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

the potential to increase survival after sudden cardiac arrest.

It makes little sense to us, though, why the authors would suggest an emergency medical service (EMS) response time of 15 minutes for a decision to implement lay defibrillation when, at 10 minutes, the potential for benefit from EMS defibrillation approaches zero. Lay defibrillation programs should be considered whenever the EMS system cannot provide effective service and lay providers can.

The effectiveness of AEDs, even when used by lay responders, is no longer in question. What holds back the widespread use of AEDs is the misconception that AEDs require medical delegation or physician supervision.

In 7 provinces and the 3 territories, AED use is not regulated, has already been deregulated or is regulated but does not require delegation. AED use is still regulated in Saskatchewan, Manitoba and Quebec, but the Quebec College has recommended that the law governing the use of AEDs be amended. There is a widespread belief that Ontario requires physician delegation and supervision of an AED program, but the College of Physicians and Surgeons of Ontario advised us that "the use of an AED in the circumstances of a collapse is not a controlled act by virtue of ss.30(5)(a) of the Regulated Health Professions Act. There is therefore no need to make any legislative change to permit an AED or public-access AED program to be established" (Dr. John Carlisle, College of Physicians and Surgeons of Ontario: personal communication, 2000). In most of the country, then, College regulations support lay AED use.

We would also like to address some of the "problems" the authors list in their article. First, whether or not a lay provider can detect a pulse is not really an issue: Eberle and colleagues convincingly showed that neither lay people nor health care professionals are very accurate in detecting a pulse.[2] Fortunately, as Schwartz and Verbeek point out, the AED will only shock a shockable rhythm.

Second, EMS medical directors should urgently address the issue of efficient transfer of care to EMS personnel. It should not be a barrier to the lay use of AEDs: at present, over 95% of people in this country who have a cardiac arrest outside of a hospital die, and efforts to improve the availability of a treatment proven to increase survival should not be held back by concerns about how to care for the survivors.[3]

Third, Gundry and colleagues' study showing that grade 6 students can use AEDs effectively and safely after 1 minute of instruction[4] goes a long way toward alleviating concerns regarding cost effectiveness of training and maintenance of skills.

Fourth, the newest AEDs perform their own maintenance, and a proactive EMS service can list all sites with AEDs and can provide a random check of AEDs in their neighbourhood.

After early treatment with fibrinolytics was proven to increase survival from acute myocardial infarction, it took more than 10 years before physicians were routinely providing the treatment in a timely manner to all who should receive it. We mustn't let the same thing happen with AEDs.

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[The authors respond:]

We thank Michael Shuster and Wes Clark for their comments about our article.[1] Unfortunately, we find no firm basis for their enthusiasm. While we have noted that the use of automated external defibrillators (AEDs) by lay responders has the *potential* to increase survival after cardiac arrest, we do not agree that its effectiveness is no longer in doubt.

Only 5 studies, reporting outcomes for 154 patients, have been published on public-access AED programs.[2,3] These were either case series or poor-quality cohort designs. At best, this would allow a grade C recommendation based on level 4 evidence.[4] Furthermore, all programs required medical supervision and used trained lay responders who were otherwise expected to take command during an emergency (e.g., security guards, flight attendants). There is no report that describes AED use by the unsupervised

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public, and concern has recently been expressed that in some settings, a worse outcome may result.[5]

It is worrisome that an organization such as the Heart and Stroke Foundation would use a personal communication (in this case, a personal email message) from the College of Physicians and Surgeons of Ontario as a *de facto* means to declare that the use of an AED by lay people is no longer a controlled act in Ontario. Defibrillation is considered by the Regulated Health Professions Act (1991) of Ontario to be a controlled act requiring direct physician delegation. Policy I-99 of the College of Physicians and Surgeons of Ontario indicates that "at all times, accountability and responsibility for the delegation of a controlled act remains with the delegating physician."[6] The subsection of the Regulated Health Professions Act quoted by the College representative indicates that the restriction against performing controlled acts "does not apply with respect to anything done by a person in the course of rendering first aid or temporary assistance in an emergency." We are unaware of any public direction given to Ontario's physicians by the College regarding the obvious dilemma caused by this contradiction. Public clarification by the College is urgently required.

While public-access AED programs may not require direct physician delegation, we believe physician supervision is vital in establishing medically sound defibrillation protocols, transfer of patient care, preservation of clinical data and continuous quality improvement programs. This is unlikely to be achieved in an unregulated environment.

We are not reassured that grade 6 students can learn to give a single shock using an AED on a mannequin. It is inappropriate to extrapolate their success to situations in which adults are using an AED during a cardiac arrest in a public setting, which are infinitely more complicated and chaotic. Other research has shown that layperson training results in disappointing AED competency after 1 year[7] and that cardiopulmonary resuscitation performed by bystanders, in addition to early defibrillation, is essential if survival rates are to be improved.[8]

Given the potential for public-access AED programs to save lives, we cautiously embrace their promotion, but

not in the way outlined by the Heart and Stroke Foundation. We believe these programs must be implemented under the supervision of responsible medical personnel to ensure integration with emergency medical service responders (e.g., paramedics, firefighters, police), who ultimately become responsible for every patient treated under a public-access AED program. Only then can the public be assured that AED use by lay people is safe and effective.

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Correction

The third sentence in the second paragraph of a recent letter to the editor from Leo Kahana[1] contained a copyediting error. It should have read: "In controlled studies the protective efficacy varies from –57% to more than 75%, and it is not clear that averaging such disparate results by meta-analysis is of any significance."[2] Kahana's affiliation should have been given as Department of Medicine, McMaster University, Hamilton, Ont.

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