# **Patient contracts for chronic** medical conditions

# Scoping review

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#### **Abstract**

**Objective** To describe how and why patient contracts are used for the management of chronic medical conditions.

**Data sources** A scoping review was conducted in the following databases: MEDLINE, Embase, AMED, PsycInfo, Cochrane Library, CINAHL, and Nursing & Allied Health. Literature from 1997 to 2017 was included.

**Study selection** Articles were included if they were written in English and described the implementation of a patient contract by a health care provider for the management of a chronic condition. Articles had to present an outcome as a result of using the contract or an intervention that included the contract.

**Synthesis** Of the 7528 articles found in the original search, 76 met the inclusion criteria for the final review. Multiple study types were included. Extensive variety in contract elements, target populations, clinical settings, and cointerventions was found. Purposes for initiating contracts included behaviour change and skill development, including goal development and problem solving; altering beliefs and knowledge, including motivation and perceived self-efficacy; improving interpersonal relationships and role clarification; improving quality and process of chronic care; and altering objective and subjective health indices. How contracts were developed, implemented, and assessed was inconsistently described.

**Conclusion** More research is required to determine whether the use of contracts is accomplishing their intended purposes. Questions remain regarding their rationale, development, and implementation.

#### **Editor's key points**

- Extensive variety exists in terms of why and how patient contracts are used for managing chronic medical conditions.
- ▶ Patient contracts tend to be used in North America despite limited evidence, are used to target vulnerable populations, and are used in outpatient and community settings.
- Gaps in the literature include limited descriptions of contract rationale, development, implementation, and evaluation processes. More comprehensive reporting and research are required to determine whether contracts are being used successfully to accomplish their intended purposes.

#### Points de repère du rédacteur

- Il existe une variété considérable de raisons et de modalités entourant l'utilisation de contrats avec les patients pour la prise en charge de problèmes de santé chroniques.
- ▶ Les contrats avec les patients ont tendance à être utilisés en Amérique du Nord, malgré des données probantes limitées à cet égard; ils sont utilisés pour cibler des populations vulnérables, dans les milieux ambulatoires et communautaires.
- Au nombre des lacunes dans la littérature médicale figuraient les descriptions limitées des processus de justification, d'élaboration, de mise en œuvre et d'évaluation des contrats. Des rapports et des recherches plus approfondis sont nécessaires pour déterminer si les contrats peuvent atteindre les objectifs prévus.

# Des contrats avec les patients pour des problèmes de santé chroniques

# Revue exploratoire

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#### Résumé

**Objectif** Décrire comment et pourquoi les contrats avec les patients sont utilisés pour la gestion de problèmes de santé chroniques.

Sources d'information Une revue exploratoire a été effectuée dans les bases de données suivantes : MEDLINE, Embase, AMED, PsycInfo, Bibliothèque Cochrane, CINAHL et Nursing & Allied Health. Les articles parus de 1997 à 2017 ont été inclus.

Sélection des études Les articles ont été retenus s'ils étaient rédigés en anglais et s'ils décrivaient la mise en œuvre d'un contrat avec un patient par un professionnel de la santé pour la gestion d'un problème chronique. Les articles devaient présenter une issue comme étant le résultat de l'utilisation du contrat ou d'une intervention qui incluait le contrat.

**Synthèse** Des 7528 articles recensés dans la recherche initiale, 76 répondaient aux critères d'inclusion dans la revue finale. De multiples types d'études ont été inclus. Une diversité considérable dans les éléments de contrat, les populations visées, les milieux cliniques et les interventions conjointes a été observée. Les raisons de conclure un contrat incluaient des changements comportementaux et le perfectionnement des compétences, y compris l'établissement d'objectifs et la solution de problèmes; la modification des croyances et des connaissances, notamment la motivation et l'auto-efficacité perçue; l'amélioration des relations interpersonnelles et la clarification des rôles; l'amélioration de la qualité et des processus des soins chroniques; la modification des indicateurs objectifs et subjectifs de la santé. Les descriptions de l'élaboration, de la mise en œuvre et de l'évaluation des contrats manquaient de cohérence.

