Should national pharmacare apply a value-based insurance design?

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rivate and public drug benefit plans in Canada use numerous forms of out-of-pocket charges for covered prescription drugs. 1,2 When applied indiscriminately, cost-sharing can reduce patient adherence to medications, even for important classes of drugs such as antidiabetic mediations. 3-7 Reduced medication adherence because of cost-sharing can negatively affect the health of vulnerable populations. The final report of the Advisory Council on the Implementation of National Pharmacare, published in June 2019, called for universal, single-payer, public pharmacare in Canada. Pharmacare is shaping up to be a defining issue of the 2019 federal election.

Consideration of national pharmacare represents an opportunity to define not only what drugs will be on any national formulary, but also what extent of coverage will be provided for those drugs. Because the level of patient charges for covered prescriptions can have substantial budget implications, some form of such "cost-sharing" might be expected under universal pharmacare. For example, an average copayment of \$10 per prescription would generate about \$6 billion in revenue. Although revenues of that scale may be welcome news to departments of finance, the design of copayments under a national pharmacare system must be considered carefully from a clinical and health policy perspective.

In an effort to balance clinical, policy and economic goals, a variety of payers in the United States have applied value-based insurance design, under which patient copayments are based on a drug's assessed clinical and economic value. Some of these approaches have generated sufficiently promising results that the application of this design deserves consideration in Canada. We describe the use of value-based insurance design in the US and discuss the practical implications of applying such an approach in the Canadian context.

Value-based insurance versus cost-based insurance

The value-based insurance approach sets the out-of-pocket costs of a covered drug based on its assessed value: drugs of higher assessed value from a health system perspective will be available with low or no copayments, and drugs of lower assessed value will be available with higher copayments. For

KEY POINTS

- The final report of the Advisory Council on the Implementation of National Pharmacare, published in June 2019, called for universal, single-payer, public pharmacare in Canada.
- Consideration of national pharmacare presents an opportunity to redesign Canada's public drug benefits using value-based principles grounded in universal terms and conditions.
- Value-based insurance design sets patient copayments based on the assessed clinical and economic value of medications.
- In the United States, these designs have promoted access to medications and patient choice while encouraging costconscious product selections.
- Augmenting existing public coverage for patients of particular ages and income levels with universal, value-based coverage of medications could achieve similar outcomes in Canada.

instance, a value-based insurance plan might waive cost-sharing for generic antihypertensive medications and impose a higher cost-share for branded statins. The primary function of the tiered copayments under a policy with value-based insurance design is to make higher-value drugs readily available while steering patients away from lower-value drugs. This also has some secondary effects of generating revenues for the health plan through increased cost-sharing and reduced use of lower-value options, and increasing the drug plan's price negotiating power with manufacturers, who may be asked to provide lower prices in exchange for having lower copayments placed on their products.

How has value-based insurance design been applied in other settings?

Policies with value-based insurance design gained in popularity among US private employer-sponsored plans beginning in the 2000s^{13,14} and have since gained traction in public policy. For example, the 2010 *Patient Protection and Affordable Care Act* required health plans to include certain preventive drugs and services without cost-sharing, such as certain generic statins.¹⁵ More recently, the US federal government has charged the Medicare Advantage program (managed care coverage for older

adults) and the TRICARE program (coverage for civilian personnel in the US Department of Defense) to pilot value-based insurance programs that reduce cost-sharing for targeted high-value health services. ^{16,17} No other country explicitly uses value-based insurance design; however, policies more broadly aimed at aligning cost-sharing and value exist in other countries, albeit in different forms (e.g., France uses a form of value-based co-insurance design, wherein the level of co-insurance under the French social health insurance system is set based on considerations of disease severity and value). ¹⁸

Thus far, most of the evidence regarding the effects of plans with value-based insurance design comes from private plans that waived or reduced cost-sharing for maintenance medications used to treat chronic conditions such as for asthma, diabetes, hypertension or hyperlipidemia. Over time frames of 1 to 3 years, most studies reported increases of 0.8%–14.3% in medication adherence. These effects of relatively simple value-based insurance policies are on the same order of magnitude as more complex and costly interventions to increase adherence to prescribed therapies.

