How to create and update an essential medicines list for Canada

FINAL REPORT

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Executive Summary

If a decision to implement an essential medicines lists is made as recommended, one can quickly be created using international guidance, experiences from other countries and existing capacities and expertise in Canada. The medicines included in Canada's essential medicines list would be a subset of the medicines included in lists of medicines that are publicly funded for certain subpopulations in Canada, and the list can be similar to essential medicines lists in other countries. An interdisciplinary committee should use defined criteria and the best syntheses of available information to recommend effective medicines for inclusion in the list. An Executive Director of a new essential medicines program should make final decisions that are insulated from political influence. The list, its processes and information that promotes the appropriate use of medicines, should be disseminated by national clinician associations, provincial and territorial governments, clinical champions and patients. The essential medicines list should be integrated with efforts to negotiate drug prices and procure medicines. Carefully tracking the effects of an implemented essential medicines list could help ensure health outcomes improve and help inform policies in other countries.

Purpose of this report

This report describes potential processes for creating and updating an essential medicines list for Canada. This report focuses on *how* to create and update an essential medicines list for Canada, and not the reasons for creating an essential medicines list. (The reasons for creating an essential medicines list are only briefly mentioned with reference to previous reports.) This report is *not* intended to argue for or against creating an essential medicines list, but rather to provide technical and practical advice in case a decision to create a national essential medicines list is made.

This is an academic project and not one initiated by a government. If a decision is made to create an essential medicines list for Canada, the report can help inform implementation.

Process for creating this report

The idea for this project was discussed during a November of 2019 meeting in Toronto about essential medicines list research. The meeting involved international experts, the World Health Organization and multiple Canadian stakeholders. An outline for the project was developed and Ms Jordan Jarvis provided expert advice on key issues. In December of 2019 stakeholders, including some who participated in the November meeting, were invited to participate in this project. A discussion paper was circulated in February of 2020. Interviews with stakeholders were conducted in March of 2020. A preliminary draft report was circulated for additional input in April of 2020. The report was drafted by the author and the views provided are not necessarily supported by the consulted stakeholders or their institutions.

Explaining two key terms: “essential medicines list” and “national formulary”

Essential medicines, as defined by the World Health Organization, “satisfy the priority health care needs of the population.”[1] One-hundred and thirty-eight countries have registered a national essential medicines list with the World Health Organization and these include 21 high-income countries such as Sweden and Malta.[1] Sub-national essential medicines lists for jurisdictions within some countries also exist (e.g. within India). Uses of essential medicines lists differ; in some jurisdictions essential medicines lists determine which medicines healthcare institutions such as hospitals are required to stock, in others essential medicines lists determine which medicines are publicly funded, while in others essential medicines lists are merely an optional guide for clinicians and healthcare institutions. The word “essential” means “needed” and it is being used in its ordinary usage in the term “essential medicines list” so essential medicines lists contain expensive treatments and treatments for infrequently encountered conditions (so called “rare diseases”) if they are deemed to be needed.

While the term “formulary” on its own usually refers to a list of medicines (e.g. the list of medicines stocked by a particular hospital), the term “national formulary” (or “formulary manual”) is often used to refer to a compendium of clinical information about a large number of medicines used in a country. Examples include the British National Formulary and the United States Pharmacopeia and National Formulary; two comprehensive documents that clinicians may use to find information about doses and contraindications for specific medicines.

Confusion may arise when the term “national formulary” is used to refer to lists of medicines that are publicly funded in a jurisdiction and, in some cases, “national formulary” is used as an umbrella term that includes “essential medicines list” and other lists that might be longer. In other cases, the term “formulary list” is used to refer to the list of all the products encompassed by a list of medicines. The final report of the 2019 Advisory Council on the Implementation of National Pharmacare recommends starting universal pharmacare by publicly funding medicines on a national essential medicines list and then later publicly funding medicines on a longer and “comprehensive” national formulary.[2] National essential medicines lists vary in length from less than 100 to approximately 1000 medicines. In this document about a national essential medicines list that includes needed medicines, the potentially ambiguous term “national formulary” will be avoided except when quoting other documents. For simplicity and clarity, the term “list” will be employed and the purpose or use of the list of medicines will be specified.

