# Developing recommendations for the reimbursement of expanded professional pharmacist's services in Ontario

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The Ontario government has initiated a number of changes to the prescription drug system over the past 5 years. Many of the changes are intended to reduce the money paid by the Ontario Ministry of Health and Long-Term Care (MOHLTC) for medications, through reductions in the reimbursed cost of generic medications and indirectly through banning professional allowances paid to pharmacists by generic manufacturers.[1] These changes generated controversy and were played out in the public arena.[2-6] At the same time as the funding reductions were announced, the Ontario MOHLTC also made a commitment to increase the funding available for professional services to patients provided by pharmacists, although the specifics of the funding were not described at the time of the announcement.[7]

The Expanding Professional Pharmacy Services Working Group (EPPS WG) was established in August 2010 to provide advice to the Minister of Health and Long-Term Care and the Executive Officer of Ontario Public Drug Programs, on pharmacist's professional services that could offer value to Ontarians and were deemed ready for immediate implementation by community pharmacists. The work of the EPPS WG was intended to provide expert advice on the specifics of the commitment made by the MOHLTC to increase funding for professional pharmacist's services. The services under review were patient-focused clinical services that occur immediately before, during or shortly after dispensing a medication or may be patient-focused nondispensing professional clinical services that are appointment-based or offered outside of the dispensing process.

Policy-makers often rely on expert committees to generate recommendations that can help inform health policy decisions. Structured expert committee discussion of a topic, including a consideration of literature evidence, is one method to improve evidence-based decision-making by policy-makers.[8,9] The ideal characteristics of respectable work produced by expert committees are that the work is transparent, evidence-based, systematic and takes into account the needs, constraints, values and preferences pertinent to the organizations, people and setting affected by the recommendations.[9,10]

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) is an increasingly accepted approach to grading quality of evidence and strength of recommendations. GRADE has been used worldwide to help develop recommendations about drugs, technologies, prevention screening and other health services.[11] It incorporates processes that facilitate high-quality work by expert committees.[12] It provides a structured approach that allows expert committees to address the ideal characteristics. The GRADE process separates judgments made about the quality of the literature evidence on the effectiveness, safety and other considerations from judgments made on the strength of the recommendations for the topic under review.[10,13] GRADE itself was created based on the findings from an overview of the literature that examined the essential components of a system to grade evidence.[14] The GRADE approach has been used by organizations worldwide, including the World Health Organization, the American College of Chest Physicians, the National Institute for Health and Clinical Excellence in the United Kingdom and the Canadian Agency for Drugs and

## Key points

- A special working group of pharmacists was convened by the Ontario Ministry of Health and Long-Term Care to provide recommendations on the types of professional pharmacist's services for reimbursement consideration by the Ministry.
- The working group used a process adapted from the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to foster transparency, be informed by evidence and to take pertinent needs, constraints, values and preferences into account.
- This approach was well suited to the group's task of making recommendations about a set of health professional services.
- The final recommendations, including a list of 28 ranked services, were made after approximately 9 weeks of work.

Technologies in Health.[11]

Policy-makers often require the results from evidence reviews or expert committee deliberations quickly. The EPPS WG was constituted and asked to carry out the work over a 2-month time period. Given the large scope and short time frame for the EPPS WG to complete the work, it was felt that components of GRADE could be useful in providing a structure to guide the EPPS WG deliberations. This article describes the adapted GRADE process used and the resultant recommendations made by the EPPS WG.

## The EPPS Working Group

The EPPS WG was made up of practising community pharmacists, representatives from the Ontario Pharmacists' Association and a Chair who has experience in pharmacy and the development of recommendations for the purpose of health care and health policy. MOHLTC staff observed most of the deliberations, although some private in camera sessions took place at each EPPS WG meeting to ensure that WG members had an opportunity to speak among themselves on some matters. The EPPS WG was administratively supported by the Ontario Public Drug Programs Branch of the MOHLTC. The EPPS WG met 5 times in 2010 during 4 teleconferences and 1 face-to-face meeting to generate recommendations and advice.

