Comparison of tiered formularies and reference pricing policies: a systematic review

STEVE MORGAN, GILLIAN HANLEY, DEVON GREYSON

ABSTRACT

Objectives: To synthesize methodologically comparable evidence from the published literature regarding the outcomes of tiered formularies and therapeutic reference pricing of prescription drugs.

Methods: We searched the following electronic databases: ABI/Inform, CINAHL, Clinical Evidence, Digital Dissertations & Theses, Evidence-Based Medicine Reviews (which incorporates ACP Journal Club, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Cochrane Methodology Register, Database of Abstracts of Reviews of Effectiveness, Health Technology Assessments and NHS Economic Evaluation Database), EconLit, EMBASE, International Pharmaceutical Abstracts, MEDLINE, PAIS International and PAIS Archive, and the Web of Science. We also searched the reference lists of relevant articles and several grey literature sources. We sought English-language studies published from 1986 to 2007 that examined the effects of either therapeutic reference pricing or tiered formularies, reported on outcomes relevant to patient care and cost-effectiveness, and employed quantitative study designs that included concurrent or historical comparison groups. We abstracted and assessed potentially appropriate articles using a modified version of the data abstraction form developed by the Cochrane Effective Practice and Organisation of Care Group.

Results: From an initial list of 2964 citations, 12 citations (representing 11 studies) were deemed eligible for inclusion in our review: 3 studies (reported in 4 articles) of reference pricing and 8 studies of tiered formularies. The introduction of reference pricing was associated with reduced plan spending, switching to preferred medicines, reduced overall drug utilization and short-term increases in the use of physician services. Reference pricing was not associated with adverse health impacts. The introduction of tiered formularies was associated with reduced plan expenditures, greater patient costs and increased rates of non-compliance with prescribed drug therapy. From the data available, we were unable to examine the hypothesis that tiered formulary policies result in greater use of physician services and potentially worse health outcomes.

Conclusion: The available evidence does not clearly differentiate between reference pricing and tiered formularies in terms of policy outcomes. Reference pricing appears to have a slight evidentiary advantage, given that patients' health outcomes under tiered formularies have not been well studied and that tiered formularies are associated with increased rates of medicine discontinuation.

Steve Morgan, PhD, is associate professor and associate director of the Centre for Health Services and Policy Research (CHSPR) in the School of Population and Public Health, University of British Columbia, Vancouver, BC, Canada. **Gillian Hanley**, MA, is a research assistant with the Program in Pharmaceutical Policy at CHSPR and a doctoral student of the School of Population and Public Health, University of British Columbia. **Devon Greyson**, MLIS, is the information specialist for the Program in Pharmaceutical Policy at CHSPR, University of British Columbia.

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Correspondence: Steven Morgan, UBC – Centre for Health Services and Policy Research, #201 – 2206 East Mall (LPC), Vancouver BC V6T 1Z3 Canada; telephone +1 604-822-7012; fax: +1 604-822-5690; morgan@chspr.ubc.ca

MOST COMMUNITY-BASED SPENDING ON prescription drugs in Canada is financed through provincial (40%) and private (35%) drug plans.[1] From 1997 to 2007, spending under provincial drug plans grew from $3.1 billion to $9.2 billion, and spending under private plans grew from $2.8 billion to $7.8 billion. Under such financial pressures, it is possible that reference pricing and tiered formularies will be adopted more and more by public and private insurers in Canada. Because these coverage policies are similar in intent but slightly different in structure, we sought to review and compare evidence concerning their effects. Although the authors of several reviews and commentaries have looked at tiered formularies and reference pricing policies,[2-5] none thus far has conducted a systematic comparison of evidence regarding these 2 formulary interventions.

