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# Strategies for Enhancing Cholesterol Lowering Medication Use Among Patients at High Cardiovascular Disease Risk: Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention



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# Strategies for Enhancing Cholesterol Lowering Medication Use Among Patients at High Cardiovascular Disease Risk: Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention

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## ABSTRACT

**Objective:** The objective of our study was to explore the perspectives of patients and general practitioners (GPs) regarding interventions to increase cholesterol lowering medication (or statin) use, including a proposed laboratory-based facilitated relay intervention.

**Design:** Qualitative descriptive study using interviews and focus groups for data collection, and thematic analysis for data analysis.

**Setting:** Primary care providers and patients in Calgary, Alberta, Canada.

**Participants:** 17 General Practitioners with primarily community-based, non-academic practices with at least 1 year of practice experience participated in semi-structured interviews. 14 patients at high risk of cardiovascular disease participated in focus groups.

**Main outcome measures:** Exploration of strategies that might be used to enhance the prescription of, and adherence to statin therapy for patients with statin-indicated conditions.

**Results:** GPs proposed a variety of interventions to improve statin use, including electronic record audit solutions, GP directed education and patient-oriented campaigns. Patients expressed that they may benefit from being provided access to their laboratory test results, as well as targeted education. Both parties provided positive feedback on the proposed laboratory-based facilitated relay intervention, while pointing out areas for improvement. Notably, GPs were concerned that the patient-directed component of the intervention might jeopardize their therapeutic relationship, and patients were concerned about accidental disclosure of their personal information. Important considerations for the design of facilitated relay messaging should include brevity, simplicity and the provision of contact information for questions.

**Conclusions:** GPs and patients described several suggestions for increasing statin use and welcomed the proposal of a laboratory-based facilitated relay strategy. These findings support further testing of this intervention which may enhance GPs' ability to successfully engage patients in cardiovascular risk reduction through statin therapy.


**Keywords**: focus groups, qualitative research, interviews, statins, facilitated relay

**Strengths & Limitations of this Study**

- This is a qualitative study, with relatively few participants – therefore we cannot say definitively if the views represented here represent those of all patients and prescribers.
- We sampled physician participants to the point of saturation, which means that we are confident the views represented here span the breadth of those held by physicians.
- The patient sample we recruited may not be representative of the broader population, as many of them had previously stated an interest in quality improvement and research.
- Given the context-dependent nature of qualitative data, the applicability of these findings to other settings is not certain.
- One of the major strengths of this study is the depth and richness of the qualitative data that were collected. By asking questions in an open-ended manner, we were able to record detailed accounts and opinions.

## INTRODUCTION

High cholesterol (or dyslipidemia) affects one-third of the general population and is a major risk factor for heart attacks and strokes(1-3). Several high quality randomized controlled trials show that people at high risk for cardiovascular disease (i.e. have a history of heart attack, stroke, diabetes, or chronic kidney disease) lower their risk of heart attack and death by reducing their cholesterol with a class of medications called statins. Despite over 30 years of clinical use, efficacy, safety and cost-effectiveness data (4, 5), only 23% to 55% of individuals who would benefit take this medication and fewer than half of individuals are treated to target cholesterol levels(4, 6-8). There is substantial unwanted variability in dyslipidemia management and health system intervention is required to promote equitable treatment (9, 10).

Evidence related to the management of other common cardiovascular risk factors, such as hypertension, provides insight into how this care gap may be closed(11-13). Integrated quality improvement strategies that target both patients and healthcare providers are more likely to achieve quality indicators than strategies which only target one aspect in isolation(12). One such strategy is facilitated relay. Facilitated relay is a quality improvement strategy whereby information about individual patients is sent directly to healthcare providers through a means other than the usual clinical encounter (14). This strategy has been shown to be effective in improving cardiovascular risk factors (12, 15), but it remains to be explored in the management of dyslipidemia. Despite this evidence, and the implementation of a number of quality improvement strategies for chronic disease management in our setting, facilitated relay remains among the least commonly used (16).

We therefore drew from behaviour change theory to develop a proposed facilitated relay intervention to increase statin uptake(17-19). Our proposed intervention uses our province's single laboratory system to identify individuals who have had their cholesterol levels measured, who are at high risk for cardiovascular disease and who are not filling statin prescriptions (i.e. identifying these individuals using validated algorithms). The general practitioner (GP) ordering the cholesterol levels and the patient, will then each receive a letter outlining the indication for treatment and the potential to benefit from statin therapy. The patient letter will encourage them to speak to their GP, and the GP letter will encourage them to make an appointment to discuss directly with the patient - both with the objective to initiate or renew statin prescriptions.

For an intervention to have the potential to maximum impact, it is important to have the input of key stakeholders prior to the application of any intervention with a qualitative study being suited to do so(20). This allows for the development of a higher quality intervention, rather than one that relies on physician feedback alone (21)**.** As such, the objective of our study was to explore the perspectives of patients GPs regarding interventions to increase cholesterol lowering medication (or statin) use, including a proposed laboratory-based facilitated relay intervention.

**METHODS:**

**Study Design**

We conducted a qualitative descriptive study(20) to explore patients' and general practitioners' perspectives on interventions to increase cholesterol lowering medication (or statin) use . Specifically, we sought directed feedback and perceptions on the acceptability of the proposed facilitated relay intervention from both patients and GPs(22). We used the consolidated criteria for reporting qualitative research (COREQ) as the reporting framework for this study(23).

**Participant Selection**

*General Practitioners:* We recruited general practitioners to participate in individual interviews, using a snowball sampling approach. First, we asked key stakeholders in areas of primary care, endocrinology, nephrology and cardiology affiliated with the university medical centre, to recommend community-based (non-academic) GPs to participate in the study. Individuals were then contacted by telephone and email with a formal invitation to participate. GPs who met the following criteria were enrolled: (1) currently practicing in community general practice settings; and, (2) have at least one year of experience as a GP. We sampled participants purposively based on several key demographic characteristics in order to achieve representation across a range of ages, genders and practice types.

*Patients:* We recruited patients who may potentially be recipients of the intervention (i.e. those at high risk of cardiovascular disease). Using a convenience sampling approach, we invited patients who were part of an established advisory panel and previously agreed to be contacted about research opportunities for study participation(24, 25). In addition, patients were recruited using poster advertisements placed throughout the academic health sciences centre and in various clinical care areas where care is provided to patients with diabetes, heart disease and kidney disease.

**Data Collection**

We developed an open-ended semi-structured interview guide (Appendix A) and focus group guide (Appendix B) based on a review of the literature and discussion with the research team. Sensitive and personal disclosures are more likely to occur with focus groups and as such we used this methodology with patient participants(26). However, we purposely used different data collection methods to offset low recruitment of community based GPs due to their competing clinical demands and importantly wanted to recruit from both urban and rural locales.

Interview and focus group guides were designed so that they initially asked study participants what they thought would be effective strategies or interventions to improve statin use (i.e. prescribing, patient use and adherence). After they had given their unprompted views, participants were then given a brief

explanation of facilitated relay, the proposed intervention, and shown a copy of the proposed intervention letter (Appendix C) and asked for their feedback.

All interviews were conducted in-person (in clinician offices) or via telephone, by a female trained research assistant (RCWL) with oversight by experienced study team members. None of the study team were acquainted with or involved in the clinical care of the participants. Physician interviews were continued until the point of theoretical saturation when no new information emerged from the interviews (27). Because the research objective was relatively focused, interviews were brief and lasted approximately 30 to 45 minutes. We convened two small focus groups of patients in our academic medical centre which each lasted approximately 90 minutes. No one but researchers (including 1 facilitator and 2 field-note takers) and participants were present. Data was collected from September 2018 to November 2018.

Interviews and focus group proceedings were digitally audio-recorded and transcribed verbatim by a professional transcriptionist. Field notes were taken to inform data analysis. All data were anonymized and stored securely. Signed informed consent was received from each study participant. Gift cards were provided to all participants. Ethics approval was granted from the University's Health Research Ethics Board.

**Data Analysis**

Analysis was completed using conventional qualitative content analysis(28), a method of interpreting interview data with the goal of describing the phenomenon of interest. Transcripts for the initial three interviews were reviewed by three team members (DC, RL and SB), with the objective of inductively establishing a preliminary coding template that was used for subsequent data analysis. All transcripts were then analyzed by two reviewers (DC and RL). Codes were generated from the interview data and systematically applied to identify themes and patterns. The process was iterative, reflexive, and interactive as continual data collection and analysis shaped each other[4]. For example, code titles or definitions identified based on earlier interviews were modified according to the data collected during subsequent interviews. The team met together to review the coding to elicit discussion about the coding strategy and attempted to achieve consensus to resolve coding discrepancies. NVivo 12 (Doncaster, Australia) qualitative data analysis software was used to facilitate the coding process.

**Patient and public involvement**

Patient partners and family members from the Libin Cardiovascular Institute's established patient and family member advisory group voiced that *prevention* was one of their top research priorities for cardiovascular health. This work is related to prevention of cardiovascular disease. Patients were included in focus groups.

**RESULTS**

We reached saturation after having completed 17 individual interviews with GPs (Table 1a). 4 physicians declined participation in the interview. The majority were women (88%) with 65% having graduated from medical school within the last ten years. All GPs spent more than 50% of their time in clinical practice, at urban centers within Primary Care Networks (PCNs). PCNs are networks of GPs that share interdisciplinary resources to enhance the delivery of primary care within geographical regions(29); they are associated with improved chronic disease care and outcomes(30).

**Table 1a.** Descriptive statistics for Primary Care Providers (n = 17).

| Physician characteristics | **Total** (%) |
|---|---|
| Age (years) | |
| < 40 | 13 (76) |
| 40 - 60 | 4 (24) |
| Gender | |
| Man | 2 (12) |
| Woman | 15 (88) |
| Years of primary care practice | |
| < 10 | 14 (83) |
| 10 – 20 | 3 (18) |
| Years since medical school graduation | |
| < 10 | 11 (65) |
| ≥10 | 6 (35) |
| Primary Care Network membership | |
| Yes | 15 (88) |
| No | 2 (12) |
| Location of primary care practice | |
| Urban | 13 (76) |
| Rural | 4 (24) |
| Focused practice interest | |
| Yes* | 9 (53) |
| No | 8 (47) |
| | |
| Clinical practice last 12 months | |
| Estimated number of patients at high CVD risk | |
| < 20 | 1 (6) |
| 20 to 99 | 7 (41) |
| ≥100 | 9 (53) |
| Use of endocrinology consultation services | |
| Yes | 5 (29) |
| No | 12 (71) |
| Use of cardiology consultation services | |
| Yes | 10 (59) |
| No | 7 (41) |
| Use of nephrology consultation services | |
| Yes | 3 (18) |
| No | 14 (82) |

* Focused practice, or special interest types: care of the elderly (n = 2), emergency medicine (n = 1), urgent care (n = 1), refugee medicine (n = 1), obstetrics (n = 2), indigenous health (n = 2), lactation (n = 1).

We hosted two focus groups for patients – one with 8 and another with 6 participants (Table 1b). There were no dominant members and all participants got equal opportunity to voice their opinions. There was a range of ages represented, with a similar distribution of men and women. Nearly all had a general practitioner and were also followed by medical specialist(s). The conditions represented in our patient group were diabetes, history of myocardial infarction and elevated cholesterol level; none reported a history of stroke, chronic kidney disease, or peripheral arterial disease.

**Table 1b.** Descriptive statistics for patient participants (n = 13).

| **Patient characteristics** | **Total** (%) |
|---|---|
| Age (years) | |
| < 40 | 2 (15) |
| 40 - 60 | 5 (39) |
| > 60 | 6 (46) |
| Gender | |
| Men | 6 (46) |
| Women | 7 (54) |
| Chronic condition qualifying as "high CVD risk" | |
| None/High cholesterol only | 3 (23) |
| Diabetes only | 6 (46) |
| Myocardial infarct (MI) only | 1 (8) |
| Diabetes & MI | 3 (23) |
| Has a primary care provider | |
| Yes | 12 (92) |
| No | 1 (8) |
| Followed by a medical specialist | |
| Yes | 10 (77) |
| No | 3 (23) |
| Self-reported awareness of high cholesterol levels | |
| Yes | 11 (85) |
| No | 2 (15) |
| Current use of statin medication | |
| Yes | 6 (46) |
| If not, had spoken with physicians about statins | 3 (23) |
| If not, had not spoken with physicians about statins | 4 (31) |

*Note one participant did not complete a demographic questionnaire

**General suggestions for potential interventions**

Several themes arose regarding interventions to improve statin use during the unprompted portion of the interviews (Table 2). General practitioner participants described that statin use may be improved by: (1) enhancing aspects of physician education to promote appropriate statin prescribing; and, (2) implementation of support tools to help physicians in decision-making and identification of patients for whom statins are indicated. In addition, patients suggested that having access to their own laboratory results may enable them to be more effective self-advocates.

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**Table 2.** General suggestions by general practitioners and patients to increase statin use

| | | |
|---|---|---|
| Providers | Treatment of specific Sub-populations | Patients with chronic kidney disease:<br>*"I struggle with the GFRs [glomerular filtration rate] – knowing when it would be safe, when it wouldn't be safe. I do get confused as to the dosing based on GFR.*<br><br>Patients who previously experienced side effects with statin(s):<br>*"I have one strategy but if somebody is still like 'no, it's completely not tolerable for me' then I don't know what the next step is after that."*<br><br>Elderly patients:<br>*"…getting some better understanding about the elderly. Are there any contraindications to starting on statin therapy? Is there one statin that may be more beneficial than another?"*<br><br>Patients with hypertriglyceridemia:<br>*"I always find it hard to know what to do with triglycerides… more education around how to manage those [patients]."* |
| | Treatment to Targets | *"Most people in my office are confused about what we are doing in terms of treating to the target of 2 mmol/L, because the cardiologist is still sending consults about that, but then we have these family medicine evidence-based groups saying that targets don't matter".*<br><br>*"I know the TOP [Towards Optimized Practice] guidelines don't necessarily correlate with CCS [Canadian Cardiovascular Society] guidelines, so there are several schools of thought"*<br><br>*"There's no real way to unify the guidelines, but to have an education session on why they're different and how to approach it so maybe you'll break down patient populations that fit better with one guideline versus another".* |
| | Preferred modality of Education | *"we have a lot of drug reps [representatives] coming to town, so it would be great to have more [education] that was not pharma, absolutely"*. |
| | EMR-based tools | *"One thing that would be helpful for me is if there was some automatic flag that came when I saw a patient that would alert to the fact that their treatment is not optimized for their conditions"*. |
| Patients | Laboratory Results | *"I would like to get a copy, in addition to the doctor. I can do with it what I want"*<br><br>*"It gets you questioning things so that you can come back to your doctor and say 'I saw these numbers, what does that mean? What do I need to do?'"* |
| | Enhanced education | *"What if somebody was going regularly to a lab, and a clinician sort of goes: 'How are you doing on this?"*. |

EMR: electronic medical record

*1)* General practitioner *education:*

Nearly all GPs highlighted that there are general areas of knowledge that could be bolstered in order to enhance statin use. One of the main content areas in which they sought enhanced education related to the treatment of specific patient sub-populations, in particular those with chronic kidney disease, prior statin side effects, elderly patients, and those with other concurrent lipid disorders (i.e. hypertriglyceridemia).

Whether providers should be treating patients to a specific cholesterol level was a major source of confusion. They frequently referenced receiving conflicting advice, including a contradiction in clinical practice guidelines(31), some of which advocate for a 'fire and forget' approach(5, 32), while Canadian(4) and European(33) specialist guidelines recommend a 'treat-to-target' approach(4).

Regarding the modality of education sessions, most preferred in-person education sessions delivered at their clinics and delivered by someone who did not have clear conflicts of interest with pharmaceutical companies. Many GPs also suggested the use of handouts, tools or algorithms to simplify their decision-making process.

*2)* General practitioner *tools*

In addition to education, several GPs suggested that the use of automated tools would facilitate their prescribing of statins. Most felt that they would benefit from optimizing the use of their electronic medical records (EMR) to 'flag' individuals who were at high cardiovascular risk or had elevated cholesterol levels. Other GPs spoke of wishing for a 'running list' of eligible patients, while some mentioned using an employee or contractor designated as a panel manager to perform these tasks.

*3) Patient results and information*

Many patients independently indicated that they would like to have access to their lipid test results, without needing to rely on this being conveyed to them by their general practitioner. Some patients also suggested that providing them with their own results might reduce the frequency of unnecessary follow-up visits; and as a result, alleviate related financial burden on the healthcare system. Doing so was also thought to help foster patient engagement with their GP. Patients also felt that having greater access to information about cholesterol and treatment might facilitate more patients being on statin therapy. Suggestions were made to deliver this through enhanced patient-facing materials (i.e. brochures), as well as pharmacists or lab technicians who were able to discuss results and treatment options.

**Feedback on the proposed facilitated relay intervention**

After briefing participants on the principles and practices of facilitated relay and showing them our preliminary documents for the intervention, we asked for feedback. Emerging themes were organized into four major categories: (1) general feedback and impression; (2) suggested changes; (3) intervention details; and, (4) workflow processing considerations.

*1) General feedback and impression*

General practitioners responded with strongly positive feedback (Table 3), which included that they found the information to be helpful and direct. They generally felt that the letter was written in a clear fashion and with a respectful tone. Several mentioned that the information provided them with reassurance and credibility in making recommendations to their patients.

GPs also voiced some questions and potential concerns after hearing about our proposed intervention. These concerns included whether the introduction of a facilitated relay intervention might increase their workload, lead to possible disclosure to patients of new diagnoses of conditions that qualified them as high risk (i.e. diabetes), and pose a threat to their therapeutic relationships with patients. In addition, logistical issues around how the letter will be best delivered to ordering providers and patients were raised as concerns.

Patients generally felt that bringing their facilitated relay letter to a scheduled appointment would be positive in their relationship by providing structure to the follow-up encounter, holding GPs to account, and enhancing patient-provider communication. Even though most were generally positive, some patients expressed concern about the facilitated relay intervention, including the possibility for privacy breaches and increasing patient anxieties.

*2) Suggested information to remove or add*

We asked GPs specifically what they would like to see changed in the preliminary materials shown. Almost unanimously, they suggested that the letter would be more appreciated if it were shortened to fit on one page. Several participants suggested removing the references, mention of clinical studies, and guideline citations to make it more reader-friendly. There was also a preference voiced for revising the introductory paragraphs to have direct relevance to individual patient(s):

> *"I'm going to read it for sure, but then when you start to read it, people might put it down and say 'oh this is a study intervention', [but] if you have the first thing at the very top: 'you know this person has been identified as being at risk' – then it's about the patient rather than being about the studies".*

A few GPs voiced opinions that specific additions could be made to improve the letter's utility. These suggestions included adding: information about health behavior change (*"the whole picture, as opposed to just medication");* adding contact information for a specialist; and details about how/why a particular individual was flagged as eligible for the facilitated relay intervention: *"It would be helpful if I got a name, condition and then the statin-indicated condition, and where the condition was pulled from"*.

Patient feedback was notable for also suggesting that the intervention provide contact information, in case they have further questions about interpreting their results:

> *"back that up with a helpline for somebody that doesn't know what the [results] mean"*. Similar to physicians, patients expressed a strong preference for brevity: *"If I have to go through 14 pages of information to figure out what that means, I'm sorry, I don't have time for that"*.

However, numerous patients also stressed the importance of not only providing results or diagnoses, but also giving some basic education and an action plan to follow.

*3) Intervention details*

In addition to general feedback, we also explicitly asked GPs whether they would prefer to receive information about their patient in the form of facilitated relay (individual letter for each patient identified) or 'audit and feedback' (summary report including a group of their patient panel). A summary list or report (audit and feedback) was preferred by roughly 2/3 of the general practitioners interviewed. Regarding receiving letters for each patient, participants stated:

*"this is going to get tiresome very quickly"*

*"Am I going to get this letter 20 times? I'm probably just going to read it once";*

*"[a list would] decrease paper burden, decrease the chance of it getting misplaced"*.

While the 'audit and feedback' approach was more popular, some GPs were clearly in favor of facilitated relay: *"I can't even think of the amount of work it would take to do it patient-specific. I'd love it. Sure go for it, if you have the means to do it, then why not?"*

We also asked pointedly about how providers would feel about receiving a follow-up reminder from the study team, if patients' had not filled the prescription as recommended in the initial letter. The response was split with roughly half of the general practitioners stating that a reminder would not be necessary.

Those who felt a reminder would be acceptable generally agreed that a 6 month window should be sufficient to ascertain whether or not the patient would have started on therapy: *"There are people that have a three-month wait list time, you may have to pick an interval more like six-months to appeal to the masses…"*.

Most patients felt that they would benefit from receiving a follow-up reminder. After considerable discussion amongst the groups, consensus was achieved that follow-up should not happen prior to four months, and possibly even as long as six months after the initial contact. One participant stated: *"close enough that I vaguely remember that I meant to do something with that, but not a few weeks later, [so] it's not irritating".*

We also asked patients if they had a preference for who had signed the letter. Most felt that having letters come from a local specialist in cardiology or endocrinology would be preferable to having them signed by another GP.

*4) Workflow processing considerations (*General practitioners *only)*

To each GP we asked specific details about how our intervention letter would be received in their offices and what would happen upon receipt. The majority stated that such a letter would be opened and processed by their front-desk staff. One participant clarified that the information on the envelope would determine who opened it: *"if it's addressed to me then it will come to me, if it has a patient name for me, then it goes through our document people [who file it]"*.

Once the letter has been opened, different offices employed a variety of different processes. In many practices, it would be given directly to the GP; while in others it would be scanned directly into a patient's file in an electronic medical record, yet in others, the hardcopy would be filed in a patient's chart.

