"Cost-effectiveness" Estimates Result in Flawed Decision-making in Listing Drugs for Reimbursement

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ABSTRACT

Background: Facing financial pressures, the provinces and territories have chosen to use "cost-effectiveness" for making decisions about drug listings. This study examines the scientific basis for the procedures used to determine cost-effectiveness in 5 Canadian provinces.

Methods: Questionnaires were mailed to key provincial informants asking about the respondent's expertise and role, the administrative and scientific basis for decision-making, organizational structures and other factors in the scientific evaluation and decision-making process, and the transparency of the process. There were also questions about the data required and received and their importance, the place of cost-effectiveness and other economic impact evaluations, the data sources for them, and the use of follow-up monitoring to evaluate the decisions made.

Results: Information required by the provinces for decision-making about cost-effectiveness is not available to them at the time of their decisions about listing new medications. The primary sources of data on both efficacy and cost-effectiveness are pharmaceutical companies. Efficacy information is generated in a scientifically rigorous manner, whereas the effectiveness and cost data are estimates potentially subject to biases and evaluated by judgement (expert opinion) alone. Moreover, there is no collaboration in the assessment process between provinces. The outcomes are large differences between provinces in the decisions made and, hence, in the pharmaceuticals accessible to residents.

Conclusions: Current methods for making decisions about provincial drug listings are based on inadequate data, and the lack of consistency in the provinces' decisions suggest they may be scientifically flawed. We recommend establishing a single national scientific review committee, with re-evaluation of each drug's cost-effectiveness after a suitable period of monitored use.

La traduction du résumé se trouve à la fin de l'article.

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The review and approval of new drugs for marketing in Canada is performed by the federal government based on evidence about efficacy and safety.[1] This process has been in place for some 30 years and has been extensively examined[2-9] and criticized.[10-14] However, under the national health program, each province and territory has the political responsibility to manage its health budget in the best interest of its citizens, including making decisions about which drugs are listed for reimbursement. The evaluation of drugs for listing and the subsequent decision-making processes performed by each province and territory have received relatively little attention and are less understood.[15]

With increasing financial pressures, many provinces and territories have undertaken to evaluate comparative effectiveness, cost and cost-effectiveness of medications as the basis for decision-making. However, the process results in large variation in the number of drugs listed and the time taken for listing.[16,17]

This study was designed to examine procedures for the scientific evaluation of drugs being considered for listing in 5 provinces.[18] The project focused on assessing the organizational structures and expertise involved, the data required for decision-making and their availability, the methods used in the evaluation process, and the accountability for and follow-up of listing decisions. These parameters were chosen to examine the extent to which current procedures satisfy accepted standards for scientific evaluation and to provide an opportunity to identify inter-provincial consistencies.

METHODS

The study employed basic survey methodology. To minimize selection bias by the investigators, 2 independent advisory groups were invited to oversee the study implementation. The Management Advisory Committee, consisting of representatives of the federal and provincial governments and the pharmaceutical industry, expedited the appropriate identification of key informants and advised on questionnaire content. An External Scientific Advisory Committee, comprising 3 experts in clinical pharmacology and population therapeutics, reviewed the study protocol, questionnaires and final results.

The survey was to be performed in 5 provinces (British Columbia, Alberta, Ontario, Quebec and New Brunswick), representing a majority of the Canadian population (87.5%) and a broad geographic distribution. Each received a general questionnaire collecting overview data on procedures and methods and, to allow for an evaluation of reproducibility, a drug-specific questionnaire about the province's assessment of 5 drugs (alendronate, olanzapine, naratriptan, celecoxib and interferon b-1b). These products were chosen to cover a spectrum of anticipated "cost-effectiveness" decision-making situations. It is emphasized that the study was of the process of listing and not a specific investigation of the drugs.

The questionnaires asked about the respondent's expertise and role, the broad administrative and scientific structure for decision-making, organizational roles and other factors in the scientific evaluation and decision-making process, the transparency of the process, and the presence of any laws that form the basis for decision-making. In addition, there were questions about data required and received and their importance, the place of cost-effectiveness and other economic impact evaluations and the data sources for them, and the use of follow-up monitoring to evaluate the decisions made. Finally, the respondent's perception of the merits or weaknesses of the process, any recommendations for improvement, and the numbers of submissions, listings and rejections in 1999 were requested. The individual items were mainly structured questions. The questionnaires were pilot tested in a non-participating province. (Copies of the questionnaires can be obtained from Dr. West.)

