Alberta Physician Achievement Review

We thank Geoff Norman and John Cunnington for their interest in the Physician Achievement Review program of the College of Physicians and Surgeons of Alberta.[1] At the request of *CMAJ*'s editors, we condensed our 2 original submissions, one describing the purpose and operational aspects of the program and the other providing statistical results, into a composite report.[2] Space limitations precluded inclusion of extensive technical results, but we would be pleased to correspond with interested readers directly and provide additional technical data.

Norman and Cunnington asked about concurrent validity and inter-rater reliability. Concurrent validity, which is the extent to which there are correlations between self, patient, peer, consultant and co-worker assessments, was investigated using confirmatory factor analysis. The factors identified for the patient surveys were positively and significantly correlated with the factors identified for the peer surveys ($r = 0.25$, $p < 0.05$), the patient factors were positively and significantly correlated with the co-worker factors ($r = 0.20$, $p < 0.05$) and the co-worker factors were positively and significantly correlated with the peer factors ($r = 0.31$, $p < 0.05$). In other words, different groups of raters tended to rate a physician in the same way.

Inter-rater reliability addresses the issue of whether different raters of the same physician tend to rate the physician the same way. Our results indicated that when a physician's performance was rated very high or very low, most of the raters assessed the physician the same way. For example, when a physician was rated low in the "clinical competency" category he or she was rated low by most peers. For this particular category there was up to 100% agreement among peers in placing physicians in the lowest group.

The Physician Achievement Review program has now been implemented as described[2-4] and the survey results provide a basis for further assessment by practice visits for some physicians. Our operational experience will be reported in due course.

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Drug approval times

According to Nigel Rawson's figures, Canada and Australia are much slower in approving new drugs than Sweden, the United Kingdom and the United States.[1] Rawson acknowledges the difference in resources available in Canada and the United States but then dismisses this difference as not being significant. Is it reasonable to assume that the Therapeutic Products Program, with a budget of just under Can$50 million, will be able to review drugs as quickly as the US Food and Drug Administration (FDA), which spends about Can$745 million in approving roughly the same number of new drugs?

Canada takes the same amount of time to approve new drugs as Australia, a country with roughly the same level of resources in terms of population size and level of development. It is true that Sweden, a country with roughly 25% of Canada's population, approves new drugs more rapidly, but some of the drugs on the Swedish market have been approved through the centralized European procedure, which could have skewed the figures.

There are 2 additional questions that Rawson did not consider: Is safety compromised by quicker approvals? How important are new drugs to the health of Canadians?

A study of postapproval risks for drugs approved by the FDA between 1976 and 1985 found that 102 of the 198 drugs for which data were available had serious postapproval risks that could lead to hospitalization, increases in the length of hospitalization, severe or permanent disability, or death. Among drugs approved in fewer than 4 years, those that had serious postapproval risks had generally been approved in a shorter time than those without such risks.[2] In a 1998 survey, 12 FDA reviewers identified 25 new drugs in the previous 3 years that they felt had been approved too quickly.[3]

The Patented Medicine Prices Review Board categorizes new drugs according to their expected therapeutic benefit. Between 1994 and 1998, 408 patented medicines were introduced into Canada. Discounting the 171 that were not new chemical entities, only 24 of 237 or just over 10% were classified as "breakthrough" drugs or major therapeutic advances.[4] Between April 1996 and 1998, the British Columbia Therapeutics Initiative assessed 60 new drugs for the BC Ministry of Health. For 46 of the drugs (77%), it found no evidence of a therapeutic advantage over existing therapies.[5,6]

Rawson states, "Physicians want to be able to prescribe the most effective drugs for their patients, and patients want access to these drugs to get well quickly."[1] The implication is that more rapid drug approvals will lead to better health. New drugs do not need to show any advantage over existing therapies to be approved; they merely have to be better than placebo. Until the new drugs that the industry produces represent better value and until we are sure

that approving new drugs more rapidly does not compromise safety, we are better off putting our limited resources into other areas such as improving Canada's woefully inadequate postmarketing evaluation system.

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[The author responds:]

Longer approval times in Canada cannot simply be attributed to fewer resources. Both the Swedish and UK drug regulatory agencies have similar resources to those of the Therapeutic Products Program yet consistently review and approve drugs in a similar timeframe to that of the United States. Although Australia has similar overall approval times to those in Canada, its scientific review is completed in significantly less time than Canada's.[1]

The Therapeutic Products Program's own performance standard and its actual performance on some drug submissions indicate that a full scientific evaluation can be completed in 6 months. The median time consumed by the safety and efficacy evaluation in a recent study of Therapeutic Products Program internal processes was 188 days (range 74–376 days).[2] Approval times are much longer for 2 reasons: considerable downtime occurs between the receipt of the application and the start of the scientific review, and the separate assessment of manufacturing and stability data is often not coordinated with the safety and efficacy evaluation.

An evaluation of the importance of a new drug's therapeutic potential should be based not simply on the lack of a current treatment, which is the practice of the Patented Medicine Prices Review Board, but rather it should be based on several factors. The US Food and Drug Administration (FDA) classifies all new drug applications to receive either a priority or a standard review based on the significance of the drug's "improvement" over currently marketed products. Improvement is shown by increased efficacy, elimination or substantial reduction of a treatment-limiting drug reaction, enhancement of patient compliance, or safety and efficacy in a new subpopulation. Of the 87 drugs approved in Canada, Australia, Sweden and the United States in 1992–1998, 37 (43%) received a priority review in the United States. Canadian approval times were significantly longer than those in Sweden and the United States both for drugs that received an FDA priority review and for those that did not.[3] Thus, applications for all drugs, including those most likely to significantly affect the health of Canadians, are reviewed more expeditiously in Sweden and the United States than in Canada.

No one wants to trade more timely approvals for reduced safety. However, more concrete evidence about the safety of drugs given earlier approval than the reports cited by Joel Lexchin and Barbara Mintzes is available from an examination of drugs approved in the United States, but not in Canada, that were withdrawn for safety reasons. Between 1992 and 1998, there were only 4 such drugs.[4] The approval times of these drugs ranged from 469 to 926 days; thus, their reviews were not rushed. Moreover, these 4 drugs constitute only 4.6% of drugs approved in the United States at least 1 year before approval in Canada in the 7-year period.

Finally, I endorse the recommendation that Canada's inadequate postmarketing surveillance system should be improved and have proposed new approaches that could be adopted in Canada.[5–7] However, the unnecessary delays in Canada's review and approval system should also be eliminated and Canada's performance standard of 355 days for all new drug applications achieved. In that way, Canadians will no longer have to experience delayed access to potentially valuable medicines.

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Implementing public-access programs for automated external defibrillation

Brian Schwartz and Richard Verbeek have provided a fine overview of automated external defibrillators (AEDs).[1] We agree with their conclusion that defibrillation by lay responders is on the horizon and that it has