The Effectiveness of the Common Drug Review in Canada's National Drug Strategy

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Executive Summary

Where you live in Canada and your economic status make a big difference to the sort of prescription medicine you are likely to receive from public health insurance—although that is not supposed to be. In 2002, Canada's federal and provincial health ministers (except Quebec) launched the Common Drug Review (CDR), to "ensure a consistent and rigorous approach to drug reviews across the country." The Canadian Agency for Drugs and Technologies in Health's (CADTH) which administers the project identifies it as: "…a pan-Canadian process for conducting objective, rigorous reviews of the clinical, cost-effectiveness, and patient evidence for drugs. CDR also provides formulary listing recommendations to the provinces' drug plans (except Quebec)."[1] A listing on the formulary determines whether a prescribed drug will be available to eligible publicly insured patients at no, or minimal, cost.

This paper examines how closely the Common Drug Review recommendations have been reflected in the various provincial drug plans. In 369 pairwise observations of provincial drug formularies and CDR-reviewed drugs, we observed 65.3% agreement with CDR recommendations. The degree of agreement ranges from no better than random chance (50% in Ontario, PEI and Newfoundland and Labrador), to fairly high (88.2% in AB), with some of that variation depending on the recentness of the CDR recommendations studied. Disagreement between CDR recommendations and provincial formularies is not randomly distributed, but exhibits a significant negative bias, in which provinces omit to insure patients for treatments that CDR has reviewed favourably and deemed cost-effective. Our findings appear to contradict claims by CADTH, based on unpublished data, that participating drug plans agree with CDR recommendations 90% of the time.

The obvious interpretation of these results is that the CDR has not aligned provinces into a consistent, national application. Since CDR recommendations are based on cost-effectiveness, the persistent and large gap between CDR recommendations and provincial drug benefits demonstrates that provinces are wasting money on inferior treatments, as affordable clinical benefits to patients are lost.

I. Introduction

Canadians increasingly rely on pharmaceuticals.[2] From 2000 to 2007, spending on prescribed and over-the-counter drugs soared—from $14.7 billion in 2000, to $26.9 billion in 2007—making drugs the number two category of health care expenditure.[3] How to contain this cost, without needlessly losing therapeutic advantages, is a challenge.

Canada's health ministers in 2002 tasked the Canadian Agency for Drugs and Technologies in Health (CADTH) to establish a national Common Drug Review (CDR). CDR's intent was to "ensure a consistent and rigorous approach to drug reviews across the country by replacing multiple review and recommendations for new drugs with one common process".[4] CDR was positioned as a national formulary—a building block for the national pharmaceutical plan urged by the 2007 National Forum on Health, and the 2004 National Pharmaceuticals Strategy.[5]

But whether CDR has streamlined the provinces' drug review processes and achieved consistency in formulary outcomes is controversial. CADTH claims that "Participating drug plans are in agreement with the CDR recommendations more than 90% of the time,"[6] but the most recent study (June 2005), conducted early in CDRs history, found much lesser consistency.[7]

At the time CDR was created, it was widely thought that it would take 3-5 years to discern its effects on provincial formularies. A study published last year shows that as of 2008, CDR achieved "little to reduce variation in the listing of new drugs to Atlantic provincial formularies", in the words of the authors.[8] This study advances that study, by going further one more year (to 2009) and by expanding the analysis to all of Canada. We test two hypotheses: (i) whether CDR's drug review outcomes have narrowed inter-provincial differences in formularies, and; (ii) whether provinces have adopted CDR's drug review processes effectively as their own. We sampled provincial formularies at "early" and "late" time points in CDR's operation, to assess both the speed with which provinces adopted CDR's recommendations, and report on the degree of concordance or its lack.

II. Methods

In February 2009, we accessed drug reviews on the CDR's website. After excluding those less than three months old (*i.e.* too recent to be reflected in provincial formularies), we selected the first 25 drugs (the "early" dataset) and the last 25 drugs (the "late" dataset) to receive CDR recommendations. We then accessed provincial health ministry websites to search or download the current formulary status of these drugs (except in Quebec, which does not participate in CDR).[9] For accuracy, CDR and formulary data were obtained and processed in duplicate by two researchers working separately and cross-checking each other.