Questionnaires were mailed to key informants, who, as senior bureaucrats in the provincial governments, were selected to be able to respond authoritatively and responsibly for their governments. They were asked to study and complete the questionnaires as fully as possible. The mailing was followed shortly after by a visit from one or more investigators who reviewed the questionnaires with the interviewee(s). When there were queries about specific questions, the interviewers' responses were limited to explaining what the particular item meant and not advising an interviewee as to what the answer should be. The respondents were requested to answer the questions as written and, after reviewing their response, mail the completed questionnaires to the project office. To maintain the degree of anonymity guaranteed to respondents, the provinces' names were mixed and given the letters A to E.

TABLE I

Information Important for Listing Decisions and its Availability

Data Item	Mean Importance Score (range)*	Mean Availability Score (range)†
Comparative efficacy against alternative	5.0 (5 - 5)	2.4 (2 - 3)
Cost-effectiveness (cost per effect)	4.8 (4 - 5)	2.8 (2 - 4)
Dosage price (cost per dose)	4.4 (3 - 5)	5.0 (5 - 5)
Availability of alternative therapy	4.4 (4 - 5)	2.8 (2 - 4)
Cost compared with available alternatives	4.4 (3 - 5)	3.8 (3 - 5)
Impact on total costs of drug benefit program	4.4 (3 - 5)	3.6 (3 - 5)
Comparative safety against alternative	4.4 (3 - 5)	2.4 (2 - 3)
Cost per treatment course	4.2 (3 - 5)	4.2 (3 - 5)
Effect on overall health care costs in province	4.0 (3 - 5)	2.4 (2 - 3)
Contribution to current therapeutic armamentarium	3.6 (3 - 5)	3.2 (2 - 4)
Drug compliance	3.6 (3 - 5)	2.8 (2 - 5)
Patient satisfaction with drug	3.2 (2 - 4)	2.6 (1 - 5)
Comparative efficacy against placebo	3.2 (2 - 4)	4.0 (3 - 5)
Pharmacology	2.8 (2 - 3)	3.8 (3 - 5)
Drug interactions	2.8 (2 - 4)	3.2 (2 - 4)
Chemistry	1.6 (1 - 2)	3.0 (2 - 5)

* Importance scored as 1 = not important, 2 = little importance, 3 = important, 4 = very important, 5 = extremely important

† Availability scored as: 1 = never, 2 = rarely (<40% of the time), 3 = often (40-70% of the time), 4 = mostly (>70% of the time), 5 = always

TABLE II

Provinces' Estimates of the Frequency of Missing Data or Problem Areas

Data Item	100%	>70%	40-70%	<40%	0%
Efficacy					
Control was placebo while alternative therapy exists		2	3		
Treatment comparison group inappropriate		1	2	2	
Difficult to generalize from highly selected randomized clinical trial (RCT) population		4	1		
RCT follow-up is too short for chronic use	2	2	1		
Outcomes of RCTs are too focused and limited			5		
Sample size is too small			3	1	
Study quality is poor		1	2	2	
Safety					
Sample size too small		1	1	2	
Difficult to generalize from selected RCT population		2	2		
Safety outcomes too focused and limited			2	2	
Study quality is poor		1	1	2	
Economic impact					
Studied population very different from treated population		2	3		
Missing data on effectiveness (drug effect in real world)	1	3	1		
Unconvincing model used to estimate effectiveness		1	4		
Cost assessment					
Data needed to estimate drug costs are missing			5		
Data needed to estimate positive effect (e.g., fewer hospitalizations) leading to lower costs are missing		1	4		

Where a row does not sum to 5, one or more provinces did not provide an answer

RESULTS

All approached provinces and key informants agreed to participate. Comparisons between the general and drug-specific questionnaires in each province were consistent. The results of the general questionnaires are summarized in 3 categories.

Data used for decision-making

To evaluate the importance and availability of data for drug listing decisions, the questionnaire contained items for interviewees to characterize on scales of 1=not important to 5=extremely important and 1=never available to 5=always available. As Table I demonstrates, there is consistency in the importance attached to data items. However, as Table I also shows, there is discordance between information considered important for decision-making and its availability. This is particularly striking for data on comparative efficacy against alternative, cost-effectiveness, availability of alternative therapy, and impact on the overall health care costs to the province.