The effects of value-based insurance design on health are less often measured, but they appear to be either null or positive. Two randomized controlled trials provide useful evidence concerning the health impacts of value-based insurance design under which cost-sharing for preventive medications is reduced. One study randomly assigned privately insured patients who were discharged after myocardial infarction to free medications indicated for secondary prevention.²² This study found increased adherence to treatment and reductions in the rates of total major vascular events or revascularization and of first major vascular event, but no significant reduction in the primary outcome of first major vascular event or revascularization. The second study randomly assigned publicly insured US veterans with poorly controlled hypertension to receive end-of-month discounts that would effectively eliminate the \$8 copayments for antihypertensive prescriptions.²⁷ That study found no significant effects on medication use or blood pressure control across intervention groups; the authors concluded that, for these patients with treated but uncontrolled hypertension, either costs were not the major impediment to adherence or the end-of-month reduction of cost-sharing was not an effective tool to reduce such a barrier.

The studies cited above involved decreasing copayments for medications, which increases costs to the drug plan on a perprescription basis and by way of increased adherence. 19,22,28-30 However, value-based insurance design can also involve selective increases in cost-sharing for lower-value drugs. For example, in 2010, an employer-sponsored private insurance plan implemented a value-based insurance policy that reduced copayments for 72 drugs from a mean of US\$13 to \$3 and increased copayments for 197 drugs from a mean of \$16 to \$25.31-33 The policy shifted use toward higher-value medications; medications that were moved into lower copayment tiers had a 17% increase in days' supply of medication. The program also resulted in a savings of 9% of total medication spending by patients and the health plan combined. There were no significant effects on hospital admissions, emergency department visits, office visits or total health care spending.

How could value-based insurance design be applied to national pharmacare?

Table 1 provides a high-level summary of the terms of costsharing for 3 main types of beneficiaries of public drug plans in Canada: people receiving social assistance, people aged 65 years and older, and the balance of the general population. Recipients of social assistance receive first-dollar or near first-dollar coverage in all provinces. Furthermore, although some provinces have moved away from age-targeted drug benefits, people aged 65 years and older receive more extensive public drug coverage than younger populations in most provinces. This is one of the legacies of the incremental evolution of pharmacare in Canada to date; public drug plans evolved as subsidy programs for specific demographic groups. 35,36

The use of value-based insurance design in the creation of a national formulary for Canada would represent a substantial paradigm shift should a national pharmacare program be implemented. A national pharmacare program using such a design would set levels of subsidy not primarily based on the demographic characteristics of beneficiaries but primarily based on the characteristics of treatments. Under a value-based insurance approach, high-value medications with proven safety and effectiveness would receive full public coverage for all Canadians, and other medications would receive limited or no public coverage for all Canadians. Government programs might still provide first-dollar coverage for low-income households; however, a well-designed value-based insurance policy would ensure universal access to high-value treatments while still leveraging the revenue powers and "steering effects" of value-based copayments.

National pharmacare with value-based insurance design might, for example, employ 3 tiers of copayment based on the assessed economic value of the therapies from a health system perspective. The copayments could be \$0 for cost-saving medications, \$25 for good-value medications (e.g., treatments with incremental cost-effectiveness ratios of \leq \$50 000), and \$50 for acceptable-value medications (e.g., treatments with incremental cost-effectiveness ratios of \leq \$100 000). Medications that do not represent acceptable value for money or that lack evidence on value for money would not be covered under the national pharmacare plan.

Table 2 summarizes the expected effects of using a simpler 2-copayment-tier (\$0/\$25) value-based insurance design under national pharmacare on medication use and spending compared with having a flat \$0 or \$15 copayment for all covered medications. In terms of patient medication use, a flat \$0 copayment program will foster the use of all medications. A flat \$15 copayment program will foster more limited use of all medications. In contrast, national pharmacare based on a value-based insurance approach would be expected to increase the use of drugs of higher assessed value while reducing the use of drugs of lower assessed value relative to either scenario of flat \$0 or \$15 copayments. This is because the difference in copayments will tend to "steer" patients toward the higher-value option. For example, a higher-value drug with a \$0 copayment may be used more often in a program with a value-based insurance design than even in a