We made pairwise comparisons of each provincial formulary with CDR's reviews. Because provinces' nomenclature and reporting methods vary, particularly when a medicine is approved conditionally for a specific indication, we used this harmonized coding scheme to indicate general (not necessarily exact) agreement or disagreement: (1) Province agrees with CDR; (2) Province disagrees with CDR and has a drug benefit less than CDR's recommendation, or; (3) Province disagrees with CDR and has a drug benefit exceeding CDR's recommendation.

To elucidate process differences which might explain non-concordance, we contacted health ministries by telephone or email and posed the following question: "Are there any written criteria which the [provincial drug review committee] uses when deciding whether or not a particular drug that has been recommended by CDR will be made a benefit in the province?"

Finally, to verify all data's accuracy of our data, we supplied health ministries with the methods and raw data, and requested corrections. Timely requests for corrections were accommodated, where those were consistent with the study's methods, and verifiable by reference to a public rule (i.e. ministry claims lacking corroboration in other information generally available to the public were not accepted).

III. Results

Of the 50 drug reviews studied, 9 were excluded because they were not independent observations of the CDR system—6 because CDR recommended listing the drugs similar to earlier drugs in the class, and 3 because the drugs were funded federally not provincially. This left 41 drug reviews in 9 provinces (n = 369 observations), forming the basis of the analysis here. The "late" dataset captures 24 drug reviews of median age ~8 months (median date 25 June 2008) and the "early" dataset captures 17 drug reviews of median age ~51 months (median date 22 December 2004). The data, coded as described in the methods section are online.

Across all observations, agreement between CDR recommendations and provincial formularies is 65.3%. Concordance ranges from a low of 50%, or no better than random chance, for Ontario, PEI and Newfoundland and Labrador in the late dataset, to a high of 88.2% for Alberta in the early dataset (Figure 1). This non-concordance is marked by an obviously large variance (Figure 2; variance statistic unreported as data are not normally distributed).

The variance discloses meaningful patterns. Even though the mode is that all 9 study provinces agree with CDR recommendations (rightmost bar of Figure 2), there remain instances where most provinces disagree (leftmost bars of Figure 2). As expected, disagreement is commonest when the underlying CDR recommendations are recent (late dataset; purple bars), but surprisingly also occurs with CDR recommendations of several years ago (beige bars). The early dataset includes instances of CDR drug recommendations that, despite being over 4 years old, have yet to be adopted by a majority of the provinces (Table 1).

Further, when provinces disagree with CDR, they do so with a non-random negative bias, toward not insuring recommended drug benefits (Figure 3). In other words, there are more cases where provinces fail to insure medicines CDR assesses favourably (n=93), than cases where the provinces insure medicine CDR assesses unfavourably (n=35), and this difference is not random but highly statistically significant ($p<0.001$ by chi-square). The negative bias, or refusal to insure medicines favourably reviewed by CDR, affects all provinces in the late dataset. Two provinces (Manitoba and Ontario) also exhibit this negative bias in the early dataset.

To test the hypothesis that the lack of agreement between CDR and the provinces arises from the decision criteria used by provinces' drug review committees, we requested each province to supply a copy of its current decision criteria, for purposes of comparison with CDR procedures. Only one province (Alberta) did so. All others would not or could not divulge their decision criteria. Thus for 8/9 provides studied, there are no public criteria for how they decide which medicines will be insured, whether because true criteria do not exist, or because they are secret.