TABLE III

Areas of Expertise of Internal and External Reviewers, by Province

Expertise	Province A		Province B		Province C		Province D		Province E	
	Internal	External	Internal	External	Internal	External	Internal	External	Internal	External
Pharmacy	+	+	–	+	+	–	–	+	+	+
Specialist medicine	+	+	–	+	–	+	–	+	+	+
General medicine	+	–	–	+	–	+	–	+	+	+
Pharmacoeconomics	+	–	–	+	–	+	–	+	–	+
Pharmacoepidemiology	+	–	–	+	–	+	–	+	–	+
Ethics	–	+	–	+	–	–	–	–	–	–
Chemistry	–	–	–	+	–	–	–	+	–	–
Pharmacokinetics	–	–	–	–	+	–	–	–	–	–
Drug policy	–	–	–	–	+	–	–	–	–	–
Drug metabolism & analysis	–	–	–	–	+	–	–	–	–	–
Administration	–	–	–	–	–	–	–	–	+	–
Other	–	–	–	–	–	+	–	–	–	–

+ Expertise available; – Expertise not available

TABLE IV

New Drug Submissions, Reviews and Outcomes in 1999, by Province

Submissions, Reviews and Outcomes	Province A	Province B	Province C	Province D	Province E
New submissions reviewed	304	272	59	48	393
New listings to program	183	215	25	39	338
Full listing	130	194	6	*	*
Restricted listing	53	21	19	*	*
Still under review	0	22	4	0	0
Rejected submissions	121	35	30	9	55

* Not known or not available

Table II shows the areas where data are lacking and provides estimates of the frequency with which problems are encountered in applications. Economic impact data are missing at least 40% of the time and, of this, the most commonly missing is effectiveness information. In addition, the models used to estimate effectiveness were reported to be often or frequently unconvincing. For efficacy and safety, problems are frequently related to the duration of the trial, the selection of a special population, the size of the study, the choice of the outcomes, and the absence of a test of the drug under consideration against "good" alternative drugs.

Provincial scientific decision-making structures and procedures

All provinces identified the scientific review as "extremely important" in the decision-making process but none is bound by the scientific evaluation. Recommendations based on the scientific review can be overruled at an administrative level. To estimate the frequency of overrules, interviewees were asked how often a recommendation to list a drug had been rejected in the past 5 years (1 province's response was limited to 4 years). Of the 4 who responded, 3 reported no overrules and the other reported 2.

Policy decisions are made within each province's regulatory framework and 3 of the 5 provinces have laws covering drug listing. However, 2 of the 3 reported that the important scientific considerations that need to be addressed are "somewhat" covered, while the other reported that they were "not at all" covered.

The scientific review process varies among the 5 provinces, with only 3 having an internal scientific review committee. All 5 use external review groups, with usage varying between "always" and "as needed." The types of expertise used for the scientific evaluation of new products are quite consistent, as shown in Table III. However, the experts used are specific to the province.

Heterogeneity exists between provinces in the use of a scientific approach and defined criteria for the evaluation and decision-making processes. One province reported rigorously applying the criteria of evidence-based medicine. Among the other 4, there were inconsistencies in whether there were standards and criteria for evaluation and, where they exist, there was variability in the adherence to them. Only 1 province reported having criteria for determining whether a drug is cost-effective. In response to being asked whether the fact that a drug was listed in other provinces might influence their scientific evaluation, 3 responded "rarely" and 2 stated "never."

Each province requires pharmaceutical companies to make specific submissions for their drugs providing selected parts of the data submitted in the federal marketing approval application. The selected data consisted of efficacy in 5 provinces, safety in 2, basic science in 2, manufacturing in 2, and bio-equivalence in 1. This inter-provincial variation differs somewhat from the consistency in the importance of data for decision-making (Table I).

With the intention of examining the merit of the provincial listing process, interviewees were asked about the follow-up of decisions. Three provinces responded that systematic follow-up to evaluate the impact (outcomes/economics) of the decision to list was done 40-70% of the time, while the other 2 responded that it was rarely done (<40%). Two interviewees reported that drug utilization review to evaluate the quality of drug use is done 40-70% of the time, 1 reported "rarely" (<40%), and 2 responded "never". When interviewees were asked whether drugs were ever listed with the understanding that a cost-effectiveness study would be done after its usual use is established, 2 answered "rarely" and the other 3 stated "no." In the past 5 years, all 5 provinces reported that they had both removed drugs from listing status and switched drugs to restricted status.

Inter-provincial consistency in drug listing

To examine the consistency of the scientific evaluation process, interviewees were asked about the numbers of submissions and listings in their province in 1999.

These show that there are considerable differences between the provinces (Table IV).

DISCUSSION

The results of this survey are dependent upon good questionnaire design and the respondents understanding what was required of them. The questionnaires were designed in consultation with the advisory committees and were pilot-tested. Researchers met with every respondent to clarify the project's objectives and what was being asked, but were careful not to suggest answers.