In terms of the preferred delivery modality, most GPs felt that electronic delivery directly via the EMR platform would be the preferred method of receiving the intervention. However, a number still felt that conventional delivery via paper mail or fax would be preferable. Even those who expressed a preference for conventional delivery, many elaborated that such letters would often be scanned into a patient's electronic file: *"if it was to come by mail or fax, then they have to scan it onto the computer"*. A few GPs described systems which can do this process automatically: *"our office works with a new web system, so everything that comes in via the fax actually goes directly into the computer and they then allocate to the patient".*

**Table 3.** Positive and negative feedback on facilitated relay intervention from general practitioners and patients

| General Practitioners | | Patients | |
|---|---|---|---|
| **Positive** | | | |
| **Composition** | "Overall I thought it was worded quite well and was very clear"<br><br>"I think it's appropriate, it didn't take me very long to get through" | **Provides structure to interaction** | "My doctor would be okay with that. It gives them a little checklist of things to talk about" |
| **Tone** | "it's written in a way that doesn't make you feel stupid, I guess"<br><br>"it's good because [it's] not telling you to do this [start statin therapy], but telling you to have a conversation]." | **Enhances communication** | "I think that's good 'cause these doctors, some guys don't communicate." |
| **Credibility** | "it gives family physicians more confidence to do those things and know the specialists are behind them in that recommendation"<br><br>"there's so much information for people to sift through… if you can get valid information that's corroborated and consistent, that's helpful" | **Increases doctor accountability** | "I think it keeps them [doctors] honest as well. They should actually be proactive in terms of having that information already, but that's not always the case. So I don't have a problem with a patient having all their information at their disposal" |
| **Direct** | "it's a good idea… it tells you what to do, which is great. You don't have to look up the guideline every time"<br><br>"it's just one of those extra little reminders that takes the brain power out of the work you have to do day-to-day" | **Increases patient accountability** | "If [patients] are encouraged to work with their doctor to monitor your numbers, you have a bit of control as well as the doctor… like working together" |
| **Information** | "[side effects] are what people hear about in the news a lot, so it's very | **Provides peace of mind** | "It gives me a little peace of mind in that we've talked about all of the |

| | | | |
|---|---|---|---|
| | helpful to have some numbers around it, and strategies to address that"<br><br>"All the suggestions that you made are excellent. I'm reading through this and I'm like ' oh yeah, I didn't realize this' and ' this is something I can do for some of my patients'" | | things that are important and that should be covered… that we haven't left anything out" |
| | | **Negative** | |
| **Increased workload** | "I would caution against anything that causes more documents or more paperwork… there's already so much" | **Privacy concerns** | "You know what, my doctor isn't going to send it out to me, anyway. It's going to go on to a receptionist, who might pass it on to somebody else in the office, so there's no guarantee of privacy there"<br><br>"Privacy is always an issue. I mean it's like, the less information that's out there about you, the better off you are, period. I don't care what it is" |
| **Disclosing new diagnoses** | "my concern is that they get this information from a letter… my preference would be that it came straight to me" | **Difficulty interpreting results** | "Some people might know all the numbers and everything else, I don't. You give me a bunch of numbers, it means nothing to me. So unless the doctor explained it to me… I'd rather talk to my doctor" |
| **Therapeutic relationship** | "If the patient gets a letter that's like 'you need to be on a statin' and we already had a conversation that they didn't need a statin. That could cause some issues in the therapeutic relationship." | **Provoking Anxieties** | "There are people who are coming down with every disease known to man, so for someone like that, that kind of information would just send them off the deep-end, right?" |
| **Logistical concerns** | "What if a person gets a check from a walk-in clinic? My concern is then is that walk-in clinic docs are just going to ignore this letter"<br><br>"If it goes to the patient, sometimes you get lots of mail and they may just discard it" | **Lack of engagement** | "You mentioned mail outs and things like that… have they proven to be effective, though, 'cause how many people read them? How many people understand them? I don't think there would be a lot of point in it, 'cause I don't think people pay that much attention" |
| | | **Sense of intimidation** | "Some will [say] 'I can't talk to my doctor like that'. There will be some people who might be intimidated to initiate that conversation" |

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## DISCUSSION

In this study, both GPs and patients acknowledged that there is the potential to improve the prescription and use of statin therapy among those at high risk for cardiovascular disease. In unprompted questions, GPs acknowledged that there was a need for improved education on this topic, and that tools to help identify and track patients would be helpful. Patients also suggested that providing themselves with laboratory test results and information on treatment options may result in better medical care. When shown the proposed intervention, both groups were strongly supportive of the facilitated relay intervention. While there were clear benefits to the intervention, some potential downsides were raised from both GPs and patient perspectives. In general, all recipients would prefer letters to be succinct, yet contain high yield information and provide contact information where clarification could be sought.

Several strategies have been used to encourage GPs to be more engaged in ensuring that patients are started on statins appropriately(34). An educational audit and feedback intervention regarding dyslipidemia treatment in Italian primary care practices was shown to increase adherence to statins by approximately 10%(35). Improved communication and shared decision making, which are explicit goals of facilitated relay interventions, can improve patient adherence (36). While these and other studies have reviewed the clinical efficacy of quality improvement strategies (12), few have used detailed qualitative methods as we have done. One large qualitative study interviewed audit and feedback experts to generate hypotheses about the various factors that may contribute to the efficacy of such interventions(37). Others have used qualitative methods to highlight the barriers physicians face in encouraging adherence(38), but ours is unique in using such methods to design and develop an intervention to address these challenges.

The fact that participants suggested elements of our facilitated relay intervention in the unprompted portion of the interviews lends credibility and face validity to the proposed intervention. However, it is notable that while general practitioner felt they would benefit from having internal systems to monitor patients' records, none independently suggested a strategy mediated by an independent third party (such as facilitated relay or audit and feedback), as we have proposed. Investigators who wish to implement facilitated relay interventions to enhance adherence to medical therapies can use the findings of this study to help develop interventions that are more likely to be acceptable to both GPs and patients. One of the main findings is to ensure that any such information is brief and high yield, containing patient identifiers early to capture general practitioner's attention. Such interventions can be strengthened by incorporating education on controversial or little-known topics. Patients strongly preferred any correspondence to also contain direct suggestions or an action plan. Workflow and processing of these letters needs to be considered and interventions designed to be as minimally disruptive to clinical practice as possible – with most physicians preferring that it be embedded directly within the EMR; yet in healthcare settings (like ours) where there is marked heterogeneity in the use and type of EMRs, this may not be possible.

There are limitations to this study. Firstly, as in most qualitative studies, the number of participants was relatively small. This limitation is mitigated by the fact that physician interviews proceeded until the point of saturation. Patient data were not collected in this manner, and these themes may not be fully saturated and appreciate this as a limitation. Furthermore, the patient sample we recruited may not be representative of the broader population, as many of them had previously stated an interest in quality improvement and research. Secondly, given the context-dependent nature of qualitative data, the

applicability of these findings to other settings is not certain. Yet physicians face similar problems (i.e. time constraints, patient complexity and comorbidities and patient resistance to medical therapies) in numerous facets of medical care; therefore, it is conceivable that the findings of this study would apply to interactions between patients and GPs in other clinical settings. Due to time constraints of participants and researchers, member checking was not undertaken in this study. Finally, it is important to note that feedback was sought specifically about the proposed intervention. However, given the details reported, we feel that these findings are likely to be helpful to others proposing similar quality improvement interventions. One of the major strengths of this study is the depth and richness of the qualitative data that were collected. By asking questions in an open-ended manner, we were able to record detailed accounts and opinions. Another strength of this work is the fact that we also sought patient input into the development of this intervention, rather than relying on physician feedback alone.

Statin therapy has been demonstrated to effectively lower cholesterol and reduce the risk of cardiovascular events and death in individuals at high risk of cardiovascular disease. Despite this, they remain underused. There are patient, provider and system factors that contribute to the underuse of statins. Facilitated relay interventions hold promise as a potential method to address this important care gap. Our study sought perspectives of both healthcare providers and patients, which will be incorporated into intervention design to maximize acceptability. Insights gained from qualitative data will be used to improve the likelihood of success and achieve the desired clinical impact.

**Contributions**

All study team members contribute to the development of the research question. The study design was conceived by DJTC and SB. DJTC wrote the first draft of the study protocol. Data collection and analysis was completed by DJTC, RCWL and SB. All study team members contribute to the interpretation and contextualization of study findings. The first draft of the manuscript was written by DJTC. All study team members contributed substantively to further revisions of the manuscript and have consented to the publication of this version.

**Data Sharing**

No additional data available

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## Appendix A: Interview Guide for health care professional

Thank you for agreeing to participate in our interview today. We wish to discuss your experience in managing dyslipidemia (or high cholesterol) in order to better understand how we might help family physicians treat dyslipidemia (or high cholesterol). We have a proposed intervention and would like your assistance in how to enrich it.

### 1. Experience managing dyslipidemia

Please describe any challenges or difficulties that you experience in identifying and managing patients with dyslipidemia?

- Do you use any resources to guide you in the management of these patients?
    - Canadian Cardiovascular Society Guidelines
    - Diabetes Canada Guidelines
    - TOP guidelines

In addition to measuring a patient's lipids, what are some other parameters that you consider when assessing a patient for dyslipidemia, and how to optimally manage this condition?

### 2. Dyslipidemia-related practices

In your practice, do you find it helpful to quantify a patient's LDL-cholesterol or get a lipid panel?

If yes,

- Are there certain populations in whom you find this test most helpful?
- What is your chosen method/diagnostic test to do so?
    - Fasting or random lipid profile
        - Total cholesterol
        - HDL-cholesterol
        - LDL-cholesterol
    - ApoB
- How does this information change your clinical practice?
- How often do you repeat cholesterol testing for patients with with conditions that puts them at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease)?

If no,

- Why is it not particularly helpful?
    - Don't know which test to do
    - Don't know how to order it
    - Don't know in whom it is indicated

- Don't know what to do with the results

In thinking about your practice, what proportion of your patients with conditions that put them at high risk for cardiovascular disease (i.e. previous myocardial infarction, stroke, diabetes, and/or chronic kidney disease) have had their lipid profile assessed in the past 12 months?

What are some of the reasons this does not happen (in your practice and in others')?

- Didn't think it was indicated/for whom it is indicated
- Too many things to attend to
- Not perceived to be an important issue amongst all other disease/conditions that FPs manage
- Patient factors (doesn't go for test)

**3. Intervention**

If we wanted to increase the use of statins among people at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease), what might be done? What tools, resources, prompts may help facilitate increased treatment of dyslipidemia?

In your opinion, what type of educational intervention is most effective in disseminating clinical practice guidelines to family physicians? (i.e. conferences, local lectures, treatment recommendations on lab results).

We are considering the use of a facilitated relay strategy, where patient's information from Calgary Laboratory Services is used to identify those who have indications for statin therapy. Those who are not currently filling statin prescriptions at the pharmacy would receive a letter from the lab indicating that they may benefit from statins. They will be encouraged to bring this letter in to discuss this with you.

How would family physicians respond to receiving a letter from the lab prompting them to consider starting their patient on statin treatment?

- What would be the characteristics of such a letter that would make it more likely to succeed?
    - Short/Pictorial/Colorful

Would it be more helpful to have this information specific about one named patient, or rather have an audit of your entire practice that would indicate what proportion of eligible patients with statin-indicated conditions are currently being treated with statins? (i.e. Audit and Feedback)

How should such an intervention either on a specific patient or about your entire practice be received?

- Mail/Fax/EMR/combo

How would such an intervention be processed in your office?

- Who would open the envelope?
- What would they do with it? (give it to you, put it in the patient's chart)
- How likely would you be to see this information?

Who should this letter be coming from in order to have it received in the most positive way possible?

- A non-clinical academic researcher (Dr. XXXX)
- Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- An academic family doctor (Dr. Kerry McBrien)
- A respected community family doctor
- The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- Dr. Cello Tonelli, Associate Vice-President (Research) at the University of Calgary
- Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic Disease Management, Community and Rural for Alberta Health Services
- Someone else

Would it be helpful to receive a reminder or follow-up letter?

- How much later should this be sent, so as to be useful and not annoying?

If the intervention provided you with patient-oriented material about this subject, and asked you to share it with your patients, how would you feel about doing so?

- What content should be included in this patient-oriented material to enhance statin use?
- What format should this material be in? Electronic, hard-copy? How should it be delivered? Mail, email?
- Would you share it in a clinical setting?
- Would you be willing to mail it to patients directly?

Do you have any additional comments or suggestions for developing an intervention to increase the use statins in people at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease) in primary care?

Thank you for participating in today's interview. Using the information you provided, we will work on developing an intervention to improve the treatment of dyslipidemia in patients who are at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease)?

**Appendix B: Focus Group Guide for patients**

Thank you for agreeing to participate in our focus group today. There are many risk factors for heart attacks and stroke. Today we want to focus on one risk factor being high cholesterol. High cholesterol is a major risk factor for heart attacks, strokes and circulatory problems. There are no symptoms of high cholesterol and it is diagnosed by a lab test that your doctor would order. Importantly, we work for the University of Calgary and have no relationship with any medication companies.

We wish to discuss your experience in managing *cholesterol* with medications in order to better understand how we might help family physicians (*doctors)* treat high cholesterol.

1. **Experience with high cholesterol**

Think about the last time your doctor has sent you for a cholesterol test. Did your doctor talk to you about the results? Treatment? What kind of treatment was discussed (diet, exercise, a medication)?

Put yourself in the position of being told that you need to take a medication for your cholesterol. What factors would make you more likely to take it? What factors would make you not want to take it? Reasons, side effects, costs

- Would you use any resources to help you decide?
    - Doctor
    - Dietician
    - Internet
    - Family, friends

What would you think if your doctor told you that your cholesterol wasn't all that high, but because of your other health conditions she wanted to start you on a cholesterol lowering medication to reduce your risk of heart attack and stroke?

Do you think it would be helpful to get the actual result of your cholesterol level sent directly from the lab to you?

Currently, cancer screening programs send letters to patients about their results and next steps. What are your thoughts for something similar for high cholesterol?

What about information about recommended treatments and potential side effects? Would you find this to be invasive of your privacy (i.e. info from the lab about treatment and not your doctor)?

How would you feel about taking a letter with these recommendations to your doctor to discuss about a medication for high cholesterol?

How do you feel your doctor would respond to you bringing this information?

What things on the letter would make it helpful?

-length, colour, graphics,

Who should this letter be coming from in order to have it received in the most positive way possible?

- A non-clinical academic researcher (Dr. XXXX)
- Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- An academic family doctor (Dr. Kerry McBrien)
- A respected community family doctor
- The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic Disease Management, Community and Rural for Alberta Health Services
- Someone else

Would it be helpful to receive a reminder or follow-up letter?

- How much later should this be sent, so as to be useful and not annoying?

Do you have any additional comments or suggestions for developing an way to increase the use the treatment of people with high cholesterol?

## Appendix C: Facilitated Relay Letter

UNIVERSITY OF CALGARY

Date: XXXX-XX-XX

Dear Dr. [Physician Last Name],

RE: [Patient Name]

As you may recall, your Primary Care Network is involved in a study with the University of Calgary. This is an investigator-initiated study with public funding from the [*Canadian Institutes of Health Research*].

Dyslipidemia is a major risk factor for myocardial infarction and stroke[1-2]. As you know, in patients like [name], statins are indicated for their dyslipidemia because they are proven to reduce cardiovascular outcomes and mortality[3-4]. Because of numerous randomized controlled trials, guidelines recommend statin use in individuals with history of previous cardiovascular disease, diabetes, or chronic renal failure[5].

We are writing to you to consider initiating a statin in your patient. We know the importance of the therapeutic relationship that you have with your patients and know that we do not know your patient like you do. The purpose of this letter is to assist in you in your discussion with [name], about using a statin medication.

[Name] may not be taking a statin because of underestimation of their personal risk of cardiovascular disease, fear of side-effects, previous side-effects, or cost. If cost is a concern, compassionate programs are available for several statin medications. Please kindly call our study telephone number to assist in facilitating this.

The most common side effect from statins is muscle aches, and the frequency of statin-induced rhabdomyolysis is very rare (i.e. < 1 in 10,000 patients per year on statins)[6]. Studies suggest that there are several proven methods for managing people who have experienced muscle aches. For those unable to tolerate daily high intensity statins, some statin is still better than none, and the following strategies can be considered:

1. *Reducing the dose of statin*. i.e. Atorvastatin 10-20mg or Rosuvastatin 2.5-5mg[7].

2. *Trying a low potency statin medication.* Lower potency statins seem to be less strongly associated with muscle aches. Fluvastatin and Pravastatin were much less likely than Simvastatin and Atorvastatin to cause myalgia[8]. For your reference, maximum doses of these low potency statins, and their equivalencies are:

Pravastatin 80mg = Atorvastatin 20mg = Rosuvastatin 10mg
Fluvastatin XL 80mg = Atorvastatin 10mg = Rosuvastatin 5mg

3. *Reducing dose or lengthening administration interval.* Studies have demonstrated that greater than 70% of patients affected by myalgias were able to tolerate every other day administration with no recurrence of muscle symptoms[9].

There is a small chance that your patient may have been misclassified with a statin indicated condition. We sincerely apologize for this and would be most appreciative if you can call or fax us to let us know.

We welcome any questions or comments so please kindly contact us at 403-955-8327 (or fax 403-955-8249), for more information.

Sincerely,
Sonia Butalia MD, FRCPC, MSc and the study team

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# Strategies for Enhancing Cholesterol Lowering Medication Use Among Patients at High Cardiovascular Disease Risk: Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| **Domain 1: Research team and reflexivity** | | | |
| Personal Characteristics | | | |
| 1. | Interviewer/facilitator | Which author/s conducted the interview or focus group? | Line 137 |
| 2. | Credentials | What were the researcher's credentials? *E.g. PhD, MD* | Author information |
| 3. | Occupation | What was their occupation at the time of the study? | Line 137 |
| 4. | Gender | Was the researcher male or female? | Line 137 |
| 5. | Experience and training | What experience or training did the researcher have? | Line 137 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Relationship with participants | | | |
| 6. | Relationship established | Was a relationship established prior to study commencement? | Line 138-139 |
| 7. | Participant knowledge of the interviewer | What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research* | Not discussed |
| 8. | Interviewer characteristics | What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic* | Not discussed |
| **Domain 2: study design** | | | |
| Theoretical framework | | | |
| 9. | Methodological orientation and Theory | What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis* | Qualitative Description – Line 98 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Participant selection | | | |
| 10. | Sampling | How were participants selected? *e.g. purposive, convenience, consecutive, snowball* | GP – Snowball (line 106-107)<br>Patients – Convenience (line 116) |
| 11. | Method of approach | How were participants approached? e.*g. face-to-face, telephone, mail, email* | Line 106-120 |
| 12. | Sample size | How many participants were in the study? | Line 173<br>Line 186 |
| 13. | Non-participation | How many people refused to participate or dropped out? Reasons? | Line 176-177 |
| Setting | | | |
| 14. | Setting of data collection | Where was the data collected? e.*g. home, clinic, workplace* | Line 137<br>Line 142 |
| 15. | Presence of non-participants | Was anyone else present besides the participants and researchers? | Line 143 |
| 16. | Description of sample | What are the important characteristics of the sample? *e.g. demographic data, date* | Line 174-195 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Data collection | | | |
| 17. | Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Appendix A& B |
| 18. | Repeat interviews | Were repeat interviews carried out? If yes, how many? | No |
| 19. | Audio/visual recording | Did the research use audio or visual recording to collect the data? | Line 146 |
| 20. | Field notes | Were field notes made during and/or after the interview or focus group? | Line 143-144 |
| 21. | Duration | What was the duration of the interviews or focus group? | Line 142-143 |
| 22. | Data saturation | Was data saturation discussed? | Line 140 + limitations section |
| 23. | Transcripts returned | Were transcripts returned to participants for comment and/or correction? | No |
| **Domain 3: analysis and findings** | | | |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Data analysis | | | |
| 24. | Number of data coders | How many data coders coded the data? | Line 156-160 |
| 25. | Description of the coding tree | Did authors provide a description of the coding tree? | Line 157 |
| 26. | Derivation of themes | Were themes identified in advance or derived from the data? | Line 157-158 (inductive) |
| 27. | Software | What software, if applicable, was used to manage the data? | Line 164-165 |
| 28. | Participant checking | Did participants provide feedback on the findings? | Line 414-415 |
| Reporting | | | |
| 29. | Quotations presented | Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number* | In-text and Table 3 |
| 30. | Data and findings consistent | Was there consistency between the data presented and the findings? | Yes |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| 31. | Clarity of major themes | Were major themes clearly presented in the findings? | Results section |
| 32. | Clarity of minor themes | Is there a description of diverse cases or discussion of minor themes? | Table 2 & 3 |

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# Strategies for Enhancing the Initiation of Cholesterol Lowering Medication Among Patients at High Cardiovascular Disease Risk: A Qualitative Descriptive Exploration of Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention in Alberta, Canada



| | |
|---|---|
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# Strategies for Enhancing the Initiation of Cholesterol Lowering Medication Among Patients at High Cardiovascular Disease Risk: A Qualitative Descriptive Exploration of Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention in Alberta, Canada

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## ABSTRACT

**Objective:** The objective of our study was to explore the perspectives of patients and general practitioners (GPs) regarding interventions to increase initiation of cholesterol lowering medication (or statins), including a proposed laboratory-based facilitated relay intervention.

**Design:** Qualitative descriptive study using interviews and focus groups for data collection, and thematic analysis for data analysis.

**Setting:** Primary care providers and patients in Calgary, Alberta, Canada.

**Participants:** 17 General Practitioners with primarily community-based, non-academic practices with at least 1 year of practice experience participated in semi-structured interviews. 14 patients at high risk of cardiovascular disease participated in focus groups.

**Main outcome measures:** Exploration of strategies that might be used to enhance the prescription of, and adherence to statin therapy for patients with statin-indicated conditions.

**Results:** GPs proposed a variety of interventions to improve statin prescription, including electronic record audit solutions, GP directed education and patient-oriented campaigns. Patients expressed that they may benefit from being provided access to their laboratory test results, as well as targeted education. Both parties provided positive feedback on the proposed laboratory-based facilitated relay intervention, while pointing out areas for improvement. Notably, GPs were concerned that the patient-directed component of the intervention might jeopardize their therapeutic relationship, and patients were concerned about accidental disclosure of their personal information. Important considerations for the design of facilitated relay messaging should include brevity, simplicity and the provision of contact information for questions.

**Conclusions:** GPs and patients described several suggestions for increasing statin initiation and welcomed the proposal of a laboratory-based facilitated relay strategy. These findings support further testing of this intervention which may enhance GPs' ability to successfully engage patients in cardiovascular risk reduction through statin therapy.