## Adapted GRADE approach used to develop recommendations for professional pharmacist's services

An overview of the GRADE approach and how the EPPS WG used components of the approach is depicted in Table 1. The process used by the EPPS WG is outlined in Appendix 1. First, the EPPS WG explicitly identified the main principles considered important for recommending a service from a population health view. The population health perspective meant that the EPPS WG was asked to consider the benefits and downsides of a pharmacist service as it could affect the health outcomes of a group of individuals (i.e., the population of Ontario), including the distribution of health outcomes within the group. The identification of principles helped the EPPS WG refine the health care question it was being asked to address by explicitly defining the population under consideration (Ontarians), intervention under consideration (professional pharmacist's services that could be implemented immediately) and the outcomes of interest (value-added to the patient and value-added to the health care system).

Second, the EPPS WG generated a list of, then rated and ranked, possible values and preferences that were felt to have the potential to influence individuals to recommend (or not recommend) a service to generate the most highly held values and preferences across the EPPS WG. This list of values and preferences helped individuals understand what was driving their individual and group recommendations.

Third, the EPPS WG identified the outcomes deemed critical or important for decision-making (i.e., that the service would be expected to have an impact; that it would be helpful to see evidence/data that show how the service affects it). Explicit identification of the outcomes allowed the EPPS WG to quickly sort out which professional pharmacist's services had literature evidence available that demonstrated benefit on outcomes the EPPS WG thought were important and which services did not have demonstrated benefit.

Fourth, an initial list of pharmacist's services for the EPPS WG to consider was compiled based on lists of services or initial literature review provided by the Ontario Pharmacists' Association, the Canadian Pharmacists Association, the Ontario Ministry of Health and Long-Term Care Health System Planning and Research Branch and relevant pharmacy practice literature gathered by the Chair of the EPPS WG. An initial screen excluded some pharmacist services, because they were services that required legislative or regulatory changes, required pharmacists to undergo additional training or for other reasons were felt to be outside the scope of the EPPS WG. The EPPS WG carried out a rating and ranking exercise to help determine which of the remaining services the group felt were of higher versus lower priority prior to a full group discussion. The information gathered was used as one of the inputs to determine whether a service would continue to be considered by the EPPS and if so what the discussion order would be when the EPPS WG began their detailed discussion of each service.

Fifth, information about services under consideration, including literature on the effectiveness of a service, costs and cost-effectiveness of a service, implementation considerations (time required to

deliver the service, additional education or training required/recommended to deliver the service, whether other health care providers could provide better treatment for patients, ease of implementation), patient perspective about the service and budget impact, and other types of data were summarized from reports submitted based on responses to a specific detailed request from the EPPS WG to the Ontario MOHLTC Health System Planning & Research Branch, the Ontario Pharmacists' Association and the Canadian Pharmacists Association. Effectiveness of the service on health-related quality of life, surrogate health outcomes, adverse events, patient symptoms, mortality, clinical outcomes, medication appropriateness and medication adherence was requested.

Sixth, the EPPS WG had a structured detailed discussion about each service that remained on the list. The WG reviewed a description of the service, discussed considerations regarding the service brought up by any WG member and then reviewed the evidence (benefits and harms to patient health, effectiveness on patient drug therapy, costs, cost-effectiveness, ease of implementation, effect on other health care providers, patient perspective) available to the WG. The WG members then scored each service from a score of 2 (definitely do it) to –2 (definitely don't do it) using the adapted GRADE grid (Table 2)[15] and provided the key primary and secondary values and preferences that guided their rating on whether or not to recommend a service. The description of each service was intended to provide a general sense of the service. It was not intended to be a final definition of the service as it would be implemented in Ontario. Some definitions were altered based on discussion points raised by the members of the WG. At times, the Chair provided extra information on the research evidence for some services if that evidence was not included in the summary reports provided by the