Under reference pricing policies, a drug plan generally covers low-cost options within specified drug categories and requires patients to pay any price differences if higher-cost products are prescribed. Categories may include only chemically equivalent drugs (generic reference pricing), or they may include chemically distinct products with comparable therapeutic effects (therapeutic reference pricing). Public and private insurers in Canada and abroad use generic reference pricing extensively. The province of British Columbia and several countries outside Canada have applied therapeutic reference pricing.[6,7]

Under a tiered formulary, patients generally face incrementally higher copayments for different treatment options: a relatively low copayment applies to "preferred" drugs within a class (e.g., $5 for generics), a higher copayment to second-tier products within a class (e.g., $10 for "preferred brands" for which the insurer has negotiated a rebate) and an even higher copayment to other drugs on the formulary (e.g., $25 for other brands within a drug class). Tiered formularies are used most extensively in the United States. As of 2007, 91% of US workers with employer-sponsored drug coverage faced at least 2 cost-sharing tiers for prescription drugs, and 75% faced at least 3 tiers.[8]

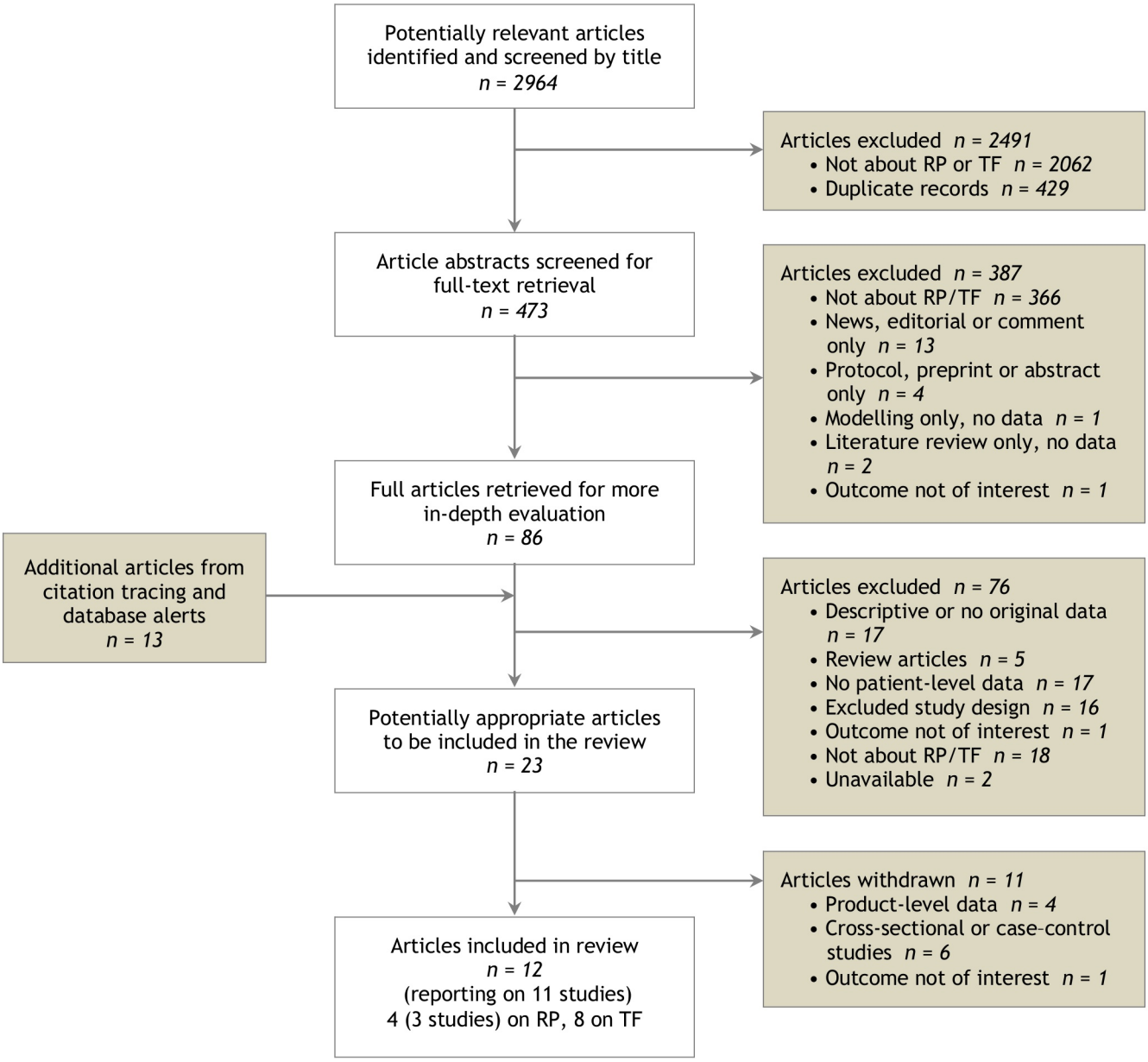
As reference pricing and tiered formularies are already commonly used to decrease drug plan expenditures, it is important to understand their implications for drug costs, use of medicines and patients' health outcomes. Our objective in this study was to synthesize and contrast methodologically comparable evidence from the published literature regarding the outcomes of both reference pricing and tiered formulary policies.

