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The development of a value based pricing index for new drugs in metastatic colorectal cancer

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ABSTRACT

Background: Worldwide, prices for cancer drugs have been under downward pressure where several governments have mandated price cuts of branded products. A better alternative to government mandated price cuts would be to estimate a final price based on drug performance, cost effectiveness and a country's ability to pay. We developed a global pricing index for new cancer drugs in patients with metastatic colorectal cancer (mCRC) that encompasses all of these attributes.

Methods: A pharmacoeconomic model was developed to simulate mCRC patients receiving chemotherapy plus a 'new drug' that improves survival by 1.4, 3 and 6 months, respectively. Cost and utility data were obtained from cancer centres and oncology nurses ($n = 112$) in Canada, Spain, India, South Africa and Malaysia. Multivariable analysis was then used to develop the pricing index, which considers survival benefit, per capita GDP and income dispersion (as measured by the Gini coefficient) as predictor variables.

Results: Higher survival benefits were associated with elevated drug prices, especially in higher income countries such as Canada. For Argentina with a per capita GDP of $15,000 and a Gini coefficient of 51, the index estimated that for a drug which provides a 4 month survival benefit in mCRC, the value based price would be $US 630 per dose. In contrast, the same drug in a wealthier country like Norway (per capita GDP=$50,000) could command a price of $US 2,775 per dose.

Conclusions: The application of this index to estimate a price based on cost effectiveness and the wealth of a nation would be important for opening dialogue between the key stakeholders and a better alternative to government mandated price cuts.

1. Introduction

The cost of health care has been growing rapidly over the past decade.[1] There are several contributing factors such as an ageing population, a more aggressive treatment culture and the availability of more effective drugs that have replaced medical procedures previously requiring hospitalisation.[2–4] One of the most identifiable parts of increased health care costs has been pharmaceuticals. Using oncology drugs as an illustration, it was reported from 1993 to 2004, total sales for oncology drugs in Europe alone increased seven times from €840 to €6170 million.[5] Similar trends have also been reported in the United States where cancer drug expenditures increased from $3 billion in 1997 to $11 billion in 2004.[6]

Rising drug costs have now become a global concern as institutionalised health care systems struggle to offer modern

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treatments within limited budgets. Combined with the global economic recession, many governments have responded by mandating cuts in branded pharmaceuticals of up to 30%.[7–9] However, government mandated price cuts may not serve the patient in the long term because they would deter innovative pharmaceutical companies from making large investments into research and development. Without such investment, new drug discovery would be compromised. In the end, manufacturers should be rewarded for innovation because new drugs have been a major contributor towards improved patient outcomes and reduced health care costs.[4,5]

A better and more systematic alternative to government mandated price cuts is the establishment of a drug price based on performance during randomised trials and the total value that it brings to society. Such value based pricing schemes have been proposed in several countries.[10,11] As an illustration, the new government of the United Kingdom (UK) recently announced its intent to revise the current free drug pricing scheme and move towards a value based approach.[11] Specifics of this new system have yet to be announced nor is it known who will administer it. However, previous drug pricing initiatives by the National Institute of Clinical Excellence (NICE) would suggest that value thresholds involving the cost per quality adjusted life year (QALY) gained coupled with comprehensive pharmacoeconomic (PE) models would likely play a central role in the new product pricing system.

The application of value based drug price estimation requires the establishment of a threshold for societal value where drugs at or below this level would be reimbursed by publicly funded health care systems. As an illustration, the National Health Service (NHS) of the UK has established a threshold for drug coverage at £30,000 per QALY gained.[12] In the Netherlands, the unofficial threshold is €18,000 per QALY.[5] One of the challenges in the use of such thresholds is that the wealth of an individual country is not considered. To address this, the World Health Organization (WHO) has proposed to use multiples of a country's per capita gross domestic product (GDP) to establish thresholds for economic value.[13,14] Based on the WHO criteria, products less than or equal three times the per capita GDP would be considered cost effective.[13]

What would be of interest to all the key stakeholders would be the development of a drug pricing index that is linked to both product performance and value thresholds that also consider the wealth of a nation. In this study, we describe the development of such an index that can be applied to new therapies indicated for the treatment of metastatic colorectal cancer (mCRC).

2. Methods

2.1. Modeling the pharmacoeconomic outcomes of mCRC

mCRC was chosen because several new anticancer agents have been approved in this disease site but their high cost has led to their outright refusal for reimbursement by government payers.[15,16] The development of a pricing index for new drugs in mCRC began with the construction of a PE model. The model was designed to simulate the clinical and economic outcomes in patients receiving standard chemotherapy with the addition of a 'new drug' that provides a survival increment between 1.4 and 6 months. Details of the model's development, validation and its population are described elsewhere.[17] Briefly, the timeframe was from the first cycle of first line chemotherapy until death. The current standard of care for the first line treatment of mCRC is oxaliplatin in combination with infusional 5-fluorouracil (FOLFOX).[18,19] In patients who have disease progression or intolerable toxicity, second line irinotecan in combination with infusional 5-fluorouracil (FOLFIRI) is a recommended treatment.[18] Therefore, the model began with FOLFOX (± the 'new drug') followed by FOLFIRI upon disease progression or the discontinuation of first line therapy because of intolerable toxicity. The clinical data required to populate the model were obtained from the oncology literature.[19,20] The drug that provided the point estimates for the incremental benefits quantified by the pricing index was bevacizumab, an agent that targets the vascular endothelial growth factor (VEGF) and is associated with a 1.4 month survival benefit in mCRC.[20]

2.2. Multinational data collection

The intent of this study was to develop a pricing index that could be used across many countries to estimate a value based price for new drugs in patients with mCRC. The PE model had to be populated with cost and utility data in order to generate the cost effectiveness pricing outputs required to develop the pricing index. The required data were collected in cancer centres from Canada, Spain, South Africa, Malaysia and India. The selection of these countries provided a per capita GDP ranging from $3100 to $39,000 (Table 1).

2.3. Estimation of treatment costs

For each country, costs for anticancer drugs, materials for drug delivery, patient monitoring, other related hospital resources (e.g. laboratory and diagnostic tests) as well as palliative care costs for terminally ill cancer patients were collected from local cancer centres and from the international oncology literature.[17,21–24] All costs and outputs in the current study were reported in 2010 US dollars.

2.4. Health state utilities

Health state utilities are scores between 0 and 1, where 0 represents death and 1 is a state of perfect health or optimal quality of life. In economic evaluations, they are used to adjust the survival benefit of a new drug by the quality of life experienced by a patient during that time period. In the current study, quality-adjusted life periods were measured as 'healthy months equivalent' for the time spent in each outcome of the PE, model using the Time Trade-off technique[17,25,26] Utilities for the various outcomes in the PE model (16 in total) were obtained from a sample of oncology nurses and pharmacists (total n = 112) involved in the treatment of mCRC patients in each of the respective countries.[17,21–24]

2.5. Estimating a value based price for each country

Using the country specific cost and utility data, a cost utility analysis was performed to estimate a value based price for