Is Cost-Effectiveness Analysis a Tool to Exercise Value-Based Pricing or Monopsony Power? Evidence from Canada and Other Countries

Poster # HPR129

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Background

- Many countries are now considering value-based pricing (VBP) to curb the rising cost of pharmaceuticals and health care spending, while maximizing the value of the drug to the population.
- VBP ensures that the pricing strategy is driven by a drug's value to the patient population along with consideration of its impact on the budget, rather than the manufacturer's profit margin augmenting the actual cost of production[1]. This approach maximizes the value provided to the population within a fixed budget.
- One of the most well-used tools to implement VBP in healthcare is using cost-effectiveness analysis (CEA) directly to drive the pricing strategy that sets the right incentives for healthcare systems, or indirectly as part of their multi-criteria decision analysis (MCDA) where weights are attached to multiple drivers.

Objective

- The aim of this study is to review the use of cost-effectiveness in the current country Health Technology Assessment (HTA) agencies and their implementation of VBP policies, in addition to assessing their impact on the pharmaceutical market.

Methods

- A targeted literature search was conducted to identify published studies, white papers, policy briefs and published HTA guidelines globally to:
  - Identify countries that use formalized HTA guidelines in assessing the cost and benefit of pharmaceutical products.
  - Review the pricing guidelines of HTA bodies.
  - Identify HTA bodies using CEA directly to inform their pricing guidelines and negotiations.
  - Review the evidence where the above identified HTA bodies utilize their monopsony power on the pricing guidelines.'
- The Institute for Clinical and Economic Review (ICER US), is an independent organization that assesses VBP, and reviews the cost-effectiveness analysis of pharmaceutical products. However, since it is not an official HTA body and does not regulate launch prices, it was excluded from the analysis.
- Countries such as France, Germany, Italy, Spain and Thailand do not systematically use only cost-effectiveness for pricing strategies, but also the additional clinical and therapeutic value among other elements[1]. However, there was a lack of consistency in the implementation of guidelines (such as the discounts on list price in Germany)[1,3] ,lack of transparency in the weights for the CEA results and how it has been used in pricing negotiations[3,4]. Thus, they were excluded from the analysis.
- Through the process, 30 studies and reports were identified that provided context and evidence on the implementation of VBP for Canada, United Kingdom (UK), Australia, New Zealand and Japan.

Results

Table 1. Comparison of HTA Characteristics, VBP implementation, and Outcomes by Country

