Special Article

The Need for Guidelines and the Use of Economic Evidence in Decision-Making in Thailand: Lessons Learnt from the Development of the National List of Essential Drugs

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Since 2004, the Subcommittee for Development of the National List of Essential Drugs (NLED) has embarked upon an historical evolution of applying evidence to the revision, inclusion and exclusion of medicines into and from the list. Then, the revision of the 2008 NLED was the first time in Thai history where the drug selection process in Thailand formally incorporated pharmacoeconomics. At present, the lack of a standard methodology for conducting economic evaluation is a major barrier that diminishes the potential use of economic evidence. The development of national economic evaluation guidelines by a group of national experts was subsequently endorsed by members in the Subcommittee as useful tools for future NLED revision. They emphasize that these guidelines should be applied not only to those evaluations conducted by public institutions but also by private pharmaceutical companies that often use this evidence for their marketing, or even for future requirements of economic information from industry, as complementary evidence for inclusion of health technology.

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Rationing is inevitable for any health care system, particularly in resource-inadequate developing country settings. Practically, developing countries apply "implicit" rationing where resources are limited. There are usually neither clear decisions about which care is provided nor are the bases for those decisions clearly expressed. Market failure in healthcare can result in harmful implicit rationing due to asymmetry of information between patients and providers, monopolies and externalities. For instance, a patient's choice of physicians or hospitals is typically limited by the managed care plan's gatekeepers, so health care may be denied to those suffering from conditions of ill-health by not referring them to secondary or tertiary providers. Treatment being not withheld altogether, but delayed due to long waiting lists, at times, results in the worsening of patient conditions. In addition, most patients do not have clinical knowledge as complete as clinicians, health care can be diluted by not providing optimal treatment, as in most cases it is new and expensive.

Relying on implicit rationing may make the lives of decision-makers easier, but it is clearly not transparent and not in the best interest of patients, taxpayers and society as a whole[1]. There have recently been wider discussions and debates about explicit rationing which require clarity in definition and principles by which decisions regarding access to scarce resources are determined. Thus, definite rules/criteria are needed to ensure evidence-based decisions. Although it is impossible that all people will agree on the preset criteria to be initially applied in rationing, only using explicit evidence in decision-making

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encourages debate that will eventually support better evidence being generated.

Since 2004, the Subcommittee for Development of the National List of Essential Drugs (NLED) has embarked upon an historical evolution of applying evidence to the revision, inclusion and exclusion of medicines into and from the list. The NLED is referred to, by all three public health insurance schemes, as medicine benefit for the whole population; therefore, the process of revision of the NLED is extremely vital, as it has major implications for the whole population who are beneficiaries and the insurance funds who are the payers.

Not only drug safety and efficacy, but also the effectiveness and costs are taken into account. For example, in the revision of the 2004 NLED, there was an explicit application of cost and efficiency criteria in terms of "ISafE score" and "Essential Medical Cost Index" (EMCI)[2]. ISafE stands for Information, Safety and ease of use (namely patient adherence) and Efficacy of each medicine, and is used as the basis for computing the score. The composite ISafE score (ranging from 0 to 1) indicates the relative merit of each drug. Drugs with an ISafE score below the 50th percentile in the same group are initially excluded; those more than the 50th percentile pass the threshold of quality to be further assessed where EMCI is applied as sequential criteria, based on the cost of daily defined dose (DDD) of that medicine per ISafE score. The lower the cost of DDD per ISafE score, the higher the likelihood of it being adopted into the NLED.

Since the 2004 NLED revision, the ISafE score and EMCI have been established and applied to the revision of the NLED, though we have found some limitations. For example, these criteria cannot be used when comparing drugs with different and/or multiple outcomes, or comparing values of medications with other treatment modalities *e.g.* surgical or radiation procedures. As a result, the revision of the 2008 NLED was the first time in Thai history where the drug selection process in Thailand formally incorporated pharmacoeconomics.

Given resource and research capacity constraints in health technology assessment, six groups of drugs were initially selected to require pharmacoeconomic evidence for consideration in the revision of the 2008 NLED (see detailed information about the criteria and topic selection process in Lertpitakpong *et al* 2008[3]). These included osteoporosis drugs, HMG-CoA reductase inhibitors (statin), insulin analogues, recombinant human erythropoietin, medications for treatment of Alzheimer's disease and medications for treatment of Hepatitis B and C.

During the process, the members of the Subcommittee and its Health Economic Working Group have gained more experience concerning use of evidence, and have foreseen difficulties in its future use. There is consensus that economic evaluation is useful for guiding policy decisions, but only when it is performed correctly and reported accurately. At present, the lack of a standard methodology for conducting economic evaluation is a major barrier that diminishes the potential use of economic evidence[4].