Purpose and scope of a pan-Canadian essential medicines list

The 2019 Mandate letter to the Minister of Health identified this priority: "Continue to implement national universal pharmacare, including the establishment of the Canada Drug Agency, and implementing a national formulary and a rare disease drug strategy to help Canadian families save money on high-cost drugs". The 2019 Advisory Council on the Implementation of National Pharmacare recommended that "federal, provincial and territorial governments launch national pharmacare by offering universal coverage for a list of essential medicines by January 1, 2022".[2] The Advisory Council was established after the 2018 Report of the Standing Committee on Health included a recommendation to "develop a common voluntary national prescription drug formulary" for drugs dispensed outside of hospitals.[3] The 2016 Citizens' Reference Panel on Pharmacare in Canada recommended that "only the most effective treatments available for the price be covered by this program, with drugs undergoing a rigorous, evidence-based evaluation of their clinical value and their cost-effectiveness before being added to a national public formulary" and highlighted "coverage of an essential medicines list as an urgent first step".

Recommendations for creating an essential medicines list cite three purposes or goals of a national formulary within a universal pharmacare program: (1) equitable access (2) appropriate use of medicines or avoidance of potentially inappropriate medicine use, and (3) to reduce drug prices and the amount being overpaid for medicines. Some sources also cite acceptability to clinicians or ease of use by clinicians.

Medicines dispensed outside of hospital are the focus of a national formulary since medicines for inpatients are already publicly funded.[4] Medicines dispensed outside of hospital include treatments for common conditions such as hypertension and asthma, treatments for infrequently encountered conditions (so-called "rare diseases") and some cancer treatments. Decisions about routine vaccinations are generally handled by public health authorities and can also be excluded from an essential medicines list for Canada, at least initially, although COVID-19 illustrates the importance of national coordination of vaccine availability. For the purposes of this document, the scope of the new essential medicines list is outpatient medicines. The general approaches described here may apply with some adaptations to other medicines including inpatient medicines.

Recommendations

Criteria and information to guide medicine selection and removal

1.1 Listing decisions should be based primarily on effectiveness as only effective medicines are needed.

1.2 The list should include only a small number of medicines in the same therapeutic area or class.

1.3 An essential medicines list for Canada should include a subset of medicines included in longer lists of medicines that are publicly funded for specific populations in different jurisdictions such as provinces.

1.4 Clinical effects, and not cost or cost-effectiveness, should be the basis for most listing decisions.

1.5 An active process for removing medicines is important.

Medicine selection process

2.1 An interdisciplinary committee should be formed to review evidence and make recommendations about which medicines should be listed.

2.2 Advisory committees and individual experts should be consulted on an ad hoc basis.

2.3 A conflict of interest policy for committee members based on international guidance and Canadian practice should be implemented.

2.4 An open process for suggesting medicines to be added or removed from the list should be developed.

2.5 A public servant should be appointed to review committee recommendations and make final decisions about listing on behalf of government without involvement of elected officials.

Implementing an essential medicines list for Canada

3.1 The purpose of the essential medicines list, its processes and the current medicines should be easily available to members of the public and to clinicians.

3.2 Important information about medicines included on the list should be easily available to both patients and clinicians.

3.3 Professional organizations, provincial governments and trusted clinician champions should be engaged in dissemination.

3.4 The essential medicines list should generally be in alignment with clinical practice guidelines.

3.5 The list should be integrated with ongoing initiatives such as those to procure medicines in order to realize the benefits of an essential medicines list.

3.6 The effects of the essential medicines list should be carefully tracked.

Summary of international guidance on and experience with essential medicines list processes

An essential medicines list is a key part of a country's medicine policy, according to guidance from the WHO. The WHO provides guidance about the principles and processes for selecting essential medicines. According to guidance from the WHO, the main criterion for selecting medicines should be evidence of efficacy and safety. Relative cost-effectiveness is to be considered only within a therapeutic area.

The WHO emphasizes that the process for selecting essential medicines should result in a list that will be acceptable to users including clinicians and patients. The process should be consultative and transparent, employ explicit criteria for selecting medicines, and the process should be linked with clinical practice guidelines and other credible guidance. The essential medicines lists should be updated at least every two years.