**TABLE 1 GRADE approach and adaptations made by the Expanding Professional Pharmacy Services Working Group[13]**

| Adaptation of GRADE made by the EPPS | GRADE approach |
|---|---|
| The main principles to guide the reasoning for recommending a service for reimbursement were identified to assist with defining the health care question. | Not applicable at this stage.* |
| The health care question was defined in terms of the population (Ontarians), alternative management strategies (pharmacist service compared to standard care/no service) and outcomes (value-added to patients, value-added to the health care system). | Health care question is defined in terms of the populations, alternative management strategies (an intervention, sometimes experimental and a comparator, sometimes standard care) and all patient-important outcomes. |
| The main values and preferences influencing individuals to recommend (or not recommend) a service were delineated. | Not applicable at this stage.* |
| Outcomes deemed critical, important and not important for decision-making were identified and classified. | Outcomes are classified according to how important they are to a decision (critical, important but not critical, not important) |
| An expedited narrative literature review was conducted by asking 3 organizations to provide literature evidence of effectiveness of all services as well as cost data and implementation data. A best combined numerical estimate and an index of uncertainty for results across studies were not determined. | A systematic overview is done to synthesize relevant literature evidence. A best combined numerical estimate (i.e., meta-analysis) of the effect on each patient-important outcome and an index (typically a confidence interval [CI]) of the uncertainty associated with that estimate is calculated. |
| The quality of the evidence was raised and generally discussed when discussing each service. A formal rating of quality was not determined. | A rating of the quality of evidence is done for each outcome, across studies. Randomized controlled studies start with a high rating and observational studies with a low rating. A final rating of quality for each outcome is generated (high, moderate, low or very low). Then a final decision regarding the rating of overall quality of evidence is made. |
| The working group members discussed the effectiveness, cost-effectiveness, and implementation evidence, quality of the evidence, balance of desirable/undesirable outcomes and values and preferences considered. They then decided on the direction (for/against) by scoring each service from a score of 2 (definitely do it) to –2 (definitely don't do it), using an adapted GRADE grid. The ratings of the members were averaged, producing a ranking of services that provided a basis for determining whether to recommend a service or not. Strength of the recommendation was indirectly conveyed by the average of GRADE grid scores across WG members. | Decide on the direction (for/against) and grade strength (strong/weak) of the recommendation considering quality of the evidence, balance of desirable/undesirable outcomes, values and preferences. Decide if any revision of direction or strength is necessary, considering resource use. |

* Would be discussed during the final step of the GRADE process when deciding on the direction and strength of a recommendation.

organizations previously mentioned. Some services were combined with others or removed from further consideration based on the discussion of the group. The timing of the work carried out by the EPPS WG is depicted in Appendix 1.

## Results of EPPS WG deliberations

*Principles, values and preferences, and outcomes*

The **main principles** that guided the EPPS WG reasoning for recommending a service for reimbursement as determined by a ratings exercise undertaken by the EPPS WG were:

- Demonstrated value-added to the patient (a group of patients)
- Makes funding for pharmacists available more easily and quickly so that pharmacists can continue providing key patient-focused services
- Demonstrated value-added to the health care system
- Evidence available that demonstrates beneficial impact on patient health or resource utilization
- Meets a key Ontario Ministry of Health priority for the needs of Ontarians (e.g., diabetes, smoking cessation)

**Values and preferences** that were rated the highest and therefore would be expected to have had the most influence on EPPS WG decision-making were the following:

- If a service was taken away it would negatively affect the patient
- Maximizes pharmacist role
- Already being delivered in pharmacies but not reimbursed
- Maximizes funding for pharmacists
- Better quality (including improved safety) of medication prescribing
- Ease of implementation by pharmacists

**Outcomes** that the EPPS WG deemed critical or important for making a decision to recommend (or not) a pharmacist service were:

- (Optimal) health care resource utilization (hospitalizations, ER visits, drug uses)
- Patient symptom improvements
- Medication adherence (improvements)
- Adverse events (reductions)
- Health-related quality of life (improvements)
- (Improved) medication appropriateness for patients

*Recommended pharmacist's professional services*

An initial list of 60 pharmacist's professional services was considered. After initial screening, 42 services remained to undergo full review and consideration by the EPPS WG. Some pharmacist's services were excluded at this stage because they were services that required legislative or regulatory changes, required pharmacists to undergo additional training or for other reasons were felt to be outside the scope of the EPPS WG. Based on group discussion of each service, some services were combined with others or deleted from further consideration. A final list of services was more fully discussed and rated during a full day face-to-face meeting of the EPPS WG. Some new services were identified during the discussion, however, these were not put forward to the EPPS WG for formal rating, because it was felt that none of these services would replace others that would be recommended in the Top 10.