**Conclusion** Il faut plus de recherches pour déterminer si l'utilisation de contrats permet d'atteindre les objectifs prévus. Des questions demeurent sans réponses quant à leur justification, leur élaboration et leur mise en œuvre.

hronic disease management is a substantial part of the clinical workload in primary care. Many practitioners use a patient contract to manage these conditions,1 which is defined as "any type of agreement, verbal or written, by which one or both parties agree to a set of behaviours related to the care of a patient."1 Examples include no-smoking agreements, treatment plans, and medication agreements. Given the dominance of the chronic care model for disease with patient self-management and a collaborative approach to these activities, it is apparent why these are applied broadly in primary care.2

At the time of this study, there were only 2 reviews of patient contracts and their effectiveness. In 2007, the Cochrane Collaboration conducted a systematic review of randomized controlled trials (RCTs) to assess the effectiveness of contracts between patients and health care practitioners on patient adherence to treatment, prevention, and health promotion.1 They concluded that there was not enough reliable evidence to recommend the routine use of contracts.1 A review of opioid contracts in 2016 by the Centers for Disease Control and Prevention found limited evidence regarding benefits and harms of opioid contracts for preventing the abuse and selling of opioids.3 The Cochrane Collaboration article focused on RCTs that evaluated the effects of contracts on patient adherence to health care provider recommendations and limited the scope to interventions in high-income countries.1 Even within this subset of contracts, there was substantial complexity and heterogeneity in patient contracts, making it difficult to determine their overall effectiveness.1 The review noted that trials testing contracts that demonstrated positive effects, particularly in the realm of substance addiction, were small and their quality uncertain.1 Many studies failed to consider potential harms of contracts.1

Despite their lack of reliable evidence, practitioners continue to use patient contracts across a range of activities, adapting them to their settings, populations, and scopes of practice.1 The Cochrane review suggests there may be extensive heterogeneity in the way patient contracts are used, even within the limited populations and indications considered in the review.1 A broader understanding of patient contracts is required to understand the pervasiveness of their use, despite the lack of convincing evidence to support contracts. Second, capturing a comprehensive description of how contracts are rationalized, developed, implemented, and assessed will enable further research in determining their effectiveness.

We conducted a scoping review to increase breadth of knowledge around how and why patient contracts are used for the management of chronic medical conditions in health care settings. Specifically, we sought to understand the purpose, development, implementation, and composition of contracts.

### --- Methods ---

#### **Data sources**

We conducted a scoping review using the 5 steps outlined by Arksey and O'Malley. 4,5 The protocol is available from https://medm-backend.fammedmcmaster.ca/ wp-content/uploads/2018/05/Contracts-scopingreview-protocol-17-July-2019-EG.pdf. We searched the following databases: MEDLINE, Embase, AMED, PsycInfo, Cochrane Library, CINAHL, and Nursing & Allied Health. To balance feasibility with breadth and comprehensiveness, we included literature from 1997 to 2017. The final search was conducted on June 6, 2017.

#### Study selection

We originally selected articles using the search terms contract or contracts. As familiarity with the literature increased, exclusion terms were added through an iterative process to further refine the search results (Appendix A, available from CFPlus\*). Two university librarians were consulted in developing the search strategy. The research team was composed of physicians and public health professionals with expertise in the management of chronic conditions and experience with scoping review methodology. Inclusion criteria were the following: articles had to be written in English, they had to describe the implementation of a patient contract by a health care provider for the management of a chronic condition, and the contract had to specify at least 1 treatment, prevention, or health promotion activity to be observed. Articles were excluded if they only addressed a process of informed consent for a treatment, were not primary research articles (eg, review or commentary articles), or were inaccessible to the researchers. The first 35 articles from the Cochrane database were reviewed by 2 independent researchers for possible inclusion. Disagreements were discussed in detail until consensus was reached. A detailed article selection protocol was then developed and 3 researchers were recruited to participate in the remainder of the article selection process. A subset of 30 articles was initially reviewed by all 3 researchers to ensure consistency in the selection for inclusion, where there was unanimous agreement. The rest of the articles were divided among the 3 researchers, with uncertainty decided upon by consensus of all 3 researchers.

### Data collection and management

We extracted data onto a standardized form using a broad set of variables (Box 1). The research team, composed of physicians and public health professionals with expertise in the management of chronic disease and patient contracts, approved the variables used. Three screening researchers independently extracted these

<sup>\*</sup>Appendices A, B, and C are available from https://www.cfp.ca. Go to the full text of the article online and click on the CFPlus tab.

data for the first 10 articles and then met to check agreement. Each screening researcher then proceeded independently; any uncertainties were discussed with the other 2 screening researchers and final decisions were reached through consensus.