	Canada	UK	Australia	New Zealand	Japan
Payer type	Single-payer	Single-payer	Single-payer	Single-payer	Single-payer
HTA body	CADTH/INESSS (Quebec)	National Institute of Health and Care Excellence (NICE)	Pharmaceutical Benefits Advisory Committee (PBAC)	Pharmaceutical Management Agency (PHARMAC)	Center for Outcomes Research and Economic Evaluation for Health (C2H)
Negotiating Entity	pan-Canadian Pharmaceutical Alliance (pCPA)	National Health Service (NHS)	Pharmaceutical Benefits Advisory Committee (PBAC)	Pharmaceutical Management Agency (PHARMAC)	Ministry of Health, Labour and Welfare (MHLW) - Central Social Insurance Medical Council
Value Criteria	QALYs Additional therapeutic value (graded)	QALYs	QALYs Additional clinical value	QALYs Additional clinical and cost value	Drug Innovation Additional cost value (graded)
Importance of ICER	Most important criterion for HTA recommendations	Most important criterion for HTA recommendations	Used in confidential price negotiations	Used in confidential price negotiations	Used in price adjustments
Managed Entry Agreement (MEAs)	Financial and Performance-based MEAs	Financial and Performance-based MEAs	Financial and Performance-based MEAs	Financial MEAs (No evidence of Performance-based MEAs)	None
Summary of VBP guideline Implementation	• CADTH and INESSS review pharmacoeconomic evidence against a CET of $50,000 CAD/QALY (can be higher for oncology and rare diseases), and provide recommendations to pCPA. • PMPRB regulates prices for all patented drugs based on therapeutic value and reference pricing.	• NICE evaluates the pharmacoeconomic value and makes funding recommendations to NHS based on the official cost-effectiveness threshold of £20,000 - £30,000 per QALY per year (can be higher for oncology and rare diseases) • The NHS indirectly controls these initial prices through "reasonable" profit margin agreements; insured via the Pharmaceutical Price Regulation Scheme.	In parallel or post-approval of drug by the Australian Therapeutics Goods Administration, PBAC will assess the submission. The Economic Subcommittee assesses the clinical and economic evidence. The Drug Utilization Sub-committee assesses the projected usage and financial cost for medicines.	PHARMAC used clinical and economic evaluation to negotiate the prices of drugs, and manages a capped national budget for outpatient and cancer pharmaceuticals.	CEA applied for price adjustment after reimbursement, for those with ICER higher than ¥5 million/QALY in a step-wise manner. Special CET considerations for rare diseases, pediatric indications, oncology drugs.
Positive Impact on Pricing	Lower public spending on pharmaceuticals compared to the average for OECD countries.	• Controlled growth of spending on pharmaceutical drugs in line with NHS budget. • Lower price of drugs at launch. • Competitive tendering in hospitals incentivized manufacturers to price drugs lower than generics.	Use of evidence-based medicine has lowered costs for new substances relative to other countries (50% compared to the United States)	• Reduced pharmaceutical expenditures by up to 90% for some drugs. • Universal and nationally consistent pharmaceutical coverage • Controlled pharmaceutical budget • Lower patient co-pays for drugs	• Consistent decreases in drug prices drives affordability. • Encourages increase in competition for generics and biosimilars.
Negative/Unintended Impact on Market	Proposed changes to the PMPRB guidelines could result in: • Lower access or delayed launch to innovative drugs • Lower pharmaceutical R&D spending	Public and political pressure led to oncology and end-of-life drugs deemed not cost-effective by NICE to still be financed. The high prices of the drugs quickly depleted the budget and has been closed. Instead, now NICE uses higher CET are used for such drugs.	Collapse of the generic drug market as competitive prices were not sustainable. Companies exited or merged that resulted in higher generic drug prices.	• Access to a smaller range of drugs compared to other countries. • Reduced access and/or delayed launch of innovative drugs • Lower pharmaceutical R&D spending	• High barriers to entry due to ever-changing and complicated guidelines. • Lower access to innovative drugs • Generic drug market is slowly becoming less lucrative.

Abbreviations: CADTH - Canadian Agency for Drugs and Technologies in Health; INESSS - Institut National D'excellence En Santé Et Services Sociaux; QALYs – Quality Adjusted Life Year; OECD - Organization for Economic Co-operation and Development; R&D – Research and Development; CET – Cost-effectiveness Threshold; PMPRB - Patented Medicine Prices Review Board; HTA – Health Technology Assessment; ICER – Incremental Cost-effectiveness Ratio; VBP – Value-based pricing

Discussion

- Countries like Canada, United Kingdom (UK) and Japan provide explicit policies on how pricing is based on the CEA results (using some form of VBP)
- Australia and New Zealand use CEA to drive their confidential pricing negotiations.
- Countries have been able to leverage their monopsony powers to utilize CEA along with other pricing strategies such as solo-tendering, reference-based pricing, etc. has proven to be very effective in balancing static and dynamic efficiency in pharmaceutical prices, especially in those countries with a fixed budget (UK, Japan, New Zealand). It has led to higher competition (especially in generics) and lower pharmaceutical expenditures.
- Countries such as Canada, UK and Japan have used CEA to signal more lucrative markets to pharmaceutical companies by setting higher willingness-to-pay (WTP) thresholds for rare diseases, cancers and pediatric indications.
- However, these strategies have resulted in many unintended consequences such as lower and/or delayed access to innovative drugs, unsustainable competition, higher barriers of entry and shortened drug formularies.

Conclusion

Cost-effectiveness analysis can be used as a primary driver for value-based pricing strategies to maximize the value of the drug to the population.

Countries wielding their monopsony power have found this to be a valuable tool in their arsenal to combat rising pharmaceutical costs and maintain a fixed budget.

While it can be used to correct the pharmaceutical prices in the market, it can also be used by single-payer countries to exercise monopsony power to directly and indirectly influence the prices and competition in the market.

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