A multidisciplinary committee should be appointed to provide advice about medicine selection. This committee should be comprised of clinicians and other experts. Consultations with other stakeholders including professional bodies, pharmaceutical companies, and government finance or budget groups are recommended, but the committee should make medicine selection decisions independently.

WHO guidance emphasizes the need to compare similar medicines in order to select the most suitable one or ones and this contrasts to regulatory approval decisions where multiple similar medicines are approved.

WHO guidance also recommends that the list be divided into different levels of care (i.e. primary, secondary, tertiary care).

The essential medicines list should be easily available in both print and electronic versions, and a dissemination plan is crucial according to WHO guidance. Clinical leaders should be actively engaged.

The WHO created a model list of essential medicines in 1977 and has updated it every two years since then; the 21st edition was published in 2019. The WHO recommends that countries adapt the model list to their unique circumstances. 138 countries have registered essential medicines lists with the World Health Organization. These national essential medicines lists range in length from less than one hundred to almost one thousand. There are large numbers of differences between national lists and the WHO's model list, and many of these differences are apparently not explained by differences in health needs. The similarities and differences between national essential medicines lists have been summarized in academic articles.[1]

Some countries have published details of their processes that help to understand how international guidance has been adapted at the national level. South Africa has well-described policies and procedures for its national essential medicines list that is one part of its national drug policy. Members of the national essential medicines committee can be recommended by provincial bodies. The Wise List developed in Stockholm, Sweden has achieved a high rate of adherence through engaging with clinicians and clinical experts and a public outreach campaign that included displaying the lists owl symbol on buses.[5] The United States Veteran's Administration, which provides health care services to approximately 9 million veterans and their dependents annually, moved from 170 separate institutional

formularies to a single national list of publicly funded medicines in 1996.[6] The Veteran's Administration has apparently been able to secure lower prices for some medicines than other large payors in the United States.[7]

Canadian context

Canada enjoys relatively good health outcomes and ranks well in life-expectancy (approximately 82 years according to Statistics Canada). Opportunities for improvements in the Canadian healthcare system were recently identified, especially in equity and access.[8]

"Medically necessary" health care services for inpatients and outpatients are publicly funded and medicines are publicly funded for inpatients, while a patchwork of public and private insurance systems exist for outpatient medicines. While most healthcare services are administered by provincial and territorial governments, the federal government provides conditional cash transfers to provincial and territorial governments called the Canada Health Transfer that are meant to support the principles of the *Canada Health Act*: universality, comprehensiveness, portability, accessibility and public administration. Healthcare delivery including clinical care and medicine dispensing is generally private.[9] Canada is a high-income country (GDP USD$45k per capita) with per capita pharmaceutical expenditures that are relatively high even among other high-income countries (USD$832 per year per capita).[10]

Decisions about medicines in Canada are made by various bodies including the federal government, provincial and territorial governments and authorities, clinicians and patients. Most healthcare is administered at the provincial and territorial government, while the federal government plays important regulatory roles and has *de facto* influence over some aspects of healthcare delivery through federal health transfers to provinces and territories.

Health Canada reviews new drug submissions to determine which medicines can be legally sold in Canada. Health Canada may also withdraw approval of medicines.

The Patented Medicine Prices Review Board sets "price ceilings" or maximum average potential prices for patented medicines and can order price lowering and penalize companies if pricing is deemed excessive. The Competition Bureau can investigate pricing irregularities and issued reports in 2007 and 2008 about the prices of generic medicines. The pan-Canadian Pharmaceutical Alliance negotiates prices on patented, generic, and biosimilar products on behalf of the federal, provincial and territorial governments. Drug shortages are reported publicly on drugshortages.ca. Several generic and brand pharmaceutical companies have facilities in Canada; these companies can import and produce medicines for sale in Canada and abroad.

Medicines can be paid for out-of-pocket, can be covered fully or partially by private insurance plans that enroll more than half of Canadians, and can be covered fully or partially by public insurance plans for certain populations such as social assistance recipients (including welfare and disability support recipients) and older adults (e.g. those 65 years or older).[9]

The Canadian Agency for Drugs and Technologies in Health (CADTH), an organization supported by federal, provincial and territorial governments reviews medicines and provides recommendations that

decision makers at the federal, provincial and territorial level can review when deciding whether or not to publicly fund a medicine for those with public insurance. CADTH provides detailed information about its processes.[11] Briefly, when a new medicine is under consideration, CADTH synthesizes evidence and seeks input from stakeholders including patients. A committee comprised of clinicians, researchers, patients or members of the public and others reviews the assembled information and makes a recommendation about whether the medicine should be publicly funded and reasons for the decision are publicly posted.

