensures maximum benefit.

Continual change in price of the medical devices

As discussed, the fact that medical devices undergo continuous research and development, they have a much shorter product life-cycle compared to pharmaceutical products. This is especially true for electronic medical devices, where the product life-cycle is now around one to three years[13]. One drawback of the continuous development of medical devices is that older technologies can sometimes appear more cost-effective since prices of older technologies drop considerably once a new technology has been introduced. For example, while drug-eluting stents were initially found to be cost-effective when they were first introduced into the United Kingdom, after four years this was no longer the case, because the price of the nearest treatment competitor, bare-metal stents, had decreased significantly in the wake of the introduction of the newest technology[16]. This means that there are significant methodological difficulties with conducting economic evaluations for medical devices.

Guidelines for Health Technology Assessment in Thailand (second edition): Recommendations for the economic evaluation of medical devices

1. The costs and outcomes resulting from treatments of the screened or diagnosed diseases should be taken into account when evaluating the cost-effectiveness of screening or diagnostic medical devices. Even where various treatment options may be available, use of standard practice for management of the disease should be used as the comparator wherever possible, rather than no treatment. Moreover, the overall costs and outcomes resulting from appropriate practice should be used to model for the effectiveness of the device, rather than constructing a sub-model for each disease or condition.

2. When evaluating the cost-effectiveness of medical devices that require expert personnel for their operation, all data sources should be described and a justification for the use of effectiveness information in reference to that device should be clearly stated. Where secondary data are applied, a discussion should be included that explains whether information is appropriate for other analytical contexts.

3. Where the cost-effectiveness of the medical device under consideration depends on other factors such as distribution or usage, a feasibility analysis for such medical devices in the context of analysis is also recommended.

4. Where the value of the medical device under consideration depends on economies-of-scale, both fixed and variable costs should be obtained in order to calculate the break even point to determine the proper output value.

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Potential conflicts of interest

None.

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ความท้าทายของการประเมินความคุ้มค่าด้านสุขภาพที่เกี่ยวข้องกับเครื่องมือแพทย์

ปฤษฐพร กิ่งแก้ว, ยศ ตีระวัฒนานนท์

การประเมินความคุ้มค่าทางสาธารณสุขไม่ว่าจะเป็นเทคโนโลยีทางการแพทย์ชนิดใดก็ตาม โดยทั่วไปมีหลักการพื้นฐานสำหรับการประเมินที่เหมือนกัน แนวทางการประเมินความคุ้มค่าทางสาธารณสุขในปัจจุบัน มักเน้นเนื้อหาการประเมินของเทคโนโลยีที่เป็นยามากกว่าเครื่องมือแพทย์ อย่างไรก็ตามเครื่องมือแพทย์มีขอบเขตคำจำกัดความที่กว้างในทางปฏิบัติ และหากทำการประเมินความคุ้มค่าของเครื่องมือแพทย์จึงมีข้อพึงระวังที่สำคัญ ได้แก่ คุณภาพของข้อมูลประสิทธิผล เครื่องมือแพทย์ที่มีหลายข้อบ่งใช้ ปฏิสัมพันธ์ระหว่างเครื่องมือแพทย์และผู้ใช้งาน การพัฒนาของเครื่องมือแพทย์อย่างต่อเนื่อง ปัจจัยแวดล้อมที่มีผลต่อประสิทธิผลของเครื่องมือแพทย์ต้นทุน และการประหยัดต่อขนาดในกรณีที่เครื่องมือแพทย์มีราคาสูงหรือแม้แต่ราคาเครื่องมือแพทย์ที่มีการเปลี่ยนแปลงอย่างต่อเนื่อง ซึ่งเกิดจากการมีเทคโนโลยีใหม่แทนที่อยู่ตลอดเวลาเป็นต้น ทั้งนี้บทความนี้ได้ให้ข้อเสนอแนะสำหรับการประเมินความคุ้มค่าทางสาธารณสุขที่เกี่ยวข้องกับเครื่องมือแพทย์เพื่อเป็นประโยชน์แก่ผู้วิจัยในอนาคต