Methods

Searching. We searched for English-language studies published from 1986 to 2007 that examined drug plan enrollees affected by the introduction of either therapeutic reference pricing or tiered formularies, reported on outcomes relevant to patient care and cost effectiveness, and employed quantitative study designs that included concurrent or historical comparison groups. The starting date for the search was chosen to predate what were believed to be the first introductions of reference pricing policies, in 1989. Because those formulary interventions came into use in the late 1980s, a 20-year window beginning shortly beforehand was thought to be sufficient to capture the relevant literature.

We searched the following electronic databases: ABI/Inform, CINAHL, Clinical Evidence, Digital Dissertations & Theses, Evidence-Based Medicine Reviews (which incorporates ACP Journal Club, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Cochrane Methodology Register, Database of Abstracts of Reviews of Effectiveness, Health Technology Assessments and NHS Economic Evaluation Database), EconLit, EMBASE, International Pharmaceutical Abstracts, MEDLINE, PAIS International and PAIS Archive, and the Web of Science. We also performed web-based and open repository searches for grey literature, traced citations to and from relevant articles, hand-searched core journals from which several citations had been found electronically and searched our personal libraries for additional articles. We searched databases using subject headings and key words clustered around the concepts of prescription drugs, the interventions of interest (using various synonyms for copayments, tiers, and reference pricing) and, where possible, study methodologies; see Online Appendix 1 (http://openmedicine.ca/article/view/270/254) for search details.

Study selection. Articles were screened without blinding, through a sequence of title (by DG), abstract (by DG and SM), and full-text review and data abstraction (by SM and GH, plus EK and JL to reconcile discrepancies). As an aid in selecting the studies, we used a modified version of the data abstraction form developed by the Cochrane Effective Practice and Organisation of Care Group.[9] We chose our inclusion criteria to select quantitative studies that analyzed the impact of tiered formularies or reference pricing using



patient-level data in an acceptable research design. The following designs were deemed acceptable: randomized controlled policy trials; before-and-after, or pre/post, studies with nonrandomized comparison groups; interrupted time series analyses with or without comparison groups, and pre/post studies without a comparison group. We excluded analyses that were based on post-only or cross-sectional designs, analyses that used aggregated drug utilization and/or cost data, and analyses pertaining to policies in developing countries. We did not perform inter-rater reliability assessments but relied on a third reviewer to resolve discrepancies.