FIGURE 1

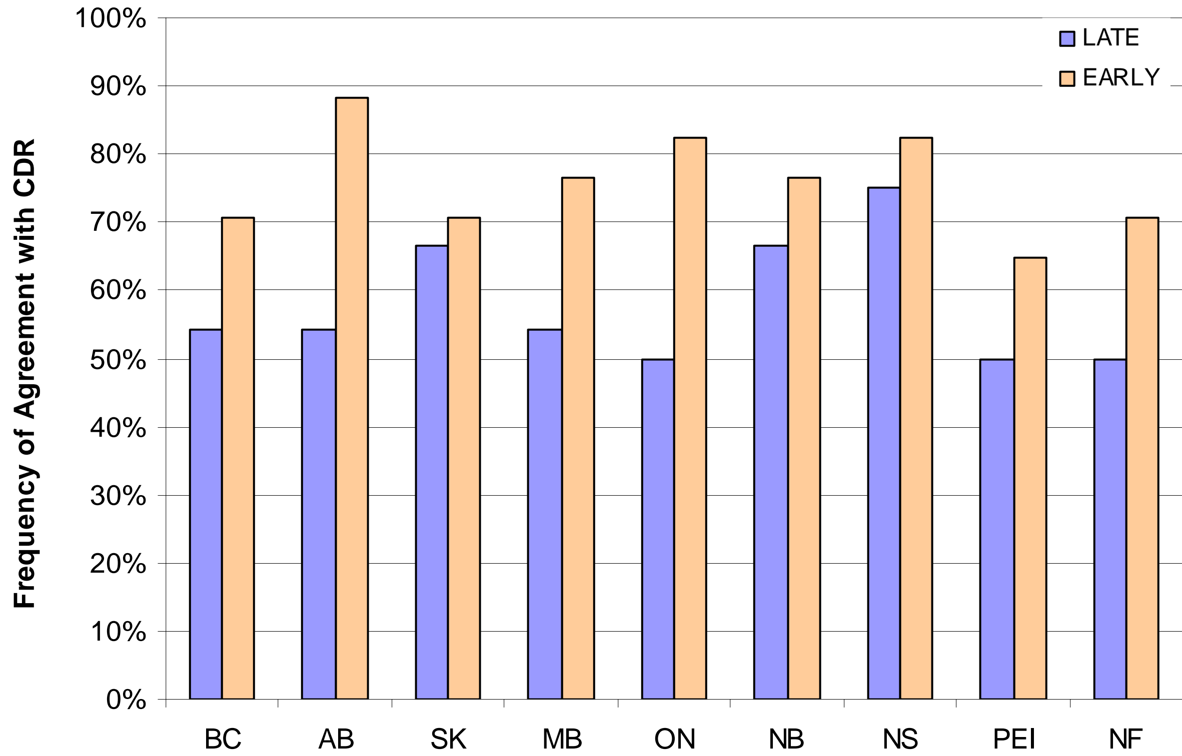


FIGURE 2

