Ontario’s Formulary Committee
How Recommendations Are Made

Anne M. PausJenssen,1 Peter A. Singer 2,3,4 and Allan S. Detsky 2,3,5

1 Department of Medicine, University of Saskatchewan, Saskatoon, Saskatchewan, Canada
2 Department of Medicine, University Health Network and Mount Sinai Hospital, Toronto, Ontario, Canada
3 Department of Medicine, The University of Toronto, Toronto, Ontario, Canada
4 The University of Toronto Joint Centre for Bioethics, Toronto, Ontario, Canada
5 Department of Health Policy, Management and Evaluation, The University of Toronto, Toronto, Ontario, Canada

Abstract

Background: In 1996, the provincial government in Ontario, Canada required pharmaceutical manufacturers seeking to list their products on the provincial formulary to provide a formal economic analysis documenting the products’ cost effectiveness. The provincial formulary lists pharmaceutical products for which reimbursement is provided for residents on the Ontario Drug Benefit Program (ODB).

Objective: To describe how listing decisions are made, and specifically the role of economic analysis in this process.

Design: A qualitative case study approach was taken. Data were analysed using the pattern-matching technique. Data consisted of meeting transcripts and interviews with committee members, which were coded and weighted for analysis using the pattern-matching technique.

Setting: Nine meetings of the Drug Quality and Therapeutics Committee (DQTC), which makes listing recommendations to the ODB, were observed.

Participants: Seven individual committee members were interviewed.

Results: Complex economic analyses (i.e. analyses more involved than a simple cost-consequence analysis) played a limited role. The clinical factor dominated the perception of costs. Generic and ‘me-too’ products with no price premium did not require complex economic analyses. Poor quality analyses were not useful and the DQTC members’ lack of in-depth knowledge of health economics influenced the extent to which analyses were discussed. The DQTC did discuss economic issues however, and often performed informal economic analyses to guide decisions.

Conclusions: Complex economic analyses had an impact on provincial drug benefit decisions in a limited number of circumstances, principally for expensive innovative products. However, the committee did use some form of economic analysis to guide decisions in almost all cases, and therefore requesting economic analyses, even simple ones, from manufacturers seeking formulary listing is a useful healthcare policy.
Historically, new pharmaceutical products, once licensed, were readily adopted by physicians into practice. Physicians, well known to disregard product cost when making prescribing decisions, were the biggest ‘buyers’ of new products.[1] More recently, large organisations such as health maintenance organisations (HMOs) and other third-party payers have become the new buyers. The traditional mechanism by which these organisations managed drug benefits was to develop a ‘formulary’ – a list of pharmaceutical products that they would supply or provide reimbursement for beneficiaries. Formulary committees, once primarily focused on the clinical efficacy and safety of products, now consider economic issues when reviewing products for inclusion.

In the early 1990s, the Ontario Ministry of Health (MOH), manager of a large drug benefit program, reacted to rapidly increasing drug costs by deciding that simple unit costs were no longer sufficient information on which to base formulary decisions. In 1993, Ontario’s pharmacoeconomic guidelines were drafted with the intention that companies seeking listing of their products on the provincial formulary must undertake an economic analysis outlining a comprehensive accounting of products’ costs and effects.[2]

Ontario’s guidelines, implemented in 1996, came under heavy criticism. Industry claimed that the true goal behind the policy was not ‘value for money’ but rather cost containment. Academics raised concerns that economic analysis would be expected by the MOH to give ‘one correct answer’ to a listing decision.[3] The controversy surrounding the implementation of the guidelines prompted the interest in undertaking this study.

While formulary committees worldwide employ economic analyses in an ‘ad hoc’ manner to aid listing decisions, Australia and Ontario have been leaders in this regard. Many lessons about the role of economic analysis in formulary decision-making by a government agency can be learned from Ontario’s early experience. This may be of particular interest to those in the US debating the merits and logistics of a Medicare Drug Benefit Program.