Data abstraction. Full-text reviewers (SM and GH) independently abstracted data from the studies. They first abstracted the setting in which the study had been conducted, including the study population and geographic setting. They then described the intervention of interest, including an indication of whether the intervention involved introduction of a tiered formulary or reference pricing, the date of introduction and the policy prior to the introduction. The reviewers then outlined the specific outcomes that each study examined (e.g., drug use for acute conditions, drug expenditures, physician visits), as well as the study design, the analytic methods and the total

observation period for the study. Finally, the reviewers independently abstracted the key findings from each article for each outcome of interest. These abstractions were then entered into a table, examined and translated into narrative abstracts.

Results

We identified a total of 2964 potentially relevant citations (Figure 1). By reviewing the citation titles, we eliminated 2491 citations (primarily drug-specific clinical studies). Review of the remaining abstracts eliminated all but 86 articles. An additional 13 articles were identified through citation tracing, of which 1 article was found to be unavailable because it was under peer review. After full-text screening, 12 articles representing 11 studies were deemed eligible for inclusion in our review.

Four of the included papers, representing 3 studies, assessed the impact of reference pricing. All of these studies examined the implementation of reference pricing during the mid-1990s under BC's PharmaCare program for senior citizens.[10-13] The other 8 studies assessed the impact of changes in tiered formularies. Seven of these looked at the effect of changes in tiered formularies for non-elderly enrollees of employment-related private insurance in the United States.[14-20] The eighth study assessed the impact of changes in tiered formularies on child dependents of enrollees of employment-related private insurance plans in the United States.[21]

Impacts of reference pricing policies. The associations reported in the 3 studies of reference pricing included in this review are summarized in Table 1. These studies assessed the impact of reference pricing for a total of 3 categories of drug treatment: nitrate drugs, angiotensin-converting enzyme (ACE) inhibitors, and calcium channel blockers (CCBs). Schneeweiss and colleagues[11-13] and Grootendorst and colleagues[10] found that between 9% and 34% of patients switched to fully covered (reference) products after reference pricing was implemented. Grootendorst and colleagues[10] found that overall use of CCBs declined upon implementation of reference pricing, whereas Schneeweiss and colleagues[13] found that the reduction in overall use of CCBs was not statistically significant after adjustment for pre-policy trends. The reverse was true for these authors' findings with respect to the use of ACE inhibitors.[10,12]

Schneeweiss and colleagues[12,13] found that the changes in utilization associated with reference pricing resulted in savings to insurers that ranged from 12% to 19% ($1.67 million to $6.7 million per year) of spending on related medicines. Both sets of researchers found that reference pricing in British Columbia was associated with an increase in physician services during the first 2 to 4 months after the policy change, which partially offset the savings in drug costs to the insurer.[10-13] The researchers observed different patterns with respect to longer-term use of physician services: Schneeweiss and colleagues[11-13] found no such association, whereas Grootendorst and colleagues[10] found evidence of increased use of physician services beyond 4 months for 2 of the 3 categories studied (CCBs and ACE inhibitors). Schneeweiss and colleagues[12,13] estimated that the annual net savings after accounting for expenses related to medical care were between $1.62 million and $6 million.

For 2 of the 3 drug categories investigated (CCBs and ACE inhibitors), Schneeweiss and colleagues[11,13] and Grootendorst and colleagues[10] found that reference pricing was not associated with any change in the use of hospital services. In the single study investigating the impact of reference pricing for nitrate drugs, Grootendorst and colleagues found that reference pricing was associated with increased long-term probability of bypass or revascularization.[10]

Impacts of tiered formularies. The associations observed in the studies of tiered formularies included in this review are summarized in Table 2. Despite differences in the populations and drug categories examined, these studies yielded a number of consistent findings. Most studies assessing such associations found that adding tiers to copayments for prescription drugs in the US private insurance market was associated with a reduction in total spending (decreases of 5%–20%).[16,18,20,21] Nair and colleagues[15] did not find statistically significant associations between adding tiers to formularies and changes in total spending. Where such associations were observed, reductions in total spending were the result of 3 common findings across the studies and across the drug classes investigated. Adding tiers to copayment structures was associated with increased switching within drug classes in all 8 included studies (switching toward "preferred" drugs on formulary occurring among 5% to 49.4% of patients),[14-21] decreased overall utilization of affected medicines,[15,16,18,19,21] and either no change[21] or an increase in the rate of discontinuation of prescribed drug treatments.[14-17,19]