**Keywords**: focus groups, qualitative research, interviews, statins, facilitated relay

**Strengths & Limitations of this Study**

- This is a qualitative study, with relatively few participants – therefore we cannot say definitively if the views represented here represent those of all patients and prescribers.
- We sampled physician participants to the point of saturation, which means that we are confident the views represented here span the breadth of those held by physicians.
- The patient sample we recruited may not be representative of the broader population, as many of them had previously stated an interest in quality improvement and research – and therefore may be attuned to the importance of preventive therapies more than other members of the general public. Additionally, this group was not sampled to saturation, as opposed to the physician participants.
- Given the context-dependent nature of qualitative data, the applicability of these findings to other settings is not certain.
- One of the major strengths of this study is the depth and richness of the qualitative data that were collected. By asking questions in an open-ended manner, we were able to record detailed accounts and opinions.

## INTRODUCTION

Vascular disease, including coronary artery disease, peripheral artery disease, and cerebrovascular disease, remains among the leading causes of mortality worldwide (1). A class of medications, HMG-CoA reductase inhibitors, commonly known as statins, have been proven to be effective for lowering the risk of vascular events (2). Individuals who have previously had vascular disease (i.e. secondary prevention) derive a greater absolute risk reduction from statins than those who have never had vascular disease (i.e. primary prevention) (3). There are some individuals who have never had vascular disease, such as those with diabetes or chronic kidney disease, who also have been shown in randomized controlled trials to benefit from therapy (4-6). Despite over 30 years of clinical use, efficacy, safety and cost-effectiveness data (7, 8), only 23% to 55% of individuals who would benefit take this medication and fewer than half of individuals are treated to target cholesterol levels(7, 9-11). There is substantial unwanted variability in dyslipidemia management and health system intervention is required to promote equitable treatment (12, 13). The lack of statin treatment for patients with indicated conditions results in significant excess morbidity and mortality. In Canada, specifically, if all patients with indications for statins were treated, this would result in nearly 40,000 cardiovascular events avoided (14). In the United States, 13% of cardiovascular deaths could be averted with perfect statin adherence among patients at high cardiovascular risk (15).

Physicians and patients face numerous barriers when it comes to prescribing and adhering to statin therapy, from the providers perspective this includes lack of knowledge, conflicting clinical guidelines, lack of systems to identify patients who should be taking statins (16). On the other hand, patients often experience or fear side effects or are simply averse to taking additional medications (16). Furthermore, patients that face social disadvantages such as low income, lack of health insurance, and minority race are more likely to not use statins (17). A large US-based survey found that side effects were common and that many former statin users were unsatisfied with the explanation provided by their prescriber about the importance of the medication (18). Providers need resources to help them provide this counselling to patients and to arm them with strategies to mitigate common statin side effects, like muscle aches (19).

There are clearly many challenges that lead to the observed clinical treatment gap for patients who have indications for statin treatment. However, some studies have shown that such treatment gaps, in related conditions like hypertension, can be closed using quality improvement strategies (20-22). Integrated quality improvement strategies that target both patients and healthcare providers are more likely to achieve quality indicators than strategies which only target one aspect in isolation (21). One such strategy is facilitated relay. Facilitated relay is a quality improvement strategy whereby information about individual patients is sent directly to healthcare providers through a means other than the usual clinical encounter (23). Despite the establishment and promotion of facilitated relay and other quality improvement strategies, there remain significant treatment gaps in hypertension (24) and other chronic conditions (25). Furthermore, while facilitated relay has been shown to be effective in improving a number of cardiovascular risk factors (21, 26), it remains among the least commonly used quality improvement strategies (27) and has not been explored in the management of dyslipidemia.

For an intervention to have the potential to maximum impact, it is important to have the input of key stakeholders prior to the application of any intervention with a qualitative study being suited to do so (28). This allows for the development of a higher quality intervention, rather than one that relies on physician feedback alone (29). As such, the objective of our study was to explore the perspectives of patients and GPs regarding interventions to increase cholesterol lowering medication (or statin) prescription, including specific feedback on a proposed laboratory-based facilitated relay intervention.

## METHODS:

### Study Design

We conducted a qualitative descriptive study (28) to explore patients' and general practitioners' (GPs) perspectives on interventions to increase initiation of statins for cardiovascular risk reduction and treatment of high cholesterol. In addition to generic thoughts on potential hypothetical interventions, we specifically sought directed feedback and perceptions on the acceptability of the proposed facilitated relay intervention from both patients and GPs (30). We used the consolidated criteria for reporting qualitative research (COREQ) as the reporting framework for this study (31).

### Proposed Intervention

We drew from behaviour change theory to develop a facilitated relay intervention to increase statin prescriptions (32-34) (Figure 1). Our proposed intervention partners with our province's single laboratory system to identify individuals who have elevated cholesterol levels, statin-indicated conditions, and who are not currently filling prescriptions for statins. Our lab system has access to province-wide administrative databases, including labs, pharmacy dispensations, and hospitalization data. For every elevated LDL-cholesterol level, the lab would have an algorithm that would check the patients' records for evidence of statin-indicated conditions (administrative markers of myocardial infarction, stroke, diabetes, or chronic kidney disease), and would then identify if they have recently filled a statin prescription. This is possible because of province-wide, linkable databases. For patients who are not filling statins, but who should be, their GP who had ordered the cholesterol levels and the patient, will then each receive a letter outlining the indication for treatment and the potential to benefit from statin therapy. The patient letter will encourage them to speak to their GP, and the GP letter will encourage them to make an appointment to discuss directly with the patient - both with the objective to initiate or renew statin prescriptions. We felt that it was important to include patients in the facilitated

relay to empower them in discussions with their GP and to enable shared decision-making (35), which has been demonstrated to improve adherence with statins (36).

**Participant Recruitment**

*General Practitioners:* We recruited general practitioners to participate in individual interviews, using a snowball sampling approach. First, we asked key stakeholders in areas of primary care, endocrinology, nephrology and cardiology affiliated with the university medical centre, to recommend community-based (non-academic) GPs to participate in the study. Individuals were then contacted by telephone and email with a formal invitation to participate. GPs who met the following criteria were enrolled: (1) currently practicing in community general practice settings; and, (2) have at least one year of experience as a GP. We sampled participants purposively based on several key demographic characteristics in order to achieve representation across a range of ages, genders and practice types.

*Patients:* We recruited patients who would qualify as recipients of the proposed intervention. Specifically, we were interested in recruiting those at high risk of cardiovascular disease, who self-reported a prior history of high cholesterol, preferably with co-existing vascular disease (myocardial infarction, stroke or peripheral vascular disease), diabetes, or chronic kidney disease. Using a convenience sampling approach, we invited patients who were part of an established advisory panel and previously agreed to be contacted about research opportunities for study participation (37, 38). In addition, patients were recruited using poster advertisements placed throughout the academic health sciences centre and in various clinical care areas where care is provided to patients with diabetes, heart disease and kidney disease.

**Data Collection**

Data was collected from September 2018 to November 2018 using both qualitative semi-structured interviews (with GPs) and focus groups (with patients). We chose focus groups for patients as rich personal disclosures are more likely to occur in this setting than in individual interviews (39). However, we purposely used individually scheduled interviews to offset potential aversion to focus groups by community-based GPs due to their competing clinical demands. Furthermore, we wanted to recruit from both urban and rural locales which is more challenging to do in a focus group.

*Question Guides:* Both focus groups and interviews were guided by question guides (Appendix A & B) which were developed based on a review of the literature (40, 41) and discussion with the research team. These were designed so that they initially asked study participants what they thought would be effective strategies or interventions to improve statin uptake (i.e. prescribing, patient use and adherence). After they had given their unprompted views, participants were then given a brief explanation of facilitated relay, the specifics of the proposed intervention (Figure 1), and they were shown a copy of the proposed intervention letter for GPs (Appendix C). After briefing participants on the principles and practices of facilitated relay and showing them our preliminary documents for the intervention, we asked for feedback. They were then asked for their specific feedback on this intervention.

*Provider Interviews:* All interviews were conducted in-person (in clinician offices) or via telephone, by a female trained research assistant (RCWL) with oversight by experienced study team members. Physician interviews were continued until the point of theoretical saturation when no new information emerged

from the interviews (42). Because the research objective was relatively focused, interviews were brief and lasted approximately 30 to 45 minutes.

*Patient Focus Groups:* None of the study team were acquainted with or involved in the clinical care of the patients who participated. We convened two focus groups in our academic medical centre which each lasted approximately 90 minutes. No one but researchers (including 1 facilitator and 2 field-note takers) and participants were present. Focus group facilitators tried to ensure that there were no dominant members and provide all participants with equal opportunity to voice their opinions.

Interviews and focus group proceedings were digitally audio-recorded and transcribed verbatim by a professional transcriptionist. Field notes were taken to inform data analysis. All data were anonymized and stored securely. Signed informed consent was received from each study participant. Gift cards were provided to all participants. Ethics approval was granted from the University's Health Research Ethics Board.

**Data Analysis**

Analysis was completed using conventional qualitative content analysis (43), a method of interpreting interview data with the goal of describing the phenomenon of interest. Transcripts for the initial three interviews were reviewed by three team members (DC, RL and SB), with the objective of inductively establishing a preliminary coding template that was used for subsequent data analysis. All transcripts were then analyzed by two reviewers (DC and RL). Codes were generated from the interview data and systematically applied to identify themes and patterns. The process was iterative, reflexive, and interactive as continual data collection and analysis shaped each other. For example, code titles or definitions identified based on earlier interviews were modified according to the data collected during subsequent interviews. The team met together to review the coding to elicit discussion about the coding strategy and attempted to achieve consensus to resolve coding discrepancies. NVivo 12 (Doncaster, Australia) qualitative data analysis software was used to facilitate the coding process.

**Patient and public involvement**

Patient partners and family members from the Libin Cardiovascular Institute's established patient and family member advisory group (44) voiced that *prevention* was one of their top research priorities for cardiovascular health. This work is related to prevention of cardiovascular disease. Patients were included in focus groups.

**RESULTS**

In total, we eventually reached out to 27 GPs to invite them to participate, 4 declined to participate, 3 didn't respond to the invitation, 19 were scheduled for interviews, with 2 cancelling. We reached saturation after having completed 17 individual GP interviews (Table 1a). The majority were women (88%) with 65% having graduated from medical school within the last ten years. All GPs spent more than 50% of their time in clinical practice, most were in urban centers within Primary Care Networks (PCNs). PCNs are networks of GPs that share interdisciplinary resources to enhance the delivery of primary care within geographical regions(45); they are associated with improved chronic disease care and outcomes(46).

**Table 1a.** Descriptive statistics for General Practitioners (n = 17).

| Physician characteristics | **Total** (%) |
|---|---|
| Age (years) | |
| < 40 | 13 (76) |
| 40 - 60 | 4 (24) |
| Gender | |
| Man | 2 (12) |
| Woman | 15 (88) |
| Years of primary care practice | |
| < 10 | 14 (83) |
| 10 – 20 | 3 (18) |
| Years since medical school graduation | |
| < 10 | 11 (65) |
| ≥10 | 6 (35) |
| Primary Care Network membership | |
| Yes | 15 (88) |
| No | 2 (12) |
| Location of primary care practice | |
| Urban | 13 (76) |
| Rural | 4 (24) |
| Focused practice interest | |
| Yes* | 9 (53) |
| No | 8 (47) |
| | |
| Clinical practice last 12 months | |
| Estimated number of patients at high CVD risk | |
| < 20 | 1 (6) |
| 20 to 99 | 7 (41) |
| ≥100 | 9 (53) |
| Use of endocrinology consultation services | |
| Yes | 5 (29) |
| No | 12 (71) |
| Use of cardiology consultation services | |
| Yes | 10 (59) |
| No | 7 (41) |
| Use of nephrology consultation services | |
| Yes | 3 (18) |
| No | 14 (82) |
| | |
| Proportion of patients who would be considered high risk on the basis of cardiovascular risk factors (n=14) | Mean: 32%<br>Range 10-75% |
| | |
| Proportion of high-risk patients who have a current LDL-level on file (n=9) | Mean: 82%<br>Range 70-90% |

* Focused practice, or special interest types: care of the elderly (n = 2), emergency medicine (n = 1), urgent care (n = 1), refugee medicine (n = 1), obstetrics (n = 2), indigenous health (n = 2), lactation (n = 1).

Our patient focus groups had 8 and 6 participants, respectively (Table 1b). There was a range of ages represented among patients, with a similar number of men and women. Nearly all had a general practitioner and were also followed by medical specialist(s). The conditions represented in our patient group were diabetes, history of myocardial infarction and elevated cholesterol level; none reported a history of stroke, chronic kidney disease, or peripheral arterial disease.

**Table 1b.** Descriptive statistics for patient participants based on self-report (n = 14).

| **Patient characteristics** | **Total** (%) |
|---|---|
| Age (years) | |
| < 40 | 2 (15) |
| 40 - 60 | 5 (39) |
| > 60 | 6 (46) |
| Gender | |
| Men | 6 (46) |
| Women | 7 (54) |
| Chronic condition qualifying as "high CVD risk" | |
| High cholesterol only | 3 (23) |
| Diabetes only | 6 (46) |
| Myocardial infarct (MI) only | 1 (8) |
| Diabetes & MI | 3 (23) |
| Has a primary care provider | |
| Yes | 12 (92) |
| No | 1 (8) |
| Followed by a medical specialist | |
| Yes | 10 (77) |
| No | 3 (23) |
| Self-reported awareness of high cholesterol levels | |
| Yes | 11 (85) |
| No | 2 (15) |
| Current use of statin medication | |
| Yes | 6 (46) |
| If not, had spoken with physicians about statins | 3 (23) |
| If not, had not spoken with physicians about statins | 4 (31) |

*Note one participant did not complete a demographic questionnaire

**General suggestions for potential interventions**

Several themes arose regarding interventions to improve statin initiation during the unprompted portion of the interviews (Table 2). General practitioner participants described that statin prescribing may be improved by: (1) enhancing aspects of physician education to promote appropriate statin prescribing; and, (2) implementation of support tools to help physicians in decision-making and identification of patients for whom statins are indicated. In addition, patients suggested that having access to their own laboratory results may enable them to be more effective self-advocates.

| **Table 2.** General suggestions by general practitioners and patients to increase initiation of statins | | |
|---|---|---|
| Providers | Treatment of specific Sub-populations | Patients with chronic kidney disease:<br>*"I struggle with the GFRs [glomerular filtration rate] – knowing when it would be safe, when it wouldn't be safe. I do get confused as to the dosing based on GFR."* (GP-05)<br><br>Patients who previously experienced side effects with statin(s):<br>*"I have one strategy but if somebody is still like 'no, it's completely not tolerable for me' then I don't know what the next step is after that."* (GP-13)<br><br>Elderly patients:<br>*"…getting some better understanding about the elderly. Are there any contraindications to starting on statin therapy? Is there one statin that may be more beneficial than another?"* (GP-10)<br><br>Patients with hypertriglyceridemia:<br>*"I always find it hard to know what to do with triglycerides… more education around how to manage those [patients]."* (GP-15) |
| | Treatment to Targets * | *"Most people in my office are confused about what we are doing in terms of treating to the target of 2 mmol/L, because the cardiologist is still sending consults about that, but then we have these family medicine evidence-based groups saying that targets don't matter".* (GP-02)<br><br>*"I know the TOP [Towards Optimized Practice] guidelines don't necessarily correlate with CCS [Canadian Cardiovascular Society] guidelines, so there are several schools of thought".* (GP-09)<br><br>*"There's no real way to unify the guidelines, but to have an education session on why they're different and how to approach it so maybe you'll break down patient populations that fit better with one guideline versus another".* (GP-08) |
| | Preferred modality of Education | *"we have a lot of drug reps [representatives] coming to town, so it would be great to have more [education] that was not pharma, absolutely"*. (GP-04) |
| | EMR-based tools | *"One thing that would be helpful for me is if there was some automatic flag that came when I saw a patient that would alert to the fact that their treatment is not optimized for their conditions"*. (GP-06) |
| Patients | Laboratory Results | *"I would like to get a copy, in addition to the doctor. I can do with it what I want"* (Pt-09)<br><br>*"It gets you questioning things so that you can come back to your doctor and say 'I saw these numbers, what does that mean? What do I need to do?'"* (Pt-02) |

| | | |
|---|---|---|
| | Enhanced education | *"What if somebody was going regularly to a lab, and a clinician sort of goes: 'How are you doing on this?"*. (Pt-08) |

EMR: electronic medical record

* Specialist guidelines, the 2016 Canadian Cardiovascular Society guideline (47) advocates that patients at high risk (based on risk calculators) or those with 'statin-indicated conditions' (defined as diabetes, chronic kidney disease, or preexisting vascular disease be treated with statin therapy to achieve a target LDL-c level of < 2.0 mmol/L. GP Guidelines, the 2015 TOP Alberta Guideline (48) encourages GPs to treat high risk patients with moderate-to-high intensity statins and should not repeat lipid levels, or attempt to treat to a fixed target.

*1)* General practitioner *education:*

Nearly all GPs highlighted that there are general areas of knowledge that could be bolstered in order to enhance statin prescription. One of the main content areas in which they sought enhanced education related to the treatment of specific patient sub-populations, in particular those with chronic kidney disease, prior statin side effects, elderly patients, and those with other concurrent lipid disorders (i.e. hypertriglyceridemia).

Whether providers should be treating patients to a specific cholesterol level was a major source of confusion. They frequently referenced receiving conflicting advice, including a contradiction in clinical practice guidelines(49), some of which advocate for a 'fire and forget' approach(8, 50), while Canadian(7) and European(51) specialist guidelines recommend a 'treat-to-target' approach(7).

Regarding the modality of education sessions, most preferred in-person education sessions delivered at their clinics and delivered by someone who did not have clear conflicts of interest with pharmaceutical companies. Many GPs also suggested the use of handouts, tools or algorithms to simplify their decision-making process.

*2)* General practitioner *tools*

In addition to education, several GPs suggested that the use of automated tools would facilitate their prescribing of statins. Most felt that they would benefit from optimizing the use of their electronic medical records (EMR) to 'flag' individuals who were at high cardiovascular risk or had elevated cholesterol levels. Other GPs spoke of wishing for a 'running list' of eligible patients, while some mentioned using an employee or contractor designated as a panel manager to perform these tasks.

*3) Patient results and information*

Many patients independently indicated that they would like to have access to their lipid test results, without needing to rely on this being conveyed to them by their general practitioner. Some patients also suggested that providing them with their own results might reduce the frequency of unnecessary follow-up visits; and as a result, alleviate related financial burden on the healthcare system. Doing so was also thought to help foster patient engagement with their GP. Patients also felt that having greater access to information about cholesterol and treatment might facilitate more patients being on statin therapy. Suggestions were made to deliver this through enhanced patient-facing materials (i.e. brochures), as well as pharmacists or lab technicians who were able to discuss results and treatment options. Further

information about patient education, shared decision-making, and clinical decision support tools are described in our other report from this work (16).

**Feedback on the proposed facilitated relay intervention**

Emerging themes regarding our proposed intervention were organized into four major categories: (1) general feedback and impression; (2) suggested changes; (3) intervention details; and, (4) workflow processing considerations.

*1) General feedback and impression*

General practitioners responded with strongly positive feedback (Table 3), which included that they found the information to be helpful and direct. They generally felt that the letter was written in a clear fashion and with a respectful tone. Several mentioned that the information provided them with reassurance and credibility in making recommendations to their patients.

GPs also voiced some questions and potential concerns after hearing about our proposed intervention. These concerns included whether the introduction of a facilitated relay intervention might increase their workload, lead to possible disclosure to patients of new diagnoses of conditions that qualified them as high risk (i.e. diabetes), and pose a threat to their therapeutic relationships with patients. In addition, logistical issues around how the letter will be best delivered to ordering providers and patients were raised as concerns.

Patients generally felt that bringing their facilitated relay letter to a scheduled appointment would be positive in their relationship by providing structure to the follow-up encounter, holding GPs to account, and enhancing patient-provider communication. Even though most were generally positive, some patients expressed concern about the facilitated relay intervention, including the possibility for privacy breaches and increasing patient anxieties.

*2) Suggested information to remove or add*

We asked GPs specifically what they would like to see changed in the preliminary materials shown. Almost unanimously, they suggested that the letter would be more appreciated if it were shortened to fit on one page. Several participants suggested removing the references, mention of clinical studies, and guideline citations to make it more reader-friendly. There was also a preference voiced for revising the introductory paragraphs to have direct relevance to individual patient(s):

> *"I'm going to read it for sure, but then when you start to read it, people might put it down and say 'oh this is a study intervention', [but] if you have the first thing at the very top: 'you know this person has been identified as being at risk' – then it's about the patient rather than being about the studies".* (GP-16)

A few GPs voiced opinions that specific additions could be made to improve the letter's utility. These suggestions included adding: information about health behavior change (*"the whole picture, as opposed to just medication"* (GP-04)*);* adding contact information for a specialist; and details about how/why a particular individual was flagged as eligible for the facilitated relay intervention: *"It would be helpful if I got a name, condition and then the statin-indicated condition, and where the condition was pulled from"*. (GP-01)

Patient feedback was notable for also suggesting that the intervention provide contact information, in case they have further questions about interpreting their results:

> *"back that up with a helpline for somebody that doesn't know what the [results] mean"* (Pt-10). Similar to physicians, patients expressed a strong preference for brevity: *"If I have to go through 14 pages of information to figure out what that means, I'm sorry, I don't have time for that"* (Pt-07).

However, numerous patients also stressed the importance of not only providing results or diagnoses, but also giving some basic education and an action plan to follow.

*3) Intervention details*

In addition to general feedback, we also explicitly asked GPs whether they would prefer to receive information about their patient in the form of facilitated relay (individual letter for each patient identified) or 'audit and feedback' (summary report including a group of their patient panel). A summary list or report (audit and feedback) was preferred by roughly 2/3 of the general practitioners interviewed. Regarding receiving letters for each patient, participants stated:

> *"this is going to get tiresome very quickly"* (GP-05)

> *"Am I going to get this letter 20 times? I'm probably just going to read it once"* (GP-03)

> *"[a list would] decrease paper burden, decrease the chance of it getting misplaced"*. (GP-13)

While the 'audit and feedback' approach was more popular, some GPs were clearly in favor of facilitated relay: *"I can't even think of the amount of work it would take to do it patient-specific. I'd love it. Sure go for it, if you have the means to do it, then why not?"* (GP-10)

We also asked pointedly about how providers would feel about receiving a follow-up reminder from the study team, if patients' had not filled the prescription as recommended in the initial letter. The response was split with roughly half of the general practitioners stating that a reminder would not be necessary.