Consistent with scoping review methodology,4 the quality of the studies was not formally assessed, as the substance of all studies was considered important for understanding concepts to address the research question. While our interest was in primary care use, with the general move toward vertical integration of care, we decided to include descriptions of primary research in primary care, primary health care, and secondary and tertiary health care settings. Data were summarized quantitatively using simple frequency counts of general, development, and implementation variables for contracts. We used thematic (semantic) analysis to describe commonly occurring themes in terms of the purposes of contracts.6 Having multiple members of the research team with expertise in the use of contracts also contributed to rigour of this analysis. We applied PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) to ensure all essential items were reported for a scoping review (Appendix B, available from CFPlus\*).

# -Synthesis —

#### **General** information

In total, 76 articles met the inclusion criteria (Figure 1). Charting for each variable within each article can be found in Appendix C, available from CFPlus.\* There were 21 articles from 1997 to 2003, 29 articles from 2004 to 2010, and 26 articles from 2011 to 2017. Most studies were based in the United States (n=51, 67%). The remaining 33% were from the United Kingdom (n=4); Australia and the Netherlands (n=3 each); France, Canada, and Germany (n=2 each); and Malawi, Korea, Portugal, Cameroon, Sweden, Puerto Rico, Norway, Japan, and Thailand (n=1 each).

The most common study design was RCTs (n=42, 55%), followed by observational studies (n=23, 30%) and

#### Box 1. Data extraction variables

- · General study characteristics (title, author, year, country, health care setting)
- · Chronic condition and target population
- · Purpose of the contract and specific target or desired
- Contract development characteristics (underpinning behaviour theory, development process, and contract elements)
- Contract implementation characteristics and processes (training for use [how health care providers were trained to use the contracting details], cointerventions or incentives, and opportunity for patient input and goals)

non-randomized interventional studies (n=11, 15%). We found an extensive variety of chronic conditions commonly encountered in primary care (Table 1).7-82 While we found that contracts were interchangeably referred to using other terms in the studies, only 3 did not include the word contract in their names, instead referring to an agreement<sup>8,78</sup> or plan.<sup>38</sup> In general, the contract terminology identified the process of care or treatment, the purpose of the contract, and the parties in the contract.

We found that contracts were initiated across a broad spectrum of health care settings, including in the community, primary care clinics, and hospital outpatient clinics (Table 2). The interventions typically targeted adults (n=57, 75%), with some directed at adolescents and young adults (n=11, 14%), children (n=2, 3%), geriatric populations (n=5, 7%), or unknown populations (n=1, 1%). Most contracts were between the patients and their health care providers (n=51, 67%) (Table 3).

#### Contract purpose and development

We assessed contract purpose and found 5 common categories (**Table 4**).37,39,74,78,82 Only 11 articles (14%) described how the contracts had been developed, with 33 articles (43%) reporting using patient input in devising the contracts, although the range of initial input varied considerably. While many theories of behaviour were used to rationalize the use of a particular intervention, it was not always clear if the theory was specific to the use or development of the contract (**Box 2**). 12,17,31,36,48-50,53,55,58,71,73,79,81 Only 14 articles (20%) mentioned health behaviour theories specific to their respective contracts (**Box 2**). 12,17,31,36,48-50,53,55,58,71,73,79,81

#### **Contract implementation**

Only 11 articles (14%) mentioned or described training of health care professionals for the implementation of

Figure 1. Article inclusion process

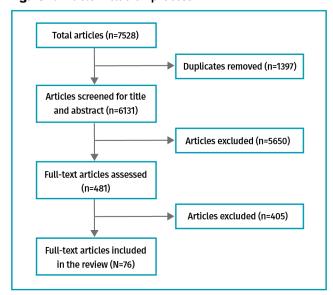


Table 1. Chronic conditions for which patient contracts were used and the names given to the contracts by the health care provider