The EPPS WG also considered some topics arising from WG discussion that were felt to impact the list of recommended pharmacist's professional services. On the topic of recommending either a general comprehensive medication assessment service, a general chronic disease management service or individual services for specific chronic diseases, the EPPS WG decided that condition-specific chronic diseases should be combined into one chronic dis-

**TABLE 2 GRADE grid for recording committee members' recommendations in development of pharmacist's services[15]**

| | GRADE score* | | | | |
|---|---|---|---|---|---|
| | 2 | 1 | 0 | −1 | −2 |
| Balance between desirable and undesirable consequences of intervention | Desirable clearly outweigh undesirable | Desirable probably outweigh undesirable | Trade-offs equally balanced or uncertain | Undesirable probably outweigh desirable | Undesirable clearly outweigh desirable |
| | Strong: "Definitely do it" | Weak: "Probably do it" | No specific recommendation | Weak: "Probably don't do it" | Strong: "Definitely don't do it" |
| Recommendation | | | | | |

*For each proposed service, please mark with an "X" the cell that best corresponds to your assessment of the available evidence, in terms of benefits versus disadvantages

ease management service that was initially limited to the chronic diseases rated most highly by the EPPS. The EPPS WG felt that this approach would be feasible for immediate implementation, since the top-rated conditions had established guidelines that most pharmacists were well versed in and it also allowed for easier expansion to other chronic diseases, as new priorities in health care delivery emerged over time. The EPPS WG advised that if a chronic disease management service were implemented, then the service should be reviewed regularly by the Pharmacy Council, the Ministry or other relevant groups to determine if the service should add or change the focus of chronic medical conditions addressed by the service.

A final list of 28 ranked services was generated. The Top 10 pharmacist's professional services that the EPPS WG felt could offer value to Ontarians and which were deemed ready for immediate implementation by community pharmacists are provided in Table 3.

Advice and additional general guidance statements on issues related to implementation of new pharmacist's services was also provided to the MOHLTC, including the issues of payment approaches (e.g., fee structure, payment to pharmacies versus pharmacists), perceived barriers to successful program implementation, documentation requirements, including the use of standardized forms, communication of the new programs to stakeholder groups, methods to track the impact of these services based on the outcomes, timing, coverage (recipients of the services) and issues related to the general and specific planning, implementation or evaluation of professional services delivered by pharmacists. The themes generated from the discussion were synthesized by the chair, based on discussions about individual services, as well as general discussions on the topic, and the main points raised during these discussions formed part of the EPPS WG report.

## Usefulness of GRADE

The GRADE approach was well suited to formulating EPPS WG recommendations, given the time frame available, the scope and amount of material for the EPPS WG to review and the potential diversity of opinion of EPPS WG members. It took approximately 9 weeks to complete the work. Most components of GRADE were used, but reordered and adapted to meet the needs of the EPPS WG and the time and resources available. Many EPPS WG members had not had any prior expert committee experience. The structure allowed each working group member to quickly understand what their specific task was for each stage of the process and to make a personal contribution to the discussion.

