Deprescribing statins for adults 65 years of age and older

Evidence-based clinical practice guideline

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Abstract

Objective To develop an evidence-based guideline to support clinicians in making decisions around continuation or discontinuation (deprescribing) of a statin for their older patients.

Methods The target audience was clinicians. The scope was patients 65 years and older taking statins. *Deprescribing* was defined as discontinuation. The guideline was developed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework. The guideline panel included 10 clinicians (family physicians, pharmacists, a geriatrician, a cardiologist, a neurologist, and a nurse practitioner) and 1 patient and public member. There was a patient and public consultant group of 5 people 65 years and older taking statins. Recommendations were informed by evidence reviews on the benefits and harms of deprescribing versus continuation of statins; benefits and harms of initiating statins in older adults; feasibility, acceptability, equity, and patient preferences related to statin deprescribing; and resource implications of statin deprescribing. The team refined recommendations through consensus and synthesized clinical considerations relevant to practice. The guideline was reviewed by clinicians and interest holders, and their feedback was incorporated into the guideline.

Recommendations All decisions should be tailored to the individual and include a conversation with patients and carers. Decisions may be informed by consideration of function, mobility, cognition, level of frailty, social circumstances, life expectancy, pill burden, and patient values, preferences, and health care goals. The guideline panel suggests deprescribing statins in older adults at the end of life; continuing statins for primary prevention in older adults who are not at the end of life; continuing statins for secondary prevention in older adults who are not at the end of life; and offering a conversation about continuing or discontinuing statins for select patients.

Conclusion This guideline supports patient-centred decision making around statin use for older adults. The recommendations are meant to be discussed together with patients and carers to reach decisions that reflect individual patient characteristics, values, preferences, and health care goals.

Editor's key points

- For adults 65 years of age and older not at the end of life, statin discontinuation might be associated with a higher chance of adverse outcomes compared with continuation, but this is very uncertain.
- For adults 65 years of age and older at the end of life, there is probably no difference in mortality at 60 days or cardiovascular events at 1 year for statin discontinuation compared with continuation.
- Patient and carer health care goals, preferences, and level of risk aversion related to statin discontinuation should be incorporated into individualized decisions.

Déprescription des statines chez les adultes de 65 ans et plus

Guide de pratique clinique fondé sur des données probantes

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Résumé

Objectif Élaborer un guide de pratique fondé sur des données probantes pour aider les cliniciens dans la prise de décision entourant la continuation ou la cessation (déprescription) d'une statine chez leurs patients âgés.

Méthodes Les cliniciens étaient le public cible. La portée comprenait des patients de 65 ans et plus qui prenaient des statines. La *déprescription* était définie comme étant la cessation. Le guide de pratique a été élaboré en conformité avec les critères GRADE (Grading of Recommendations Assessment, Development and Evaluation). Le panel chargé du guide regroupait 10 cliniciens (des médecins de famille, des pharmaciens, un gériatre, un cardiologue, un neurologiste et une infirmière praticienne), de même que 1 patient et membre du public. Un groupe de consultants représentait les patients et le public, qui était formé de 5 personnes de 65 ans et plus prenant des statines. Les recommandations se sont fondées sur des revues des données probantes portant sur les bienfaits et les préjudices de déprescrire plutôt que de continuer les statines; sur les bienfaits et les préjudices de commencer une statine chez les adultes âgés; sur la faisabilité, l'acceptabilité, l'équité et les préférences des patients liées à la déprescription des statines; et sur les répercussions de la déprescription sur les ressources. L'équipe a raffiné les recommandations par consensus et a fait la synthèse des éléments à considérer comme appropriés à la pratique. Le guide a été révisé par des cliniciens et d'autres parties intéressées, et leurs commentaires ont été incorporés dans le guide.

Recommandations Toutes les décisions devraient être adaptées en fonction de la personne, et reposer sur une conversation avec le patient et ses aidants. Les décisions peuvent être éclairées en prenant en compte le fonctionnement, la mobilité, la cognition, le degré de fragilité, les circonstances sociales, l'espérance de vie, le fardeau pharmacologique ainsi que les valeurs, les préférences et les objectifs des soins de santé du patient. Le panel chargé du guide suggère de déprescrire les statines chez les adultes âgés en fin de vie; de continuer les statines en prévention primaire chez les adultes âgés qui ne sont pas en fin de vie; de continuer les statines en prévention secondaire chez les adultes âgés qui ne sont pas en fin de vie; et d'offrir une conversation sur la continuation ou la cessation des statines à certains patients.

Conclusion Ce guide préconise une prise de décision centrée sur le patient entourant l'utilisation des statines par des adultes âgés. Les recommandations sont destinées à être discutées avec les patients et les aidants afin d'en arriver à des décisions qui reflètent les caractéristiques, les valeurs, les préférences et les objectifs des soins de santé de chaque patient à titre individuel.

Points de repère du rédacteur

- Chez les adultes de 65 ans et plus qui ne sont pas en fin de vie, la cessation des statines pourrait être associée à un risque plus élevé de résultats indésirables que leur continuation, mais cette constatation est très incertaine.
- Chez les adultes de 65 ans et plus qui sont en fin de vie, il n'y a probablement pas de différence sur le plan de la mortalité après 60 jours ou d'un événement cardiovasculaire après 1 an de l'arrêt des statines comparativement à leur continuation.
- Les objectifs en matière de soins de santé, les préférences et le degré d'aversion au risque liés à la cessation des statines devraient être pris en compte dans les décisions individualisées.