In most of the studies that investigated the distribution of costs, employing tiered formularies was associated with lower spending by the drug plan[14-16,20,21] and greater spending by patients.[14-16,19-21] In the study by Nair and colleagues,[17] changes in spending by the plan and by patients were consistent with the findings of other studies but were not statistically significant.

Table 1: Summary of associations between reference pricing policies and specified outcomes

Variable	Study; reported description or value		
	Grootendorst[10]	Schneeweiss[11,12]	Schneeweiss[13]
Characteristics			
Population studied	BC seniors (≥ 65 yr) taking medicines from the studied drug classes	BC seniors (≥ 65 yr) who had received ACE inhibitors priced higher than the reference price in 1996	BC seniors (≥ 65 yr) who had received CCBs before introduction of reference pricing
Intervention (year)	Reference pricing policy for nitrates (1995) Reference pricing policy for CCBs and ACE inhibitors (1997)	Reference pricing policy for ACE inhibitors (1997)	Reference pricing policy for CCBs (1997)
Drug classes studied	Nitrates, ACE inhibitors, CCBs	ACE inhibitors	CCBs
Outcomes			
Total drug costs	Not tested	Not tested	Not tested
Insurer's costs	Not tested	[-] -19% (-$6.7 million/yr)	[-] -12% (-$1.67 million/yr)
Patient's costs	Not tested	Not tested	Not tested
Net costs to insurer, including medical care	Not tested	[-] -$6 million/yr	[-] -$1.62 million/yr
Prescription drug use	[-] Nitrates and CCBs [+] ACE inhibitors	[-] for ACE inhibitors; [=] for antihypertensives*	Not significant
Switching to preferred (reference) drugs	[+] 21% to 34% of patients	[+] 18% of patients	[+] 9% of patients
Discontinuation of medicines in the drug classes studied	Not tested	Not tested	Not tested
Short-term use of physician services (within 2–4 mo of intervention)	[+] 0% to +5%	[+] +11% = +$0.7 million/yr	[+] +18% = +$0.05 million/yr
Long-term use of physician services (4 mo after intervention)	[+] +0% to +11%	Not significant	Not significant
Use of hospital services	[+] Patients taking nitrates	Not significant	Not significant
Admissions to long-term care	Not significant	Not significant	Not significant
Mortality	Not significant	Not significant	Not tested

*There was no change in overall use of antihypertensive drugs after the policy was enacted.
[+] = statistically significant positive association between policy and specified outcome
[-] = statistically significant negative association between policy and specified outcome
Not significant = no statistically significant association between policy and specified outcome
Not tested = association between policy and specified outcome not tested in study
BC = British Columbia, ACE = angiotensin-converting enzyme, CCB = calcium channel blocker.

Table 2: Summary of associations between tiered formulary policies and specified outcomes

