2014 符合成本效益的醫療科技評估模式 - 臺灣的 HTA 經驗

Affordable Health Technology Assessment in Taiwan: A Model for Middle-Income Countries

2005 年世界衛生大會(WHA)倡議會員國應成立健康基金，保障所有民眾都能享受所需的服務與照顧，並且不會因此而陷入財務困頓的窘境，此一目標簡稱健康全面覆蓋。

2007 年 WHA 定義「醫療科技」(health technology)為：一切用於解決健康問題與提升生活品質的有系統組織、知識和技術，包括醫療設備、藥品、疫苗、醫療過程等。衛生單位在提供人們健康介入服務時，必須兼顧兩個重點，首先，健康服務必須是有效的，其次是在經濟上負擔的起。

為了兼顧療效與成本控制，幾個先進國家從 1980 年代就開始推動醫療科技評估(HTA)，透過相對療效分析、成本效益分析、預算衝擊分析等方法，並考慮倫理/法律/社會層面的影響，協助政府衛生部門進行相關的決策制定。當前世界各國在 HTA 的推動上，以英國的 NICE、加拿大的 CADTH，與澳洲的 PBAC 為最常被提及的經驗模式，但是前述三個 HTA 機構，每年所需經費甚高，對於開發中國家而言，比較無力負擔。

臺灣在 1995 年開辦全民健保，目前 99.9%的國人都享有全民健保的服務，具體落實了健康全面覆蓋的理想，而且醫療支出只佔 GDP 的 6.6%。除了一般民眾外，臺灣的全民健保同時也涵蓋監獄受刑人，所提供的服務還包括了中醫、專科醫師及成人健檢等項目。

由於越來越多價格昂貴的新醫療科技問世，臺灣全民健保為提供新的新醫療科技、服務品質與避免財務浪費，自 2007 年開始針對健保給付項目進行醫療科技評估（Health Technology Assessment, HTA)，協助新藥、特材、創新醫療服務及政策上的決策及給付。

臺灣 HTA 的發展，可以分成三個階段。首先，第一階段為 1995 年健保開辦以後至 2007 年，所有給付僅由專家學者組成委員會進行評議及決策。第二階段為 2007 年到 2012 年之間，則導入 HTA 於健保給付決策上；廠商向當時的健保局提出申請後，健保局會將廠商資送至隸屬於財團法人醫藥品查驗中心(Center for Drug Evaluation, CDE) 的 HTA 組進行評估並提出報告，再轉送當時的健保藥事小組(Drug Benefit Committee, DBC)會議上做成決策。一般而言，審查過程需時約 90 天。第三階段為 2013 年台灣二代健保實施後，衛福部成立了一個獨立的 HTA 機構 -- 國家醫療科技評估中心(National Institute of Health Technology Assessment, NIHTA)，做為獨立於政府及民間的公正第三方 HTA 專業機構。

NIHTA 成立後，為配合二代健保法所成立全民健保給付項目及支付標準共同擬訂會議(Pharmaceutical Benefit and Reimbursement Scheme Joint committee, PBRS)，由來自醫療衛生體系、廠商、官方與消費者代表等 29 人所組成，取代原來的健

保藥事小組（DBC）成為健保收載與給付決策的決定者。

臺灣的 NIHTA 拮取加拿大、英國及澳洲等 HTA 機構的寶貴經驗，節省了許多摸索與嘗試的過程，共有四個特色：第一是重視品質效率及客戶滿意度，這一年多來，NIHTA 評估逐漸獲得各方利害關係人，包括健保署、廠商、醫療服務提供者、被保險民眾等的肯定。

第二特色是開始即設定評估費用、成本的範圍，以較低成本的費用進行醫療科技評估，相較國際間許多 HTA 組織，臺灣的 HTA 具有成本較低及成效不錯的特色。在成本投入上，約是加拿大 CADTH 每年經費的五分之一，英國 NICE 的二十五分之一。

第三特色為臺灣的 NIHTA 在全民覆蓋的健保制度下，設定為一公正第三方單位，以協助健保署及其他單位進行新藥等收載評估為目的，因此評估結果提供決策者的參考價值較高。

第四特色為臺灣的 NIHTA 評估報告雖然不像英國 NICE 的報告可以對 NHS 直接做出建議，但是多年來與健保署的合作過程所建立的互信機制，HTA 評估報告已經成為健保藥事小組 DBC 與共同擬定會議 PBRS 的重要決策參考文件。

自 2007 年起至 2013 年底，在如此低費用下，幾年來已協助健保署完成新藥評估 204 件、突破創新新藥評估 38 件、專案研究 35 件、特殊材料評估 8 件，以及廠商諮詢 108 件。為求即時性，每個評估案件需在 42 個日曆天內完成。每年案件完成數從早期的 59 件到目前的 68 件。

2007 年先由新藥開始，幾乎所有重要新藥均經過評估；如：新一代類風濕性關節炎藥物健保使用情形分析；依據科學實證檢討現有消化酵素藥品使用之合理性；放寬高危險族群使用降血脂藥品給付規定之財務影響評估等。

從 2011 年起，部分健保特材給付也開始進行 HTA 評估，包括療效證據評估、經濟評估，或預算衝擊的估算。2014 年開始，HTA 評估也開始應用於某些特殊的創新醫療服務的評估，目前有兩項先驅性研究正在進行，分別是有關達文西手術與各種雷射前列腺汽化術的評估研究。從業務涵蓋層面的廣度與案件的完成量與即時性，臺灣的 NIHTA 可稱得上是經濟效益極高的組織。