Statins are among the most common medications taken by older adults. In 2016, roughly 45% of older Canadians (≥65 years) were taking statins.[1] Internationally, the prevalence among persons 80 years of age and older ranges from 12% to 59%.[2] Statins have been shown to lower the risk of cardiovascular disease both in primary and secondary prevention.[3,4] The absolute benefit depends on an individual's baseline risk of cardiovascular disease.[3] Randomized controlled trials (RCTs) demonstrating benefits of statins have included individuals up to 75 years of age primarily, with comparatively fewer data on benefits and harms among those with frailty or multimorbidity. A statin may have been started when a person was younger and continued for many years, and while many older adults are healthy and well-functioning, others develop multiple chronic health problems over time, take many medications, and may experience functional or cognitive decline.[5] There may also be a shift in health care goals and treatment preferences as a person's health and life changes.[6]

It makes sense to reassess ongoing medications to ensure they continue to be a good fit for individual patients.[7] This reassessment may include considering whether to continue taking a medication, stop it, or reduce the dose. Deprescribing is defined as the planned and supervised stopping or dose reduction of a medication.[8] Deprescribing can be considered if a medication is no longer necessary, the harms outweigh the benefits, or if the medication does not align with the patient's health care goals and treatment preferences. For older adults taking statins, worsening health status or function and shifting health care goals may raise consideration of deprescribing, particularly among those with frailty or multimorbidity.

Population-based studies show statins are commonly discontinued among older adults.[9] As such, decisions about whether to continue or discontinue a statin come up routinely in care of older adults, particularly in primary care, geriatrics, and long-term care. Health care providers report a need for guidance and resources to support decision making around whether to continue, stop, or reduce medications, including statins.[10,11] Contemporary guidelines contain no or minimal guidance around when and how to stop statins.[12] Thus, we developed a statin deprescribing guideline to assist health care providers, patients, and carers in making decisions about statin therapy for older adults.

Scope

The target audience for this guideline is clinicians considering deprescribing statins for older adults. This may include physicians, nurse practitioners, pharmacists, and registered nurses, among others.

The target population for this guideline is older adults already taking and tolerating statins. We did not specify a minimum duration of statin use; however, the focus was on long-term statin users (eg, >1 year). We recognize there is heterogeneity in health status, function, cognition, frailty, and health care goals or treatment preferences as people age, and that chronologic age is not a sole marker of aging. For the practical purposes of guideline development, the panel defined an older adult as a person 65 years of age and older. We recognize that decisions around deprescribing will likely be most relevant after 75 or 80 years of age. However, the panel agreed that some persons aged 65 to 75 years may have factors that warrant consideration of discontinuation (such as frailty or end-stage illness). We consider and discuss these factors throughout the guideline. We expect that clinicians will interpret and apply recommendations to make person-centred decisions together with patients and carers.

The guideline does not specifically focus on statin intolerance management, as there are existing guidelines that address this topic,[13-15] nor does it make explicit recommendations about initiation of statins for older adults, which is also addressed by existing guidelines.[13,16]

Methods

We used Grading of Recommendations Assessment, Development and Evaluation (GRADE) methods to develop the guideline.[17,18] We followed the steps outlined in the Guidelines International Network–McMaster Guideline Development Checklist.[17] Our priority-setting exercise among Canadian clinicians caring for older adults indicated that statins were a priority topic for a deprescribing guideline.[10] We formed a guideline panel consisting of 3 family physicians, 1 patient and public member, 1 nurse practitioner, 1 geriatrician, 1 cardiologist, 1 neurologist, and 3 pharmacists. Expertise and conflict of interest statements are in Appendix 1, available from **CFPlus**.* The guideline panel was supported by 4 research assistants and 1 library scientist. We also had 5 older adults (≥65 years of age) taking statins to act as a consultant group. The role of the patient and public consultant group was to provide feedback and input on guideline messaging and recommendations, and to provide input on patient values and preferences on statin deprescribing. The patient and public consultation group did not vote on recommendations and did not declare any conflicts of interest. We identified clinician and health care organization interest holders who appraised the guideline using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) checklist,[17] and who provided critical revisions and input. The guideline was then piloted with clinicians and sent for interest holder review (see the Piloting and Clinical and Interest Holder Review section for further details).

The guideline panel identified the target audience and scope of the guideline and determined topics addressed

Appendices 1 to **3** are available from **https://www.cfp.ca**. Go to the full text of the article online and click on the **CFPlus** tab.

in the guideline. We used the Patient of Problem, Intervention, Comparison, and Outcome framework to identify key questions for the guideline. The central question we addressed was the following: Among adults 65 years of age and older, what are the benefits and harms of discontinuing statins compared with continuing them?

We conducted a systematic review to identify relevant clinical evidence on this topic (Appendix 2, available from **CFPlus***).[20] We focused on clinically important outcomes: mortality, cardiovascular mortality, cardiovascular events (myocardial infarction [MI], stroke, revascularization), quality of life, adverse effects, and health care resource use. We used the GRADE framework to judge certainty of evidence.[21,22]

We also conducted additional nonsystematic evidence reviews to support the evidence-to-recommendations process. These included a nonsystematic review of reviews examining the benefits and harms of initiating statins among adults 65 years of age and older; a nonsystematic review of feasibility, acceptability, and equity considerations, as well as patient values and preferences, related to statin deprescribing among adults 65 years of age and older; and a nonsystematic review of resource implications of statin deprescribing among adults 65 years of age and older (Appendix 2*).

