Brief to House of Commons Standing Committee on Health: National Pharmacare program, 20 April 2016

Katherine Boothe, PhD, Department of Political Science and Centre for Health Economics and Policy Analysis, McMaster University

This brief presents three key messages regarding cost containment, drug cost-effectiveness research, and formulary listing decisions, based on my research on the comparative development and reform of pharmaceutical policies in Canada, Australia, and the United Kingdom.

1. In Canada, there is a history of talking about pharmacare as if it is a program that poses unique challenges regarding cost-containment, but this is not supported by evidence. Evidence from similar countries demonstrates that pharmacare does not mean uncontrollable costs, and universal systems have access to much better tools for cost containment than Canada's present, fragmented public drug programs do.
2. A key tool for cost containment is a national or nation-wide formulary. This is a list of drugs eligible for reimbursement that applies equally across the country. We already have a good understanding of the institutional requirements for this to work in Canada.
3. Cost-effectiveness analysis is an important element of a building a national formulary. Canada has been an international leader in area of cost-effectiveness research, and has a good deal of capacity in this area. Other countries like Australia provide examples of how Canada might integrate this analysis more fully into formulary decisions and price negotiations.

1. Historical perceptions of cost-containment in Canada versus comparative evidence

Past proposals for broader public pharmaceutical insurance in Canada have tended to falter because of the *perception* that cost containment is difficult or impossible, or that a universal pharmacare program is equivalent to a "blank cheque." Although this perception is persistent, it is not based on evidence.

Expanding pharmaceutical coverage in Canada has been proposed at least five times since 1949. The federal Department of Health and Welfare drafted proposals for the minister in 1949 and 1972. A universal plan was proposed by the Royal Commission on Health Services (Hall Commission) in 1964 and by the National Forum on Health in 1997. The Commission on the Future of Health Care in Canada and the Senate Standing Committee on Social Affairs, Science, and Technology (Romanow and Kirby Reports) both proposed catastrophic or income-based pharmacare in 2002. None of these proposals received much serious political consideration, because the initial response from national decision-makers in each case was the same: broader pharmaceutical insurance would be too expensive, too risky, and make it too difficult to control costs.[1]

The fact that pharmacare would be "too expensive" has often been taken for granted in Canada, especially after the rapid increase in effective pharmaceutical therapies and drug prices in the 1960s. However, during this time, similar countries like the UK and Australia were adopting and consolidating their universal, comprehensive pharmaceutical benefit programs.

Both the UK and Australia have universal, single-payer programs for pharmaceuticals, and they both do a better job at containing costs that Canadian drug plans do currently. When it comes to combined public and private spending on pharmaceuticals, Canada pays more per capita than all OECD countries apart from the United States[2] *and* Canada pays more while providing less access.

Australia and the UK use different tools to contain costs. Australia uses a positive formulary (listing drugs eligible for coverage), and the UK uses a negative formulary (listing drugs ineligible for coverage). In both countries, the formularies are informed by cost-effectiveness analysis and other considerations such as the availability of alternative therapies, the severity of the disease or condition the drug is approved to treat, and the impact on drug budgets.[3] In both countries, there is broad use of electronic health records along with financial incentives for prescribers to aid appropriate prescribing,[4] and their universal drug programs can leverage the purchasing power of government to achieve significantly lower drug prices than Canada.[5] This means there is not a single method for achieving an efficient, affordable system, but rather a variety of tools than can be adapted to fit the Canadian context.

2. Role of a national formulary

A single, nation-wide formulary is key for both cost control and equity. A formulary ensures governments only pays for drugs that have undergone a rigorous evaluation process regarding their value to patients and society. It ensures that access is the same for patients no matter where they live in Canada, and that governments have the bargaining power they need to get fair prices for drugs.[6]

It is important to distinguish between "national" and "nation-wide" because it is not necessary for the federal government to have ownership of a formulary in order for it to be effective. In fact, provinces are already quite successful at cooperating on the process of formulary decision-making through mechanisms like the Common Drug Review (CDR) and the Pan-Canadian Pharmaceutical Alliance (pCPA). For example, a recent independent study called the CDR "a successful institution…by any measure," noting that "It maintains the full support of the funding provinces, it consistently meets timelines for review, it scrupulously follows well documented processes and it has made modifications over the years to respond to criticisms."[7] As of March 2015, the pCPA's joint negotiations on brand name drugs and price reductions on generic drugs have resulted in an estimated $490 million in combined savings annually.[8]

What provinces need is an incentive to commit to shared outcomes. Currently, the recommendations of the CDR and the joint price negotiations undertaken by the pCPA are not binding on the provincial drug plans. This is understandable given that each province has sole financial responsibility for its own plan, but it means that Canadian drug plans are not realizing the full benefits of a centralized expert drug review process *or* the potential for lower drug prices through the exercise of their combined purchasing power. This is an opportunity for the federal government to act as a crucial partner, by contributing financially and requiring consistency similar to the way it sets national standards for public hospital and medical insurance through the provisions of the Canada Health Act.

3. Cost-effectiveness analysis of pharmaceuticals

Cost-effectiveness analysis is one element of formulary decision-making, along with other factors such as budget impact and burden of disease.[9] There is a significant concentration of expertise in cost-effectiveness analysis of pharmaceuticals in Canada. Canada was among the earliest adopters of guidelines for cost-effectiveness analysis, and guidelines developed here have been a model for other jurisdictions.[10] This means that Canada already has the capacity to create an evidence-based nation-wide formulary.