NIHTA 最近的發展已不僅止於協助健保署進行給付決策，也與衛生福利部(MOHW)、疾病管制署(CDC)、國民健康署(HPA)，以及台灣血液基金會等機構合作進行政策評估。具體成果包括估算質子治療之適應症，愛滋病治療藥物之經濟評估，使某項愛滋治療藥物的成本具體降低 70%；藉由克流感原料藥轉換之效益評估；核酸檢驗法應用於捐血篩檢成本效益分析，目前已正式納入常規捐血篩檢項目。其他尚在評估中的例如四價流感疫苗導入經濟效益評估、食鹽加氟政策可行性評估、我國純母乳哺育與維生素 D 或鐵質補充之政策評估等。

結語

臺灣在 1995 年開辦全民健康保險，落實了健康全面覆蓋的理想，為了兼顧服務

品質與避免財務衝擊，台灣學習英、加、澳三國的經驗，自 2007 年開始推動 HTA，2013 並成立獨立的 NIHTA 協助全民健保及其他公私立機構進行新藥、特材、創新醫療服務及政策評估與制定。相較於先進國家的 HTA 機構，台灣的成本較低，而且達成許多效益與成果，可以說是符合成本效益的模式，也許可以提供開發中國家作為參考。

Taiwan realized the goal of providing universal health care coverage by launching the National Health Insurance (NHI) program in 1995. Covering 99.9 percent of the population, including prison inmates, the NHI gives patients access to care ranging from Western drugs and procedures to traditional Chinese medicine. The initiative was ahead of its time, with the World Health Assembly (WHA)—the decision-making body of the World Health Organization—passing in 2005 resolution WHA58.33, which urges states to develop health financing systems as part of efforts providing universal health coverage.

Among other things, WHA58.33 calls for universal health care systems to provide equal access to health resources. Treatment must be affordable to all, and that puts pressure on health care systems to control costs. Taiwan began conducting health technology assessments (HTA) to determine the suitability of new drugs within the financial context of the NHI system in 2007. HTAs were extended to medical devices in 2011 and to medical services this year. The assessments are used to support NHI Administration (NHIA) reimbursement decisions.

Taiwan's HTA development process can be divided into one preliminary stage and two implementation stages. During the 1995–2007 preliminary stage, the Drug Benefit Committee (DBC) evaluated whether new drugs were suitable for reimbursement under the NHI system, but no formal HTAs were performed. In the first implementation stage from 2007 to 2012, the DBC evaluated dossiers from drug manufacturers and reports by HTA working groups operating under the Center for Drug Evaluation.

This analysis, which also includes studying HTA agencies in Australia, Canada and the UK, paid off in the second implementation stage. This began in 2013 when the Ministry of Health and Welfare established the National Institute of Health Technology Assessment (NIHTA), an independent medical nonprofit organization that conducts HTAs free from the influence of governmental agencies and manufacturers. The most recent development in the second stage is the establishment of the Pharmaceutical Benefit and Reimbursement Scheme (PBRS), a 29-member joint appraisal committee comprising government officials, health professionals, manufacturers and members of the public. The PBRS replaces the DBC as the final arbiter of a new drug's suitability for the NHI system.

The NIHTA has four major characteristics. First, the institute prioritizes quality, efficiency and stakeholder satisfaction. Since the institute's founding, that approach has earned the affirmation of manufacturers, medical service providers, the NHIA and the public.

Second, the NIHTA maintains its focus on quality while performing HTAs at relatively low cost. The institute is able to fulfill its mission, for example, on an

annual budget equivalent to just 20 percent and 4 percent of the yearly funding for its Canadian and UK counterparts, respectively.

Third, the NIHTA's independence from government and manufacturer influence ensures that it submits unbiased reports to the NHIA. In other words, the institute's decision on a treatment's suitability for reimbursement under the NHI program is based only on empirical evidence.

Fourth, extensive cooperation between the NIHTA and NHIA has resulted in mutual trust. Although the NIHTA does not make direct recommendations to the NHIA, the NIHTA's reports have become vital reference materials for PBRS decisions on treatment suitability for the NHI system.

From 2007 to 2013, HTA working groups and the NIHTA helped the NHIA assess 204 new drugs, 38 breakthrough drugs, and eight medical devices, as well as provided 108 consultations to manufacturers.

HTAs typically evaluate treatments based on comparative effectiveness, cost-effectiveness and budget impact. As for the recently added categories of medical devices and medical services, two current pilot studies are assessing robot-assisted surgery and laser treatments for benign prostatic hyperplasia.

In addition to its ongoing cooperation with the NHIA, the NIHTA recently began working with the Centers for Disease Control and Health Promotion Administration, both of which operate under the Ministry of Health and Welfare, as well as the Taiwan Blood Services Foundation in conducting policy assessments.

The NIHTA actively participates in global and regional organizations in order to promote institutional development and exchange experiences. For example, the institute was one of the founding members of HTAsiaLink, a network established in 2011 to support collaboration between HTA agencies in Asia. Today, the NIHTA is also a member of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and Health Technology Assessment international. The institute was instrumental in bringing the ISPOR Asia-Pacific Conference to Taipei in 2012 and the upcoming 2015 HTAsiaLink annual conference to Taiwan.

Taiwan's HTA experience has shown that outstanding results can be produced on an annual budget that is significantly lower than those found in many Western countries. For middle-income countries seeking to build an HTA framework, Taiwan's NIHTA serves as a good model.