Province	Social assistance recipients	Residents aged ≥ 65 yr	General population
British Columbia	No deductible, no copayments or co-insurance	Income-based deductibles, thereafter co-insurance of 30% (25% if born before 1939)	Income-based deductibles, thereafte co-insurance of 30%
Alberta	No deductible, no copayments or co-insurance	No deductible, co-insurance of 30% subject to a maximum of \$25 per prescription	If voluntary public plan is purchased, co-insurance of 30% subject to a maximum of \$25 per prescription
Saskatchewan	No deductible, copayment of up to \$2	Income-tested program, no deductible, copayments of \$25	Copayments set so that annual patier costs equal income-based thresholds
Manitoba	No deductible, no copayments or co-insurance	Income-based deductibles, thereafter no copayments or co-insurance	Income-based deductibles, thereafte no copayments or co-insurance
Ontario	No deductible, copayment of up to \$2	Depending on income, deductibles of \$0 or \$100, thereafter copayments of \$2.00 or \$6.11	Income-based deductibles, thereafte copayment of \$2
Quebec	No deductible, no copayments or co-insurance	Monthly deductible of \$19.90 per person, thereafter co-insurance of 34.9%	Monthly deductible of \$19.90 per person, thereafter co-insurance of 34.9%
New Brunswick	No deductible, copayment of \$4 for adults, copayment of \$2 for children	Income-tested program, no deductible, copayments of \$9.05 or \$15 depending on income	If voluntary public plan is purchased, copayments of \$5 to \$30 depending o income
Nova Scotia	No deductible, copayment of \$5	If voluntary public plan is purchased, co-insurance of 30%	Income-based deductibles, thereafte co-insurance of 30%
Prince Edward Island	No deductible, no copayments or co-insurance	No deductible, copayments of \$7.69 plus first \$8.25 of drug cost	Income-based deductibles, thereafter no copayments or co-insurance
Newfoundland and Labrador	No deductible, no copayments or co-insurance	Income-tested program, no deductible, patient pays up to \$6 of dispensing fee	Co-insurance rates set so that annua patient costs equal income-based thresholds

Table 2: Expected effects of a simple value-based insurance design with \$0 copayment for drugs with higher assessed value and \$25 copayment for drugs with lower assessed value in comparison with a fixed \$15 copayment and a fixed \$0 copayment for drugs covered under national pharmacare

Outcome	Drug type	Expected effects of VBID compared with \$15 copayments for all covered medications	Expected effects of VBID compared with \$0 copayments for all covered medications
Initiation of treatment by drug type	High-value drugs	Higher	Same or higher
	Low-value drugs	Lower	Lower
Adherence to treatment by drug type	High-value drugs	Higher	Same
	Low-value drugs	Lower	Lower
Patient spending by drug type	High-value drugs	Lower	Same
	Low-value drugs	Higher	Higher
	All covered drugs	Same or lower*	Higher
Plan spending by drug type	High-value drugs	Higher	Same or higher
	Low-value drugs	Lower	Lower
	All covered drugs	Same or lower*	Lower
Total (patient + plan) spending	All covered drugs	Lower*	Lower
Other use of health services	NA	Same or lower	Same or higher

Note: NA = not applicable, VBID = value-based insurance design.

^{*}Spending will depend on factors such as how drugs are assigned to value tiers, proportion of low- and high-value drugs, and patient medication use changes as a response to

flat \$0 copayment program owing to patients switching from lower-value therapeutic substitutes that are assigned a \$25 copayment in the program with a value-based insurance design.

These changes in medication use would affect any spending projections. However, we first estimate plan drug spending purely based on copayment revenue. We assume that lowincome households of any age will be fully covered under a national pharmacare program, and that those households would account for about 30% of all prescriptions filled under the program; therefore, we assume that national pharmacare copayments would apply to about 400 million prescriptions filled by households who would not qualify for income-related waiver of copayments. Under those assumptions, the fixed \$15 copayment model would raise an estimated \$6 billion in revenue for the pharmacare program. Similar amounts of revenue would be raised under a policy with a value-based insurance design if higher-tier (\$25) copayments applied to about 60% of medications on the national formulary, which is not an unreasonable assumption given US experiences with these types of policy.³³ In contrast, of course, the option of having no copayment on covered medications will raise no revenues via cost-sharing.