The explicit discussions of core principles and values and preferences allowed the members of the EPPS WG to have a clear understanding of what was important to individual members and also how that combined to form the collective viewpoint across the group. Discussing general principles and values and preferences before talking about the literature evidence (opposite to the GRADE approach) allowed for a very useful discussion of

**TABLE 3 Top 10 professional pharmacist's services recommended for implementation by the EPPS WG**

| Rank | Service |
|---|---|
| 1 | Pharmaceutical opinion for medication interventions (also including clinical issues related to resolution of prescription processing and formulary assessment of prescription therapy) |
| 2 | Refusal to fill/dispense |
| 3 | Chronic disease medication assessment and management service for hypertension, asthma, diabetes and hypercholesterolemia |
| 4 | Continuity of care service post-hospital discharge (exemplified by medication reconciliation and resolving drug-related problems like adherence, errors, interactions, outdated records and adverse events post discharge from hospital) |
| 5 | Smoking cessation service |
| 6 | Comprehensive medication assessment service. (This is a complete assessment of all of a patient's medication therapies, with the goal of optimizing medication effectiveness, improving patient adherence, preventing or resolving adverse events and reducing waste.) |
| 7 | Prescription follow-up consultation to ensure that a patient is obtaining expected effects (benefits without harms) |
| 8 | Medication adherence follow-up (including pharmacist review of repeat prescriptions) |
| 9 | Home diagnostic device training |
| 10 | Over-the-counter (OTC) consultation |

EPPS WG: Expanding Professional Pharmacy Services Working Group.

## Points clés

*• Le ministère de la Santé et des Soins de longue durée de l'Ontario a demandé à groupe de travail spécial, formé de pharmaciens, de formuler des recommandations quant au type de services pharmaceutiques professionnels devant être remboursés par le ministère.*
*• Le groupe de travail a utilisé un processus basé sur l'approche GRADE (Grading of Recommendations Assessment, Development and Evaluation) afin de favoriser la transparence, de s'appuyer sur des preuves et de tenir compte des besoins, des contraintes, des valeurs et des préférences appropriés.*
*• Cette approche était adaptée à la tâche du groupe, à savoir formuler des recommandations sur un ensemble de services de santé professionnels.*
*• Les recommandations finales, qui comprennent une liste de 28 services classés par ordre d'importance, a été publiée après neuf semaines de travail.*

what was generally important to the working group members and an explicit recognition that the most important principle for the working group was that service be value-added (including improved health outcomes) for patients. Respectful disagreement among working group members occurred and was noted so that the group and the policy-makers were able to understand where consensus and disagreement arose. For example, while all EPPS WG members rated the implementation of pharmaceutical opinions for medical interventions highly, some felt the most important influencer of why it should be implemented was because it maximized the pharmacist role, whereas others felt the program improved the quality (including improved safety) of medication prescribing.

An explicit discussion of critical and important outcomes that the service would be expected to impact identified that the outcomes of interest for the EPPS WG were those that were both value-added for the patient, and value-added for the health care system versus only value-added for the patient, as conventionally defined by GRADE.

All steps used by the EPPS WG in the process to generate recommendations were explicitly described to promote transparency, so that policy-makers were able to understand the context of the committee. Transparency was further supported by having MOHLTC policy-makers observe most of the EPPS WG deliberations.

There were some limitations to the process used by the EPPS WG. A complete systematic review of the literature was not conducted. Therefore, it is possible that some literature evidence was not considered by the working group and that the working group did not have the benefit of a best combined numerical estimate and an index of uncertainty for results across a set of similar studies (i.e., from studies that evaluated the same service). However, 3 organizations were asked to provide evidence for all services considered to reduce the likelihood of missing important information, and it was clear that most of the services under consideration have not been studied in a rigorous manner to determine their effectiveness on important patient or health system outcomes. Another limitation to be recognized was that the time frame for the WG to do their work was quite short and this may have made it difficult for some group members to digest the volume of material, while keeping up their extremely busy regular professional commitments.

## Conclusions

The adapted GRADE approach proved to be well suited as a process for the EPPS WG to formulate recommendations given the very short time frame available, the scope and amount of material to review and the potential diversity of opinion of working group members. This example generated by the EPPS WG can be added to the growing literature on the use of GRADE by expert committees in Canada and around the world. The approach allowed the EPPS to generate recommendations that were well understood by policy-makers and to contribute to the uptake of the recommendations to form new policy that will reimburse pharmacists in Ontario for new professional services. ■

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