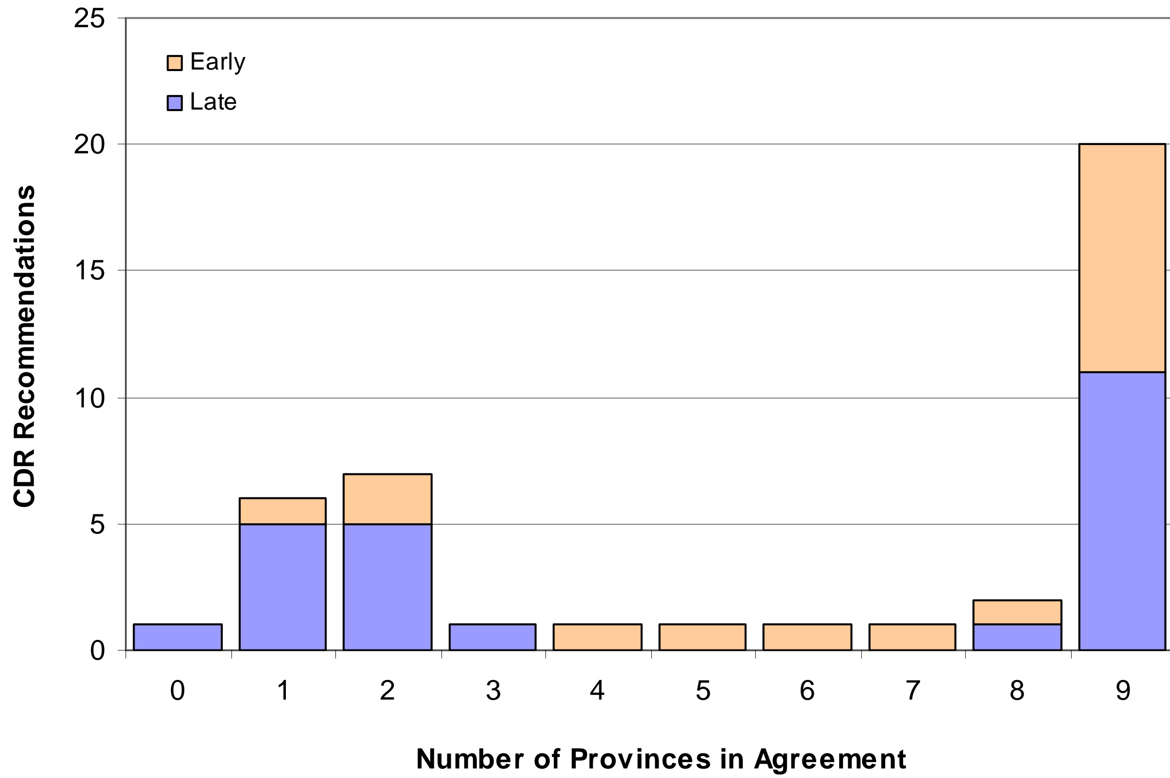
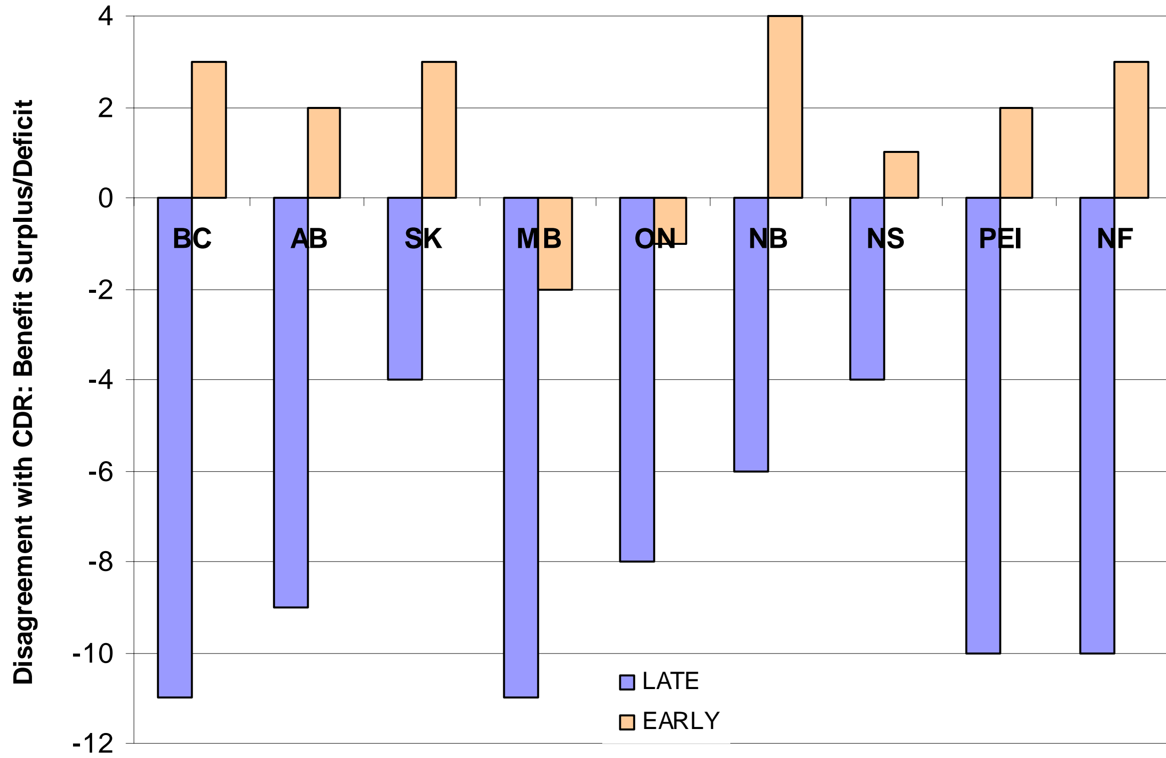