Variable	Study; reported description or value							
	Motheral and Fairman[14]	Fairman[15]	Huskamp[16]	Nair[17]	Gibson[18]	Landsman[19]	Landon[20]	Huskamp[21]
Characteristics								
Population studied	Enrollees in employment-sponsored insurance	Enrollees in employment-sponsored insurance	Enrollees and their dependents in employment-sponsored insurance	Enrollees in managed care plan	Enrollees in employment-sponsored insurance	Enrollees in employment-sponsored insurance	Enrollees in employment-sponsored insurance	Children of employees with employment-sponsored insurance
Intervention or comparison studied	2-tier to 3-tier v. stable 2-tier	2-tier to 3-tier v. stable 2-tier	1-tier to 3-tier and 2-tier to 3-tier v. stable 2-tier	2-tier to 3-tier v. stable 2-tier and stable 3-tier	2-tier to 3-tier v. stable 3-tier	2-tier to 3-tier v. stable 2-tier	Various tier increases v. stable controls	1-tier to 3-tier v. stable 2-tier
Drug classes studied	Antibiotics for otitis media, OCs and estrogens, antihypertensives, lipid drugs	All prescriptions, estrogens, OCs, antihypertensives, lipid drugs	ACE inhibitors, PPIs, statins	Medicines for hypertension, diabetes, dyslipidemia, GERD and arthritis	All prescriptions	NSAIDs, COX-2 inhibitors, TCAs, SSRIs, CCBs, ACE inhibitors, ARBs	All prescriptions	ADHD medications
Outcomes								
Total drug costs	[-] -7% growth	Not tested	Not significant	Not significant	[-] -$11 to -$16 per enrollee per quarter	Not tested	[-] -5% to -15%	[-] -20%
Insurer's costs	[-] -21% growth	[-] -26.6% growth	[-] 0% to -58%	Not significant	Not tested	Not tested	[-] -20%	-] -43%
Patient's costs	[+] +34% growth	[+] +46.5% growth	[+] 0% to +148%	Not significant	Not tested	[+] +16% to +129%	[+] +20% to +100%	[+] +46%
Prescription drug use	Not tested	[-] -4.2% growth, yr 1 Not significant, yr 2	[-] 0% to -34%	Not significant	[-] -0.16 prescriptions per enrolee per quarter	[mixed] -6.8% to +1.7%	Not tested	[-] -17%

Variable	Study; reported description or value							
	Motheral and Fairman[14]	Fairman[15]	Huskamp[16]	Nair[17]	Gibson[18]	Landsman[19]	Landon[20]	Huskamp[21]
Outcomes cont'd								
Switching to preferred drugs	[+] (lower use or cost of non-preferred drugs)	[+] (lower use or cost of non-preferred drugs)	[+] +17.6% to +49.4% of patients	[+] +5.6%	[+]	[+]	[+]	[+] +5% of patients
Discontinuation of medicines in the drug classes studied	[+] Estrogens	[+] +13% for OCs	[mixed] -7.5% to +32%	[+] +10%	Not tested	[+] 2 to 8 times higher	Not tested	Not significant
Long-term use of physician services (4 mo after intervention)	Not significant	Not significant	Not tested	Not tested	Not tested	Not tested	Not tested	Not tested
Use of hospital services	Not significant	Not significant	Not tested	Not tested	Not tested	Not tested	Not tested	Not tested

[+] = statistically significant positive association between policy and specified outcome
[-] = statistically significant negative association between policy and specified outcome
[mixed] = mixed associations found between policy and specified outcome
+/-% growth = percentage point difference in growth rates between intervention and comparison groups
Not significant = no statistically significant association between policy and specified outcome
Not tested = association between policy and specified outcome not tested in study
OC = oral contraceptive, ACE = angiotensin-converting enzyme, PPI = proton pump inhibitor, GERD = gastroesophageal reflux disease, SSRI = selective serotonin reuptake inhibitor, TCA = tricyclic antidepressant, CCBs = calcium channel blocker, ARB = angiotensin receptor blocker, ADHD = attention-deficit hyperactivity disorder, NSAID = nonsteroidal anti-inflammatory drug, COX-2 = cyclooxygenase-2.