Those who felt a reminder would be acceptable generally agreed that a 6 month window should be sufficient to ascertain whether or not the patient would have started on therapy: *"There are people that have a three-month wait list time, you may have to pick an interval more like six-months to appeal to the masses…"*. (GP-13)

Most patients felt that they would benefit from receiving a follow-up reminder. After considerable discussion amongst the groups, consensus was achieved that follow-up should not happen prior to four months, and possibly even as long as six months after the initial contact. One participant stated: *"close enough that I vaguely remember that I meant to do something with that, but not a few weeks later, [so] it's not irritating".* (GP-17)

We also asked patients if they had a preference for who had signed the letter. Most felt that having letters come from a local specialist in cardiology or endocrinology would be preferable to having them signed by another GP.

*4) Workflow processing considerations (*General practitioners *only)*

To each GP we asked specific details about how our intervention letter would be received in their offices and what would happen upon receipt. The majority stated that such a letter would be opened and processed by their front-desk staff. One participant clarified that the information on the envelope would determine who opened it: *"if it's addressed to me then it will come to me, if it has a patient name for me, then it goes through our document people [who file it]"*. (GP-09)

Once the letter has been opened, different offices employed a variety of different processes. In many practices, it would be given directly to the GP; while in others it would be scanned directly into a patient's file in an electronic medical record, yet in others, the hardcopy would be filed in a patient's chart.

In terms of the preferred delivery modality, most GPs felt that electronic delivery directly via the EMR platform would be the preferred method of receiving the intervention. However, a number still felt that conventional delivery via paper mail or fax would be preferable. Even those who expressed a preference for conventional delivery, many elaborated that such letters would often be scanned into a patient's electronic file: *"if it was to come by mail or fax, then they have to scan it onto the computer"* (GP-11). A few GPs described systems which can do this process automatically: *"our office works with a new web system, so everything that comes in via the fax actually goes directly into the computer and they then allocate to the patient".* (GP-11)

**Table 3.** Positive and negative feedback on facilitated relay intervention from general practitioners and patients

| General Practitioners | | Patients | |
|---|---|---|---|
| **Positive** | | | |
| **Composition** | "Overall I thought it was worded quite well and was very clear" (GP-08)<br><br>"I think it's appropriate, it didn't take me very long to get through" (GP-16) | **Provides structure to interaction** | "My doctor would be okay with that. It gives them a little checklist of things to talk about". (Pt-05) |
| **Tone** | "it's written in a way that doesn't make you feel stupid, I guess" (GP-11)<br><br>"it's good because [it's] not telling you to do this [start statin therapy], but telling you to have a conversation]." (GP-17) | **Enhances communication** | "I think that's good 'cause these doctors, some guys don't communicate." (Pt-13) |
| **Credibility** | "it gives family physicians more confidence to do those things and know the specialists are behind them in that recommendation" (GP-02) | **Increases doctor accountability** | "I think it keeps them [doctors] honest as well. They should actually be proactive in terms of having that information already, but that's not always the case. So I don't have a problem with a patient having all |

| | | | |
|---|---|---|---|
| | "there's so much information for people to sift through… if you can get valid information that's corroborated and consistent, that's helpful" (GP-15) | | their information at their disposal". (Pt-14) |
| **Direct** | "it's a good idea… it tells you what to do, which is great. You don't have to look up the guideline every time" (GP-04)<br><br>"it's just one of those extra little reminders that takes the brain power out of the work you have to do day-to-day" (GP-06) | **Increases patient accountability** | "If [patients] are encouraged to work with their doctor to monitor your numbers, you have a bit of control as well as the doctor… like working together". (Pt-03) |
| **Information** | "[side effects] are what people hear about in the news a lot, so it's very helpful to have some numbers around it, and strategies to address that" (GP-09)<br><br>"All the suggestions that you made are excellent. I'm reading through this and I'm like ' oh yeah, I didn't realize this' and ' this is something I can do for some of my patients'" (GP-12) | **Provides peace of mind** | "It gives me a little peace of mind in that we've talked about all of the things that are important and that should be covered… that we haven't left anything out". (Pt-05) |
| **Negative** | | | |
| **Increased workload** | "I would caution against anything that causes more documents or more paperwork… there's already so much" (GP-16) | **Privacy concerns** | "You know what, my doctor isn't going to send it out to me, anyway. It's going to go on to a receptionist, who might pass it on to somebody else in the office, so there's no guarantee of privacy there" (Pt-05)<br><br>"Privacy is always an issue. I mean it's like, the less information that's out there about you, the better off you are, period. I don't care what it is" (Pt-07) |
| **Disclosing new diagnoses** | "my concern is that they get this information from a letter… my preference would be that it came straight to me" (GP-01) | **Difficulty interpreting results** | "Some people might know all the numbers and everything else, I don't. You give me a bunch of numbers, it means nothing to me. So unless the doctor explained it to me… I'd rather talk to my doctor" (Pt-07) |

| | | | |
|---|---|---|---|
| **Therapeutic relationship** | "If the patient gets a letter that's like 'you need to be on a statin' and we already had a conversation that they didn't need a statin. That could cause some issues in the therapeutic relationship." (GP-04) | **Provoking Anxieties** | "There are people who are coming down with every disease known to man, so for someone like that, that kind of information would just send them off the deep-end, right?" (Pt-05) |
| **Logistical concerns** | "What if a person gets a check from a walk-in clinic? My concern is then is that walk-in clinic docs are just going to ignore this letter" (MD-05)<br><br>"If it goes to the patient, sometimes you get lots of mail and they may just discard it" (MD-10) | **Lack of engagement** | "You mentioned mail outs and things like that… have they proven to be effective, though, 'cause how many people read them? How many people understand them? I don't think there would be a lot of point in it, 'cause I don't think people pay that much attention" (Pt-09) |
| | | **Sense of intimidation** | "Some will [say] 'I can't talk to my doctor like that'. There will be some people who might be intimidated to initiate that conversation" (Pt-03) |

## DISCUSSION

While statins have a more limited role in certain populations (low risk and those with limited life expectancy) (52, 53), they are important for the prevention of cardiovascular disease in patients who have previous atherosclerotic disease and in those with diabetes and kidney disease (4-6, 47). In this study, both GPs and patients acknowledged that there is the potential to improve the prescription and use of statin therapy among those at high risk for cardiovascular disease. In unprompted questions, GPs acknowledged that there was a need for improved physician education on this topic, and that tools to help identify and track patients would be helpful. Patients also suggested that providing themselves with laboratory test results and information on treatment options may result in better medical care, generally supporting our hypothesis that facilitating shared decision making was a key element of a novel intervention. When shown the proposed intervention, both groups were strongly supportive of the facilitated relay intervention. While there were clear benefits to the intervention, some potential downsides were raised from both GPs and patient perspectives. In general, all recipients would prefer letters to be succinct, yet contain high yield information and provide contact information where clarification could be sought.

A number of interventions have been attempted to address the problem of statin underuse. A number of patient-centered approaches have been tried with varying success (22). While active forms of education, like cognitive education and behavioural counselling seem to work (54), more passive forms of education are often unsuccessful at changing behaviour, as in the recent ISLAND trial which found their intervention, comprised of a mail and phone education strategy to encourage patients to take prescribed medication, had no impact on adherence (55). Others have found that multifaceted interventions focusing on enhancing care provision through team-based care may be effective at increasing statin adherence (56).

However, when trying to target the problem of low statin prescribing, interventions directed only at patients are not likely to work. An alternate approach is to facilitate GPs ability to identify and prescribe

statins, to those in whom they are appropriate (57), through audit and feedback or facilitated relay. An educational audit and feedback intervention regarding dyslipidemia treatment in Italian primary care practices was shown to increase adherence to statins by approximately 10% (58). Improved communication and shared decision making, which are explicit goals of facilitated relay interventions, can improve patient adherence (59). While these and other studies have reviewed the clinical efficacy of quality improvement strategies (21), few have used detailed qualitative methods as we have done. One large qualitative study interviewed audit and feedback experts to generate hypotheses about the various factors that may contribute to the efficacy of such interventions (60). Others have used qualitative methods to highlight the barriers physicians face in encouraging adherence (61), but ours is unique in using such methods to design and develop an intervention to address these challenges. Finally, we also appreciate that as much as there is underuse of statins, there is also overuse, for example, in people with short life expectancy. Perhaps interventions to increase initiation may also include a component that conveys statin benefits are measured in years rather than months.

The fact that participants suggested elements of our facilitated relay intervention in the unprompted portion of the interviews lends credibility and face validity to the proposed intervention. However, it is notable that while GPs felt they would benefit from having internal systems to monitor patients' records, none independently suggested a strategy mediated by an independent third party (such as facilitated relay or audit and feedback), as we have proposed. Investigators who wish to implement facilitated relay interventions to enhance adherence to medical therapies can use the findings of this study to help develop interventions that are more likely to be acceptable to both GPs and patients. One of the main findings is to ensure that any such information is brief and high yield, containing patient identifiers early to capture general practitioner's attention. Such interventions can be strengthened by incorporating education on controversial or little-known topics. Patients strongly preferred any correspondence to also contain direct suggestions or an action plan. Workflow and processing of these letters needs to be considered and interventions designed to be as minimally disruptive to clinical practice as possible – with most physicians preferring that it be embedded directly within the EMR; yet in healthcare settings (like ours) where there is marked heterogeneity in the use and type of EMRs, this may not be possible.

There are limitations to this study. Firstly, as in most qualitative studies, the number of participants was relatively small. This limitation is mitigated by the fact that physician interviews proceeded until the point of saturation. Patient data were not collected in this manner, and these themes may not be fully saturated and we appreciate this as a limitation. Furthermore, the patient sample we recruited may not be representative of the broader population, as many of them had previously stated an interest in quality improvement and research and therefore may be attuned to the importance of preventive therapies more than other members of the general public. Secondly, given the context-dependent nature of qualitative data, the applicability of these findings to other settings is not certain. Yet physicians face similar problems (i.e. time constraints, patient complexity and comorbidities and patient resistance to medical therapies) in numerous facets of medical care; therefore, it is conceivable that the findings of this study would apply to interactions between patients and GPs in other clinical settings. Due to time constraints of participants and researchers, member checking was not undertaken in this study. Finally, it is important to note that feedback was sought specifically about the proposed intervention. However, given the details reported, we feel that these findings are likely to be helpful to others proposing similar quality improvement interventions. One of the major strengths of this study is the depth and richness of the qualitative data that were collected. By asking questions in an open-ended manner, we were able to record detailed accounts and opinions. Another strength of this work is the

fact that we also sought patient input into the development of this intervention, rather than relying on physician feedback alone.

Statin therapy has been demonstrated to effectively lower cholesterol and reduce the risk of cardiovascular events and death in individuals at high risk of cardiovascular disease. Despite this, they remain underused. There are patient, provider and system factors that contribute to the underuse of statins. Facilitated relay interventions hold promise as a potential method to address this important care gap. Our study sought perspectives of both healthcare providers and patients, which will be incorporated into intervention design to maximize acceptability. Insights gained from qualitative data will be used to improve the likelihood of success and achieve the desired clinical impact. The insights about these interventions are also likely to be of interest to many researchers and clinicians who are considering and designing provider- and/or patient-facing interventions to improve the uptake of preventive medications.

**Contributions**

DJTC, RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, SB collaborated to develop the research question and methods. The study design was conceived by DJTC and SB. DJTC wrote the first draft of the study protocol. Data collection and analysis was completed by DJTC, RCWL and SB. KAM, TJA, HQ, AACL, GC, ML, and CN contributed to the interpretation and contextualization of study findings. The first draft of the manuscript was written by DJTC. RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, and SB contributed substantively to further revisions of the manuscript and have consented to the publication of this version.

**Data Availability Statement**

No additional data available. Given that qualitative data are not deidentified and tell individuals' personal stories, data cannot be shared beyond the scope of this project, as per our research ethics board.

**Competing Interest Statement**

DC, RL, KAM, AL, TA, HQ, GC, SB – none. CN is a director of a private laboratory that does not currently offer testing in the jurisdiction under study.

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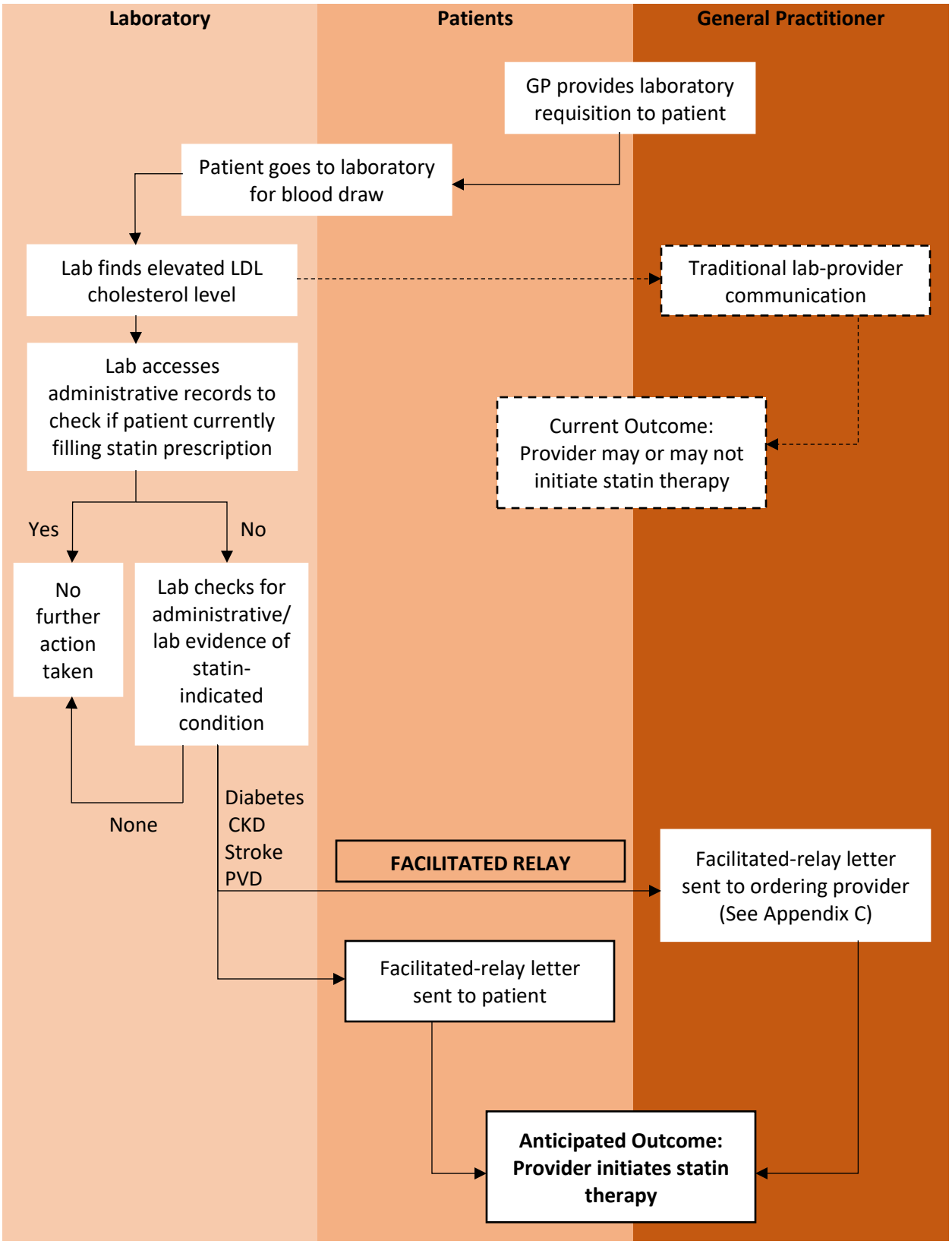


**Figure 1: Laboratory-Based Facilitated-Relay Intervention**
Dashed lines: traditional interface between lab and ordering provider

**Appendix A: Interview Guide for health care professional**

Thank you for agreeing to participate in our interview today. We wish to discuss your experience in managing dyslipidemia (or high cholesterol) in order to better understand how we might help family physicians treat dyslipidemia (or high cholesterol). We have a proposed intervention and would like your assistance in how to enrich it.

**1. Experience managing dyslipidemia**

Please describe any challenges or difficulties that you experience in identifying and managing patients with dyslipidemia?

- Do you use any resources to guide you in the management of these patients?
    - Canadian Cardiovascular Society Guidelines
    - Diabetes Canada Guidelines
    - TOP guidelines

In addition to measuring a patient's lipids, what are some other parameters that you consider when assessing a patient for dyslipidemia, and how to optimally manage this condition?

**2. Dyslipidemia-related practices**

In your practice, do you find it helpful to quantify a patient's LDL-cholesterol or get a lipid panel?

If yes,

- Are there certain populations in whom you find this test most helpful?
- What is your chosen method/diagnostic test to do so?
    - Fasting or random lipid profile
        - Total cholesterol
        - HDL-cholesterol
        - LDL-cholesterol
    - ApoB
- How does this information change your clinical practice?
- How often do you repeat cholesterol testing for patients with with conditions that puts them at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease)?

If no,

- Why is it not particularly helpful?
    - Don't know which test to do
    - Don't know how to order it
    - Don't know in whom it is indicated

- Don't know what to do with the results

In thinking about your practice, what proportion of your patients with conditions that put them at high risk for cardiovascular disease (i.e. previous myocardial infarction, stroke, diabetes, and/or chronic kidney disease) have had their lipid profile assessed in the past 12 months?

What are some of the reasons this does not happen (in your practice and in others')?

- Didn't think it was indicated/for whom it is indicated
- Too many things to attend to
- Not perceived to be an important issue amongst all other disease/conditions that FPs manage
- Patient factors (doesn't go for test)

**3. Intervention**

If we wanted to increase the use of statins among people at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease), what might be done? What tools, resources, prompts may help facilitate increased treatment of dyslipidemia?

In your opinion, what type of educational intervention is most effective in disseminating clinical practice guidelines to family physicians? (i.e. conferences, local lectures, treatment recommendations on lab results).

We are considering the use of a facilitated relay strategy, where patient's information from Calgary Laboratory Services is used to identify those who have indications for statin therapy. Those who are not currently filling statin prescriptions at the pharmacy would receive a letter from the lab indicating that they may benefit from statins. They will be encouraged to bring this letter in to discuss this with you.

How would family physicians respond to receiving a letter from the lab prompting them to consider starting their patient on statin treatment?

- What would be the characteristics of such a letter that would make it more likely to succeed?
    - Short/Pictorial/Colorful

Would it be more helpful to have this information specific about one named patient, or rather have an audit of your entire practice that would indicate what proportion of eligible patients with statin-indicated conditions are currently being treated with statins? (i.e. Audit and Feedback)

How should such an intervention either on a specific patient or about your entire practice be received?

- Mail/Fax/EMR/combo

How would such an intervention be processed in your office?

- Who would open the envelope?
- What would they do with it? (give it to you, put it in the patient's chart)
- How likely would you be to see this information?

Who should this letter be coming from in order to have it received in the most positive way possible?

- A non-clinical academic researcher (Dr. XXXX)
- Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- An academic family doctor (Dr. Kerry McBrien)
- A respected community family doctor
- The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- Dr. Cello Tonelli, Associate Vice-President (Research) at the University of Calgary
- Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic Disease Management, Community and Rural for Alberta Health Services
- Someone else

Would it be helpful to receive a reminder or follow-up letter?

- How much later should this be sent, so as to be useful and not annoying?

If the intervention provided you with patient-oriented material about this subject, and asked you to share it with your patients, how would you feel about doing so?

- What content should be included in this patient-oriented material to enhance statin use?
- What format should this material be in? Electronic, hard-copy? How should it be delivered? Mail, email?
- Would you share it in a clinical setting?
- Would you be willing to mail it to patients directly?

Do you have any additional comments or suggestions for developing an intervention to increase the use statins in people at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease) in primary care?

Thank you for participating in today's interview. Using the information you provided, we will work on developing an intervention to improve the treatment of dyslipidemia in patients who are at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease)?

**Appendix B: Focus Group Guide for patients**

Thank you for agreeing to participate in our focus group today. There are many risk factors for heart attacks and stroke. Today we want to focus on one risk factor being high cholesterol. High cholesterol is a major risk factor for heart attacks, strokes and circulatory problems. There are no symptoms of high cholesterol and it is diagnosed by a lab test that your doctor would order. Importantly, we work for the University of Calgary and have no relationship with any medication companies.

We wish to discuss your experience in managing *cholesterol* with medications in order to better understand how we might help family physicians (*doctors)* treat high cholesterol.

1. **Experience with high cholesterol**

Think about the last time your doctor has sent you for a cholesterol test. Did your doctor talk to you about the results? Treatment? What kind of treatment was discussed (diet, exercise, a medication)?

Put yourself in the position of being told that you need to take a medication for your cholesterol. What factors would make you more likely to take it? What factors would make you not want to take it? Reasons, side effects, costs

- Would you use any resources to help you decide?
    - Doctor
    - Dietician
    - Internet
    - Family, friends

What would you think if your doctor told you that your cholesterol wasn't all that high, but because of your other health conditions she wanted to start you on a cholesterol lowering medication to reduce your risk of heart attack and stroke?

Do you think it would be helpful to get the actual result of your cholesterol level sent directly from the lab to you?

Currently, cancer screening programs send letters to patients about their results and next steps. What are your thoughts for something similar for high cholesterol?

What about information about recommended treatments and potential side effects? Would you find this to be invasive of your privacy (i.e. info from the lab about treatment and not your doctor)?

How would you feel about taking a letter with these recommendations to your doctor to discuss about a medication for high cholesterol?

How do you feel your doctor would respond to you bringing this information?

What things on the letter would make it helpful?

-length, colour, graphics,

Who should this letter be coming from in order to have it received in the most positive way possible?

