

Ensuring Patient Access to Guideline-Based Therapies



Misalignment between evidence-informed clinical care guideline recommendations and reimbursement policies has created care gaps that lead to suboptimal outcomes for patients denied access to guideline-based therapies. Stroke prevention in atrial fibrillation (AFib) is discussed as an example in a study which appears in the *Canadian Journal of Cardiology*. Stroke is an extremely costly disease, imposing significant human, societal, and economic burdens. Although two-thirds of strokes are preventable with appropriate anticoagulation, this has historically been underprescribed and poorly managed.

National and international guidelines endorse direct oral anticoagulants as first-line therapy for this indication. However, no Canadian province has provided such agents with an unrestricted listing. These decisions appear to be founded on a silo-based cost assessment — the drug costs rather than the total system costs — and thus overlook several important cost-drivers in stroke. The discordance between the best scientific evidence and public policy requires healthcare providers to use a potentially suboptimal therapy, contrary to guideline recommendations.

Lack of harmonisation between reimbursement policies and evidence-informed clinical care guideline recommendations represents an increasing obstacle for the translation of knowledge and its application in the clinical setting. The aim of the *Canadian Journal of Cardiology* study was to make the case for addressing this growing access barrier to optimal care. Opportunities for improving stroke prevention in AFib are discussed as an example.

The Cost of Cost-Containment

A recent Canadian stroke-cost study reported that the average overall cost of the first year following a stroke was \$74,353. The initial three months accounted for 54.5 percent of the overall costs and were driven primarily by hospitalisation and rehabilitation. Subsequently, indirect costs such as rehabilitation, home care, and paid caregivers represented the bulk of expenditures.

AFib affects upwards of one in 10 people older than age 75 and increases the risk of stroke fivefold. Stroke in the setting of AFib carries an 80 percent probability of death or disability. Two-thirds of these strokes are preventable with appropriate anticoagulation, but this has historically been underprescribed and poorly managed despite considerable efforts, with resultant significant care gaps for the Canadian population with AFib.

National guidelines endorse direct oral anticoagulants (dabigatran, rivaroxaban, and apixaban) as being preferred to warfarin for stroke prevention and reducing the risk of intracranial bleeding, and hence the first line therapy for this indication. The Canadian Agency for Drugs and Therapeutics in Health (CADTH) has recommended that these agents receive reimbursement only if warfarin cannot be used (e.g., because of allergy) or after an initial attempt with warfarin therapy has been unsuccessful. Provincial payers have uniformly adopted CADTH's recommendations in their reimbursement guidelines.

This discordance between evidence and public policy places healthcare providers in an awkward position. They are required to treat many patients in a manner that is at variance with national guidelines and this might have a deleterious clinical effect in light of recent evidence of the heightened risk of both ischemic stroke and bleeding in the first month of initiating warfarin therapy.

Policy and Evidence Harmonisation is an Essential, Achievable Goal

Removal of funding restrictions for evidence-based therapies can be expected to increase utilisation of these therapies and thereby result in improved outcomes. Indeed, this has been demonstrated in an Institute for Clinical Evaluative Sciences study of cardiovascular outcomes after a change in the prescription policy for clopidogrel. Removing the requirement for previous authorisation led to more timely access to therapy and improved cardiovascular outcomes in patients who required coronary stenting.

Harmonisation between policy and evidence is an essential and achievable goal. Acute stroke thrombolysis is a prime example of how a therapy with a high unit cost can nevertheless have significant clinical and health system benefits, including generalised cost-effectiveness through reducing hospital and rehabilitation costs. Through collaboration between multiple specialties, support services, and government agencies, trial results were translated into standardised systems of care such as emergency room bypass protocols and hospital stroke teams.

Stroke best practice guidelines were developed and promulgated. Ministries of Health established policies and set reimbursement and fee schedules to support implementation. This process of knowledge translation at multiple levels has led to Canada boasting some of the highest rates of acute stroke treatment in the world, being approximately four times higher than that in the United States.

There Is a Better Way: A Call to Action

Knowledge translation initiatives have been implemented across Canada that encourage all healthcare professionals to collaboratively implement clinical care protocols for individuals with AFib that are derived from evidence-informed guidelines.

It must be acknowledged that cost is not addressed in evidence-based guidelines; in Canada, this has been a role assumed by CADTH. In this example, CADTH appears to have considered only direct costs (e.g., drug acquisition, treatment costs for bleeding, and avoidable stroke) in its evaluation. A more global assessment that includes opportunity costs (cost of the outcome to the patient) and indirect costs (e.g., lost productivity due to stroke, and longer-term expenses of caring for individuals who have experienced stroke) would seem more appropriate in this setting because these costs are often significant. Comprehensive cost effectiveness analyses of the direct oral anticoagulants have been published; these analyses can provide valuable information to assist policy-makers and, whenever available, should be taken into account in funding decisions.

In its CanMEDS Physician Competency Framework, the Royal College of Physicians and Surgeons of Canada lists seven roles required of physicians, one of which is health advocate. The College states that "...health advocacy involves efforts to change specific practices or policies on behalf of those served... Health advocacy is appropriately expressed both by individual and collective actions of physicians in influencing public health and policy." Indeed, health advocacy is a responsibility also shared by other healthcare providers.

Conclusions

Healthcare professionals have a role to play in system sustainability and patient accountability. It is their responsibility to interpret the best available evidence and collaborate with policy-makers in applying the evidence to formulate health policy. Cost containment is essential. However, a complete assessment of costs should be considered when making policy decisions. Silo-based cost assessments serve no one well—not patients, and not society.

Furthermore, unilaterally allowing cost considerations to trump the recommendations of evidence-informed clinical practice guidelines forces healthcare providers into an ethically untenable clinical practice environment in which they are required to prescribe therapies they know to be subordinate to the scientifically validated alternatives.

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