The development of national guidelines by a group of national experts, which were subsequently endorsed by the Health Economic Working Group, published in this special supplement is, therefore, welcomed by members in the Subcommittee. They approved the guidelines as useful tools for future NLED revision. They emphasize that these guidelines should be applied not only to those evaluations conducted by public institutions but also by private pharmaceutical companies that often use this evidence for their marketing, or even for future requirements of economic information from industry, as complementary evidence for inclusion of health technology, similar to that which has been practiced by the Pharmaceutical Benefits Advisory Committee in Australia[5]. Furthermore, in the draft revised drug bill in Thailand, there is a requirement for economic evaluation regarding new drugs that apply for market authorization. If passed into an act, it will further strengthen the pharmacoeconomic capacity in the country, and also emphasis the importance of the guidelines.

Not only do the guidelines ensure the use of economic evidence for the efficient allocation of scarce resources, they also increase the transparency of the evaluations undertaken by allowing audiences to assess accurately the appropriateness of the methods and the quality of the evidence used. The guidelines will improve the general quality of, and encourage comparisons between studies because the guidelines address all important methodological considerations. At this stage, it is difficult to predict the future application and contributions of economic evaluation as a tool for decision-making in Thailand. This crucial step of having standard methods established, endorsed nationally and publicized, will support the wide application and the potential contribution of economic evaluation as powerful input for policy decisions. Finally, the guidelines are an important capacity-building tool for all related sectors and institutions.

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ความต้องการแนวทางมาตรฐานการประเมินเทคโนโลยีด้านสุขภาพ และการใช้ข้อมูลเพื่อการตัดสินใจเชิงนโยบายในประเทศไทย: บทเรียนจากการพัฒนาบัญชียาหลักแห่งชาติ

สุวิทย์ วิบุลผลประเสริฐ ในฐานะประธานคณะอนุกรรมการพัฒนาบัญชียาหลักแห่งชาติ

ตั้งแต่ปี พ.ศ. 2547 เป็นต้นมา คณะอนุกรรมการพัฒนาบัญชียาหลักแห่งชาติ ได้ริเริ่มให้มีการประยุกต์ใช้หลักฐานทางวิชาการเพื่อทบทวนและคัดเลือกยาเข้าบรรจุในบัญชียาหลักแห่งชาติ ต่อมา ในปี พ.ศ.2551 มีการปรับปรุงบัญชียาหลักแห่งชาติ และนับเป็นครั้งแรกในประเทศไทยที่กระบวนการคัดเลือกยาได้นำเอาข้อมูลการประเมินความ คุ้มค่าทางการแพทย์มาใช้อย่างเป็นทางการ ในปัจจุบันประเทศไทยยังขาดมาตรฐานของระเบียบวิธีวิจัยสำหรับการ ประเมินความคุ้มค่าทางการแพทย์เป็นอุปสรรคที่สำคัญต่อการใช้ประโยชน์จากการประเมินความคุ้มค่าทางการ แพทย์สำหรับการตัดสินใจเชิงนโยบาย ดังนั้นคู่มือการประเมินเทคโนโลยีด้านสุขภาพจึงถูกพัฒนาขึ้นโดยกลุ่มผู้เชี่ยวชาญระดับประเทศ ซึ่งต่อมาได้รับการรับรองจากคณะอนุกรรมการพัฒนาบัญชียาหลักแห่งชาติว่าเป็น เครื่องมือที่เป็นประโยชน์สำหรับการปรับปรุงบัญชียาหลักแห่งชาติในอนาคต และยังเน้นว่าแนวทางในคู่มือ เล่มนี้ควรนำไปประยุกต์ใช้สำหรับการประเมินความคุ้มค่าทางการแพทย์ ไม่เพียงแต่ในหน่วยงานภาครัฐเท่านั้น แต่ควรนำไปใช้ในหน่วยงานภาคเอกชน เช่น บริษัทยาที่ต้องใช้ข้อมูลเหล่านี้เพื่อทำการตลาด หรือในอนาคตหน่วยงาน ที่เกี่ยวข้องในภาครัฐอาจร้องขอให้บริษัทเอกชนต้องเสนอข้อมูลการประเมินเทคโนโลยีด้านสุขภาพเพื่อใช้สำหรับ การพิจารณาคัดเลือกเทคโนโลยีให้อยู่ในชุดสิทธิประโยชน์ในระบบประกันสุขภาพ