CHRONIC CONDITIONS*	CONTRACT NAMES <sup>†</sup>
Substance use (marijuana, tobacco, alcohol, opioids) <sup>7-32</sup>	Contract, no-smoking agreement, deposit contract, behavioural continuing care contract, trilateral opioid contract, treatment contract, behavioural contract(ing), substance use disorder contract, monitoring contract, verbal contract, aftercare (participation) contract, moral contract, alcohol contract, Antabuse [ie, disulfiram] contract, contingency contract, quit contract, substance monitoring contract, commitment contract
Psychiatric disorders (suicidal, borderline personality disorder, depression, posttraumatic stress disorder, schizophrenia, bipolar disorder, disruptive behaviour, attention deficit hyperactivity disorder, dissociative identity disorder, anorexia nervosa) <sup>11,16,18,19,21,33-45</sup>	Contract(ing), contract for safety, no-suicide contract, behavioural continuing care contract, treatment contract, treatment plan, behaviour(al) contract, mental and behavioural health contract, monitoring contract, therapeutic contract, weight contract, self-referral to inpatient treatment contract, parent-teen contract
Risk factors (diet, exercise, obesity) <sup>46-52</sup>	Physical activity contract, behavioural contract, health contract calendar, contract for change tool, deposit contract, social support contract
Respiratory conditions (asthma, chronic obstructive pulmonary disease) <sup>53-61</sup>	Contingency contract(ing), behavioural contract, health contract, family contract, contract
Cardiovascular conditions (angioplasty, percutaneous coronary intervention, hypertension) <sup>27,54,62-65</sup>	Behavioural contract, treatment contract, weight-loss contract
Musculoskeletal conditions (osteoarthritis, fibromyalgia)66-69	Patient contract, therapeutic contract, negotiated follow-up contract, physical activity maintenance contract, behavioural contract
Infectious diseases (HIV, hepatitis C virus, latent tuberculosis) <sup>16,70-72</sup>	Contract referral, treatment contract, contingency contracting
Disabilities (intellectual, developmental, physical, neurologic) <sup>73-76</sup>	Behavioural contract, contract, contingency contract
Chronic pain <sup>77,78</sup>	Medication contract, pain contract, medication contract or agreement, provider-patient agreement, opioid contract
Organ failure (dialysis, liver transplant) <sup>79,80</sup>	Health contract, self-contracting
Diabetes <sup>62,81</sup>	Treatment contract, contingency contract
Contact lens wearers and glasses wearers <sup>82</sup>	Health care contract
*Some articles covered more than 1 chronic condition. *Some articles referred to contracts by more than 1 name.	

the contract. Six articles (8%) included only a contract, while most included contracts as part of complex cointerventions. The most common follow-up duration was 1 year or less (n=57, 75%), with only 2 studies following patients for more than 2 years. Follow-up duration could not be determined in 8 articles (11%). A minority of articles (n=16, 21%) described a process for reviewing the contracts following their initial implementation. Some form of incentive for patients was used in 20 articles (26%). Examples of incentives included financial rewards,10,50 the prospect of doing enjoyable activities,56 and the promise of further treatments.74 Twenty-five articles (33%) included patient goals in their contracts, which ranged from patients selecting them off a menu to having full authority over what was to be accomplished.

#### **Contract composition**

A number of easily identifiable elements existed within the contracts, including but not limited to prescribed

Table 2. Settings where contract interventions were initiated to manage chronic medical conditions

SETTING*	ARTICLE FREQUENCY
Community (pharmacy, call centre, patient home, optometry clinic, public health clinic, school)	32
Specialty outpatient medical clinic	24
Primary care medical clinic	18
Inpatient unit	4
Emergency department	2
Unknown	1
*Some articles covered more than 1 setting.	

and forbidden behaviour; rewards or incentives; consequences; medication and treatment prescriptions; action plans; information on risks and benefits of treatment; schedules for prescribed activities; explanation

Table 3. Included parties of contracts for managing chronic medical conditions

PARTIES IN THE CONTRACT	ARTICLE FREQUENCY
Patient and health care provider	51
Guardian or patient and health care provider	13
Patient and peer or health care provider	5
Unknown	7