The objective of this study was to describe in detail how one committee arrives at recommendations regarding the listing of drugs on a formulary for a large government-financed drug plan and, in particular, to examine the role of economic information in that process.

**Methods**

**Design and Setting**

A qualitative approach was taken, specifically that of a case study.[4] This case study was set around the Drug Quality and Therapeutics Committee (DQTC) of Ontario, which advises the MOH on what drugs should be listed on the provincial formulary. Ontario’s formulary is a list of products that the provincial government will financially cover for residents of the province who are over the age of 65 years, are on welfare, or whose drug costs represent a certain portion of their total income. A small co-payment based on annual income is required from a recipient. Ontario spent 1.5 billion Canadian dollars ($Can) in 1998 by covering costs for 2.15 million people.

The listing decision is separate from the licensing decision made by the Health Protections Branch of Canada. This latter decision is focused on issues of clinical efficacy and safety. Placebo-controlled trials are adequate data sources for a licensing decision; Ontario’s pharmacoeconomic guidelines state comparative trials are preferable for listing decisions.[5]

DQTC members are appointed by the MOH, and are selected based on their technical expertise and specific knowledge. There were 12 DQTC members; eight physicians, one pharmacist, one pharmacologist, and two government employees. The DQTC meets once a month for 3-hour meetings. Prior to each meeting, two expert consultants (who may or may not be DQTC members) review manufacturers’ submissions – one reviews clinical data, and the other economic data. Each consultant makes an independent recommendation as to how
the product should be listed on the formulary: full listing; limited use listing where predetermined criteria must be met; or ‘section 8’ listing whereby each prescription is reviewed by an expert after the patient’s physician has provided a written request for reimbursement. The consultants’ assessments are reviewed at the meetings, and the DQTC’s recommendation is sent to manufacturers and to the MOH for final approval. This last step in the listing process was not examined.

Gaining Access and Confidentiality Agreement

Because DQTC meetings are not open to the public, confidentiality agreements were signed. Product names and DQTC members’ names were removed from this report. The government employees and persons at the Drug Programs Branch (a section of the MOH) who liaise with the DQTC could not be interviewed. Access was not given to written reports, which included manufacturers’ submitted data, consultants’ reports, and minutes of observed meetings.

Data

Data in the form of meeting transcripts were collected from nine consecutive meetings (December 1997 to August 1998 – typical case sampling). After each meeting data were labelled, coded, and weighted to allow for ongoing analysis. The coding categories that all the codes fell under are listed and discussed as factors in the results section. Data were coded using the open coding technique. Interviews of DQTC members served as another data source. All but the government employees were approached for interviews (theoretical sampling), and seven agreed. Two members left the committee and a third member cited confidentiality concerns and declined.

Data Collection

Because of legal concerns, the DQTC meetings could not be taped and only written transcripts were allowed. The interviews were taped however.

A semi-structured interview technique was employed and member checks were performed (a means to establish internal validity through discussion of the ongoing analysis with interviewees).[6]

Data Analysis

Background reading suggested several concepts were likely to be important to formulary listing decisions and the data were examined initially for these factors. Data were analysed using the pattern-matching technique whereby empirically based data are compared to that which is predicted in the literature. This form of analysis is often used in qualitative studies as it helps to strengthen the internal validity of case studies.[4] The original data were re-coded at the end of the collection period to ensure stable analysis; correlation was high at 89%.

Results

There were several key factors (codes) that surfaced in the data and are discussed in turn in subsequent sections. Table I outlines the frequency with which the factors surfaced based on the type of drug that was discussed at the DQTC meetings. This table helps to establish the relative importance of each factor as the more often it was discussed the more important it was to the decision-making process (weighting of codes).

The decision-making process at the DQTC was complex and many decisions involved weighting several key priorities. Some decisions were straightforward, with few factors influencing the final outcome. This observation was confirmed in the interviews and all seven committee members agreed.