The lead author summarized all the available evidence, and the panel met virtually to discuss the body of evidence and deliberate on its certainty and strength (**Table 1**). The guideline lead completed the GRADE evidence-to-decision framework[23] (Appendix 3, available from **CFPlus***), which was reviewed by the panel. Draft recommendations were refined by the guideline lead and panel by group discussion and email (any disagreements were resolved via guideline panel virtual discussions or email). The team then voted on the recommendations. The cut-off for consensus on final recommendations was 80%.

Recommendations

Recommendations are outlined in **Box 1**.[24] There was unanimous support from the panel for all recommendations. Evidence reviews are in Appendix 2* and the GRADE evidence-to-decision framework is in Appendix 3*. The recommendations apply to adults 65 years of age and older taking and tolerating statins. For this guideline, we considered statin deprescribing to be discontinuation. We did not stratify by cardiovascular risk beyond considering primary and secondary prevention. We did not identify evidence that permitted us to make recommendations about reducing the dose of a statin. All decisions should be guided by a conversation with patients and carers.

Figure 1 provides a 2-page decision support algorithm based on the guideline content.[25]

Benefits and harms of statin discontinuation compared with continuation

The main piece of evidence that informed recommendations was our systematic review[20] on benefits and harms of statin discontinuation compared with continuation (Appendix 2*). Among older adults at the end of life (those with advanced, life-limiting illness and life expectancy <12 months), there is probably no difference in 60-day mortality risk or 1-year risk of cardiovascular events for statin discontinuation compared with continuation (moderate-certainty evidence from 1 RCT) and discontinuation might improve quality of life (low-certainty evidence from 1 RCT).[26]

Among older adults not necessarily at the end of life, we identified 35 nonrandomized studies that examined the effects of statin discontinuation. The mean age was 65 years and older in 23 out of 32 studies (72%) that reported age, and in 7 out of 32 studies (22%) the mean age was 60 to 64 years. Five reports from 4 studies had a mean or median age of 75 years and older. Available evidence consistently suggests statin discontinuation might be associated with higher risk of all-cause mortality, cardiovascular mortality, cardiovascular events, MI, and ischemic stroke (very low–certainty evidence; Appendix 2*). This was observed in both primary and secondary prevention. However, we are very uncertain about the benefits and harms of discontinuing statins among older adults not at the end of life due to risk of bias in nonrandomized studies. Studies mostly reported adjusted relative estimates of effect (eg, relative risk ratios, hazard ratios), and few studies reported absolute risk. This makes assessment of absolute risk of statin discontinuation challenging. There were no differences in these findings based on 75 years of age and older. Frailty and function were not well described in the available evidence; thus, we cannot say whether findings differ depending on frailty status.

Benefits and harms of statin initiation among older adults

The panel agreed that the decision to stop a statin was not the same as a decision to not start a statin. Thus, our recommendations are based primarily on evidence around discontinuation. However, evidence on statin initiation was considered as contextual and indirect when formulating our recommendations (ie, paucity of evidence around statin use or initiation for frail older adults may factor into decision making as outlined below). Our review of systematic reviews identified 62 systematic reviews and 2 existing umbrella reviews (Appendix 2*). It is widely known that RCTs examining statin initiation and cardiovascular outcomes for older adults have primarily included people 65 to 74 years of age, with fewer people 75 years of age and older or with frailty or multimorbidity included.[24] For primary prevention, there was conflicting evidence on the benefits

Table 1. Interpretation of strength of recommendations and certainty of evidence

A) STRENGTH OF RECOMMENDATIONS		
STRENGTH	**PATIENTS**	**CLINICIANS**
Strong	Most would want the recommended course of action	Most individuals should be offered this course of action
Conditional (weak)	• Many individuals would want the recommended course of action, but some may not • Individuals may have different values, preferences, and risk aversion • People will want to talk to a health care professional to make the right decision for them	• This is our suggestion, but it may be reasonable to consider an alternative approach. The benefits and risks may be finely balanced or uncertain • Consider patient circumstances, values, preferences, and risk aversion. Different choices will be appropriate for different patients • Talk to patients about their values and preferences to find the right decision for them as an individual. Decision aids may be useful to guide decisions
Good practice	Not assigned a strength (is the alternative absurd or clearly not conforming to ethical norms?)	
B) CERTAINTY OF EVIDENCE		
GRADE	**DEFINITION**	
High ⊕⊕⊕⊕	We are very confident the true effect lies close to our estimate of the effect	
Moderate ⊕⊕⊕◯	We believe the true effect is probably close to our estimate of the effect	
Low ⊕⊕◯◯	The true effect might be markedly different from our estimate of the effect	
Very low ⊕◯◯◯	We have very little confidence in our estimate of the effect; the true effect is probably markedly different from our estimate of the effect	

of statin initiation for those 75 years of age and older with respect to cardiovascular outcomes and mortality. Studies examining those 65 to 75 years of age report that statins for primary prevention reduce risk of cardiovascular events (the absolute chance of benefit depends on baseline risk). For secondary prevention, the systematic reviews we identified consistently reported that statin initiation reduces risk of cardiovascular events, including in those 75 years of age and older. We identified several reviews on different noncardiovascular outcomes (see Appendix 2* for further details).[27-29]

Feasibility, acceptability, equity, and patient values and preferences related to statin deprescribing among older adults

Evidence is summarized in Appendix 2*. Qualitative evidence on deprescribing cardiovascular medications suggests older adults are concerned about future cardiovascular events and shortened lifespan following deprescribing.[30] Further, many patients are concerned about the uncertainty of the effects of stopping statins.[31] Yet, some patients are concerned about medication burden and inconvenience of taking multiple medications.[31] Patients may also have different values and interpretations around the benefits of statins (ie, some patients may be motivated by absolute benefits in risk reduction, whereas others may not be) and the risk of harm.[31,32] Survey evidence shows that patients who prioritize taking fewer medications are more willing to stop preventive medications such as statins.[33] For older adults at the end of life, qualitative evidence similarly shows that some patients are concerned about the risks of stopping, whereas others prefer to be on fewer pills.[34] The heterogeneity in patient values, preferences, and treatment goals related to statins highlights the importance of eliciting these details and engaging in shared decision-making conversations with patients and carers where possible and desired by patients and carers.