Several lists of medicines publicly funded for specific populations exist in Canada. The Non-Insured Health Benefits drug benefit list includes medicines publicly funded for eligible First Nations and Inuit individuals. An advisory committee comprised of health care professionals makes recommendations to the Non-Insured Health Benefits program about which suggested medicines should be added. Provincial and territorial governments maintain lists of medicines that are publicly funded for social assistance recipients and for others (e.g. older adults). Similarities and differences between these lists were summarized in a report from the Patented Medicines Prices Bureau. Governments consider CADTH recommendations and may also conduct independent assessments when deciding which medicines to publicly fund. In Quebec, Institut national d'excellence en santé et en services sociaux (INESSS) assesses medicines being considered for public funding. Final decisions about public funding are generally made by public servants (e.g. Executive Officer of provincial drug plans) through a process that is insulated from political influence, sometimes by law.

There is no comprehensive set of clinical practice guidelines or "standard treatment guidelines". The Public Health Agency of Canada creates guidelines for sexually transmitted diseases and some disease-specific organizations sponsor guidelines on specific diseases. Some provincial guidelines are also created (e.g. Toward Optimized Practice in Alberta).

Regional, local or municipal public health units can also play important roles in specific issues related to medicines such as opioid overdose prevention.

Ultimately, clinicians and patients decide which medicines are taken. In general, clinicians are regulated by provincial and territorial authorities which sometimes set and enforce standards related to prescribing practices.

Criteria and information to guide medicine selection and removal

1.1 Listing decisions should be based primarily on effectiveness as only effective medicines are needed. In most circumstances, it is clear that only medicines that have proven effectiveness and safety should be included in a Canadian essential medicines list. The selection process for a Canadian essential medicines list could contain a criterion about whether or not a new prospective medicine is needed, i.e., whether it would serve a unique purpose when considering the medicines that are already listed.

1.2 The list should include only a small number of medicines in the same therapeutic area or class. Important decisions need to be made about whether to include similar medicines in an essential medicines list for Canada. A Canadian essential medicines list could either include only one or a few similar medicines, or it could contain multiple similar medicines. The exact number in each class or category could be achieved by balancing the benefits of listing fewer or more medicines. Potential benefits of shorter lists (containing one or a few similar medicines in each category) include associations with more appropriate use, potential for cost containment by increasing purchasing volumes and reducing distribution and stocking costs. Potential benefits of listing more similar medicines include the ability to shift use in case of a shortage and greater clinician and patient acceptability. Alternatively, some have argued that a short essential medicines list can help avoid shortages by facilitating measures to avoid shortages for the relatively small number of listed medicines and experiences in India and China provide some support on this notion.[12] Similar medicines can be in the same pharmacological or therapeutic class (e.g. ACE inhibitor medicines) or medicines that have similar uses or clinical effects although they may be pharmacologically distinct (e.g. diabetes treatments). National essential medicines lists generally include a small number of medicines from each class (e.g. Sweden's list contains 2 ACE inhibitors) although there are exceptions, while lists of publicly funded lists of medicines in Canada typically contain many similar medicines (e.g. Ontario's list of publicly funded medicines contains 9 ACE inhibitors). The Swedish Wise List contains 6 diabetes treatments (collapsing all forms of insulin into one medicine) while the Ontario list contains 11 (again, collapsing all forms of insulin into one medicine) including glyburide that is identified as a potentially inappropriate medicine choice when compared with alternatives such as gliclazide. Although imperfect, the Anatomical Therapeutic Chemical (ATC) Classification System can be used to classify medicines and generally no more than 3 medicines in the same chemical subgroup should be included. The World Health Organization's model essential medicines list indicates classes with therapeutic equivalence and national essential medicines lists tend to include 3 or fewer medicines from each class.