- A non-clinical academic researcher (Dr. XXXX)
- Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- An academic family doctor (Dr. Kerry McBrien)
- A respected community family doctor
- The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic Disease Management, Community and Rural for Alberta Health Services
- Someone else

Would it be helpful to receive a reminder or follow-up letter?

- How much later should this be sent, so as to be useful and not annoying?

Do you have any additional comments or suggestions for developing an way to increase the use the treatment of people with high cholesterol?

## Appendix C: Facilitated Relay Letter

UNIVERSITY OF CALGARY

Date: XXXX-XX-XX

Dear Dr. [Physician Last Name],

RE: [Patient Name]

As you may recall, your Primary Care Network is involved in a study with the University of Calgary. This is an investigator-initiated study with public funding from the [*Canadian Institutes of Health Research*].

Dyslipidemia is a major risk factor for myocardial infarction and stroke[1-2]. As you know, in patients like [name], statins are indicated for their dyslipidemia because they are proven to reduce cardiovascular outcomes and mortality[3-4]. Because of numerous randomized controlled trials, guidelines recommend statin use in individuals with history of previous cardiovascular disease, diabetes, or chronic renal failure[5].

We are writing to you to consider initiating a statin in your patient. We know the importance of the therapeutic relationship that you have with your patients and know that we do not know your patient like you do. The purpose of this letter is to assist in you in your discussion with [name], about using a statin medication.

[Name] may not be taking a statin because of underestimation of their personal risk of cardiovascular disease, fear of side-effects, previous side-effects, or cost. If cost is a concern, compassionate programs are available for several statin medications. Please kindly call our study telephone number to assist in facilitating this.

The most common side effect from statins is muscle aches, and the frequency of statin-induced rhabdomyolysis is very rare (i.e. < 1 in 10,000 patients per year on statins)[6]. Studies suggest that there are several proven methods for managing people who have experienced muscle aches. For those unable to tolerate daily high intensity statins, some statin is still better than none, and the following strategies can be considered:

1. *Reducing the dose of statin*. i.e. Atorvastatin 10-20mg or Rosuvastatin 2.5-5mg[7].

2. *Trying a low potency statin medication.* Lower potency statins seem to be less strongly associated with muscle aches. Fluvastatin and Pravastatin were much less likely than Simvastatin and Atorvastatin to cause myalgia[8]. For your reference, maximum doses of these low potency statins, and their equivalencies are:

Pravastatin 80mg = Atorvastatin 20mg = Rosuvastatin 10mg
Fluvastatin XL 80mg = Atorvastatin 10mg = Rosuvastatin 5mg

3. *Reducing dose or lengthening administration interval.* Studies have demonstrated that greater than 70% of patients affected by myalgias were able to tolerate every other day administration with no recurrence of muscle symptoms[9].

There is a small chance that your patient may have been misclassified with a statin indicated condition. We sincerely apologize for this and would be most appreciative if you can call or fax us to let us know.

We welcome any questions or comments so please kindly contact us at 403-955-8327 (or fax 403-955-8249), for more information.

Sincerely,
Sonia Butalia MD, FRCPC, MSc and the study team



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# Strategies for Enhancing Cholesterol Lowering Medication Use Among Patients at High Cardiovascular Disease Risk: Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| **Domain 1: Research team and reflexivity** | | | |
| Personal Characteristics | | | |
| 1. | Interviewer/facilitator | Which author/s conducted the interview or focus group? | Line 137 |
| 2. | Credentials | What were the researcher's credentials? *E.g. PhD, MD* | Author information |
| 3. | Occupation | What was their occupation at the time of the study? | Line 137 |
| 4. | Gender | Was the researcher male or female? | Line 137 |
| 5. | Experience and training | What experience or training did the researcher have? | Line 137 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Relationship with participants | | | |
| 6. | Relationship established | Was a relationship established prior to study commencement? | Line 138-139 |
| 7. | Participant knowledge of the interviewer | What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research* | Not discussed |
| 8. | Interviewer characteristics | What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic* | Not discussed |
| **Domain 2: study design** | | | |
| Theoretical framework | | | |
| 9. | Methodological orientation and Theory | What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis* | Qualitative Description – Line 98 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Participant selection | | | |
| 10. | Sampling | How were participants selected? *e.g. purposive, convenience, consecutive, snowball* | GP – Snowball (line 106-107)<br>Patients – Convenience (line 116) |
| 11. | Method of approach | How were participants approached? e.*g. face-to-face, telephone, mail, email* | Line 106-120 |
| 12. | Sample size | How many participants were in the study? | Line 173<br>Line 186 |
| 13. | Non-participation | How many people refused to participate or dropped out? Reasons? | Line 176-177 |
| Setting | | | |
| 14. | Setting of data collection | Where was the data collected? e.*g. home, clinic, workplace* | Line 137<br>Line 142 |
| 15. | Presence of non-participants | Was anyone else present besides the participants and researchers? | Line 143 |
| 16. | Description of sample | What are the important characteristics of the sample? *e.g. demographic data, date* | Line 174-195 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Data collection | | | |
| 17. | Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Appendix A& B |
| 18. | Repeat interviews | Were repeat interviews carried out? If yes, how many? | No |
| 19. | Audio/visual recording | Did the research use audio or visual recording to collect the data? | Line 146 |
| 20. | Field notes | Were field notes made during and/or after the interview or focus group? | Line 143-144 |
| 21. | Duration | What was the duration of the interviews or focus group? | Line 142-143 |
| 22. | Data saturation | Was data saturation discussed? | Line 140 + limitations section |
| 23. | Transcripts returned | Were transcripts returned to participants for comment and/or correction? | No |
| **Domain 3: analysis and findings** | | | |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Data analysis | | | |
| 24. | Number of data coders | How many data coders coded the data? | Line 156-160 |
| 25. | Description of the coding tree | Did authors provide a description of the coding tree? | Line 157 |
| 26. | Derivation of themes | Were themes identified in advance or derived from the data? | Line 157-158 (inductive) |
| 27. | Software | What software, if applicable, was used to manage the data? | Line 164-165 |
| 28. | Participant checking | Did participants provide feedback on the findings? | Line 414-415 |
| Reporting | | | |
| 29. | Quotations presented | Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number* | In-text and Table 3 |
| 30. | Data and findings consistent | Was there consistency between the data presented and the findings? | Yes |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| 31. | Clarity of major themes | Were major themes clearly presented in the findings? | Results section |
| 32. | Clarity of minor themes | Is there a description of diverse cases or discussion of minor themes? | Table 2 & 3 |

BMJ Open

# Strategies for Enhancing the Initiation of Cholesterol Lowering Medication Among Patients at High Cardiovascular Disease Risk: A Qualitative Descriptive Exploration of Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention in Alberta, Canada



| | |
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| Primary Subject Heading: | Cardiovascular medicine |
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| Keywords: | QUALITATIVE RESEARCH, GENERAL MEDICINE (see Internal Medicine), Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Cardiology < INTERNAL MEDICINE, PREVENTIVE MEDICINE |
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# Strategies for Enhancing the Initiation of Cholesterol Lowering Medication Among Patients at High Cardiovascular Disease Risk: A Qualitative Descriptive Exploration of Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention in Alberta, Canada

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## ABSTRACT

**Objective:** The objective of our study was to explore the perspectives of patients and general practitioners (GPs) regarding interventions to increase initiation of cholesterol lowering medication (or statins), including a proposed laboratory-based facilitated relay intervention.

**Design:** Qualitative descriptive study using interviews and focus groups for data collection, and thematic analysis for data analysis.

**Setting:** Primary care providers and patients in Calgary, Alberta, Canada.

**Participants:** 17 General Practitioners with primarily community-based, non-academic practices with at least 1 year of practice experience participated in semi-structured interviews. 14 patients at high risk of cardiovascular disease participated in focus groups.

**Main outcome measures:** Exploration of strategies that might be used to enhance the prescription of, and adherence to statin therapy for patients with statin-indicated conditions.

**Results:** GPs proposed a variety of interventions to improve statin prescription, including electronic record audit solutions, GP directed education and patient-oriented campaigns. Patients expressed that they may benefit from being provided access to their laboratory test results, as well as targeted education. Both parties provided positive feedback on the proposed laboratory-based facilitated relay intervention, while pointing out areas for improvement. Notably, GPs were concerned that the patient-directed component of the intervention might jeopardize therapeutic relationships, and patients were concerned about accidental disclosure of personal health information. Important considerations for the design of facilitated relay messaging should include brevity, simplicity and the provision of contact information for inquiries.

**Conclusions:** GPs and patients described several suggestions for increasing statin initiation and welcomed the proposal of a laboratory-based facilitated relay strategy. These findings support further testing of this intervention which may enhance GPs' ability to successfully engage patients in cardiovascular risk reduction through statin therapy.


**Keywords**: focus groups, qualitative research, interviews, statins, facilitated relay

**Strengths & Limitations of this Study**

- This is a qualitative study, with relatively few participants – therefore we cannot say definitively if the views represented here represent those of all patients and prescribers.
- We sampled physician participants to the point of saturation, which means that we are confident the views represented here span the breadth of those held by physicians.
- The patient sample we recruited may not be representative of the broader population, as many of them had previously stated an interest in quality improvement and research – and therefore may be attuned to the importance of preventive therapies more than other members of the general public. Additionally, this group was not sampled to saturation, as opposed to the physician participants.
- Given the context-dependent nature of qualitative data, the applicability of these findings to other settings is not certain.
- One of the major strengths of this study is the depth and richness of the qualitative data that were collected. By asking questions in an open-ended manner, we were able to record detailed accounts and opinions.

## INTRODUCTION

Vascular disease, including coronary artery disease, peripheral artery disease, and cerebrovascular disease, remains among the leading causes of mortality worldwide (1). A class of medications, HMG-CoA reductase inhibitors, commonly known as statins, have proven to be effective for lowering the risk of vascular events (2). Individuals who have previously had vascular disease (i.e. secondary prevention) derive a greater absolute risk reduction from statins than those who have never had vascular disease (i.e. primary prevention) (3). There are some individuals who have never had vascular disease, such as those with diabetes or chronic kidney disease, who have also been shown in randomized controlled trials to benefit from therapy (4-6). Despite over 30 years of clinical use, efficacy, safety and cost-effectiveness data (7, 8), only 23% to 55% of individuals who would benefit take this medication and fewer than half of individuals are treated to target cholesterol levels (7, 9-11). There is substantial unwanted variability in dyslipidemia management, and health system intervention is required to promote equitable treatment (12, 13). The lack of statin treatment for patients with indicated conditions results in significant excess morbidity and mortality. In Canada, specifically, if all patients with indications for statins were treated, this would result in nearly 40,000 averted cardiovascular events annually (14). In the United States, 13% of cardiovascular deaths could be prevented with perfect statin adherence among patients at high cardiovascular risk (15).

Physicians and patients face numerous barriers when it comes to prescribing and adhering to statin therapy, from the providers perspective this includes lack of knowledge, conflicting clinical guidelines, lack of systems to identify patients who should be taking statins (16). On the other hand, patients often experience or fear side effects or are simply averse to taking additional medications (16). Furthermore, patients that face social disadvantages such as low income, lack of health insurance, and minority race are more likely to not use statins (17). A large US-based survey found that side effects were common and that many former statin users were unsatisfied with the explanation provided by their prescriber about the importance of the medication (18). Providers need resources to help them provide this counselling to patients and to arm them with strategies to mitigate common statin side effects, like muscle aches (19).

There are clearly many challenges that lead to the observed clinical treatment gap for patients who have indications for statin treatment. However, some studies have shown that such treatment gaps, in related conditions like hypertension, can be closed using quality improvement strategies (20-22). Integrated quality improvement strategies that target both patients and healthcare providers are more likely to achieve quality indicators than strategies which only target one aspect in isolation (21). One such strategy is facilitated relay. Facilitated relay is a quality improvement strategy whereby information about individual patients is sent directly to healthcare providers through a means other than the usual clinical encounter (23). Despite the establishment and promotion of facilitated relay and other quality improvement strategies, there remain significant treatment gaps in hypertension (24) and other chronic conditions (25). Furthermore, while facilitated relay has been shown to be effective in improving a number of cardiovascular risk factors (21, 26), it remains among the least commonly used quality improvement strategies (27) and has not been explored in the management of dyslipidemia.

For an intervention to have the potential to yield maximum impact, it is important to qualitatively seek the input of key stakeholders prior to the application of any intervention (28). This allows for the development of a higher quality intervention, rather than one that relies on physician feedback alone (29)**.** As such, the objective of our study was to explore the perspectives of both patients and general practitioners' (GPs) regarding interventions to increase cholesterol lowering medication (or statin) prescription, including specific feedback on a proposed laboratory-based facilitated relay intervention.

**METHODS:**

**Study Design**

We conducted a qualitative descriptive study (28) to explore patients' and GPs' perspectives on interventions to increase initiation of statins for cardiovascular risk reduction and treatment of high cholesterol in those at high cardiovascular risk. In addition to generic thoughts on potential hypothetical interventions, we specifically sought directed feedback and perceptions on the acceptability of the proposed facilitated relay intervention from both patients and GPs (30). We used the consolidated criteria for reporting qualitative research (COREQ) as the reporting framework for this study (31).

**Proposed Intervention**

We drew from behaviour change theory to develop a facilitated relay intervention to increase statin prescriptions (32-34) (Figure 1). Our proposed intervention partners with our province's single unified laboratory system to identify individuals who have elevated cholesterol levels, statin-indicated conditions, and who are not currently filling prescriptions for statins. Our lab system has access to province-wide administrative databases, including labs, pharmacy dispensations, and hospitalization data. For every elevated LDL-cholesterol level, the lab would have an algorithm that would check the patients' records for evidence of statin-indicated conditions (administrative markers of myocardial infarction, stroke, diabetes, or chronic kidney disease), and would then identify if the patient has recently filled a statin prescription. This is possible because of province-wide, linkable databases. For patients who are not filling statins, but who should be, their GP (who had ordered the cholesterol level) and the patient, will then each receive a letter outlining the indication for treatment and the potential to benefit from statin therapy. The patient letter will encourage them to speak to their GP, and the GP letter will encourage them to make an appointment to discuss directly with the patient - both with the objective to initiate or renew statin prescriptions. We felt that it was important to include patients in the

facilitated relay to empower them in discussions with their GP and to enable shared decision-making (35), which has been demonstrated to improve adherence with statins (36).

**Participant Recruitment**

*General Practitioners:* We recruited general practitioners to participate in individual interviews, using a snowball sampling approach. First, we asked key stakeholders in areas of primary care, endocrinology, nephrology and cardiology affiliated with the university medical centre, to recommend community-based (non-academic) GPs to participate in the study. Individuals were then contacted by telephone and email with a formal invitation to participate. GPs who met the following criteria were enrolled: (1) currently practicing in community general practice settings; and, (2) at least one year of experience working as a GP in independent practice. We sampled participants purposively based on several key demographic characteristics in order to achieve representation across a range of ages, genders and practice types.

*Patients:* We recruited patients who would qualify as recipients of the proposed intervention. Specifically, we were interested in recruiting those at high risk of cardiovascular disease, who self-reported a prior history of high cholesterol, preferably with co-existing vascular disease (myocardial infarction, stroke or peripheral vascular disease), diabetes, or chronic kidney disease. Using a convenience sampling approach, we invited patients who were part of an established advisory panel and previously agreed to be contacted about research opportunities for study participation (37, 38). In addition, patients were recruited using poster advertisements placed throughout the academic health sciences centre and in various clinical care areas where care is provided to patients with diabetes, heart disease and kidney disease.

**Data Collection**

Data was collected from September 2018 to November 2018 using both qualitative semi-structured interviews (with GPs) and focus groups (with patients). We chose focus groups for patients as rich personal disclosures are more likely to occur in this setting than in individual interviews (39). However, we purposely used individually scheduled interviews to offset potential aversion to focus groups by community-based GPs due to their competing clinical demands. Furthermore, we wanted to recruit from both urban and rural locales which is more challenging to do in a focus group.

*Question Guides:* Both focus groups and interviews were guided by question guides (Appendix A & B) which were developed based on a review of the literature (40, 41) and discussion with the research team. These were designed so that they initially asked study participants what they thought would be effective strategies or interventions to improve statin uptake (i.e. prescribing, patient use and adherence). After they had given their unprompted views, participants were then given a brief explanation of facilitated relay, the specifics of the proposed intervention (Figure 1), and they were shown a copy of the proposed intervention letter for GPs (Appendix C). After briefing participants on the principles and practices of facilitated relay and showing them our preliminary documents for the intervention, we asked them to provide feedback on this proposed intervention.

*Provider Interviews:* All interviews were conducted in-person (in clinician offices) or via telephone, by a female trained research assistant (RCWL) with oversight by experienced study team members. Physician interviews were continued until the point of theoretical saturation when no new information emerged

from the interviews (42). Because the research objective was relatively focused, interviews were brief and lasted approximately 30 to 45 minutes.

*Patient Focus Groups:* None of the study team were acquainted with or involved in the clinical care of the patients who participated. We convened two focus groups in our academic medical centre which each lasted approximately 90 minutes. No one but researchers (including 1 facilitator and 2 field-note takers) and participants were present. Focus group facilitators tried to ensure that there were no dominant members and provide all participants with equal opportunity to voice their opinions.

Interviews and focus group proceedings were digitally audio-recorded and transcribed verbatim by a professional transcriptionist. Field notes were recorded to inform data analysis. All data were anonymized and stored securely. Signed informed consent was received from each study participant. Gift cards were provided to all participants. Ethics approval was granted from the University's Health Research Ethics Board.

**Data Analysis**

Analysis was completed using conventional qualitative content analysis (43), a method of interpreting interview data with the goal of describing the phenomenon of interest. Transcripts for the initial three interviews were reviewed by three team members (DJTC, RCWL and SB), with the objective of inductively establishing a preliminary coding template that was used for subsequent data analysis. All transcripts were then analyzed by two reviewers (DJTC and RCWL). Codes were generated from the interview data and systematically applied to identify themes and patterns. The process was iterative, reflexive, and interactive as continual data collection and analysis shaped each other. For example, code titles or definitions identified based on earlier interviews were modified according to the data collected during subsequent interviews. The team met together to review the coding to elicit discussion about the coding strategy and attempted to achieve consensus to resolve coding discrepancies. NVivo 12 (Doncaster, Australia) qualitative data analysis software was used to facilitate the coding process.

**Patient and public involvement**

Patient partners and family members from the Libin Cardiovascular Institute's established patient and family member advisory group (44) voiced that *prevention* was one of their top research priorities for cardiovascular health. This work is related to prevention of cardiovascular disease. Patients were included in focus groups.

**RESULTS**

In total, we eventually reached out to 27 GPs to invite them to participate, 4 declined to participate, 4 didn't respond to the invitation, 19 were scheduled for interviews, with 2 cancelling. We reached saturation after having completed 17 individual GP interviews (Table 1a). The majority were women (88%) with 65% having graduated from medical school within the last ten years. All GPs spent more than 50% of their time in clinical practice, most were in urban centers within Primary Care Networks (PCNs). PCNs are networks of GPs that share interdisciplinary resources to enhance the delivery of primary care within geographical regions (45); they are associated with improved chronic disease care and outcomes(46).

**Table 1a.** Descriptive statistics for General Practitioners (n = 17).

| Physician characteristics | **Total** (%) |
|---|---|
| Age (years) | |
| < 40 | 13 (76) |
| 40 - 60 | 4 (24) |
| Gender | |
| Man | 2 (12) |
| Woman | 15 (88) |
| Years of primary care practice | |
| < 10 | 14 (83) |
| 10 – 20 | 3 (18) |
| Years since medical school graduation | |
| < 10 | 11 (65) |
| ≥10 | 6 (35) |
| Primary Care Network membership | |
| Yes | 15 (88) |
| No | 2 (12) |
| Location of primary care practice | |
| Urban | 13 (76) |
| Rural | 4 (24) |
| Focused practice interest | |
| Yes* | 9 (53) |
| No | 8 (47) |
| | |
| Clinical practice last 12 months | |
| Estimated number of patients at high CVD risk | |
| < 20 | 1 (6) |
| 20 to 99 | 7 (41) |
| ≥100 | 9 (53) |
| Use of endocrinology consultation services | |
| Yes | 5 (29) |
| No | 12 (71) |
| Use of cardiology consultation services | |
| Yes | 10 (59) |
| No | 7 (41) |
| Use of nephrology consultation services | |
| Yes | 3 (18) |
| No | 14 (82) |
| | |
| Proportion of patients in their practice who would be considered high risk on the basis of cardiovascular risk factors (n=14) | Mean: 32%<br>Range 10-75% |
| | |
| Proportion of high-risk patients in their practice who have a current LDL-level on file (n=9) | Mean: 82%<br>Range 70-90% |

* Focused practice, or special interest types: care of the elderly (n = 2), emergency medicine (n = 1), urgent care (n = 1), refugee medicine (n = 1), obstetrics (n = 2), indigenous health (n = 2), lactation (n = 1).

Our patient focus groups had 8 and 6 participants, respectively (Table 1b). There was a range of ages represented among patients, with a similar number of men and women. Nearly all had a general practitioner and were also followed by medical specialist(s). The conditions represented in our patient group were diabetes, history of myocardial infarction and elevated cholesterol level; none reported a history of stroke, chronic kidney disease, or peripheral arterial disease.

