Editorial

Outdated criteria for drug plan reimbursement obstruct evidence-based care

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An important flaw in the funding approach used by Canada's public drug plans is highlighted by the findings of 2 articles related to the clinical value of direct oral anticoagulants (DOACs), published this week in *CMAJ*.[1,2] Kimpton and colleagues found that apixaban was both more effective and less expensive than the alternatives when used for primary venous thromboprophylaxis in patients with cancer;[1] Grewal and colleagues showed that older adults with a head injury who were taking a DOAC were less likely to have an intracranial bleed than patients taking warfarin.[2]

These findings are in keeping with a large body of research showing that DOACs, which have been clinically available for more than a decade, are effective drugs and that the risk of bleeding is in general lower than with warfarin.[3] The National Institute for Health and Care Excellence in the United Kingdom, which uses evidence about cost-effectiveness to guide its recommendations, suggests DOACs as first-line anticoagulants in patients with atrial fibrillation.[4] Yet Canada's publicly funded drug plans continue to restrict prescribing of DOACs. In British Columbia, Alberta and Ontario, government-funded formularies will not reimburse apixaban for stroke prevention in patients with atrial fibrillation (the most common reason for oral anticoagulation in older adults) unless patients have first failed to achieve adequate anticoagulation with warfarin or have a contraindication to warfarin.[5–7]

Why is practice lagging the evidence? Unfortunately, decisions that are made shortly after a drug is first licensed in Canada are often not updated as new evidence becomes available. This leads some physicians to game the system to provide the best and safest treatment for their patients by saying their patients meet reimbursement criteria when they do not. Physicians will game a system if they feel that a lie (e.g., saying a patient cannot tolerate warfarin when that is not true) is worth the benefit to their patients. The fact that almost 3 times as many patients in the Ontario study of intracranial hemorrhage in patients on anticoagulants were on DOACs as were on warfarin[2] reflects the likely magnitude of physicians' deception; true warfarin intolerance is not common. Medical ethicists have defended the use of such deceptions when physicians feel that a patient's well-being is harmed by unjust or poorly functioning health systems.[8]

Many physicians, including us, believe it is appropriate for publicly funded drug plans to not reimburse drugs that are cost ineffective, because health care resources should be used judiciously for the public good. However, evidence evolves and the process for determining reimbursement should be iterative.

Decisions about reimbursement for most Canadian public drug plans are guided by recommendations made by the Canadian Drug Expert Committee of the Canadian Agency for Drugs and Technology in Health.[9] Quebec has a parallel but independent process. There is strong concordance between these recommendations and final coverage decisions. Almost all new recommendations come with criteria to limit their use, either by restricting prescribing to certain types of patients or by physician expertise.

Only a few opportunities for changing decisions exist once they have been made. A pharmaceutical manufacturer can request a broader indication for a drug if new evidence emerges, and drug plans can ask for a review of reimbursement criteria for a drug or for a class of drugs (such as all anticoagulants). However, the emergence of important new evidence does not automatically trigger a review.

When reimbursement criteria for drugs are outdated, nobody benefits. Physicians are forced into challenging choices between advocating for patients or upholding professional standards for honesty. Patients suffer because physicians who follow outdated government directives may offer suboptimal care. Health systems are seen as indifferent to high-quality evidence when making policy decisions and tolerating gaming of the system.

Three changes to the process may help address this problem. First, recommendations could come with an automatic time for review or incorporate regular reviews of evidence. Guidelines from the National Institute for Health and Care Excellence include an active process for surveilling for new data and a standard check for new evidence every 5 years.[10]

Second, allowing others to request a review may be beneficial. Both clinical societies (e.g., the Canadian Hematology Society) and advocacy groups for patients (e.g., Heart & Stroke) may have grounds for requesting that criteria be revisited that differ from those of manufacturers or public insurers. Processes that allow these groups to request reconsideration of criteria would make for a more patient-centred system.

Third, public drug plans could regularly audit prescribing to identify patterns that indicate large-scale nonadherence to restricted prescribing criteria, thereby triggering a review of those criteria.

Regular review of drugs will increase the workload and resource requirements of drug reimbursement committees. However, a regularly updated formulary is essential to having a trusted, responsive and efficient public drug reimbursement plan.

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