Patients are generally open to being offered a conversation about deprescribing of cardiovascular medications regardless of their individual preferences around treatment.[31,35] They prefer to have a conversation with a trusted provider to discuss their individual circumstances, health, and treatment goals.[36] Prescribers have different views about when it is appropriate to offer a conversation about statins in their older patients and may be more open to having a conversation in the context of primary prevention, shorter life expectancy, functional limitations, cognitive impairment, polypharmacy, or palliative care.[31] Time constraints and lack of resources are common barriers to having deprescribing conversations for prescribers. We did not identify any literature specific to health equity and statin deprescribing. Given that conversations often happen in primary care, patients without a family physician or other primary care provider may have less access to deprescribing.

Resource implications of statin deprescribing among older adults

Evidence is in Appendix 2*. Statin deprescribing reduced drug costs in 1 RCT.[26] A retrospective cohort study suggested that addressing overuse of statins for persons 80 years and older in France would lead to drug cost savings of more than €900,000.[37] Statin initiation in people

75 years of age and older in the United States is estimated to be cost-effective with a 10-year time horizon, but functional limitations of patients may offset cost-effectiveness.[38]

Evidence to recommendations

The evidence-to-decision framework is in Appendix 3*. The recommendation in favour of deprescribing at the end of life is based on evidence that statin discontinuation is probably not harmful in this context. The recommendation is conditional (weak) because there is evidence of heterogeneity in patient preferences, suggesting that some patients may not wish to pursue deprescribing and that a conversation around shared decision making is essential. The recommendation to continue statins in primary and secondary prevention for people not at the end of life is based on very low–certainty evidence of potential harms of discontinuation in this context. Our recommendations for primary and secondary prevention were rated conditional (weak) because in some patients, there may be more uncertainty around the benefits of statin therapy (including those experiencing frailty, cognitive impairment, and functional limitations). Further, there is heterogeneity in patient preferences around deprescribing. Thus, it is crucial to consider patient-specific factors and have a conversation that incorporates values, preferences, and treatment goals to make decisions. While many patients will prefer to continue statins, some may not, which is reflected in the conditional (weak) strength of the recommendation.

Box 1. Recommendations for persons ≥65 years currently tolerating statins

We suggest deprescribing statins in older adults at end of life (conditional recommendation, low-certainty evidence)

- *End of life* means a clinician would not be surprised if the person died in the next year (the definition used in the 1 randomized controlled trial[22] informing this recommendation)

We suggest continuing statins for primary prevention in older adults who are not at the end of life (conditional recommendation, very low–certainty evidence)

- Decisions may be informed by consideration of patient function, mobility, cognition, individual cardiovascular risk, level of frailty, social circumstances, life expectancy, pill burden, and discussion of patient values, preferences, and health care goals

We suggest continuing statins for secondary prevention in older adults who are not at the end of life (conditional recommendation, very low–certainty evidence)

- Decisions may be informed by consideration of patient function, mobility, cognition, individual cardiovascular risk, level of frailty, social circumstances, life expectancy, pill burden, and discussion of patient values, preferences, and health care goals

We suggest offering a conversation about continuing or discontinuing statins in select patients (ungraded good-practice statement)

- Factors to consider for initiating a conversation include patient function, mobility, cognition, individual cardiovascular risk, level of frailty, social circumstances, change in health status, pill burden, and life expectancy. The panel members agree that this conversation should include a discussion of available evidence, patient values, preferences, patient illness understanding, and health care goals, which can be used to guide decisions

Clinical considerations

Making shared decisions. Reassessing medications may bring about consideration of statin deprescribing. Possible triggers for discussion include medication reviews, changes in care setting, or changes in health or functional status. A survey of older adults in the United States that asked about preferred explanations for considering deprescribing statins found that framing around benefit-harm balance of statins was preferred over a focus on treatment burden.[39]

Shared decisions around statin continuation versus discontinuation ideally involves creating awareness that options exist (either continuation or discontinuation); sharing available evidence on the benefits and harms of both continuing and discontinuing the statin; exploring the patient preferences around each option; and choosing the option that is the best fit for an individual.[40] Patients and carers might vary in their desired role in shared decision-making processes.[41] Even if patients do not want to be involved in decision making, they may still participate in aspects of the decision (eg, sharing what matters most to them).[42]

Our evidence review and patient consultation group highlighted how patients value their individual health and risk factors being taken into account in decision making. Our patient consultation group indicated that they would appreciate discussing their cardiovascular risk and the absolute benefits of statins based on their risk as part of decision making (eg, using validated risk calculators for persons aged 65 to 74 years in primary prevention)[13] in addition to discussing the benefits and harms of statin discontinuation. We recognize that few studies on statin discontinuation included estimates of absolute harm of stopping statins. In observational studies reporting adjusted absolute outcome rates for statin discontinuation compared with continuation, the associated absolute rate increase for major cardiovascular events was 9 per 1000 persons per year (95% confidence interval [CI] 5 to 12 per 1000 persons per year) for primary prevention in 1 study, and 25 per 1000 patients over 2.5 years in another study, compared with 13 per 1000 persons per year for secondary prevention (95% CI 8 to 17 per 1000 persons per year).[43,44]

Decisions and conversations can be revisited as appropriate (eg, change in health status or transition in care setting).