**Table 1b.** Descriptive statistics for patient participants based on self-report (n = 14).

| **Patient characteristics** | **Total** (%) |
|---|---|
| Age (years) | |
| < 40 | 2 (15) |
| 40 - 60 | 5 (39) |
| > 60 | 6 (46) |
| Gender | |
| Men | 6 (46) |
| Women | 7 (54) |
| Chronic condition qualifying as "high CVD risk" | |
| High cholesterol only | 3 (23) |
| Diabetes only | 6 (46) |
| Myocardial infarct (MI) only | 1 (8) |
| Diabetes & MI | 3 (23) |
| Has a primary care provider | |
| Yes | 12 (92) |
| No | 1 (8) |
| Followed by a medical specialist | |
| Yes | 10 (77) |
| No | 3 (23) |
| Self-reported awareness of high cholesterol levels | |
| Yes | 11 (85) |
| No | 2 (15) |
| Current use of statin medication | |
| Yes | 6 (46) |
| If not, had spoken with physicians about statins | 3 (23) |
| If not, had not spoken with physicians about statins | 4 (31) |

*Note one participant did not complete a demographic questionnaire

**General suggestions for potential interventions**

Several themes arose regarding interventions to improve statin initiation during the unprompted portion of the interviews (Table 2). GPs described that statin prescribing may be improved by: (1) enhancing aspects of physician education to promote appropriate statin prescribing; and, (2) implementation of support tools to help physicians in decision-making and identification of patients for whom statins are indicated. In addition, patients suggested that having access to their own laboratory results may enable them to be more effective self-advocates.

| **Table 2.** General suggestions by general practitioners and patients to increase initiation of statins | | |
|---|---|---|
| Providers | Treatment of specific Sub-populations | Patients with chronic kidney disease:<br>*"I struggle with the GFRs [glomerular filtration rate] – knowing when it would be safe, when it wouldn't be safe. I do get confused as to the dosing based on GFR."* (GP-05)<br><br>Patients who previously experienced side effects with statin(s):<br>*"I have one strategy but if somebody is still like 'no, it's completely not tolerable for me' then I don't know what the next step is after that."* (GP-13)<br><br>Elderly patients:<br>*"…getting some better understanding about the elderly. Are there any contraindications to starting on statin therapy? Is there one statin that may be more beneficial than another?"* (GP-10)<br><br>Patients with hypertriglyceridemia:<br>*"I always find it hard to know what to do with triglycerides… more education around how to manage those [patients]."* (GP-15) |
| | Treatment to Targets * | *"Most people in my office are confused about what we are doing in terms of treating to the target of 2 mmol/L, because the cardiologist is still sending consults about that, but then we have these family medicine evidence-based groups saying that targets don't matter".* (GP-02)<br><br>*"I know the TOP [Towards Optimized Practice] guidelines don't necessarily correlate with CCS [Canadian Cardiovascular Society] guidelines, so there are several schools of thought".* (GP-09)<br><br>*"There's no real way to unify the guidelines, but to have an education session on why they're different and how to approach it so maybe you'll break down patient populations that fit better with one guideline versus another".* (GP-08) |
| | Preferred modality of Education | *"we have a lot of drug reps [representatives] coming to town, so it would be great to have more [education] that was not pharma, absolutely"*. (GP-04) |
| | EMR-based tools | *"One thing that would be helpful for me is if there was some automatic flag that came when I saw a patient that would alert to the fact that their treatment is not optimized for their conditions"*. (GP-06) |
| Patients | Laboratory Results | *"I would like to get a copy, in addition to the doctor. I can do with it what I want"* (Pt-09)<br><br>*"It gets you questioning things so that you can come back to your doctor and say 'I saw these numbers, what does that mean? What do I need to do?'"* (Pt-02) |

| | | |
|---|---|---|
| | Enhanced education | *"What if somebody was going regularly to a lab, and a clinician sort of goes: 'How are you doing on this?"*. (Pt-08) |

EMR: electronic medical record

* Specialist guidelines, the 2016 Canadian Cardiovascular Society guideline (47) advocates that patients at high risk (based on risk calculators) or those with 'statin-indicated conditions' (defined as diabetes, chronic kidney disease, or preexisting vascular disease be treated with statin therapy to achieve a target LDL-c level of < 2.0 mmol/L. GP Guidelines, the 2015 TOP Alberta Guideline (48) encourages GPs to treat high risk patients with moderate-to-high intensity statins and should not repeat lipid levels, or attempt to treat to a fixed target.

*1)* General practitioner *education:*

Nearly all GPs highlighted that there are general areas of knowledge that could be bolstered in order to enhance statin prescription. One of the main content areas in which they sought enhanced education related to the treatment of specific patient sub-populations, in particular those with chronic kidney disease, patients who have had prior statin intolerance/side-effects, elderly patients, and those with other concurrent lipid disorders (i.e. hypertriglyceridemia).

Whether providers should be treating patients to a specific cholesterol level was a major source of confusion. They frequently referenced receiving conflicting advice, including a contradiction in clinical practice guidelines(49), some of which advocate for a 'fire and forget' approach(8, 50), while Canadian(7) and European(51) specialist guidelines recommend a 'treat-to-target' approach(7).

Regarding the modality of education sessions, most preferred in-person education sessions delivered at their clinics and delivered by someone who did not have clear conflicts of interest with pharmaceutical companies. Many GPs also suggested the use of handouts, tools or algorithms to simplify their decision-making process.

*2)* General practitioner *tools*

In addition to education, several GPs suggested that the use of automated tools would facilitate their prescribing of statins. Most felt that they would benefit from optimizing the use of their electronic medical records (EMR) to 'flag' individuals who were at high cardiovascular risk or had elevated cholesterol levels. Other GPs spoke of wishing for a 'running list' of eligible patients, while some mentioned using an employee or contractor designated as a panel manager to perform these tasks.

*3) Patient results and information*

Many patients independently indicated that they would like to have access to their lipid test results, without needing to rely on this being conveyed to them by their general practitioner. Some patients also suggested that providing them with their own results might reduce the frequency of unnecessary follow-up visits; and as a result, alleviate related financial burden on the healthcare system. Doing so was also thought to help foster patient engagement with their GP.

Patients also felt that having greater access to information about cholesterol and treatment might facilitate more patients being on statin therapy. Suggestions were made to deliver this through enhanced patient-facing materials (i.e. brochures), as well as pharmacists or lab technicians who were

able to discuss results and treatment options. Further information about patient education, shared decision-making, and clinical decision support tools are described in our other report from this work (16).

**Feedback on the proposed facilitated relay intervention**

Emerging themes regarding our proposed intervention were organized into four major categories: (1) general feedback and impression; (2) suggested changes; (3) intervention details; and, (4) workflow processing considerations.

*1) General feedback and impression*

General practitioners responded to the proposed intervention with strongly positive feedback (Table 3), which included stating that they found the information to be helpful and direct. They generally felt that the letter was written in a clear fashion and with a respectful tone. Several mentioned that the information provided them with reassurance and credibility in making recommendations to their patients.

GPs also voiced some questions and potential concerns after hearing about our proposed intervention. These concerns included whether the introduction of a facilitated relay intervention might increase their workload, lead to possible disclosure to patients of new diagnoses of conditions that qualified them as high risk (i.e. diabetes), and pose a threat to their therapeutic relationships with patients. In addition, logistical issues around how the letter will be best delivered to ordering providers and patients were raised as concerns.

Patients generally felt that bringing their facilitated relay letter to a scheduled appointment would be positive in their relationship by providing structure to the follow-up encounter, holding GPs to account, and enhancing patient-provider communication. Even though most were generally positive, some patients expressed concern about the facilitated relay intervention, including the possibility for privacy breaches and increasing patient anxieties.

*2) Suggested information to remove or add*

We asked GPs specifically what they would like to see changed in the preliminary materials shown. Almost unanimously, they suggested that the letter would be more appreciated if it the two-page document were shortened to fit on one page. Several participants suggested removing the references, mention of clinical studies, and guideline citations to make it more reader-friendly. There was also a preference voiced for revising the introductory paragraphs to have direct relevance to individual patient(s):

> *"I'm going to read it for sure, but then when you start to read it, people might put it down and say 'oh this is a study intervention', [but] if you have the first thing at the very top: 'you know this person has been identified as being at risk' – then it's about the patient rather than being about the studies".* (GP-16)

A few GPs voiced opinions that specific additions could be made to improve the letter's utility. These suggestions included adding: information about health behavior change (*"the whole picture, as opposed to just medication"* (GP-04)*);* adding contact information for a specialist; and details about how/why a

particular individual was flagged as eligible for the facilitated relay intervention: *"It would be helpful if I got a name, condition and then the statin-indicated condition, and where the condition was pulled from"*. (GP-01)

Patient feedback was notable for also suggesting that the intervention provide contact information, in case they have further questions about interpreting their results: *"back that up with a helpline for somebody that doesn't know what the [results] mean"* (Pt-10). Similar to physicians, patients expressed a strong preference for brevity: *"If I have to go through 14 pages of information to figure out what that means, I'm sorry, I don't have time for that"* (Pt-07).

However, numerous patients also stressed the importance of not only providing results or diagnoses, but also giving some basic education and an action plan to follow.

*3) Intervention details*

In addition to general feedback, we also explicitly asked GPs whether they would prefer to receive information about their patient in the form of facilitated relay (individual letter for each patient identified) or 'audit and feedback' (summary report including a group of their patient panel). A summary list or report (audit and feedback) was preferred by roughly 2/3 of the general practitioners interviewed. Regarding receiving letters for each patient, participants stated:

> *"this is going to get tiresome very quickly"* (GP-05)
>
> *"Am I going to get this letter 20 times? I'm probably just going to read it once"* (GP-03)
>
> *"[a list would] decrease paper burden, decrease the chance of it getting misplaced"*. (GP-13)

While the 'audit and feedback' approach was more popular, some GPs were clearly in favor of facilitated relay: *"I can't even think of the amount of work it would take to do it patient-specific. I'd love it. Sure go for it, if you have the means to do it, then why not?"* (GP-10)

We also asked pointedly about how providers would feel about receiving a follow-up reminder from the study team, if patients had not filled the prescription as recommended in the initial letter. The response was split with roughly half of the general practitioners stating that a reminder would not be necessary.

Those who felt a reminder would be acceptable generally agreed that a 6 month window should be sufficient to ascertain whether or not the patient would have started on therapy: *"There are people that have a three-month wait list time, you may have to pick an interval more like six-months to appeal to the masses…"*. (GP-13)

Most patients felt that they would benefit from receiving a follow-up reminder. After considerable discussion amongst the groups, consensus was achieved that follow-up should not happen prior to four months, and possibly even as long as six months after the initial contact. One participant stated: *"close enough that I vaguely remember that I meant to do something with that, but not a few weeks later, [so] it's not irritating".* (GP-17)

We also asked patients if they had a preference for who had signed the letter. Most felt that having letters come from a local specialist in cardiology or endocrinology would be preferable to having them signed by another GP.

*4) Workflow processing considerations (*General practitioners *only)*

To each GP we asked specific details about how our intervention letter would be received in their offices and what would happen upon receipt. The majority stated that such a letter would be opened and processed by their front-desk staff. One participant clarified that the information on the envelope would determine who opened it: *"if it's addressed to me then it will come to me, if it has a patient name for me, then it goes through our document people [who file it]"*. (GP-09)

Once the letter has been opened, different offices employed a variety of different processes. In many practices, it would be given directly to the GP; while in others it would be scanned directly into a patient's file in an electronic medical record, yet in others, the hardcopy would be filed in a patient's chart.

In terms of the preferred delivery modality, most GPs felt that electronic delivery directly via the EMR platform would be the preferred method of receiving the intervention. However, a number still felt that conventional delivery via paper mail or fax would be preferable. Even those who expressed a preference for conventional delivery, many elaborated that such letters would often be scanned into a patient's electronic file: *"if it was to come by mail or fax, then they have to scan it onto the computer"* (GP-11). A few GPs described systems which can do this process automatically: *"our office works with a new web system, so everything that comes in via the fax actually goes directly into the computer and they then allocate to the patient".* (GP-11)

**Table 3.** Positive and negative feedback on facilitated relay intervention from general practitioners and patients

| General Practitioners | | Patients | |
|---|---|---|---|
| **Positive** | | | |
| **Composition** | "Overall I thought it was worded quite well and was very clear" (GP-08)<br><br>"I think it's appropriate, it didn't take me very long to get through" (GP-16) | **Provides structure to interaction** | "My doctor would be okay with that. It gives them a little checklist of things to talk about". (Pt-05) |
| **Tone** | "it's written in a way that doesn't make you feel stupid, I guess" (GP-11)<br><br>"it's good because [it's] not telling you to do this [start statin therapy], but telling you to have a conversation]." (GP-17) | **Enhances communication** | "I think that's good 'cause these doctors, some guys don't communicate." (Pt-13) |

| | | | |
|---|---|---|---|
| **Credibility** | "it gives family physicians more confidence to do those things and know the specialists are behind them in that recommendation" (GP-02)<br><br>"there's so much information for people to sift through… if you can get valid information that's corroborated and consistent, that's helpful" (GP-15) | **Increases doctor accountability** | "I think it keeps them [doctors] honest as well. They should actually be proactive in terms of having that information already, but that's not always the case. So I don't have a problem with a patient having all their information at their disposal". (Pt-14) |
| **Direct** | "it's a good idea… it tells you what to do, which is great. You don't have to look up the guideline every time" (GP-04)<br><br>"it's just one of those extra little reminders that takes the brain power out of the work you have to do day-to-day" (GP-06) | **Increases patient accountability** | "If [patients] are encouraged to work with their doctor to monitor your numbers, you have a bit of control as well as the doctor… like working together". (Pt-03) |
| **Information** | "[side effects] are what people hear about in the news a lot, so it's very helpful to have some numbers around it, and strategies to address that" (GP-09)<br><br>"All the suggestions that you made are excellent. I'm reading through this and I'm like ' oh yeah, I didn't realize this' and ' this is something I can do for some of my patients'" (GP-12) | **Provides peace of mind** | "It gives me a little peace of mind in that we've talked about all of the things that are important and that should be covered… that we haven't left anything out". (Pt-05) |
| **Negative** | | | |
| **Increased workload** | "I would caution against anything that causes more documents or more paperwork… there's already so much" (GP-16) | **Privacy concerns** | "You know what, my doctor isn't going to send it out to me, anyway. It's going to go on to a receptionist, who might pass it on to somebody else in the office, so there's no guarantee of privacy there" (Pt-05)<br><br>"Privacy is always an issue. I mean it's like, the less information that's out there about you, the better off you are, period. I don't care what it is" (Pt-07) |

| | | | |
|---|---|---|---|
| **Disclosing new diagnoses** | "my concern is that they get this information from a letter… my preference would be that it came straight to me" (GP-01) | **Difficulty interpreting results** | "Some people might know all the numbers and everything else, I don't. You give me a bunch of numbers, it means nothing to me. So unless the doctor explained it to me… I'd rather talk to my doctor" (Pt-07) |
| **Therapeutic relationship** | "If the patient gets a letter that's like 'you need to be on a statin' and we already had a conversation that they didn't need a statin. That could cause some issues in the therapeutic relationship." (GP-04) | **Provoking Anxieties** | "There are people who are coming down with every disease known to man, so for someone like that, that kind of information would just send them off the deep-end, right?" (Pt-05) |
| **Logistical concerns** | "What if a person gets a check from a walk-in clinic? My concern is then is that walk-in clinic docs are just going to ignore this letter" (MD-05)<br><br>"If it goes to the patient, sometimes you get lots of mail and they may just discard it" (MD-10) | **Lack of engagement** | "You mentioned mail outs and things like that… have they proven to be effective, though, 'cause how many people read them? How many people understand them? I don't think there would be a lot of point in it, 'cause I don't think people pay that much attention" (Pt-09) |
| | | **Sense of intimidation** | "Some will [say] 'I can't talk to my doctor like that'. There will be some people who might be intimidated to initiate that conversation" (Pt-03) |

## DISCUSSION

While statins have a more limited role in certain populations (low risk and those with limited life expectancy) (52, 53), they are important for the prevention of cardiovascular disease in patients who have previous vascular disease and in those with diabetes and kidney disease (4-6, 47). In this study, both GPs and patients acknowledged that there is the potential to improve the prescription and use of statin therapy among those at high risk for cardiovascular disease. In unprompted questions, GPs acknowledged that there was a need for improved physician education on this topic, and that tools to help identify and track patients would be helpful. Patients also suggested that if directly receiving laboratory test results and information on treatment options may result in better medical care, generally supporting our hypothesis that facilitating shared decision making was a key element of a novel intervention. When shown the proposed intervention, both groups were strongly supportive of the facilitated relay intervention. While there were clear benefits to the intervention, some potential downsides were raised by both GPs and patients. In general, all recipients would prefer letters to be succinct, yet contain high yield information and provide contact information where clarification could be sought.

Many interventions have been attempted to address the problem of statin underuse. A number of patient-centered approaches have been tried with varying success (22). While active forms of education, like cognitive education and behavioural counselling seem to work (54), more passive forms of education are often unsuccessful at changing behaviour, as in the recent ISLAND trial which found their intervention, comprised of a mail and phone education strategy to encourage patients to take

prescribed medication, had no impact on adherence (55). Others have found that multifaceted interventions focusing on enhancing care provision through team-based care may be effective at increasing statin adherence (56).

However, when trying to target the problem of low statin prescribing, interventions directed only at patients are not likely to work. An alternate approach is to facilitate GPs ability to identify and prescribe statins, to those in whom they are appropriate (57), through audit and feedback or facilitated relay. An educational audit and feedback intervention regarding dyslipidemia treatment in Italian primary care practices was shown to increase adherence to statins by approximately 10% (58). Improved communication and shared decision making, which are explicit goals of facilitated relay interventions, can improve patient adherence (59). While these and other studies have reviewed the clinical efficacy of quality improvement strategies (21), few have used detailed qualitative methods as we have done. One large qualitative study interviewed audit and feedback experts to generate hypotheses about the various factors that may contribute to the efficacy of such interventions (60). Others have used qualitative methods to highlight the barriers physicians face in encouraging adherence (61), but ours is unique in using such methods to design and develop an intervention to address these challenges. Finally, we also appreciate that as much as there is underuse of statins, there is also overuse, for example, in people with short life expectancy. Perhaps interventions to increase initiation may also include a component that conveys statin benefits are measured in years rather than months.

The fact that participants suggested elements of our facilitated relay intervention in the unprompted portion of the interviews lends credibility and face validity to the proposed intervention. However, it is notable that while GPs felt they would benefit from having internal systems to monitor patients' records, none independently suggested a strategy mediated by an independent third party (such as facilitated relay or audit and feedback), as we have proposed. Investigators who wish to implement facilitated relay interventions to enhance adherence to medical therapies can use the findings of this study to help develop interventions that are more likely to be acceptable to both GPs and patients. One of the main findings is to ensure that any information provided is brief and high yield, containing patient identifiers early to capture general practitioner's attention. Such interventions can be strengthened by incorporating education on controversial or little-known topics. Patients strongly preferred any correspondence to also contain direct suggestions or an action plan. Workflow and processing of these letters needs to be considered and interventions designed to be as minimally disruptive to clinical practice as possible – with most physicians preferring that it be embedded directly within the EMR; yet in healthcare settings (like ours) where there is marked heterogeneity in the use and type of EMRs, this may not be possible.

There are limitations to this study. Firstly, as in most qualitative studies, the number of participants was relatively small. This concern over sample size is mitigated by the fact that physician interviews proceeded until the point of saturation. Patient data were not collected in this manner, and these themes may not be fully saturated and we appreciate this as a limitation. Furthermore, the patient sample we recruited may not be representative of the broader population, as many of them had previously stated an interest in quality improvement and research and therefore may be attuned to the importance of preventive therapies more than other members of the general public. Secondly, given the context-dependent nature of qualitative data, the applicability of these findings to other settings is not certain. Yet physicians in most settings face similar problems (i.e. time constraints, patient complexity and comorbidities and patient resistance to medical therapies) in numerous facets of medical care; therefore, it is conceivable that the findings of this study would apply to interactions between patients and GPs in other clinical settings. Due to time constraints of participants and researchers, member

checking was not undertaken in this study. Finally, it is important to note that feedback was sought specifically about the proposed intervention. However, given the details reported, we feel that these findings are likely to be helpful to others proposing similar quality improvement interventions. One of the major strengths of this study is the depth and richness of the qualitative data that were collected. By asking questions in an open-ended manner, we were able to record detailed accounts and opinions. Another strength of this work is the fact that we also sought patient input into the development of this intervention, rather than relying on physician feedback alone.

Statin therapy has been demonstrated to effectively lower cholesterol and reduce the risk of cardiovascular events and death in individuals at high risk of cardiovascular disease. Despite this, they remain underused. There are patient, provider and system factors that contribute to statin underuse. Facilitated relay interventions hold promise as a potential method to address this important care gap. Our study sought perspectives of both healthcare providers and patients, which will be incorporated into intervention design to maximize acceptability. Insights gained from qualitative data will be used to improve the likelihood of success and achieve the desired clinical impact. The insights about these interventions are also likely to be of interest to many researchers and clinicians who are considering and designing provider- and/or patient-facing interventions to improve the uptake of preventive medications.

**Contributions**

DJTC, RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, SB collaborated to develop the research question and methods. The study design was conceived by DJTC and SB. DJTC wrote the first draft of the study protocol. Data collection and analysis was completed by DJTC, RCWL and SB. KAM, TJA, HQ, AACL, GC, ML, and CN contributed to the interpretation and contextualization of study findings. The first draft of the manuscript was written by DJTC. RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, and SB contributed substantively to further revisions of the manuscript and have consented to the publication of this version.

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**Data Availability Statement**

No additional data available. Given that qualitative data are not deidentified and tell individuals' personal stories, data cannot be shared beyond the scope of this project, as per our research ethics board.

**Competing Interest Statement**

DC, RL, KAM, AL, TA, HQ, GC, SB – none. CN is a director of a private laboratory that does not currently offer testing in the jurisdiction under study.