Clinical Factor

Central to all decisions was the clinical factor – the product’s perceived clinical merit. This was the driving force in the decision to list a product on the provincial formulary. This observation was confirmed through the use of member checks and was consistent with other literature (pattern-matching
technique). Most time was spent dissecting manufacturers' clinical claims by critically appraising the submitted studies. The strength of the clinical claim affected how the economic part of the submission was viewed. If a product was deemed not to have clinical merit then discussion would end, and it was not listed. One interviewee said: "Cost is an issue, but the first thing that even economic analysis hinges on is effectiveness. So I think it is much more of an issue to initially look at issues of efficacy and safety" (Interview #4:6.1-3).

The DQTC looked at 'effect size' – the product's ability to achieve clinical benefits throughout the dosage range. This often was an issue when different dosages had different prices, as this led to different cost-effectiveness ratios. It was not uncommon that manufacturers based submissions on the most cost-effective dosage, which was not always the most clinically relevant.

Another reason why the clinical factor dominated related to the general make-up of the committee – while four of eight physician members had extensive training in clinical epidemiology, only one had training in health economics. This member was often asked to review products with high associated costs. Overall the committee expressed that they relied on the economic consultant (who was often external to the DQTC) to tell them whether the product was good value for the money. One member said: “Often as a group we reverse the recommendation of the clinical reviewer, because we have enough expertise in the room to do that. The same is not true for the economic reviewer. We are so much more dependent on that single reviewer” (Interview #5:3.1-13).

### Type of Drug

In the nine meetings observed, 134 drugs were discussed. Fifty-three of the 134 were generic products, 49 were ‘me-too’ (or therapeutically similar) products, and 32 were innovative products.

The type of drug that was discussed – generic, ‘me-too’, or innovative – had a substantial effect on discussions as this influenced the extent to which other factors entered the decision-making process. The most straightforward decisions involved generic products, and the most complicated surrounded innovative products. This observation was confirmed through the use of member checks, but had not been previously described in the literature.

Generic products seeking listing simply had to prove bio-equivalence. Because Ontario regulates the cost of generic products (25–40% less expensive than their brand name counterparts), other factors rarely entered the discussions. Generic products were often discussed ‘en bloc’, and up to 12 products were voted on at one time.

The ‘me-too’ products fell into two different groups depending on whether the manufacturer had asked for a price premium relative to similar products already listed. Given a ‘me-too’ product met standards of clinical efficacy and safety, those not seeking a price premium often succeeded in their bid to be listed. Those ‘me-too’ products with a price premium involved more complicated dis-

<table>
<thead>
<tr>
<th>Drug type</th>
<th>Clinical factor</th>
<th>Unit cost</th>
<th>Impact analysis</th>
<th>Economic analysis</th>
<th>Quality of data</th>
<th>Consistency</th>
<th>Values and political factor</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic</td>
<td>10</td>
<td>41</td>
<td>3</td>
<td>1</td>
<td>8</td>
<td>4</td>
<td>0</td>
<td>53</td>
</tr>
<tr>
<td>Me-too (–PP)</td>
<td>7</td>
<td>17</td>
<td>7</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>21</td>
</tr>
<tr>
<td>Me-too (+PP)</td>
<td>6</td>
<td>23</td>
<td>14</td>
<td>2</td>
<td>6</td>
<td>5</td>
<td>2</td>
<td>23</td>
</tr>
<tr>
<td>Me-too (UK)</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Innovative</td>
<td>27</td>
<td>11</td>
<td>19</td>
<td>8</td>
<td>21</td>
<td>7</td>
<td>8</td>
<td>32</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td>92</td>
<td>44</td>
<td>11</td>
<td>41</td>
<td>17</td>
<td>12</td>
<td>134</td>
</tr>
</tbody>
</table>

UK = unknown from discussion whether manufacturer sought a price premium; –PP = no price premium; +PP = price premium.
Cussions as manufacturers had to justify increased costs.

The discussions involving innovative products were often the most complicated. Innovative products, the first of a new class of product, are expensive and may be the sole treatment option available for a given disease process. This created problems in establishing appropriate clinical and economic comparators.