FIGURE 3



IV. Interpretation

This study demonstrates that, seven years following CDR's creation, provinces did not achieve alignment with that system. There is still no national formulary, and hence, still no foundation for realizing the 2004 National Pharmaceuticals Strategy and the national formulary that it requires.

The range of provincial concordance that we report (50% — 82.4%) suggests little coordination between the provinces and CDR; indeed the bottom of that range reflects coordination no better than random chance, as might be achieved by flipping a coin. Our data appear to contradict CADTH's claim (echoed in the peer-reviewed literature) that "[p]articipating drug plans are in agreement with the CDR recommendations more than 90% of the time." [10] We wrote to CADTH specifically requesting that it provide "evidence please in support of that claim", but received the answer that the underlying data were "not published".

In the absence of published data to substantiate CADTH's claim, and considering that CADTH is not an entity at arm's length from government (its Board of Directors draws heavily from current government employees) we cannot exclude the worrisome possibility that CADTH's claim is based on incorrect data or is falsified. The large difference between CADTH's claim and our findings potentially affect a large number of Canadians' ability (or not) to access medicines. As such, we strongly recommend an investigation by the Auditor General of Canada on this critical issue, and echo an earlier call by the House of Commons for such an audit.[11]

A statistically significant finding of this study is that disagreement between CDR and provincial decisions is not random, but negatively biased away from insuring medicines that CDR recommends as cost-effective. Negative bias may be viewed charitably or not: either as provinces furthering the public interest to save money in a struggle of cost containment, or as injuring the public interest by denying patients treatments which are cost-effective and clinically beneficial. One's preference between these two narratives is a question of ideology—but a definitely unarguable fact is that provinces are failing to base decisions on economic and clinical evidence, as CDR assiduously does. Put this way, the outcome is grossly unacceptable, in either ideological characterization.

These realities suggest little, if any, progress has been made in the last decade on harmonizing Canadians' access to medicines around a national standard of care. Two studies published by Anis, Grégoire and colleagues before CDR's creation in 2002 show a comparable degree of non-concordance between formulary listings in the provinces to our study.[12] [13] Our study also proves that time lags in provincial adoption of CDR recommendations can be very long. Where McMahon and colleagues observed that "that some provinces have not made coverage decisions many months after a CDR recommendation," our data now show that provinces fail to complete such decisions even after several years.

As CDR's former chair, Andreas Laupacis, has written, "Drug policy is a mix of scientific evidence, judgement, altruism, self-interest and politics, superimposed on a complex, semi-

rational, over-burdened, constantly changing health care system."[14] We propose that to assist CDR's ability to make rational interventions in this morass, CADTH must insist, perhaps as a condition of continued membership, that provinces publicly disclose their criteria for formulary listing. Transparency of criteria can ensure provincial conformity with CDR processes—or at least it can ensure that provinces must have a reason to fail to conform. Currently, eight of nine provinces we studied either could not or would not publicly disclose their criteria for drug evaluation (BC, SK, MB, ON, NB, NS, PEI, NL). That is unfortunate, for without transparent criteria, arbitrary decisions are likely to be made, setting Canada back on its much-delayed goal of a national formulary, and equity and fairness for Canadians seeking medical treatment.

Paper Details

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Role of the Authors: AA conceived the study and wrote the manuscript. RC and AT collected and compiled the data. RC and AT contributed equally to the work.

Conflict of Interest Statement: No pharmaceutical industry funding has been accepted by the authors within the past seven years (i.e. since the inception of CDR).

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