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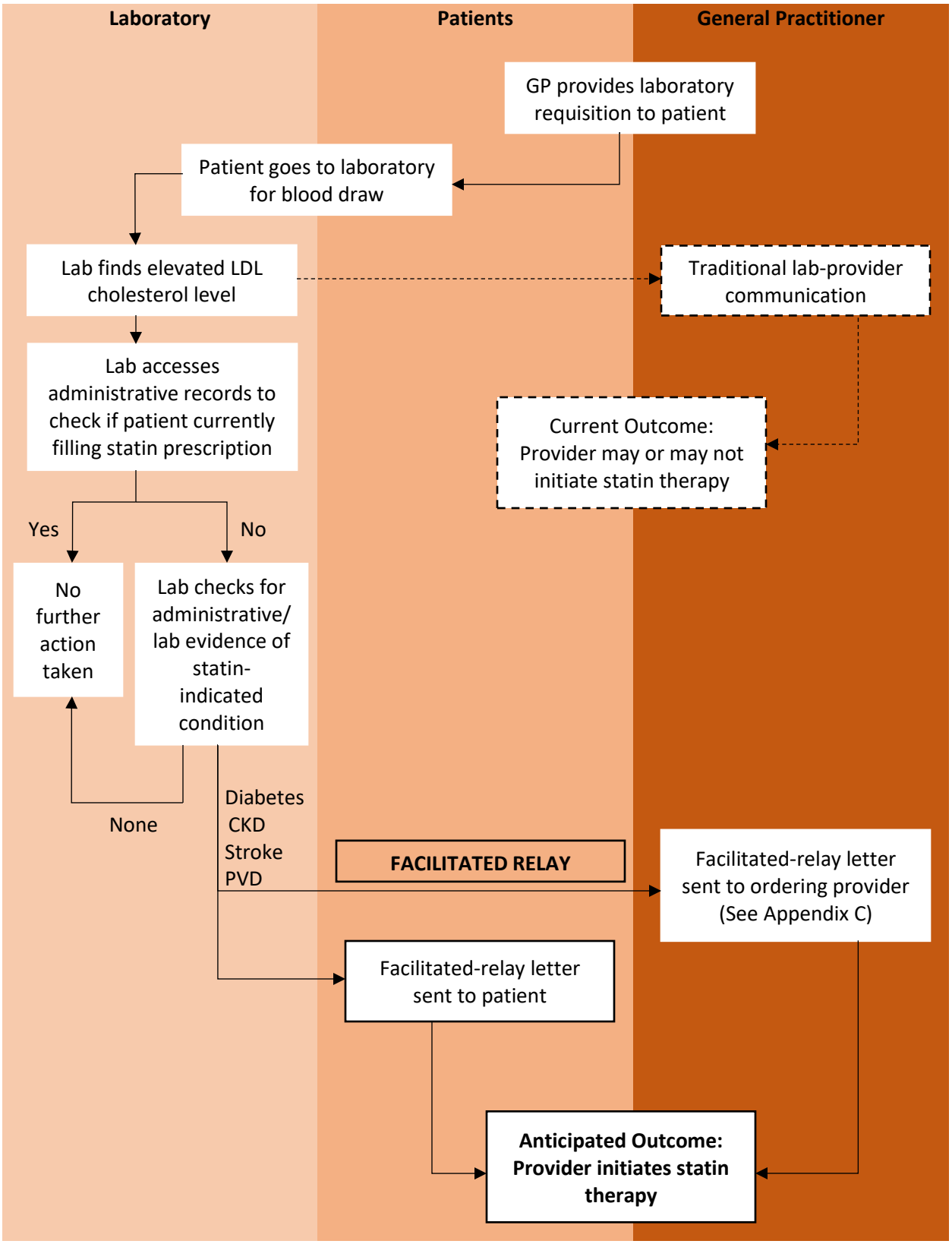


**Figure 1: Laboratory-Based Facilitated-Relay Intervention**
Dashed lines: traditional interface between lab and ordering provider

**Appendix A: Interview Guide for health care professional**

Thank you for agreeing to participate in our interview today. We wish to discuss your experience in managing dyslipidemia (or high cholesterol) in order to better understand how we might help family physicians treat dyslipidemia (or high cholesterol). We have a proposed intervention and would like your assistance in how to enrich it.

**1. Experience managing dyslipidemia**

Please describe any challenges or difficulties that you experience in identifying and managing patients with dyslipidemia?

- Do you use any resources to guide you in the management of these patients?
    - Canadian Cardiovascular Society Guidelines
    - Diabetes Canada Guidelines
    - TOP guidelines

In addition to measuring a patient's lipids, what are some other parameters that you consider when assessing a patient for dyslipidemia, and how to optimally manage this condition?

**2. Dyslipidemia-related practices**

In your practice, do you find it helpful to quantify a patient's LDL-cholesterol or get a lipid panel?

If yes,

- Are there certain populations in whom you find this test most helpful?
- What is your chosen method/diagnostic test to do so?
    - Fasting or random lipid profile
        - Total cholesterol
        - HDL-cholesterol
        - LDL-cholesterol
    - ApoB
- How does this information change your clinical practice?
- How often do you repeat cholesterol testing for patients with with conditions that puts them at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease)?

If no,

- Why is it not particularly helpful?
    - Don't know which test to do
    - Don't know how to order it
    - Don't know in whom it is indicated

- Don't know what to do with the results

In thinking about your practice, what proportion of your patients with conditions that put them at high risk for cardiovascular disease (i.e. previous myocardial infarction, stroke, diabetes, and/or chronic kidney disease) have had their lipid profile assessed in the past 12 months?

What are some of the reasons this does not happen (in your practice and in others')?

- Didn't think it was indicated/for whom it is indicated
- Too many things to attend to
- Not perceived to be an important issue amongst all other disease/conditions that FPs manage
- Patient factors (doesn't go for test)

**3. Intervention**

If we wanted to increase the use of statins among people at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease), what might be done? What tools, resources, prompts may help facilitate increased treatment of dyslipidemia?

In your opinion, what type of educational intervention is most effective in disseminating clinical practice guidelines to family physicians? (i.e. conferences, local lectures, treatment recommendations on lab results).

We are considering the use of a facilitated relay strategy, where patient's information from Calgary Laboratory Services is used to identify those who have indications for statin therapy. Those who are not currently filling statin prescriptions at the pharmacy would receive a letter from the lab indicating that they may benefit from statins. They will be encouraged to bring this letter in to discuss this with you.

How would family physicians respond to receiving a letter from the lab prompting them to consider starting their patient on statin treatment?

- What would be the characteristics of such a letter that would make it more likely to succeed?
    - Short/Pictorial/Colorful

Would it be more helpful to have this information specific about one named patient, or rather have an audit of your entire practice that would indicate what proportion of eligible patients with statin-indicated conditions are currently being treated with statins? (i.e. Audit and Feedback)

How should such an intervention either on a specific patient or about your entire practice be received?

- Mail/Fax/EMR/combo

How would such an intervention be processed in your office?

- Who would open the envelope?
- What would they do with it? (give it to you, put it in the patient's chart)
- How likely would you be to see this information?

Who should this letter be coming from in order to have it received in the most positive way possible?

- A non-clinical academic researcher (Dr. XXXX)
- Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- An academic family doctor (Dr. Kerry McBrien)
- A respected community family doctor
- The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- Dr. Cello Tonelli, Associate Vice-President (Research) at the University of Calgary
- Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic Disease Management, Community and Rural for Alberta Health Services
- Someone else

Would it be helpful to receive a reminder or follow-up letter?

- How much later should this be sent, so as to be useful and not annoying?

If the intervention provided you with patient-oriented material about this subject, and asked you to share it with your patients, how would you feel about doing so?

- What content should be included in this patient-oriented material to enhance statin use?
- What format should this material be in? Electronic, hard-copy? How should it be delivered? Mail, email?
- Would you share it in a clinical setting?
- Would you be willing to mail it to patients directly?

Do you have any additional comments or suggestions for developing an intervention to increase the use statins in people at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease) in primary care?

Thank you for participating in today's interview. Using the information you provided, we will work on developing an intervention to improve the treatment of dyslipidemia in patients who are at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease)?

**Appendix B: Focus Group Guide for patients**

Thank you for agreeing to participate in our focus group today. There are many risk factors for heart attacks and stroke. Today we want to focus on one risk factor being high cholesterol. High cholesterol is a major risk factor for heart attacks, strokes and circulatory problems. There are no symptoms of high cholesterol and it is diagnosed by a lab test that your doctor would order. Importantly, we work for the University of Calgary and have no relationship with any medication companies.

We wish to discuss your experience in managing *cholesterol* with medications in order to better understand how we might help family physicians (*doctors)* treat high cholesterol.

1. **Experience with high cholesterol**

Think about the last time your doctor has sent you for a cholesterol test. Did your doctor talk to you about the results? Treatment? What kind of treatment was discussed (diet, exercise, a medication)?

Put yourself in the position of being told that you need to take a medication for your cholesterol. What factors would make you more likely to take it? What factors would make you not want to take it? Reasons, side effects, costs

- Would you use any resources to help you decide?
    - Doctor
    - Dietician
    - Internet
    - Family, friends

What would you think if your doctor told you that your cholesterol wasn't all that high, but because of your other health conditions she wanted to start you on a cholesterol lowering medication to reduce your risk of heart attack and stroke?

Do you think it would be helpful to get the actual result of your cholesterol level sent directly from the lab to you?

Currently, cancer screening programs send letters to patients about their results and next steps. What are your thoughts for something similar for high cholesterol?

What about information about recommended treatments and potential side effects? Would you find this to be invasive of your privacy (i.e. info from the lab about treatment and not your doctor)?

How would you feel about taking a letter with these recommendations to your doctor to discuss about a medication for high cholesterol?

How do you feel your doctor would respond to you bringing this information?

What things on the letter would make it helpful?

-length, colour, graphics,

Who should this letter be coming from in order to have it received in the most positive way possible?

- A non-clinical academic researcher (Dr. XXXX)
- Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- An academic family doctor (Dr. Kerry McBrien)
- A respected community family doctor
- The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic Disease Management, Community and Rural for Alberta Health Services
- Someone else

Would it be helpful to receive a reminder or follow-up letter?

- How much later should this be sent, so as to be useful and not annoying?

Do you have any additional comments or suggestions for developing an way to increase the use the treatment of people with high cholesterol?

## Appendix C: Facilitated Relay Letter

UNIVERSITY OF CALGARY

Date: XXXX-XX-XX

Dear Dr. [Physician Last Name],

RE: [Patient Name]

As you may recall, your Primary Care Network is involved in a study with the University of Calgary. This is an investigator-initiated study with public funding from the [*Canadian Institutes of Health Research*].

Dyslipidemia is a major risk factor for myocardial infarction and stroke[1-2]. As you know, in patients like [name], statins are indicated for their dyslipidemia because they are proven to reduce cardiovascular outcomes and mortality[3-4]. Because of numerous randomized controlled trials, guidelines recommend statin use in individuals with history of previous cardiovascular disease, diabetes, or chronic renal failure[5].

We are writing to you to consider initiating a statin in your patient. We know the importance of the therapeutic relationship that you have with your patients and know that we do not know your patient like you do. The purpose of this letter is to assist in you in your discussion with [name], about using a statin medication.

[Name] may not be taking a statin because of underestimation of their personal risk of cardiovascular disease, fear of side-effects, previous side-effects, or cost. If cost is a concern, compassionate programs are available for several statin medications. Please kindly call our study telephone number to assist in facilitating this.

The most common side effect from statins is muscle aches, and the frequency of statin-induced rhabdomyolysis is very rare (i.e. < 1 in 10,000 patients per year on statins)[6]. Studies suggest that there are several proven methods for managing people who have experienced muscle aches. For those unable to tolerate daily high intensity statins, some statin is still better than none, and the following strategies can be considered:

1. *Reducing the dose of statin*. i.e. Atorvastatin 10-20mg or Rosuvastatin 2.5-5mg[7].

2. *Trying a low potency statin medication.* Lower potency statins seem to be less strongly associated with muscle aches. Fluvastatin and Pravastatin were much less likely than Simvastatin and Atorvastatin to cause myalgia[8]. For your reference, maximum doses of these low potency statins, and their equivalencies are:

Pravastatin 80mg = Atorvastatin 20mg = Rosuvastatin 10mg
Fluvastatin XL 80mg = Atorvastatin 10mg = Rosuvastatin 5mg

3. *Reducing dose or lengthening administration interval.* Studies have demonstrated that greater than 70% of patients affected by myalgias were able to tolerate every other day administration with no recurrence of muscle symptoms[9].

There is a small chance that your patient may have been misclassified with a statin indicated condition. We sincerely apologize for this and would be most appreciative if you can call or fax us to let us know.

We welcome any questions or comments so please kindly contact us at 403-955-8327 (or fax 403-955-8249), for more information.

Sincerely,
Sonia Butalia MD, FRCPC, MSc and the study team



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# Strategies for Enhancing Cholesterol Lowering Medication Use Among Patients at High Cardiovascular Disease Risk: Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| **Domain 1: Research team and reflexivity** | | | |
| Personal Characteristics | | | |
| 1. | Interviewer/facilitator | Which author/s conducted the interview or focus group? | Line 137 |
| 2. | Credentials | What were the researcher's credentials? *E.g. PhD, MD* | Author information |
| 3. | Occupation | What was their occupation at the time of the study? | Line 137 |
| 4. | Gender | Was the researcher male or female? | Line 137 |
| 5. | Experience and training | What experience or training did the researcher have? | Line 137 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Relationship with participants | | | |
| 6. | Relationship established | Was a relationship established prior to study commencement? | Line 138-139 |
| 7. | Participant knowledge of the interviewer | What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research* | Not discussed |
| 8. | Interviewer characteristics | What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic* | Not discussed |
| **Domain 2: study design** | | | |
| Theoretical framework | | | |
| 9. | Methodological orientation and Theory | What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis* | Qualitative Description – Line 98 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Participant selection | | | |
| 10. | Sampling | How were participants selected? *e.g. purposive, convenience, consecutive, snowball* | GP – Snowball (line 106-107)<br>Patients – Convenience (line 116) |
| 11. | Method of approach | How were participants approached? e.*g. face-to-face, telephone, mail, email* | Line 106-120 |
| 12. | Sample size | How many participants were in the study? | Line 173<br>Line 186 |
| 13. | Non-participation | How many people refused to participate or dropped out? Reasons? | Line 176-177 |
| Setting | | | |
| 14. | Setting of data collection | Where was the data collected? e.*g. home, clinic, workplace* | Line 137<br>Line 142 |
| 15. | Presence of non-participants | Was anyone else present besides the participants and researchers? | Line 143 |
| 16. | Description of sample | What are the important characteristics of the sample? *e.g. demographic data, date* | Line 174-195 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Data collection | | | |
| 17. | Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Appendix A& B |
| 18. | Repeat interviews | Were repeat interviews carried out? If yes, how many? | No |
| 19. | Audio/visual recording | Did the research use audio or visual recording to collect the data? | Line 146 |
| 20. | Field notes | Were field notes made during and/or after the interview or focus group? | Line 143-144 |
| 21. | Duration | What was the duration of the interviews or focus group? | Line 142-143 |
| 22. | Data saturation | Was data saturation discussed? | Line 140 + limitations section |
| 23. | Transcripts returned | Were transcripts returned to participants for comment and/or correction? | No |
| **Domain 3: analysis and findings** | | | |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Data analysis | | | |
| 24. | Number of data coders | How many data coders coded the data? | Line 156-160 |
| 25. | Description of the coding tree | Did authors provide a description of the coding tree? | Line 157 |
| 26. | Derivation of themes | Were themes identified in advance or derived from the data? | Line 157-158 (inductive) |
| 27. | Software | What software, if applicable, was used to manage the data? | Line 164-165 |
| 28. | Participant checking | Did participants provide feedback on the findings? | Line 414-415 |
| Reporting | | | |
| 29. | Quotations presented | Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number* | In-text and Table 3 |
| 30. | Data and findings consistent | Was there consistency between the data presented and the findings? | Yes |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| 31. | Clarity of major themes | Were major themes clearly presented in the findings? | Results section |
| 32. | Clarity of minor themes | Is there a description of diverse cases or discussion of minor themes? | Table 2 & 3 |

BMJ Open

# Strategies for Enhancing the Initiation of Cholesterol Lowering Medication Among Patients at High Cardiovascular Disease Risk: A Qualitative Descriptive Exploration of Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention in Alberta, Canada



| | |
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| Keywords: | QUALITATIVE RESEARCH, GENERAL MEDICINE (see Internal Medicine), Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Cardiology < INTERNAL MEDICINE, PREVENTIVE MEDICINE |
| | |

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# Strategies for Enhancing the Initiation of Cholesterol Lowering Medication Among Patients at High Cardiovascular Disease Risk: A Qualitative Descriptive Exploration of Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention in Alberta, Canada

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## ABSTRACT

**Objective:** The objective of our study was to explore the perspectives of patients and general practitioners (GPs) regarding interventions to increase initiation of cholesterol lowering medication (or statins), including a proposed laboratory-based facilitated relay intervention.

**Design:** Qualitative descriptive study using interviews and focus groups for data collection, and thematic analysis for data analysis.

**Setting:** Primary care providers and patients in Calgary, Alberta, Canada.

**Participants:** 17 General Practitioners with primarily community-based, non-academic practices with at least 1 year of practice experience participated in semi-structured interviews. 14 patients at high risk of cardiovascular disease participated in focus groups.

**Main outcome measures:** Exploration of strategies that might be used to enhance the prescription of, and adherence to statin therapy for patients with statin-indicated conditions.

**Results:** GPs proposed a variety of interventions to improve statin prescription, including electronic record audit solutions, GP directed education and patient-oriented campaigns. Patients expressed that they may benefit from being provided access to their laboratory test results, as well as targeted education. Both parties provided positive feedback on the proposed laboratory-based facilitated relay intervention, while pointing out areas for improvement. Notably, GPs were concerned that the patient-directed component of the intervention might jeopardize therapeutic relationships, and patients were concerned about accidental disclosure of personal health information. Important considerations for the design of facilitated relay messaging should include brevity, simplicity and the provision of contact information for inquiries.

**Conclusions:** GPs and patients described several suggestions for increasing statin initiation and welcomed the proposal of a laboratory-based facilitated relay strategy. These findings support further testing of this intervention which may enhance GPs' ability to successfully engage patients in cardiovascular risk reduction through statin therapy.


**Keywords**: focus groups, qualitative research, interviews, statins, facilitated relay

**Strengths & Limitations of this Study**

- This is a qualitative study, with relatively few participants – therefore we cannot say definitively if the views represented here represent those of all patients and prescribers.
- We sampled physician participants to the point of saturation, which means that we are confident the views represented here span the breadth of those held by physicians.
- The patient sample we recruited may not be representative of the broader population, as many of them had previously stated an interest in quality improvement and research – and this group was not sampled to saturation.
- Given the context-dependent nature of qualitative data, the applicability of these findings to other settings is not certain.
- By collecting qualitative data through open-ended questions, we were able to record detailed accounts and opinions.

## INTRODUCTION

Vascular disease, including coronary artery disease, peripheral artery disease, and cerebrovascular disease, remains among the leading causes of mortality worldwide (1). A class of medications, HMG-CoA reductase inhibitors, commonly known as statins, have proven to be effective for lowering the risk of vascular events (2). Individuals who have previously had vascular disease (i.e. secondary prevention) derive a greater absolute risk reduction from statins than those who have never had vascular disease (i.e. primary prevention) (3). There are some individuals who have never had vascular disease, such as those with diabetes or chronic kidney disease, who have also been shown in randomized controlled trials to benefit from therapy (4-6). Despite over 30 years of clinical use, efficacy, safety and cost-effectiveness data (7, 8), only 23% to 55% of individuals who would benefit take this medication and fewer than half of individuals are treated to target cholesterol levels (7, 9-11). There is substantial unwanted variability in dyslipidemia management, and health system intervention is required to promote equitable treatment (12, 13). The lack of statin treatment for patients with indicated conditions results in significant excess morbidity and mortality. In Canada, specifically, if all patients with indications for statins were treated, this would result in nearly 40,000 averted cardiovascular events annually (14). In the United States, 13% of cardiovascular deaths could be prevented with perfect statin adherence among patients at high cardiovascular risk (15).

Physicians and patients face numerous barriers when it comes to prescribing and adhering to statin therapy, from the providers perspective this includes lack of knowledge, conflicting clinical guidelines, lack of systems to identify patients who should be taking statins (16). On the other hand, patients often experience or fear side effects or are simply averse to taking additional medications (16). Furthermore, patients that face social disadvantages such as low income, lack of health insurance, and minority race are more likely to not use statins (17). A large US-based survey found that side effects were common and that many former statin users were unsatisfied with the explanation provided by their prescriber about the importance of the medication (18). Providers need resources to help them provide this counselling to patients and to arm them with strategies to mitigate common statin side effects, like muscle aches (19).

There are clearly many challenges that lead to the observed clinical treatment gap for patients who have indications for statin treatment. However, some studies have shown that such treatment gaps, in related conditions like hypertension, can be closed using quality improvement strategies (20-22).

Integrated quality improvement strategies that target both patients and healthcare providers are more likely to achieve quality indicators than strategies which only target one aspect in isolation (21). One such strategy is facilitated relay. Facilitated relay is a quality improvement strategy whereby information about individual patients is sent directly to healthcare providers through a means other than the usual clinical encounter (23). Despite the establishment and promotion of facilitated relay and other quality improvement strategies, there remain significant treatment gaps in hypertension (24) and other chronic conditions (25). Furthermore, while facilitated relay has been shown to be effective in improving a number of cardiovascular risk factors (21, 26), it remains among the least commonly used quality improvement strategies (27) and has not been explored in the management of dyslipidemia.

For an intervention to have the potential to yield maximum impact, it is important to qualitatively seek the input of key stakeholders prior to the application of any intervention (28). This allows for the development of a higher quality intervention, rather than one that relies on physician feedback alone (29)**.** As such, the objective of our study was to explore the perspectives of both patients and general practitioners' (GPs) regarding interventions to increase cholesterol lowering medication (or statin) prescription, including specific feedback on a proposed laboratory-based facilitated relay intervention.

**METHODS:**

**Study Design**

We conducted a qualitative descriptive study (28) to explore patients' and GPs' perspectives on interventions to increase initiation of statins for cardiovascular risk reduction and treatment of high cholesterol in those at high cardiovascular risk. In addition to generic thoughts on potential hypothetical interventions, we specifically sought directed feedback and perceptions on the acceptability of the proposed facilitated relay intervention from both patients and GPs (30). We used the consolidated criteria for reporting qualitative research (COREQ) as the reporting framework for this study (31).

**Proposed Intervention**

We drew from behaviour change theory to develop a facilitated relay intervention to increase statin prescriptions (32-34) (Figure 1). Our proposed intervention partners with our province's single unified laboratory system to identify individuals who have elevated cholesterol levels, statin-indicated conditions, and who are not currently filling prescriptions for statins. Our lab system has access to province-wide administrative databases, including labs, pharmacy dispensations, and hospitalization data. For every elevated LDL-cholesterol level, the lab would have an algorithm that would check the patients' records for evidence of statin-indicated conditions (administrative markers of myocardial infarction, stroke, diabetes, or chronic kidney disease), and would then identify if the patient has recently filled a statin prescription. This is possible because of province-wide, linkable databases. For patients who are not filling statins, but who should be, their GP (who had ordered the cholesterol level) and the patient, will then each receive a letter outlining the indication for treatment and the potential to benefit from statin therapy. The patient letter will encourage them to speak to their GP, and the GP letter will encourage them to make an appointment to discuss directly with the patient - both with the objective to initiate or renew statin prescriptions. We felt that it was important to include patients in the facilitated relay to empower them in discussions with their GP and to enable shared decision-making (35), which has been demonstrated to improve adherence with statins (36).