Quality Factor

The quality of the data was another important factor in the decision-making process. Surrogate outcomes and short periods of follow-up in clinical trials were criticised, and the resulting assumptions employed in the economic analyses were carefully reviewed for validity. The DQTC often disagreed with manufacturers’ interpretations of data, believing that manufacturers overstated benefits. Again this finding was confirmed in the interviews and was consistent with other studies.

Those DQTC members who also served as clinical consultants complained about the poor organisation of the manufacturers’ submissions (the Ontario pharmacoeconomic guidelines outline to manufacturers how to format their submissions). Three claimed to have spent 1–2 hours organising the submissions prior to assessing the data and others performed their own literature searches to check for completeness. One said: “Sometimes you find things hidden away that contradict everything else that they said. It makes you wonder if their conclusions are valid” (Interview #1:73-75).

If the data were not clear or was questionable, then recommendations were deferred. Poor quality submissions influenced the listing decision for 31% of the drugs reviewed during this case study.

Consistency Factor

Past decisions were used to guide the decision-making process, a factor that was most evident in discussions involving generic and ‘me-too’ products. A generic product could not be listed unless its reference product was, and ‘me-too’ products were also compared to each other: “How can we reject this drug when the other was listed just 6 months ago?” (meeting transcript Dec. K.10).

Member checks were used to confirm this observation and it was consistent with the literature.

The DQTC also concerned itself with the impact that present decisions had on future ones. The DQTC often tried to discuss similar products at one meeting to ensure that equal attention was paid to all, promoting consistency.

The Role of the Unit Cost and the Impact Analysis

At the DQTC meetings, it became obvious how much the different economic variables – the unit cost, the impact analysis and the economic analysis – are inter-related. The unit cost of the drug (price per tablet) drives the impact analysis, the estimate of the total annual cost faced by the MOH if the product in question is listed. A higher unit cost results in larger costs to the drug budget. A similar relationship exists between the unit cost and the economic analysis: value for money is estimated by looking at the ratio of incremental cost to incremental benefit. A higher unit cost means that incremental costs are higher, and leads to less favourable cost-effectiveness ratios.

The DQTC members understood the above relationships, and often referred to costing tables (a list of unit prices of formulary drugs used to treat the same health state). For a ‘me-too’ product with the same clinical effects for which a price premium was not requested, this costing data was all that was required to perform a cost-comparison analysis.

The impact analysis served as a magnifier – high estimated costs to the MOH led to more careful examination of the data. Again member checks were used to confirm this finding. One interviewee said: “Standards of evidence and requirements for economic attractiveness would be much stricter if it’s a $Can20 million-per-year drug than let’s say a $Can300 000 per-year drug” (Interview #7:30.3). The DQTC felt their job, as a government committee, was to ensure that the money spent on drugs was spent wisely: “The committee realises that the
cost for paying for medications is huge and...our job is trying to ensure that the government spends its monies well and the consumers get what they need...we tend to be hard on medications that are being presented” (Interview #2:46.2).

However, the importance of the impact analysis was second to that of the economic analysis; a product with an attractive cost-effectiveness ratio would not be rejected on the basis of the impact analysis alone. One member said: “Certainly we are aware that the Ministry would like to keep costs down, but this has been done globally, and has not affected the listing of one drug in particular. A drug has never been rejected in an attempt to keep the budget down – instead it (the MOH) has issued caps on the budget, or co-payments, or has delayed issuing a new formulary” (Interview #5:3.19-25).

Note however that the Ontario pharmacoeconomic guidelines were not specific on what constituted an ‘attractive’ cost-effectiveness ratio; this rather was a subjective decision made by the DQTC.