Table 4. Purposes of patient contracts

CONTRACT PURPOSE	EXAMPLE
Altering objective or subjective health indices	A contract specifying goal weights for patients with anorexia nervosa <sup>37</sup>
Improving interpersonal relationships and role clarification	A contract clarifying the roles of family members in managing the illness of their family member with schizophrenia <sup>39</sup>
Behaviour change and skill development, including goal development and problem solving	Mandating a paraplegic patient to receive regular wound care before being accepted for a surgical intervention <sup>74</sup>
Improving the quality or process of chronic care	Improving the safety of care by using a contract outlining the conditions for which controlled medications would be prescribed for the management of chronic noncancer pain <sup>78</sup>
Altering beliefs and knowledge, including motivation and perceived self-efficacy	An educational program for contact lens wearers regarding proper lens and eye care <sup>82</sup>

#### **Box 2.** Theories of behaviour behind interventions in contracts aimed at managing chronic medical conditions

- Social cognitive theory
   <sup>12,48,53,55,58,73,81</sup>
- Behavioural ecological model<sup>17,71</sup>
- Behavioural economics31,50
- · Kernberg's theory for transference-focused psychotherapy36
- Behaviour modification model<sup>49</sup>
- King's goal attainment theory79

of threats and barriers to success, and suggested techniques to overcome them; responsibilities of those signing the contract; instructions, education, and rationale for the content of the contract; goals and targets for patient behaviour; identified social support for the patient; and objective assessment of health status. Patient input into the contract could occur through the inclusion of incentives and self-identified goals.

#### **Identified** gaps

There was extensive variability in the purposes, elements, development, and implementation processes for patient

contracts. We have also identified major gaps in reporting around contracts, particularly around contract development and implementation processes (Appendix C\*).

## Discussion —

We found extensive variety in the nature and implementation of patient contracts for managing chronic medical conditions. Five general purposes for initiating a contract were discovered: to encourage behaviour change and skill development, to alter beliefs and knowledge, to improve interpersonal relationships and clarify roles, to improve the quality and process of chronic care, and to alter objective and subjective health indices. Many elements were included in individual contracts, such as prescribed and forbidden behaviour; rewards and incentives; consequences; medication and treatment prescriptions; action plans; risks and benefits of treatment; schedules; threats and barriers to success and techniques to overcome them; responsibilities of those signing the contract; instructions, education, and rationale; goals and targets; social support for the patient; and assessment of health status.

#### Strengths and fit with the broader literature

The Cochrane review of patient contracts for managing chronic conditions was limited in scope.1 This review found inadequate evidence for their effectiveness, with most research failing to consider potential harms.1 Despite the paucity of evidence for effectiveness, we discovered that reporting of contracts in the literature has not tapered off in the past decade or more. This may be in part because contracts seem to fit into popular behaviour change theories (ie, self-determination theory, theory of planned behaviour, stages of change, self-efficacy theory) that are tied to concepts of motivation, intention, and self-efficacy.83-86 This scoping review highlights the lack of explicit application of such theories in contract intervention development and implementation, likely hindering support of effectiveness.

Similar to the findings of the Cochrane review, addiction, hypertension, and obesity were common targets for contracts. This study identified many additional chronic conditions for which these tools are applied (Table 1).7-82

#### Weaknesses

A focus on the word contract in the search string may have resulted in missing literature, but this provides a clearer conceptual analysis regarding the term contract. It is possible that interventions labeled as agreements, plans, or other related terminology may imply or demand alternative theories or processes for implementation. We did not search the gray literature because of limitations on time and resources for the project.

The fact that at least 2 researchers did not review and extract data from each article created potential for

reporting bias. Nevertheless, this approach was deemed appropriate for our study in which we simply describe the literature as opposed to assessing the quality of the evidence or systematically reviewing it.

### Practice and policy implications

Most of the literature on contracts was produced in the United States, a society that reputedly values personal autonomy. The patient's desire for personal autonomy can create tension, as contracts often do not take patient input and goals into consideration. Contracts are frequently targeted toward vulnerable populations, including those with mental illness and substance use disorder. While targeting groups with greater need is the most effective way to improve health equity, if a contract does not take into consideration patient input and goals, this goes against the process of empowerment that vulnerable populations often require, including skill development and continuity of resources.87

Most contracts in the literature occur in the outpatient community setting between a patient and health care provider, with fewer than 25% occurring in primary care clinics. It is possible that lack of frequent contact and a specialized focus are, and will continue to be, motivating factors for use of contracts in non-primary care settings.