1.3 An essential medicines list for Canada should include a subset of medicines included in longer lists of medicines that are publicly funded for specific populations in different jurisdictions such as provinces. While these longer lists will contain medicines that the essential medicines list does not, the opposite should rarely happen. That is, a medicine should rarely be on the essential medicines list but not on longer lists of medicines publicly funded for some individuals. Given that provinces and territories of different sizes already have lists of publicly funded medicines, and that a national essential medicines list must be acceptable across the country, medicines that most jurisdictions do not or would not publicly fund could be left off of a national essential medicines list. Jurisdictions could decide whether or not to publicly fund such medicines through their existing programs for a subset of the population, and

these decisions could be based on condition prevalence, the presence of specialist treatment centres, jurisdictional priorities or other jurisdictional considerations. Examples of medicines that might be handled in this way include so-called “specialty” medicines such as treatments for certain forms of multiple sclerosis.

1.4 Clinical effects, and not cost or cost-effectiveness, should be the basis for most listing decisions. When medicines with similar clinical features (uses, benefits, risks, contraindications) but different costs are available, cost or cost-effectiveness could be considered. Note importantly that cost-effectiveness is only considered in special circumstances and not in many common scenarios such as decisions between members of the same class (e.g. ACE inhibitors where the known clinical effects of different members are the similar or identical and prices are similar). Cost-effectiveness is also not relevant for pharmacologically different medicines with similar uses (e.g. anticoagulants, diabetes treatments, treatments for rheumatoid arthritis) where the clinical effects (benefits and risks) are importantly different. Need, and not cost-effectiveness, should be considered when there are important differences in clinical effects. Thus, contingent recommendations to list a medicine (that is, recommendations that are contingent on the price) are generally unnecessary. Instead, decisions to list should be based on the need and then, after a decision to list is made, prices can be negotiated. The current prices paid for medicines is sometimes covered by non-disclosure agreements between payors and suppliers and it may be difficult to estimate the price after listing, and the lack of this information represents an additional barrier to considering cost or cost-effectiveness in the selection process even when there may be a reason to do so. Cost-effectiveness analyses that are a common element in assessments of medicines and other health technologies should generally not be included in the assessments of medicines under consideration for an essential medicines list for Canada. Including cost-effectiveness analyses when they are not required could be misleading (as many cost-effectiveness analyses favor the use of more expensive treatments) and could distract from the more important considerations such as the clinical effects of the medicine.

1.5 An active process for removing medicines is important. Lists of medicines tend to grow over time. Discoveries of new medicines should lead to a growth in the length of an essential medicines list for Canada. Likewise, new information about medicines should lead to some medicines being removed from the list either because new data may lead to new conclusions about their benefits or because they are superseded by superior treatments that are added to the list. Additions to lists are suggested by clinicians, patients or manufacturers who may be keen to have a particular medicine added to the list but there is often less incentive to remove medicines from lists. In practice, suggestions to remove medicines are rare. Thus, there should be active surveillance for medicines that should be considered for removal from the list. The list could be reviewed, for example, every two years to identify medicines that have been supplanted by others or medicines that should be re-evaluated in light of new data or clinical practice guideline recommendations. Each addition to the list should prompt a review of medicines listed for the same indication or condition to determine if any are no longer needed.

Medicine selection process

2.1 An interdisciplinary committee should be formed to review evidence and make recommendations about which medicines should be listed. Essential medicines lists are created for the benefit of patients and, in practice, must be acceptable to clinicians and patients. The committee that will make recommendations about whether specific medicines to add should thus be comprised of individuals who are both competent to provide this advice and who are respected by clinicians. These will include clinicians and other experts from different disciplines with knowledge of different clinical or therapeutic areas and relevant methodologies. An essential medicines list for Canada should be supported by a committee with representation from across Canada. In some countries (e.g. South Africa), sub-national governments may recommend individuals for membership in a national committee. Since it may be challenging to ensure representation of both all relevant disciplines and all jurisdictions while keeping the size of the committee workable, a process where jurisdictions within Canada recommend potential members to a national process may be practicable. Today, not all jurisdictions within Canada are represented in the Canadian Drug Expert Committee of CADTH, and this committee makes recommendations that are considered across Canada. Some selection processes both internationally and in Canada involve patients and or members of the public. It seems appropriate to include members of the public in the selection committee. As with any body that makes important decisions, membership should reflect the diversity of Canada with respect to characteristics such as gender and ethnicity.