The projected drug-spending changes of a program with a value-based insurance design accounting for changes in use are harder to quantify. This will depend on the extent to which tiered copayments induce changes in use of lower- and higher-value medications and the relative costs of those medications to the pharmacare program. However, it is often the case that high-value drugs are also lower-cost options. Thus, it could be that tiered copayments will reduce plan spending on medications relative to either types of flat copayments that would apply to all drugs on the formulary provided there are high-value, low-cost options for most patients' needs.

What could hinder the application of valuebased insurance design in national pharmacare?

If national pharmacare were to apply principles of value-based insurance design, careful consideration would need to be given to avoid mechanisms that reduce the ability of tiered copayments to give incentives for use of medications according to assessed value. These mechanisms include copayment coupons provided by manufacturers and secondary insurance.³⁷ When coupons cover patient out-of-pocket costs for the manufacturers' products, they negate the ability of tiered cost-sharing formularies to steer use toward drugs of higher assessed value. This affects program costs directly, as higher-value medications are often those available at lower cost to the program. It also reduces manufacturers' incentives to lower prices if it is cheaper for them to simply pay patients' copayments rather than to compete on price. One solution applied in certain states in the US is to ban the use of copayment coupons for medications with generic equivalents.^{38,39}

A potential solution might be to apply reference-based reimbursement within therapeutically equivalent medication class that would require patients to cover the full price differential between a given product and the reference-based reimbursement level, as in Germany and the Netherlands. This would steer

patients to the most cost-effective treatment options and would remove the incentive for manufacturers to offer copayment coupons. However, such a system is typically limited to assuming equal effectiveness of medications within class and only functions well in markets with little or no confidential rebates paid by manufacturers of covered drugs and to insurers. To the degree that drugs within class differ in effectiveness (as well as costs and rebate levels), a reference-based reimbursement scheme could misalign copayments with value.

Most Canadian workers would probably continue to receive extended health insurance as part of their work-related compensation packages if national pharmacare were to be implemented. If extended health insurance plans in Canada were to cover copayments under the national pharmacare program, they could mitigate the intended effects of value-based insurance design. A solution to this would be to make pharmacare the payer of last resort for lower-value drugs. This would continue to ensure universal, first-payer coverage of higher-value drugs while reducing public liability for lower-value drugs.

Value-based insurance design also requires accurate and precise estimates of treatment value. To the degree that value estimates are unavailable or inaccurate for the pharmacare population or that value is heterogeneous (e.g., use of treatments for primary v. secondary prevention), value-based insurance design may not appropriately give incentives for treatment adherence. Despite this, the US experience is that this system can produce cost savings without harming patients. The proposed approach of setting \$0 cost-sharing to treatments with strong evidence of high value to the population that is expected to use it is a good first step. More nuanced systems could be considered in the future.

A related issue is that the value measure itself needs to reflect the values of the population. For instance, it is recognized that there are additional dimensions of value that are not traditionally captured in an incremental cost-effectiveness ratio estimate (e.g., disease rarity, end-of-life treatments).⁴⁰ Such additional values could be accounted for by setting a more generous incremental cost-effectiveness ratio threshold for drugs with additional value dimensions³¹ or by inflating the incremental cost-effectiveness ratio estimate based on approaches to explicitly gather and analyze stakeholder input.⁴¹

Conclusion

Cost-sharing reduces prescription drug use and can place substantial financial burdens on patients. At the same time, cost-sharing can be a tool to help finance a drug plan, steer patients toward cost-effective therapies, and encourage manufacturers to price their medications at levels that reflect the best value. If Canada seeks to control any future national pharmacare program costs while ensuring access to a diverse set of drugs and encouraging use of drugs of the greatest value to the medicare system, we suggest that the program apply principles of value-based insurance design. Such a system would allow cost-sharing to be modified by both sociodemographic and value considerations such that no charges would apply to patients who could not afford it, and no charges would apply to medications of the highest value to the Canadian health care system, regardless of

the patient's income or age. Provided careful consideration is given to design details, value-based insurance design could help national pharmacare to balance the sometimes competing goals of access, equity, value and choice.

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