#### **Research implications**

The development process for patient contracts, which underpins theory and rationale, and training for contract implementation were rarely included in the literature. In many cases, it was difficult to assess the rigour and fidelity with which contracts were implemented. The follow-up time generally appeared short, considering that behaviour change is often necessary for chronic disease self-management and this may take some time for the patient to implement. Few studies reported details of contract development and implementation, and there was no systematic approach for describing the composition elements. Tools such as the TIDierR (template for intervention description and replication) checklist can improve reporting of interventions and support more effective analysis and replication.87 These details are important if effectiveness is demonstrated, as they will help clarify the key elements of a contract. More comprehensive description and reporting in studies of contracts, including the elements we have described, would help determine contract effectiveness and key elements (see our example checklist in Table 5). These deficiencies could be addressed in future research.

Development of a common set of relevant outcome measures would also be useful in systematic analyses

**Table 5.** Checklist for reporting patient contract interventions

CHECKLIST ITEM	DESCRIPTION
Contract development	
• Purpose of contract	What behaviour does the contract intend to influence? What are the desired outcomes?
• Underpinning behaviour theory	Did formal behavioural theory influence the choice of contract as an intervention or influence contract development?
<ul> <li>Development process</li> </ul>	How was the contract developed? Who developed the contract (were patients involved)?
<ul> <li>Validation process</li> </ul>	How was the contract validated?
Contract elements	What elements made up the contract? Were incentives included?
<ul> <li>Target population</li> </ul>	Who did the contract intend to target? Include all demographic variables
• Partners to the contract	Who initiated the contract? Who signed the contract?
Contract implementation	
• Implementation setting	Did the overall intervention take place in a primary health care, primary care, secondary care, or tertiary care setting?
<ul> <li>Implementation training</li> </ul>	What training took place for those implementing the contract?
Cointerventions or incentives	What other types of interventions took place alongside the contract? How were these accounted for in assessing outcomes?
Patient input	Was there an opportunity for the patient to alter the implementation of the contract or its content?
<ul> <li>Implementation process</li> </ul>	How was the contract implemented? Was there opportunity for review and revision?
• Follow-up duration	How much time passed between the implementation of the contract and measurement of outcomes?
<ul> <li>Assessment of fidelity of implementation</li> </ul>	Was the contract used in the way it was intended? To what extent was implementation faithful to the intervention description?
<ul> <li>Effectiveness measured against target outcome</li> </ul>	What was the measure of effectiveness of the contract intervention?

across heterogeneous purposes and settings to determine whether contracts can be used to achieve their intended purposes. Finally, research aiming to provide further conceptual clarity between contracts and related terminology, such as agreements and plans, may provide further insight into which elements of interventions support positive changes for chronic disease management, if they in fact differ.

#### Conclusion

The nature and use of patient contracts for the management of chronic medical conditions are highly variable, and the existing review literature describes variable quality and comprehensiveness. Questions remain regarding the rationale, development, implementation, and effectiveness of patient contracts. Given their current broad application and the commitment required of health care providers and patients in their implementation, future research is needed to address this knowledge gap.

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#### Contributors

Dr Erin Gallagher conceived and designed the study, conducted the literature review, executed data gathering, contributed to data interpretation, and helped develop the final research paper as her master of public health thesis project. Dr Elizabeth Alvarez was the project supervisor and contributed to project development and knowledge synthesis. Dr Lin lin helped with data acquisition and interpretation. Drs Dale Guenter and Lydia Hatcher sat on the thesis committee as content experts, refining the research question, data gathering, and interpretation processes. Dr Andrea Furlan was invited as an external reviewer for thesis defence and substantial improvements to the final paper resulted from her input.

#### Acknowledgments

We thank Laura Banfield and Stephanie Sanger, librarians who helped with search strategy development; Cindy Cheng and Bethina Loiseau for their help with data extraction: Dr Fran Scott, Director of the Master of Public Health Program at McMaster University in Hamilton, Ont; and Dr Derelie Mangin, Larkin Lamarche, and Dr Michelle Howard for their editing contributions.

#### Competing interests

None declared

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This article has been peer reviewed.

Cet article a fait l'objet d'une révision par des pairs.

Can Fam Physician 2022;68:e169-77. DOI: 10.46747/cfp.6805e169