

# Cost–Effectiveness Analysis Of Medicines And Formulary Coverage Decisions: Methodological Issues And Controversies

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Assessing new drug therapies for their cost effectiveness is becoming standard in an increasing number of countries around the world. In addition to Australia, Canada, and several other countries, the Netherlands and Finland have also recently taken steps in the direction of introducing pharmacoeconomic guidelines within a formal evidence-based decision-making mechanism. The most recent addition has been the establishment of the National Institutes of Clinical Excellence (NICE) in the UK with the mandate undertakes cost-effectiveness analysis to facilitate drug formulary inclusion decision making for the British National Health Service.

In Canada, each province has established a set of criteria and guidelines to implement economic evaluation driven evidence-based formulary decision-making.

The British Columbia (BC) Pharmacoeconomic Initiative (PI) has the mandate to review and critically evaluate all pharmacoeconomic studies submitted by industry to guide the coverage decision making. The objective of the PI is to maximize the health benefits received by British Columbians from a limited provincial drug insurance plan budget. For the PI to achieve its mandate, pharmaceutical manufacturers must present pharmacoeconomic evaluations with the submissions for their drug products. These submissions are then critically evaluated and reviewed by a volunteer expert committee. Drug manufacturers usually choose to submit one of the following types of economic analysis: cost comparison, cost consequence, budget impact, cost minimization, cost-effectiveness, cost-utility, and cost-benefit.

In this presentation, I will first outline the impact of the above new informational requirement on by funding agencies on the design and conduct of clinical trials of new drugs. Clinical Trial design is affected because in addition to the standard safety and efficacy evaluation, affordability in terms of cost-effectiveness must also now be concurrently assessed. Using economic evaluations to make policy decisions poses a few additional challenges beyond those encountered when performing economic evaluations. I will next present the results of two recently published analyses that present the experiences gained, as the Director of the PI of BC in using economic evaluations to make formulary coverage decisions.

The interaction of methodological issues with respect to economic evaluations and the policy needs of the funder have created some controversies regarding the choice of the appropriate comparator, modeling

etc. and these will also be presented.

Finally, comments on the importance and applicability of the issues presented today within the context of countries such as Korea will be solicited from the audience.