Figure 1. Decision support algorithm

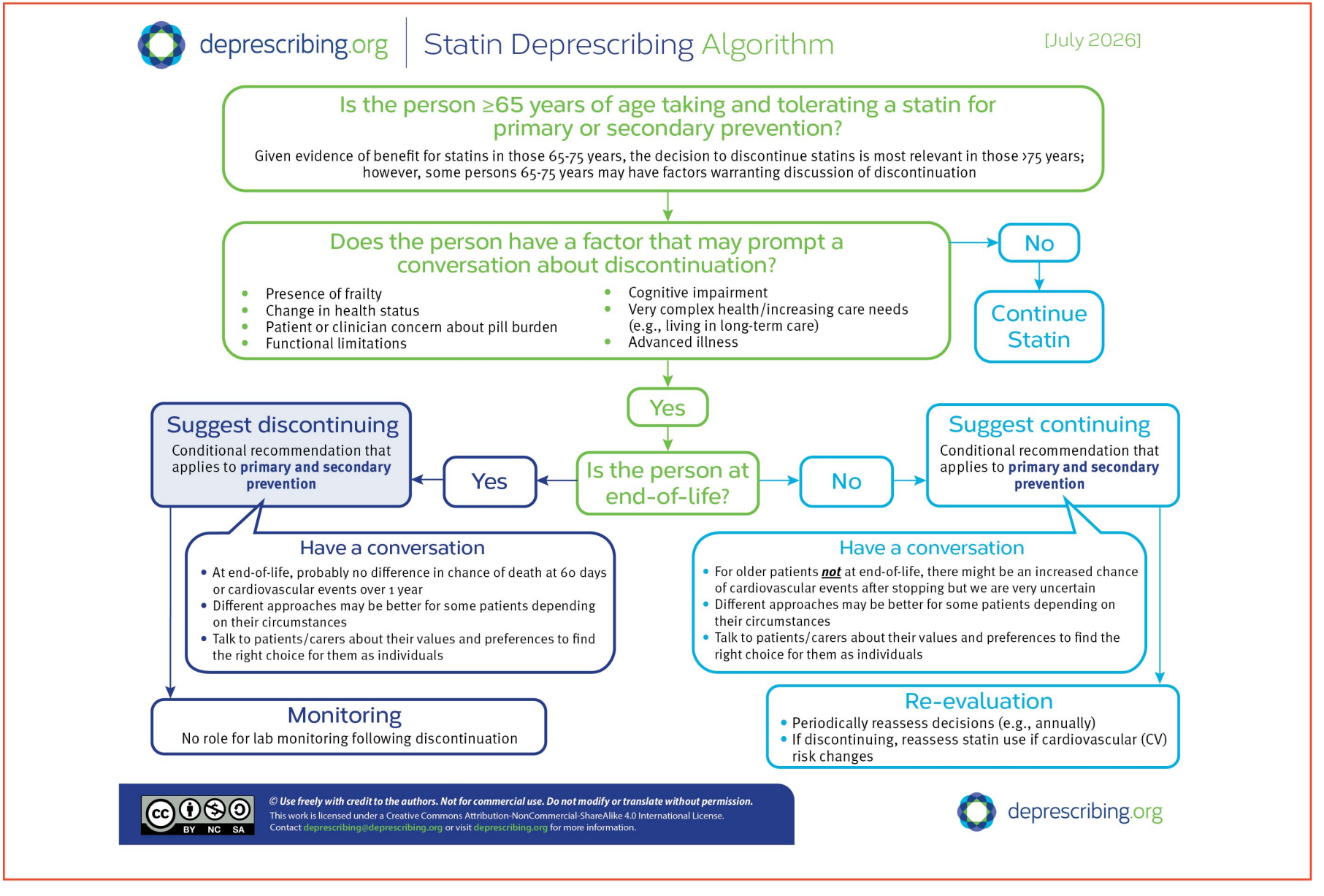


Figure 1 *continued on page 541*

Figure 1 *continued from page 540*

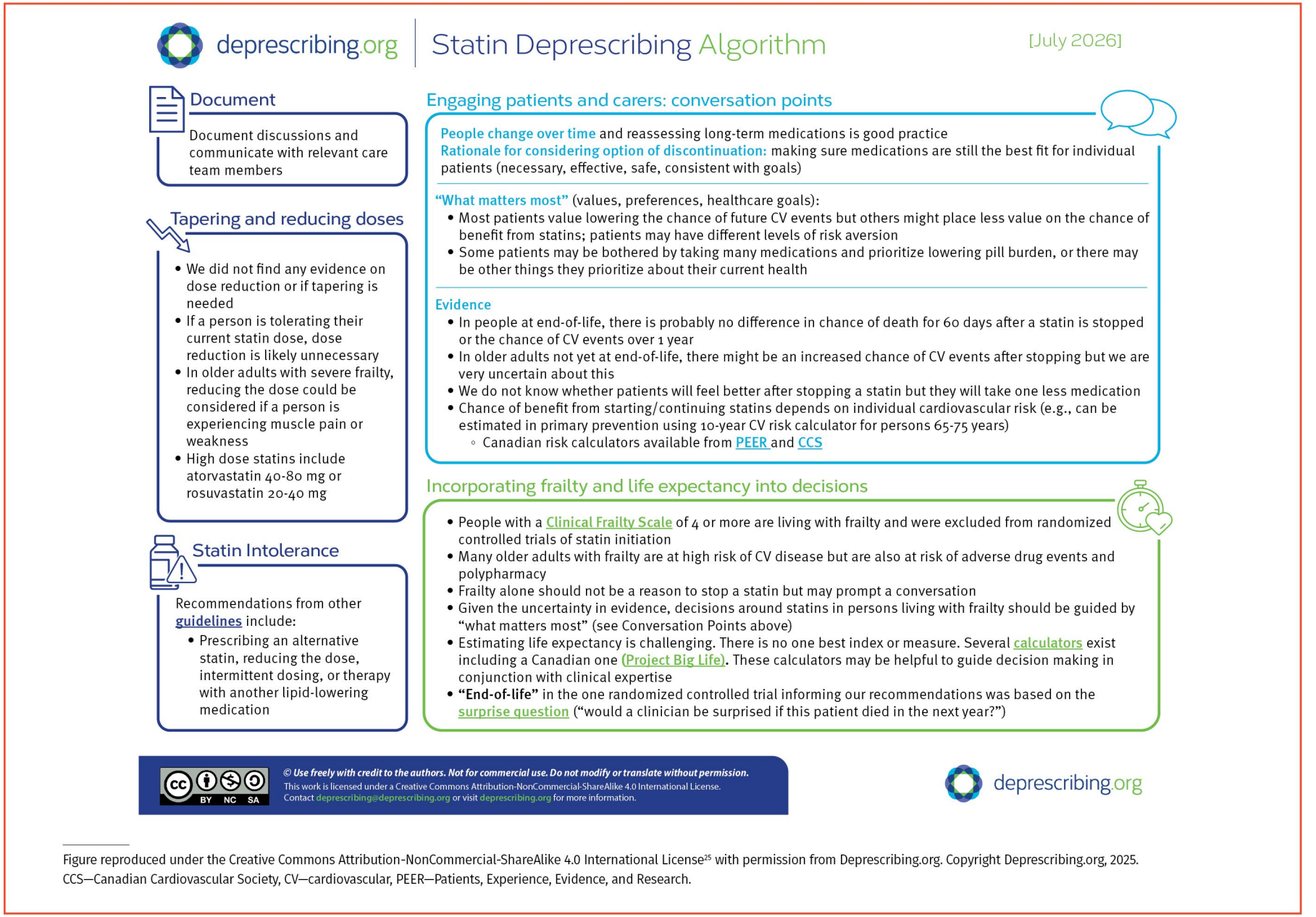


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CCS—Canadian Cardiovascular Society, CV—cardiovascular, PEER—Patients, Experience, Evidence, and Research.

Incorporating frailty and life expectancy into decisions. Frailty is a multidimensional syndrome of loss of reserves such as energy, physical ability, cognition, and health, giving rise to vulnerability.[45,46] Many older adults with frailty are at high risk of atherosclerotic cardiovascular disease, yet are also at increased risk of adverse drug events.[47] Frailty and multimorbidity thus introduce competing risks—there may be competition between guideline recommendations, health priorities, and adverse effects of treatment on other coexisting illnesses.[48,49]

While the presence of frailty alone should not warrant statin deprescribing, it may be a reason for bringing up the option to stop a statin. The best decision for an individual thus depends on their treatment priorities and health care goals, with consideration of the net benefit of statins in the context of an individual's level of frailty, other health problems, function, and life expectancy.[48] Consideration of time-to-benefit in conjunction with a person's life expectancy has also been advocated in assessing appropriateness of statin use for older adults.[50] This consideration applies primarily to initiation of statins rather than people who have been taking them for several years. For primary prevention, time-to-benefit for statins has been estimated at 2.5 years.[50] In the context of discontinuation, consideration of time-to-benefit may be relevant for older adults with limited life expectancy who have recently been started on a statin.

Various frameworks have been proposed that formally integrate the above principles in detail, including the 2022 American College of Cardiology (ACC) Expert Consensus Decision Pathway.[48] Tools focusing on severity of frailty, such as the Clinical Frailty Scale,[45] provide general prognostic information that may help to identify patients with limited life expectancy.[51] Hawley et al[24] propose a similar approach to the ACC pathway, which incorporates the Geriatrics 5Ms framework.[52]

Our suggestion to deprescribe statins at the end of life is based on 1 RCT,[26] which used the (surprise) question "Would you be surprised if this patient died in the next 12 months?"[53] to enroll patients. We recognize that estimating life expectancy is challenging and that existing indices or calculators have variable performance and cannot be used without clinical expertise and judgement. We do not advocate for a single measure, calculator, or index, but several examples exist[54] that may help guide decision making in conjunction with clinical expertise.

Statin intolerance management. Clinicians may be faced with patients experiencing possible adverse effects from statins and wonder about discontinuation in this context. *Statin intolerance* is defined as 1 or more adverse effects associated with statin use, with resolution following dose reduction or withdrawal.[14] Statin intolerance management alone is beyond the scope of the guideline and existing guidelines already address this topic[13-15,55]; however, it is discussed briefly here.