None of the studies of tiered formularies included in our review assessed the potential health outcomes resulting from the policy. However, 2 studies showed that moving from a 2-tier formulary to a 3-tier formulary was not associated with increased use of medical or hospital services.[14,15]

The single study of the effects of tiered formularies on the use of medicines by children was the only study not to find an association between the policy and medicine discontinuation.[21] In the single study that assessed differences in effects on treatments for acute and chronic conditions, there were greater relative reductions in the utilization of and persistence with treatments for acute conditions.[19]

Discussion

The rapid rise in the use of tiered formularies by private insurance plans in the United States may be a harbinger of future trends in Canada: given rising medicine costs, it is likely that incentive structures for cost-sharing with patients will be adopted more widely here in the future. Policy-makers and health care managers will therefore require as much evidence as possible regarding such incentives. In this study, we have weighed the evidence regarding 2 comparable policy options: tiered formularies and reference pricing.

Despite over a decade of experience with the implementation of these policy interventions, and despite extensive searching of the literature on our part, we found few studies of the impacts of reference pricing and tiered formularies that met our relatively strict inclusion criteria. The most common finding was that patients facing either reference pricing or tiered formularies often switched to medications with preferred coverage. Studies of reference pricing suggest that this approach is also associated with short-term increases in the use of physician services, which may be interpreted as a transaction cost associated with switching medications. The balance of the evidence concerning health services use, hospital admissions and deaths indicates that reference pricing has not been associated with adverse health impacts. Surprisingly, only 2 of the 8 studies of tiered formularies included in this review assessed such outcomes or surrogates thereof.[14,15] This gap in knowledge is potentially critical, given that tiered formularies were associated with reduced use of medicines, increased medicine discontinuation or both in 7 of the 8 studies of this policy approach.[14-19,21] More research is required to examine the hypothesis that tiered formulary policies may result in increased use of physician services and potentially worse health outcomes.

The evidence that we examined in this systematic review suggests that the patient incentives created by reference pricing policies and tiered formularies work, insofar as they alter prescription drug use and save on drug costs. However, the gaps in evidence are sources of some concern. We conclude that reference pricing has a slight evidentiary advantage, given that patients' health outcomes under tiered formularies have not been adequately studied and given that tiered formularies were associated with increased rates of medicine discontinuation.

Because of our stringent inclusion criteria regarding study design and outcomes, the final number of studies included in this systematic review was small. Moreover, the literature we found pertaining to reference pricing and tiered copayments described 2 distinct contexts: public insurance in a Canadian province and private insurance in the United States. Our focus on studies published in English is a potential limitation in this regard, given that there may be non-English literature concerning reference pricing and tiered formularies in other settings, such as Germany. The English literature on experiences outside of North America did not meet our inclusion criteria.

When policy options for Canada are considered, information costs and transaction costs for both prescribers and patients should be taken into account along with the evidence presented here. With dozens of potential formularies to consider for their patient rosters, US physicians may not have the time or resources necessary to determine for each patient which drugs are on which tier. Drugs with high copayments may be prescribed unintentionally under such circumstances, potentially increasing patients' costs, straining physician–patient relationships, reducing adherence to treatments and worsening health outcomes. These problems may explain the association between tiered copayments and medicine discontinuation in the United States. Such adverse policy outcomes might be minimized if cost-sharing with patients, through reference pricing or tiered formularies, were to be harmonized across all payers within a jurisdiction (e.g., within each province).

Synthesizing the evidence for the purposes of this systematic review revealed an important gap in the existing research: specifically, the impacts of tiered formulary policies on patients' health have not been adequately studied. This gap is particularly significant given that tiered formularies are associated with increased rates of medicine discontinuation. Further research regarding the impact of tiered formularies on patients' health outcomes is warranted.

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Contributors: Steve Morgan was responsible for project conception and acquisition of funding, reviewing article titles, abstracts and full text for possible inclusion in the study, abstracting information from included articles, and producing the first draft of the research article. Gillian Hanley was responsible for reviewing full text of articles for possible inclusion in the study, abstracting information from included articles, and revising the manuscript for important intellectual content. Devon Greyson was responsible for designing and implementing the search strategy, reviewing article titles, abstracts and full text for possible inclusion in the study, and revising the manuscript for important intellectual content. All of the authors gave final approval of the version to be published.

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