2.2 Advisory committees and individual experts should be consulted on an ad hoc basis. Because it may not be possible to strike a committee with relevant expertise in all relevant areas, the services of individual expert advisors or advisory committees could also be established. These external advisors could study a specific issue (e.g. the feasibility of prescribing a prospective new medicine) and provide the main committee with answers to specific questions. The main committee would still be charged with making the recommendation about whether the medicine is added to the national essential medicines list.

2.3 A conflict of interest policy for committee members based on international guidance and Canadian practice should be implemented. Multiple guidance documents on managing conflicts of interest are available and the Canadian Medical Association Journal and the Canadian Task Force on Preventative Health Care both recently adopted the principles of the Guidelines International Network.[13, 14] While the guidance is intended for clinical practice guidelines, the principles are applicable to other similar processes. Individuals with substantial conflicts generally do not participate in assessments and minor conflicts are publicly declared.

2.4 An open process for suggesting medicines to be added or removed from the list should be developed. Members of the public, patients, clinicians, subnational governments, and pharmaceutical companies should all be allowed to suggest changes to the list such as adding a specific medicine. A triage process could combine suggestions and address suggestions that have already been handled recently. Regardless of the source and content of the suggestion, all of the relevant data should be synthesized for review by the committee. Pharmaceutical companies have an important role to play in providing information for review by the committee.

2.5 A public servant should be appointed to review committee recommendations and make final decisions about listing on behalf of government without involvement of elected officials. International guidance and experiences as well as the typical approach in Canada all indicate that the final decision about selecting (or deselecting) a medicine for inclusion in the essential medicines list should likely reside in a public servant (e.g. equivalent of an Executive Officer) and these decisions should be insulated from political influence. That is, elected officials should not be involved in deciding which medicines are included in a national essential medicines list. Such insulation ensures that suggested changes and decisions are made through the established process and not through appealing to an elected official. Ultimate responsibility for the list processes could reside with the federal government that would have the power to change regulations that govern the list processes. There could also be a governance structure that involves representation of provincial and territorial governments similar to CADTH. The Executive Officer and her staff will play an important role in selecting members for the Committee, appointing the Committee chair, managing conflicts of interest, prioritizing agenda items for Committee meetings in coordination with the Chair, and communicating both Committee recommendations and final decisions to others including to those involved with procurement and price negotiations.

Implementing an essential medicines list for Canada

3.1 The purpose of the essential medicines list, its processes and the current medicines should be easily available to members of the public and to clinicians. Misunderstandings about the list can be avoided by providing clear information. The difference between a medicine being included in the list and a health product being approved for sale by Health Canada, a medicine being included in a provincial formulary, and a medicine being covered by private insurers should be clear to the public and to clinicians. Lessons can be learned from the implementation of the Wise List as part of a public awareness in Sweden that included ads on buses. In addition to communicating the purpose of the list and being transparent about processes, branding the list with a name or logo may help. Experiences with the Wise list in Sweden indicate that public awareness campaigns can help to promote acceptability by both patients and clinicians. Patient organizations and allied groups should be engaged in disseminating the list.

3.2 Important information about medicines included on the list should be easily available to both patients and clinicians. This information should include uses, expected benefits, contraindications, risks, dosing, monitoring and other information. Information should also be available based on the condition or use and, where appropriate, medicines can be classified as first line or second line treatments. Information should be available both electronically and in print. Ideally, this information will be integrated in electronic health records used at the point of care and electronic tools used to communicate prescriptions between prescribers and dispensing pharmacists. When the essential medicines list is first used, there may be a large number of medicine switches within a pharmacological class (e.g. from ACE inhibitors not on the list to ones on the list) and these could be supported by software that would suggest a dose conversion.

3.3 Professional organizations, provincial governments and trusted clinician champions should be engaged in dissemination. The Canadian Medical Association, the College of Family Physicians of Canada, the Canadian Pharmacists Association, and the Canadian Federation of Nurses Union can help disseminate the list to members. Provincial and territorial governments can help disseminate the list, in part, by integrating the national list in materials that describe provincial and territorial lists of publicly funded medicines. Provincial and territorial governments can also support clinician and patient organizations in disseminating this list and other resources to promote appropriate medicine use. Since prescribers can be influenced by their peers, trusted clinical champions should be engaged to help disseminate the list and its processes. Patient champions could similarly help to

disseminate the list.