The risk of adverse events attributable to statins is considered low, and statins are generally considered to have a favourable benefit-harm balance.[56,57] Statins have been shown to increase the risk of self-reported muscle symptoms.[56] Serious adverse events, such as rhabdomyolysis (<0.1%) and hepatotoxicity (0.001%), are rare.[57] Patients may stop taking a statin due to subjective concerns—most commonly muscle symptoms without objective evidence of myositis. It is believed that a substantial proportion of perceived (and reported) intolerance results from the nocebo effect, which is supported by multiple well-designed crossover studies including N-of-1 trials.[58-60] The nocebo effect refers to negative consequences (including possible adverse effects) that are perceived to occur from a medication as a result of negative expectations rather than pharmacologic causation.[61]

When perceived adverse effects of statins are present, the first step is for the clinician to determine whether there is true intolerance. This can be achieved by reducing the statin dose, stopping the statin, or switching to another statin, and assessing whether the perceived symptoms improve. These strategies are necessary to identify statin intolerance because intolerance is only considered present when symptoms resolve upon dose reduction or withdrawal after trying at least 2 different statins. Patients and public involved in our guideline believe that patients who perceive adverse effects from statins may appreciate a trial of pausing their statin with reassessment.

Guidelines provide advice on managing statin intolerance.[13-15] Recommendations for managing statin intolerance are based on whether statin intolerance is partial or complete, where partial intolerance indicates intolerance to select doses and complete intolerance refers to intolerance to any dose.[14] Recommendations for partial statin tolerance include prescribing an alternative statin, intermittent dosing, and using adjunctive nonstatin lipid-lowering agents to supplement a reduced statin dose.[14]

What about reducing the dose of a statin versus discontinuation? There was no evidence in our systematic review examining the effects of reducing the dose of a statin.[20] Some patients who are experiencing an adverse effect, particularly muscle-related symptoms, may perceive an improvement in symptoms with a lower dose of statin, as the incidence of myopathy tends to increase with a higher statin dose.[57] Regarding guideline-recommended and evidence-informed dosing, both the 2021 Canadian Cardiovascular Society (CCS)[62] dyslipidemia guideline and 2023 Patients, Experience, Evidence, and Research (PEER) simplified lipid guideline[13] recommend high-intensity statin therapy (eg, 40 to 80 mg of atorvastatin or 20 to 40 mg rosuvastatin daily) in patients with established cardiovascular disease (ie, secondary prevention). However, if a patient is unable to tolerate a high-intensity dose, then the maximum tolerated dose is typically recommended,

which should be individualized for each patient. For primary prevention, there is no clear consensus regarding statin dosing among the guidelines. Therefore, the decision to continue versus discontinue statin therapy is likely more relevant than the specific dose. The 2023 PEER simplified lipid guideline[13] advocates moderate-intensity statin therapy (eg, 10 to 20 mg of atorvastatin or 5 to 10 mg of rosuvastatin daily) in primary prevention patients with a 10-year cardiovascular risk of 10% or more, and high-intensity therapy in patients with a 10-year cardiovascular risk of 20% or more.[5] The 2021 CCS lipid guideline[62] recommends a threshold-based approach to lipid-lowering therapy, where patients—depending on their baseline risk—are recommended to receive intensification of their lipid-lowering therapy depending on their serum low-density lipoprotein cholesterol (or alternate lipid parameter). If a patient is tolerating their current statin dose, dose reduction is unlikely to be necessary. However, patient factors (eg, severe frailty), patient preference, and shared decision making in the context of guideline-directed principles outlined above may open discussion of dose reduction. For example, given the lack of evidence for high-intensity statin therapy in severely frail older adults, reducing to a moderate dose of statin could be considered for a person experiencing muscle pain or weakness.

How should patients be monitored after discontinuing statin therapy? Our guideline panel believes there is generally no role for routine monitoring of lipid parameters after deprescribing statins, particularly at the end of life. As most patients with dyslipidemia are asymptomatic, it is unlikely patients will notice any difference in their symptoms or quality of life after discontinuing their statin. In the 1 RCT of statin deprescribing in patients with a life expectancy of less than 1 year, the mean quality of life score was higher in the discontinuation versus continuation group, but the clinical significance of this difference is questionable.[24] Patients should be supported in making an informed decision to potentially restart statin therapy if there is a change in their cardiovascular risk profile (eg, after a cardiovascular event or if they are diagnosed with a chronic medical condition that increases their cardiovascular risk, such as diabetes or chronic kidney disease).

What if I am not the person who started the statin? In practice, conversations about statin discontinuation may occur in a variety of settings and with different health care providers, including primary care clinicians, pharmacists, or relevant specialists (eg, geriatricians, cardiologists, neurologists, internal medicine specialists). Health care providers and patients may be hesitant to stop a medication started by another prescriber. In the context of deprescribing cardiovascular medications, different prescribers may have different views on when it is appropriate to consider deprescribing.[63]

The guideline panel highlighted the importance of documentation and communication when stopping a statin that was started by another prescriber. They stressed the importance of the shared decision-making conversation around deprescribing to identify the best decision for an individual patient. They also recommended a summary of the conversation between the patient and provider be documented. If discontinuation is the best choice, a short note can be sent to the original prescriber (or relevant other specialists or team members, for example) highlighting the decision, summarizing the conversation, and including the rationale for deprescribing, as well as contact information (telephone number or email address) for further discussion. The panel noted that when there may be a difference of opinion or uncertainty, the original prescriber could be contacted directly by telephone to discuss the decision.

Our panel stressed that the focus should be on supporting patient preferences and health care goals once the benefits and harms of options have been reviewed. The focus of decisions should be what matters most to patients, rather than what matters most to clinicians. This framing may appropriately shift the focus away from preferences of health care providers to preferences of patients. However, documentation and communication with relevant team members is the responsibility of clinicians making medication changes and remains crucial to ensure continuity of care.