An impressive finding is the consistency in the data requirements for the evaluation process and the importance placed on data items by the provinces (Table I). Of concern is that much of the required data are reported as not being adequately available. This was not unexpected because, for most items considered important, the data do not exist before marketing. Nevertheless, overall provincial requirements are inadequately met and important decisions are based on attempted evaluations of unsatisfactory data.

By far, the most common data limitations (Table II) result from the inherent design characteristics of the pharmaceutical companies' pre-marketing efficacy and safety studies. These relate to the use of a placebo as a comparator; studying a highly selected population with a resultant inability to generalize the results; the relatively short duration of studies of longer-term treatments; and the number of participants.

The primary sources of data for the provinces for both efficacy and cost-effectiveness analyses are the companies. Companies' efficacy data are generated in a scientifically rigorous manner according to standardized rules and criteria. However, pre-marketing cost-effectiveness data provided by companies raise concern. At the time of submission for listing, effectiveness (how well a drug performs in real clinical situations),[19] comparative safety, cost to the system, and cost-effectiveness data have not been assembled. The information in submissions on these aspects of the new drug is, at best, soft data modelled from efficacy information and is of uncertain validity.

The structure of the scientific review committee shows consistency among the provinces in the kinds of expertise involved (Table III), which implies duplication of effort. Furthermore, with the exception of one province, the required expertise does not exist within the internal committees. Provinces depend upon outside consultants to evaluate the submitted data, which raises questions about the comparability of the consultants' qualifications and the consistency of evaluations within and between provinces.

There is also no collaboration among provinces. Respondents reported that decisions in other provinces had little or no impact on their own decisions.

The differences in the provincial decision-making processes lead to different outcomes (Table IV). Such variation occurs in all 10 provinces.[17] This raises both a fundamental concern over the adequacy of the current drug listing system and a serious public health concern relating to equity in access to drugs across Canada, which may lead to differences in health status.

Finally, there are minimal, if any, mechanisms to examine the cost-effectiveness of a drug once it is listed. Thus, there is no way of re-visiting a decision once made.

RECOMMENDATIONS

We strongly recommend collaboration among provinces to share expertise, prevent duplication, ensure consistency in the evaluation, and increase the quality of the decision-making process. Ideally, the assessment of comparative effectiveness and safety and the true cost-effectiveness of new medications compared with alternative drugs should be performed by a single, national scientific review committee. Assessments of new drugs should be made after a suitable period of monitored clinical use and the original listing decision re-evaluated based on hard data.[20]

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RÉSUMÉ

Contexte : Face aux pressions financières, les provinces et territoires ont choisi de se servir des études « coût-efficacité » pour prendre les décisions concernant l'admission des nouveaux médicaments sur les formulaires provinciaux. Cette étude examine la base scientifique du processus d'évaluation coût-efficacité dans cinq provinces.

Méthodes : Un questionnaire a été envoyé aux personnes responsables dans chaque province pour obtenir des renseignements sur leur rôle et expertise, les bases administratives et scientifiques entourant la prise de décision ainsi que la structure organisationnelle et tout autre facteur pouvant affecter le processus de décision et sa transparence. D'autres questions portaient sur les données utilisées pour la prise de décision afin de déterminer leur importance dans le processus décisionnel et leur disponibilité au moment de la prise de décision. Le questionnaire s'attachait, enfin à déterminer l'importance des études coût-efficacité pour la prise de décision, la source des données économiques et les modalités de suivi une fois la décision prise.

Résultats : De nombreuses données sur le coût et l'efficacité considérées comme importantes par les provinces pour la prise de décision ne sont pas disponibles quand la décision est prise. Les compagnies pharmaceutiques constituent la principale source d'information concernant l'efficacité réelle (dans la vie habituelle) et le ratio coût-efficacité. Alors que les renseignements sur l'efficacité expérimentale proviennent d'une approche scientifique et rigoureuse, les données sur l'efficacité dans la vie habituelle et celles concernant les coûts sont issues d'estimations (opinions d'experts) avec possibilité de biais et risque de subjectivité. L'enquête révèle également qu'il n'y a pas de collaboration entre les provinces, ce qui explique de grandes différences entre les provinces quant aux décisions prises; ce dernier point soulève la question de l'équité des populations vis à vis de l'accessibilité aux médicaments.

Conclusions : Le processus actuel de revue des médicaments par les provinces repose sur des données inadéquates et scientifiquement défectueuses; ce qui explique de grandes différences entre les provinces quant aux décisions prises. Dans ces conditions, nous recommandons l'établissement d'un comité national de revue scientifique des médicaments après leur mise sur le marché pour réévaluer après quelques années leur ratio coût-efficacité.

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