3.4 The essential medicines list should generally be in alignment with clinical practice guidelines. Clinical practice guidelines provide recommendations to clinicians including guidance about which medicines to use in particular clinical scenarios. Conflicts between guidelines and the essential medicines can arise when medicines recommended by guidelines are not listed or when listed medicines are not recommended. Unexplained conflicts may lead to confusion and decrease the credibility of both the list and the guidelines. A number of independent organizations produce guidelines that do not always align with government decisions about which medicines are publicly funded (or with other

guidelines). Apparent discrepancies between the essential medicines list and clinical practice guidelines are an opportunity to consider changes to the list. In the future, provincial and territorial governments and clinician organizations could play a larger role in creating clinical practice guidelines that complement the essential medicines list by providing advice about when and how to use medicines and, importantly, when non-pharmaceutical interventions are preferred. This already happens to some extent and examples include Toward Optimized Practice guidelines from the Alberta Medical Association and Quality Standards from Health Quality Ontario. There are benefits to keeping clinical practice guidelines independent of the essential medicines list, and provincial and territorial governments and clinician organizations may be better positioned than the federal government to provide detailed guidance to clinicians.

3.5 The list should be integrated with ongoing initiatives such as those to procure medicines in order to realize the benefits of an essential medicines list. The list of essential medicines will have to be evolved into a list of products that specify the strengths and formulations of each medicine. Provinces could work together through the pan-Canadian Pharmaceutical Alliance to determine appropriate reimbursement rates for each medicine based on negotiations and prices in comparable countries. In the future, tendering could be done at the national level. Existing regulations and processes intended to ensure medicines are priced appropriately should be applied by the Competition Bureau and the Patented Medicines Prices Review Board.

3.6 The effects of the essential medicines list should be carefully tracked. Medicines are ultimately supposed to promote health, and an implemented essential medicines list should ultimately lead to better health outcomes. Measuring health outcomes at the level of the population will help to determine whether the essential medicines list and associated policies and procedures are having their desired effects. Relevant health outcomes could be measured in specific populations before and after a medicine is added to the list. Medicine access, utilization and prices should also be tracked in order to help guide process improvements and to inform policies in other countries.

Practical considerations

Once a decision is made to create an essential medicines list for Canada, it could take approximately 3 to 12 months to have a list that can be used. A list can be developed quickly by basing it on existing lists and by expediting the process for providing input before implementation.

The first steps could include appointing an Executive Director and assembling a team to support the selection committee. The team should include individuals with experience evaluating medicines including those with experience in existing institutions that evaluate medicines and other health technologies.

Next the selection committee should be formed. The processes for the national essential medicines list should be led by the Executive Director and the support staff with input from the selection committee.

Then partnerships should be established with institutions that will be relied on including those that synthesize information about medicines and clinical associations that will provide input and assist with dissemination.

A draft essential medicines list can be created by the Executive Director and the support based on existing lists such as those used by provinces and national essential medicines of other countries. The selection committee should then review and revise the list as needed. The list could be shared with the provinces and territories. After this a draft version of the list could be publicly shared and suggestions for additions or removals could be submitted. The suggestions could be reviewed by the selection committee once the necessary information about medicines is assembled.

The resulting list could then be publicly announced together with the revision process. Efforts to disseminate the list could then ramp up.

Suggested further reading

Selection of essential medicines at country level: using the WHO Model List of Essential Medicines to update a national essential medicines list. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

https://www.who.int/publications-detail/selection-of-essential-medicines-at-country-level

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https://www.cmaj.ca/content/191/40/E1093

Stakeholders consulted

The views expressed are those of the author and not necessarily the participants or their institutions. Stakeholders were provided with a discussion paper and invited to participate in interviews and provide written feedback. Input from stakeholders helped to inform this report and the content of the report is the responsibility of the author. The stakeholders kindly agreed to provide input despite disruptions related to the COVID-19 pandemic. Stakeholders are listed alphabetically. Some stakeholders preferred not to be named.

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