The Role of the Economic Analysis

Complex economic analyses (i.e. analyses more involved than a simple cost-consequence analysis) were frequently either unnecessary or not discussed. One reason for this was that the majority of reviewed products were generic products and ‘me-too’ products not requesting a price premium (74 out of 134 products). In these circumstances, unit price comparison sufficed. Another reason why the economic analysis was not discussed related to the strength of the clinical data. The DQTC routinely discussed the clinical aspects of a product before the economic aspects, and so it became unnecessary to discuss the economic analysis if a product failed to make its clinical case. Moreover, if the quality of the economic analysis was poor – specifically questionable assumptions made regarding clinical benefits or projected savings in healthcare utilisation – then it was not discussed. The last reason why the submitted economic analysis was not discussed occurred only once: an analysis was not submitted, as the manufacturer claimed the benefits and costs were too hard to estimate. Overall, in this case study, the manufacturers’ submitted economic analyses had a substantial impact on the decision to list a product for 11 of the 134 products discussed.

The submitted economic analysis played a larger role in the decision to list innovative products (in 8 of 32 products). At first glance, associated drug costs appeared high but resulted in considerable cost savings in other healthcare sectors. Even in cases where the DQTC did not utilise manufacturers’ specific economic analyses, the DQTC did rely on general principles of economic analysis to aid the decision-making process. In fact, at the meetings it became clear that the committee performed it’s own crude cost-consequence analysis. The committee routinely used the costing tables which allowed for a gross estimation of cost-effectiveness ratios. This was most easily done for ‘me-too’ products: “There are some that are so absolutely clear that you do not have to read an economic analysis to come up with an answer. You look at $Can12 a day versus $Can3 a day and you know that the studies are not so compelling that there is much difference” (Interview #3.23.1-2).

All those interviewed agreed with the above observations and moreover were concerned about the validity of the assumptions and three raised concerns about the number of assumptions made in the economic analyses. However, one member stated that this is an ‘unfixable problem’ as the number of assumptions made will always be greater at early stages of drug development – when manufacturers seek listing – because less is known about long-term gains.

Value Judgments

Some DQTC members complained about the use of value judgments in economic analysis. Two of those interviewed recognised the pervasive nature of value judgments in each step of the listing decision. They felt each member had his/her own set of values that influenced the perception of the product, including its clinical merit. Different physicians had different ideas as to what disease processes were the most important to treat. One inter-
viewee, however, felt that the different values and perspectives reflected in the committee was the committee’s strength: “It is better to have opinionated vocal people who speak up and bring up issues, whatever they may be. It broadens the decision” (Interview #5:9.2-4).

The DQTC members also clearly recognised the importance of factors other than clinical merit and economic attractiveness to the listing recommendation. Equity of access was felt to be a political factor, best left to politicians to consider in the final stages of the listing decision. The DQTC based its recommendations on the best available evidence believing this to be their mandate.

Figure 1 illustrates the inter-relationships among the many factors that were involved in the decision to list a product. Figure 2 details factors affecting the ability of the economic analysis to serve as an effective decision aid.

**Discussion**

This study found the role of formal complex economic analysis in the formulary-listing decision at the DQTC to be limited. This result is supported by other research – surveys of formulary decision-makers in the US found economic analysis difficult to incorporate into decisions. Researchers in Australia, the first country to formally tie economic analysis to formulary listing, recently reported several methodological problems that made the economic analysis less useful. Therefore, finding that economic analysis plays a limited role in the decision-making process at the DQTC was not unexpected. However, the main contribu-

---

Fig. 1. Schemata of the decision making process at the Drug Quality and Therapeutics Committee (DQTC) of Ontario, Canada.
tion of this study is its description of a decision-making process. No case study has previously documented the formulary decision-making process, and this study describes in detail how this committee made decisions. Moreover, this case study examined the use of economic analysis in the context of formulary decision-making, not in isolation. This work further describes six reasons for the limited role of complex economic analysis in the formulary listing process.