Piloting and clinical and interest holder review

This guideline underwent clinical review by 2 family physicians, 2 geriatricians, 2 pharmacists, and 2 methods reviewers. The 2 methods reviewers appraised the guideline using the AGREE II Global Rating Scale tool and all reviewers provided critical feedback. The guideline and algorithm (**Figure 1**[25]) were then piloted by 16 long-term care providers (9 physicians, 3 nurse practitioners, 4 pharmacists). We incorporated feedback and input from the pilot into the guideline and algorithm. The guideline was then sent to interest holders for review and endorsement.

Guideline updates

The panel will provide updates when new evidence emerges that might change recommendations. Our team will scope for new evidence annually after publication of the guideline.

Evaluation and monitoring criteria

Given the preference-sensitive nature of decisions around statin deprescribing, the guideline panel believed measures of shared decision making would be the most appropriate way to evaluate guideline implementation. Evaluation criteria could include patient, carer, and health care provider measures of shared decision making, such as satisfaction with treatment decisions, confidence in decisions, or perceptions around whether shared decision making occurred.[64]

Other guidelines

Cardiovascular disease prevention guidelines generally provide limited or no guidance around statin deprescribing in older adults.[12] Some contemporary guidelines do make recommendations related to deprescribing.[13,16] Our recommendations generally align with other guidelines making recommendations around statin discontinuation. The PEER simplified lipid guideline 2023 update makes a strong recommendation against stopping statins or reducing the dose just because patients are 75 years of age and older.[13] The 2018 American Heart Association–ACC guideline on management of blood cholesterol levels suggests deprescribing may be reasonable for older adults when risks outweigh meaningful benefit[16] (eg, functional decline, frailty, or reduced life expectancy). The 2022 ACC Expert Consensus Decision Pathway advocates for individualized, shared decisions around cardiovascular preventive therapy,[48] suggesting that among those at the end of life, deprescribing may be considered. The Screening Tool of Older Persons Prescriptions in Frail adults with limited life expectancy[65] considers statins as potentially inappropriate in people with end-stage irreversible pathologies, poor 1-year survival prognosis, severe functional or cognitive impairment, or in situations where symptom control is a priority rather than prevention of disease progression.

Gaps in knowledge

The main gap is the lack of high-certainty clinical evidence on the benefits and harms of statin discontinuation compared with continuation, particularly outside of the end-of-life context. Such evidence should come from a double-blind RCT in appropriately selected individuals (ie, persons where the benefits and harms of continuing statins are less certain, such as frail older adults and persons ≥80 years of age taking statins for primary prevention). An ongoing RCT on statin discontinuation among persons 80 years of age and older treated for primary prevention will provide insight to guide decisions.[66] More evidence on whether frailty or multimorbidity modifies statin-related outcomes would also be helpful for decision making. Data from ongoing RCTs on statin initiation among healthy older adults (Statins in Reducing Events in the Elderly[67] and Pragmatic Evaluation of Events and Benefits of Lipid Lowering in Older Adults[68]) will better inform decisions around statin therapy in this population, although the issue of frailty will not be addressed.

Conclusion

People often continue to take statins for many years. While a statin may have been reasonable and appropriate when started, people's health and function often change as they age, necessitating reassessment. Deprescribing involves having a conversation about ongoing medication use. Our guideline synthesizes available evidence on statin deprescribing to support clinicians and patients in making decisions.

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Contributors

All authors contributed to conception and drafting of the guideline, and preparation of the manuscript for submission.

Competing interests

Dr Arden R. Barry reports an honorarium from *Pharmacy Practice + Business* magazine and the American College of Clinical Pharmacy for article writing, and from RxFiles and the Canadian Society of Hospital Pharmacists for speaking engagements. **Dr Celeste Fung** reports an honorarium from the Ontario Centres for Learning, Research & Innovation in Long-Term Care for serious illness conversation training. **Dr Dar Dowlatshahi** declares he is Site Principal Investigator for the SATURN cerebral hemorrhage statin discontinuation clinical trial (NCT03936361). **Dr Lisa M. McCarthy** reports research grants related to deprescribing from the Canadian Institutes of Health Research (CIHR) and the University of Toronto. Additional research support from Ontario Centres for Learning, Research & Innovation in Long-Term Care at Bruyère Health Research Institute and Health Canada. **Dr Lise M. Bjerre** declares that she holds the University of Ottawa and Institut du Savoir Montfort Chair in Family Medicine, jointly funded by the University of Ottawa Department of Family Medicine, the Institut du Savoir Montfort, and the Fondation Montfort; **Dr Bjerre** also receives clinical income for the practice of community-based comprehensive family medicine from the Ontario Ministry of Health. **Dr Parag Goyal** has been supported by grants from the National Institutes of Health, National Institute on Aging (R03, K76), the American Heart Association (Innovative Project Award and Career Development Award), the Fan Fox & Leslie R. Samuels Foundation, and the New York Community Trust; he has received personal fees from Sensorum Health, Agepha Pharma, and Axon Therapies. **Dr Rita K. McCracken** reports research grants from CIHR and Providence Healthcare Foundation related to deprescribing. **Dr Wade Thompson** reports research grants related to deprescribing from the United States National Institute on Aging and Health Canada; salary support from Michael Smith Health Research BC related to deprescribing guideline development; and an honorarium from *Pharmacy Practice + Business* magazine for an article on deprescribing.

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