Currently, cost-effectiveness analysis is applied on a pan-Canadian basis through the Common Drug Review, but as noted above, the CDR's role is advisory only. Australia is another international leader in the development and application of cost-effectiveness analysis of pharmaceuticals, and it provides an example of one way to integrate this analysis into formulary decision-making.

Australia has an expert body analogous to the CDR's Canadian Drug Expert Committee, called the Pharmaceutical Benefits Advisory Committee (PBAC). PBAC's official mandate is to recommend new drugs for listing on the national formulary, taking into account clinical effectiveness, safety and cost-effectiveness compared with other treatments.[11] The committee's recommendation may include a requirement that a drug be subsidized only for a restricted population[12], and it can make recommendations regarding price or cost offsets. If the committee makes a positive recommendation, the drug goes to the Pharmaceutical Benefits Pricing Authority to discuss a final listing price. If the committee's recommendation is negative, the manufacturer may resubmit the drug after gathering new evidence or proposing a more limited patient population or lower price.[13] Australian policy experts often refer to this as a system of "no means no, and yes means maybe": drugs can only be listed on the national formulary with expert approval, but the minister has the final say.

A final point to consider regarding cost-effectiveness analysis: this is a tool for ensuring value-for-money, not for containing overall costs. A drug that offers significant new therapeutic benefits may be cost-effective even if it is relatively expensive and increases drug budgets. Understanding what this tool does mean we can put it to its best use, along with other tools to ensure a national pharmacare plan is equitable, evidence-based, and affordable.

Notes

1. Katherine Boothe, "Ideas and the Limits on Program Expansion: the Failure of Nationwide Pharmacare in Canada Since 1944," *Canadian Journal of Political Science* 46, no. 2 (May 24, 2013): 419–53.
2. Nuffield Trust, "Annual Prescribing Spend Per Person in the UK," *nuffieldtrust.org.uk*, 2014, http://www.nuffieldtrust.org.uk/data-and-charts/prescribing-spend-person-uk; OECD, "OECD Heath Data 2015," *stats.oecd.org* 2015, http://stats.oecd.org/Index.aspx?DataSetCode=SHA#.
3. Australia. Department of Health, "PBAC Guidelines | Role of PBAC," *pbac.pbs.gov.au*, January 16, 2014, https://pbac.pbs.gov.au/information/role-of-pbac.html; Joshua Parsons Cohen, Elly Stolk, and Maartje Niezen, "Role of Budget Impact in Drug Reimbursement Decisions," *Journal of Health Politics, Policy and Law* 33, no. 2 (2008): 225–47; National Institute for Health and Care Excellence, "NICE Technology Appraisals Guidance," *nice.org.uk*, 2016, https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-technology-appraisal-guidance.
4. Steve G Morgan et al., "Toward an Understanding of High Performance Pharmaceutical Policy Systems: a 'Triple-a' Framework and Example Analysis," *The Open Health Services and Policy Journal* 2, no. 1 (February 27, 2009): 1–9; Cathy Schoen et al., "A Survey of Primary Care Physicians in Ten Countries Shows Progress in Use of Health Information Technology, Less in Other Areas," *Health Affairs* 28, no. 6 (November 2, 2009): w1171–83; Steve G Morgan, Jamie R Daw, and M R Law, "Rethinking Pharmacare in Canada," C.D. How Institute Commentary No. 384, (C.D. Howe Institute, 2013).
5. Patented Medicines Prices Review Board, "Generic Drugs in Canada, 2013," *pmprb-cepmb.gc.ca*, (Government of Canada, 2014); "Annual Report 2013," *pmprb-cepmb.gc.ca*, (Government of Canada, 2014).
6. Commission on the Future of Health Care in Canada, *Building on Values* (Ottawa: Commission on the Future of Health Care in Canada, 2002); Senate Standing Committee on Social Affairs, Science and Technology, *The Health of Canadians: the Federal Role*, (Ottawa: Parliament of Canada, 2002); Aidan Hollis and Stephen Law, "A National Formulary for Canada," *Canadian Public Policy/Analyse De Politiques* 30, no. 4 (December 2004): 445–52.
7. Angela Rocchi et al., "Common Drug Review Recommendations," *Pharmacoeconomics* 30, no. 3 (2012): 229–46.
8. Council of the Federation, "The Pan-Canadian Pharmaceutical Alliance," *The Council of the Federation*, 2016, http://www.pmprovincesterritoires.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance.
9. Rosemary C R Taylor et al., "Inclusion of Cost Effectiveness in Licensing Requirements of New Drugs: the Fourth Hurdle," *British Medical Journal* 329, no. 7472 (October 23, 2004): 972–75; Joshua Parsons Cohen, Elly Stolk, and Maartje Niezen, "Role of Budget Impact in Drug Reimbursement Decisions." *Journal of Health Politics, Policy, and Law* 33 no. 2 (2008): 225–247.
10. Katherine Boothe, "Evaluating the Cost-Effectiveness of Pharmaceuticals in Canada," *Health Reform Observer* 4, no. 1 (2016).

11. Australia. Department of Health, "Pharmaceutical Benefits Advisory Committee (PBAC)," *pbs.gov.au*, (Australian Government Department of Health, October 2015), http://www.pbs.gov.au/info/industry/listing/participants/pbac.
12. This ensures a drug is only subsidized for the uses for which it is approved, clinically effective and/or cost-effective.
13. Fiona M Clement et al., "Using Effectiveness and Cost-Effectiveness to Make Drug Coverage Decisions," *Journal of the American Medical Association* 302, no. 13 (October 7, 2009): 1437–43.