First, the economic analysis was dominated by the clinical factor. Clinical benefits are paramount as the economic value ascribed to a product depends on its ability to achieve clinical targets. The clinical factor was the most important in the decision to list a product on the formulary. This was true for the decision-making process at the DQTC and for formulary decision makers’ elsewhere.[7-10]

Second, the type of drugs reviewed at the DQTC influenced the role of the economic analysis. The majority reviewed were generic and ‘me-too’ products with no price premium which negated the need for complex economic analyses. While the influence of drug type on economic analysis has not been previously described in the literature, this makes sense. Recent research suggests that cost-comparison analysis, used most commonly at the DQTC, is ideally suited to formulary decision making.[11]

Third, the ability of the economic analysis to have an impact on some decisions was hampered by poor quality analyses. This seems to be an ongoing problem – previous studies have documented serious flaws in published economic analyses.[12,13] Educating manufacturers, however, is likely to have little impact as most problems stem from different interpretations of clinical data. Manufacturers view economic analysis as a marketing tool – and as such interpret data more optimistically than reviewers are prone to do.[14,15] Guidelines on how to undertake economic analysis, despite being prolific in number, will not change this bias.

Fig. 2. Factors influencing the usefulness of economic analysis. ODB = Ontario Drug Benefit Program.
Fourth, the economic analysis was limited by the DQTC members’ knowledge of economic analysis. The majority did not have sufficient training in health economics to adequately critique either the manufacturers’ submissions or the external economic consultants’ assessments. This limited the discussion of economic analyses at meetings, and hence the importance of the economic analysis to decisions made. HMOs have reported similar problems.[7,10] The MOH has addressed this problem; the DQTC of today now has three members with considerable training in health economics.

Fifth, the perception of economic analysis as a valid decision aid is weakened by the reliance of the economic analysis on value judgments. Researchers’ values help shape all parts of the economic analysis, and hence influence its conclusions.[14,15] Economic analysis was not, however, designed to give one correct answer to a resource allocation problem but rather to outline potential costs and consequences.[16] The DQTC members viewed the economic analysis as a ‘softer science’ than that used to determine clinical merit. Moreover, the DQTC was concerned with potential bias given pharmaceutical sponsorship.

Finally, the economic analysis was influenced by the context in which it was applied, that of priority setting. The economic analysis alone cannot answer questions of priority setting; this is why the final step in the listing decision is political. The MOH must take into account other factors, such as fairness, equity and accountability. Economic analysis may initially appear to simplify this process, but resource allocation is a broader process in which economic analysis is only one input.[17-21]

There are several limitations to this work. Written documents were not reviewed – an important reliability check. Interviewing government employees may have shed further light on the listing decision. The data collected described the role of the economic analysis at the DQTC at a particular time period. The results may not be generalisable to other formulary committees or even to the DQTC today. While the findings of this case study support other work, it is hypothesis generating only.

**Conclusions**

Currently, formal complex economic analysis plays a limited role in the decision-making process at the DQTC. In many cases, complex analyses are not required; simple unit-price comparisons suffice. In other cases, however, the limited role of economic analyses is in part due to the inherent structure of economic analysis itself, and in part its application to a process of resource allocation. Some reasons are modifiable, and others are not. However, while economic analysis is an imperfect tool, there are no alternatives, and it does succeed in bringing difficult issues out into the open for discussion particularly in the case of expensive new innovative drugs. For this reason, some form of economic analysis should continue to be used in formulary decision-making.

**Acknowledgements**

This project was supported by a grant from the Ontario Ministry of Health, Canada. Peter A. Singer is supported by an Investigator Award from the Canadian Institutes of Health Research.

The authors wish to thank the Drug Quality and Therapeutics Committee of Ontario and the Ontario Ministry of Health for facilitating this research project. In particular, Dr Lesia Babiak and Ms Linda Tennant were very helpful.

The authors also wish to acknowledge the input of Dr G. Naglie and Dr D. Martin. Mrs Mena Cali and Mrs Rebecca Heckbert provided invaluable technical support.

The authors have no conflicts of interest to declare.

**References**

20. Klein R. Puzzling out priorities: why we must acknowledge that rationing is a political process. BMJ 1998; 317: 959-60

Correspondence and offprints: Dr Allan S. Detsky, Mount Sinai Hospital, Room 427, 600 University Avenue, Toronto, Ontario M5G 1X5, Canada.
E-mail: allan.detsky@uhn.on.ca