**Participant Recruitment**

*General Practitioners:* We recruited general practitioners to participate in individual interviews, using a snowball sampling approach. First, we asked key stakeholders in areas of primary care, endocrinology, nephrology and cardiology affiliated with the university medical centre, to recommend community-based (non-academic) GPs to participate in the study. Individuals were then contacted by telephone and email with a formal invitation to participate. GPs who met the following criteria were enrolled: (1) currently practicing in community general practice settings; and, (2) at least one year of experience working as a GP in independent practice. We sampled participants purposively based on several key demographic characteristics in order to achieve representation across a range of ages, genders and practice types.

*Patients:* We recruited patients who would qualify as recipients of the proposed intervention. Specifically, we were interested in recruiting those at high risk of cardiovascular disease, who self-reported a prior history of high cholesterol, preferably with co-existing vascular disease (myocardial infarction, stroke or peripheral vascular disease), diabetes, or chronic kidney disease. Using a convenience sampling approach, we invited patients who were part of an established advisory panel and previously agreed to be contacted about research opportunities for study participation (37, 38). In addition, patients were recruited using poster advertisements placed throughout the academic health sciences centre and in various clinical care areas where care is provided to patients with diabetes, heart disease and kidney disease.

**Data Collection**

Data was collected from September 2018 to November 2018 using both qualitative semi-structured interviews (with GPs) and focus groups (with patients). We chose focus groups for patients as rich personal disclosures are more likely to occur in this setting than in individual interviews (39). However, we purposely used individually scheduled interviews to offset potential aversion to focus groups by community-based GPs due to their competing clinical demands. Furthermore, we wanted to recruit from both urban and rural locales which is more challenging to do in a focus group.

*Question Guides:* Both focus groups and interviews were guided by question guides (Appendix A & B) which were developed based on a review of the literature (40, 41) and discussion with the research team. These were designed so that they initially asked study participants what they thought would be effective strategies or interventions to improve statin uptake (i.e. prescribing, patient use and adherence). After they had given their unprompted views, participants were then given a brief explanation of facilitated relay, the specifics of the proposed intervention (Figure 1), and they were shown a copy of the proposed intervention letter for GPs (Appendix C). After briefing participants on the principles and practices of facilitated relay and showing them our preliminary documents for the intervention, we asked them to provide feedback on this proposed intervention.

*Provider Interviews:* All interviews were conducted in-person (in clinician offices) or via telephone, by a female trained research assistant (RCWL) with oversight by experienced study team members. Physician interviews were continued until the point of theoretical saturation when no new information emerged from the interviews (42). Because the research objective was relatively focused, interviews were brief and lasted approximately 30 to 45 minutes.

*Patient Focus Groups:* None of the study team were acquainted with or involved in the clinical care of the patients who participated. We convened two focus groups in our academic medical centre which each lasted approximately 90 minutes. No one but researchers (including 1 facilitator and 2 field-note takers) and participants were present. Focus group facilitators tried to ensure that there were no dominant members and provide all participants with equal opportunity to voice their opinions.

Interviews and focus group proceedings were digitally audio-recorded and transcribed verbatim by a professional transcriptionist. Field notes were recorded to inform data analysis. All data were anonymized and stored securely. Signed informed consent was received from each study participant. Gift cards were provided to all participants. Ethics approval was granted from the University's Health Research Ethics Board.

**Data Analysis**

Analysis was completed using conventional qualitative content analysis (43), a method of interpreting interview data with the goal of describing the phenomenon of interest. Transcripts for the initial three interviews were reviewed by three team members (DJTC, RCWL and SB), with the objective of inductively establishing a preliminary coding template that was used for subsequent data analysis. All transcripts were then analyzed by two reviewers (DJTC and RCWL). Codes were generated from the interview data and systematically applied to identify themes and patterns. The process was iterative, reflexive, and interactive as continual data collection and analysis shaped each other. For example, code titles or definitions identified based on earlier interviews were modified according to the data collected during subsequent interviews. The team met together to review the coding to elicit discussion about the coding strategy and attempted to achieve consensus to resolve coding discrepancies. NVivo 12 (Doncaster, Australia) qualitative data analysis software was used to facilitate the coding process.

**Patient and public involvement**

Patient partners and family members from the Libin Cardiovascular Institute's established patient and family member advisory group (44) voiced that *prevention* was one of their top research priorities for cardiovascular health. This work is related to prevention of cardiovascular disease. Patients were included in focus groups.

**RESULTS**

In total, we eventually reached out to 27 GPs to invite them to participate, 4 declined to participate, 4 didn't respond to the invitation, 19 were scheduled for interviews, with 2 cancelling. We reached saturation after having completed 17 individual GP interviews (Table 1a). The majority were women (88%) with 65% having graduated from medical school within the last ten years. All GPs spent more than 50% of their time in clinical practice, most were in urban centers within Primary Care Networks (PCNs). PCNs are networks of GPs that share interdisciplinary resources to enhance the delivery of primary care within geographical regions (45); they are associated with improved chronic disease care and outcomes(46).

**Table 1a.** Descriptive statistics for General Practitioners (n = 17).

| **Physician characteristics** | **Total** (%) |
|---|---|
| Age (years) | |
| < 40 | 13 (76) |

| | |
|---|---|
| 40 - 60 | 4 (24) |
| Gender | |
| Man | 2 (12) |
| Woman | 15 (88) |
| Years of primary care practice | |
| < 10 | 14 (83) |
| 10 – 20 | 3 (18) |
| Years since medical school graduation | |
| < 10 | 11 (65) |
| ≥10 | 6 (35) |
| Primary Care Network membership | |
| Yes | 15 (88) |
| No | 2 (12) |
| Location of primary care practice | |
| Urban | 13 (76) |
| Rural | 4 (24) |
| Focused practice interest | |
| Yes* | 9 (53) |
| No | 8 (47) |
| | |
| Clinical practice last 12 months | |
| Estimated number of patients at high CVD risk | |
| < 20 | 1 (6) |
| 20 to 99 | 7 (41) |
| ≥100 | 9 (53) |
| Use of endocrinology consultation services | |
| Yes | 5 (29) |
| No | 12 (71) |
| Use of cardiology consultation services | |
| Yes | 10 (59) |
| No | 7 (41) |
| Use of nephrology consultation services | |
| Yes | 3 (18) |
| No | 14 (82) |
| | |
| Proportion of patients in their practice who would be considered high risk on the basis of cardiovascular risk factors (n=14) | Mean: 32%<br>Range 10-75% |
| | |
| Proportion of high-risk patients in their practice who have a current LDL-level on file (n=9) | Mean: 82%<br>Range 70-90% |

* Focused practice, or special interest types: care of the elderly (n = 2), emergency medicine (n = 1), urgent care (n = 1), refugee medicine (n = 1), obstetrics (n = 2), indigenous health (n = 2), lactation (n = 1).

Our patient focus groups had 8 and 6 participants, respectively (Table 1b). There was a range of ages represented among patients, with a similar number of men and women. Nearly all had a general practitioner and were also followed by medical specialist(s). The conditions represented in our patient group were diabetes, history of myocardial infarction and elevated cholesterol level; none reported a history of stroke, chronic kidney disease, or peripheral arterial disease.

**Table 1b.** Descriptive statistics for patient participants based on self-report (n = 14).

| **Patient characteristics** | **Total** (%) |
|---|---|
| Age (years) | |
| < 40 | 2 (15) |
| 40 - 60 | 5 (39) |
| > 60 | 6 (46) |
| Gender | |
| Men | 6 (46) |
| Women | 7 (54) |
| Chronic condition qualifying as "high CVD risk" | |
| High cholesterol only | 3 (23) |
| Diabetes only | 6 (46) |
| Myocardial infarct (MI) only | 1 (8) |
| Diabetes & MI | 3 (23) |
| Has a primary care provider | |
| Yes | 12 (92) |
| No | 1 (8) |
| Followed by a medical specialist | |
| Yes | 10 (77) |
| No | 3 (23) |
| Self-reported awareness of high cholesterol levels | |
| Yes | 11 (85) |
| No | 2 (15) |
| Current use of statin medication | |
| Yes | 6 (46) |
| If not, had spoken with physicians about statins | 3 (23) |
| If not, had not spoken with physicians about statins | 4 (31) |

*Note one participant did not complete a demographic questionnaire

**General suggestions for potential interventions**

Several themes arose regarding interventions to improve statin initiation during the unprompted portion of the interviews (Table 2). GPs described that statin prescribing may be improved by: (1) enhancing aspects of physician education to promote appropriate statin prescribing; and, (2) implementation of support tools to help physicians in decision-making and identification of patients for whom statins are indicated. In addition, patients suggested that having access to their own laboratory results may enable them to be more effective self-advocates.

**Table 2.** General suggestions by general practitioners and patients to increase initiation of statins

| | | |
|---|---|---|
| Providers | Treatment of specific Sub-populations | Patients with chronic kidney disease:<br>*"I struggle with the GFRs [glomerular filtration rate] – knowing when it would be safe, when it wouldn't be safe. I do get confused as to the dosing based on GFR."* (GP-05)<br><br>Patients who previously experienced side effects with statin(s):<br>*"I have one strategy but if somebody is still like 'no, it's completely not tolerable for me' then I don't know what the next step is after that."* (GP-13)<br><br>Elderly patients:<br>*"…getting some better understanding about the elderly. Are there any contraindications to starting on statin therapy? Is there one statin that may be more beneficial than another?"* (GP-10)<br><br>Patients with hypertriglyceridemia:<br>*"I always find it hard to know what to do with triglycerides… more education around how to manage those [patients]."* (GP-15) |
| | Treatment to Targets * | *"Most people in my office are confused about what we are doing in terms of treating to the target of 2 mmol/L, because the cardiologist is still sending consults about that, but then we have these family medicine evidence-based groups saying that targets don't matter".* (GP-02)<br><br>*"I know the TOP [Towards Optimized Practice] guidelines don't necessarily correlate with CCS [Canadian Cardiovascular Society] guidelines, so there are several schools of thought".* (GP-09)<br><br>*"There's no real way to unify the guidelines, but to have an education session on why they're different and how to approach it so maybe you'll break down patient populations that fit better with one guideline versus another".* (GP-08) |
| | Preferred modality of Education | *"we have a lot of drug reps [representatives] coming to town, so it would be great to have more [education] that was not pharma, absolutely"*. (GP-04) |
| | EMR-based tools | *"One thing that would be helpful for me is if there was some automatic flag that came when I saw a patient that would alert to the fact that their treatment is not optimized for their conditions"*. (GP-06) |
| Patients | Laboratory Results | *"I would like to get a copy, in addition to the doctor. I can do with it what I want"* (Pt-09)<br><br>*"It gets you questioning things so that you can come back to your doctor and say 'I saw these numbers, what does that mean? What do I need to do?'"* (Pt-02) |
| | Enhanced education | *"What if somebody was going regularly to a lab, and a clinician sort of goes: 'How are you doing on this?"*. (Pt-08) |

EMR: electronic medical record

* Specialist guidelines, the 2016 Canadian Cardiovascular Society guideline (47) advocates that patients at high risk (based on risk calculators) or those with 'statin-indicated conditions' (defined as diabetes, chronic kidney disease, or preexisting vascular disease be treated with statin therapy to achieve a target LDL-c level of < 2.0 mmol/L. GP Guidelines, the 2015 TOP Alberta Guideline (48) encourages GPs to treat high risk patients with moderate-to-high intensity statins and should not repeat lipid levels, or attempt to treat to a fixed target.

*1)* General practitioner *education:*

Nearly all GPs highlighted that there are general areas of knowledge that could be bolstered in order to enhance statin prescription. One of the main content areas in which they sought enhanced education related to the treatment of specific patient sub-populations, in particular those with chronic kidney disease, patients who have had prior statin intolerance/side-effects, elderly patients, and those with other concurrent lipid disorders (i.e. hypertriglyceridemia).

Whether providers should be treating patients to a specific cholesterol level was a major source of confusion. They frequently referenced receiving conflicting advice, including a contradiction in clinical practice guidelines(49), some of which advocate for a 'fire and forget' approach(8, 50), while Canadian(7) and European(51) specialist guidelines recommend a 'treat-to-target' approach(7).

Regarding the modality of education sessions, most preferred in-person education sessions delivered at their clinics and delivered by someone who did not have clear conflicts of interest with pharmaceutical companies. Many GPs also suggested the use of handouts, tools or algorithms to simplify their decision-making process.

*2)* General practitioner *tools*

In addition to education, several GPs suggested that the use of automated tools would facilitate their prescribing of statins. Most felt that they would benefit from optimizing the use of their electronic medical records (EMR) to 'flag' individuals who were at high cardiovascular risk or had elevated cholesterol levels. Other GPs spoke of wishing for a 'running list' of eligible patients, while some mentioned using an employee or contractor designated as a panel manager to perform these tasks.

*3) Patient results and information*

Many patients independently indicated that they would like to have access to their lipid test results, without needing to rely on this being conveyed to them by their general practitioner. Some patients also suggested that providing them with their own results might reduce the frequency of unnecessary follow-up visits; and as a result, alleviate related financial burden on the healthcare system. Doing so was also thought to help foster patient engagement with their GP.

Patients also felt that having greater access to information about cholesterol and treatment might facilitate more patients being on statin therapy. Suggestions were made to deliver this through enhanced patient-facing materials (i.e. brochures), as well as pharmacists or lab technicians who were able to discuss results and treatment options. Further information about patient education, shared

decision-making, and clinical decision support tools are described in our other report from this work (16).

**Feedback on the proposed facilitated relay intervention**

Emerging themes regarding our proposed intervention were organized into four major categories: (1) general feedback and impression; (2) suggested changes; (3) intervention details; and, (4) workflow processing considerations.

*1) General feedback and impression*

General practitioners responded to the proposed intervention with strongly positive feedback (Table 3), which included stating that they found the information to be helpful and direct. They generally felt that the letter was written in a clear fashion and with a respectful tone. Several mentioned that the information provided them with reassurance and credibility in making recommendations to their patients.

GPs also voiced some questions and potential concerns after hearing about our proposed intervention. These concerns included whether the introduction of a facilitated relay intervention might increase their workload, lead to possible disclosure to patients of new diagnoses of conditions that qualified them as high risk (i.e. diabetes), and pose a threat to their therapeutic relationships with patients. In addition, logistical issues around how the letter will be best delivered to ordering providers and patients were raised as concerns.

Patients generally felt that bringing their facilitated relay letter to a scheduled appointment would be positive in their relationship by providing structure to the follow-up encounter, holding GPs to account, and enhancing patient-provider communication. Even though most were generally positive, some patients expressed concern about the facilitated relay intervention, including the possibility for privacy breaches and increasing patient anxieties.

*2) Suggested information to remove or add*

We asked GPs specifically what they would like to see changed in the preliminary materials shown. Almost unanimously, they suggested that the letter would be more appreciated if it the two-page document were shortened to fit on one page. Several participants suggested removing the references, mention of clinical studies, and guideline citations to make it more reader-friendly. There was also a preference voiced for revising the introductory paragraphs to have direct relevance to individual patient(s):

> *"I'm going to read it for sure, but then when you start to read it, people might put it down and say 'oh this is a study intervention', [but] if you have the first thing at the very top: 'you know this person has been identified as being at risk' – then it's about the patient rather than being about the studies".* (GP-16)

A few GPs voiced opinions that specific additions could be made to improve the letter's utility. These suggestions included adding: information about health behavior change (*"the whole picture, as opposed to just medication"* (GP-04)*);* adding contact information for a specialist; and details about how/why a particular individual was flagged as eligible for the facilitated relay intervention: *"It would be helpful if I*

*got a name, condition and then the statin-indicated condition, and where the condition was pulled from"*. (GP-01)

Patient feedback was notable for also suggesting that the intervention provide contact information, in case they have further questions about interpreting their results: *"back that up with a helpline for somebody that doesn't know what the [results] mean"* (Pt-10). Similar to physicians, patients expressed a strong preference for brevity: *"If I have to go through 14 pages of information to figure out what that means, I'm sorry, I don't have time for that"* (Pt-07).

However, numerous patients also stressed the importance of not only providing results or diagnoses, but also giving some basic education and an action plan to follow.

*3) Intervention details*

In addition to general feedback, we also explicitly asked GPs whether they would prefer to receive information about their patient in the form of facilitated relay (individual letter for each patient identified) or 'audit and feedback' (summary report including a group of their patient panel). A summary list or report (audit and feedback) was preferred by roughly 2/3 of the general practitioners interviewed. Regarding receiving letters for each patient, participants stated:

> *"this is going to get tiresome very quickly"* (GP-05)
>
> *"Am I going to get this letter 20 times? I'm probably just going to read it once"* (GP-03)
>
> *"[a list would] decrease paper burden, decrease the chance of it getting misplaced"*. (GP-13)

While the 'audit and feedback' approach was more popular, some GPs were clearly in favor of facilitated relay: *"I can't even think of the amount of work it would take to do it patient-specific. I'd love it. Sure go for it, if you have the means to do it, then why not?"* (GP-10)

We also asked pointedly about how providers would feel about receiving a follow-up reminder from the study team, if patients had not filled the prescription as recommended in the initial letter. The response was split with roughly half of the general practitioners stating that a reminder would not be necessary.

Those who felt a reminder would be acceptable generally agreed that a 6 month window should be sufficient to ascertain whether or not the patient would have started on therapy: *"There are people that have a three-month wait list time, you may have to pick an interval more like six-months to appeal to the masses…"*. (GP-13)

Most patients felt that they would benefit from receiving a follow-up reminder. After considerable discussion amongst the groups, consensus was achieved that follow-up should not happen prior to four months, and possibly even as long as six months after the initial contact. One participant stated: *"close enough that I vaguely remember that I meant to do something with that, but not a few weeks later, [so] it's not irritating".* (GP-17)

We also asked patients if they had a preference for who had signed the letter. Most felt that having letters come from a local specialist in cardiology or endocrinology would be preferable to having them signed by another GP.

*4) Workflow processing considerations (*General practitioners *only)*

To each GP we asked specific details about how our intervention letter would be received in their offices and what would happen upon receipt. The majority stated that such a letter would be opened and processed by their front-desk staff. One participant clarified that the information on the envelope would determine who opened it: *"if it's addressed to me then it will come to me, if it has a patient name for me, then it goes through our document people [who file it]"*. (GP-09)

Once the letter has been opened, different offices employed a variety of different processes. In many practices, it would be given directly to the GP; while in others it would be scanned directly into a patient's file in an electronic medical record, yet in others, the hardcopy would be filed in a patient's chart.

In terms of the preferred delivery modality, most GPs felt that electronic delivery directly via the EMR platform would be the preferred method of receiving the intervention. However, a number still felt that conventional delivery via paper mail or fax would be preferable. Even those who expressed a preference for conventional delivery, many elaborated that such letters would often be scanned into a patient's electronic file: *"if it was to come by mail or fax, then they have to scan it onto the computer"* (GP-11). A few GPs described systems which can do this process automatically: *"our office works with a new web system, so everything that comes in via the fax actually goes directly into the computer and they then allocate to the patient".* (GP-11)

**Table 3.** Positive and negative feedback on facilitated relay intervention from general practitioners and patients

| General Practitioners | | Patients | |
|---|---|---|---|
| **Positive** | | | |
| **Composition** | "Overall I thought it was worded quite well and was very clear" (GP-08)<br><br>"I think it's appropriate, it didn't take me very long to get through" (GP-16) | **Provides structure to interaction** | "My doctor would be okay with that. It gives them a little checklist of things to talk about". (Pt-05) |
| **Tone** | "it's written in a way that doesn't make you feel stupid, I guess" (GP-11)<br><br>"it's good because [it's] not telling you to do this [start statin therapy], but telling you to have a conversation]." (GP-17) | **Enhances communication** | "I think that's good 'cause these doctors, some guys don't communicate." (Pt-13) |
| **Credibility** | "it gives family physicians more confidence to do those things and know the specialists are behind them in that recommendation" (GP-02) | **Increases doctor accountability** | "I think it keeps them [doctors] honest as well. They should actually be proactive in terms of having that information already, but that's not always the case. So I don't have a |

| | | | |
|---|---|---|---|
| | "there's so much information for people to sift through… if you can get valid information that's corroborated and consistent, that's helpful" (GP-15) | | problem with a patient having all their information at their disposal". (Pt-14) |
| **Direct** | "it's a good idea… it tells you what to do, which is great. You don't have to look up the guideline every time" (GP-04)<br><br>"it's just one of those extra little reminders that takes the brain power out of the work you have to do day-to-day" (GP-06) | **Increases patient accountability** | "If [patients] are encouraged to work with their doctor to monitor your numbers, you have a bit of control as well as the doctor… like working together". (Pt-03) |
| **Information** | "[side effects] are what people hear about in the news a lot, so it's very helpful to have some numbers around it, and strategies to address that" (GP-09)<br><br>"All the suggestions that you made are excellent. I'm reading through this and I'm like ' oh yeah, I didn't realize this' and ' this is something I can do for some of my patients'" (GP-12) | **Provides peace of mind** | "It gives me a little peace of mind in that we've talked about all of the things that are important and that should be covered… that we haven't left anything out". (Pt-05) |
| **Negative** | | | |
| **Increased workload** | "I would caution against anything that causes more documents or more paperwork… there's already so much" (GP-16) | **Privacy concerns** | "You know what, my doctor isn't going to send it out to me, anyway. It's going to go on to a receptionist, who might pass it on to somebody else in the office, so there's no guarantee of privacy there" (Pt-05)<br><br>"Privacy is always an issue. I mean it's like, the less information that's out there about you, the better off you are, period. I don't care what it is" (Pt-07) |
| **Disclosing new diagnoses** | "my concern is that they get this information from a letter… my preference would be that it came straight to me" (GP-01) | **Difficulty interpreting results** | "Some people might know all the numbers and everything else, I don't. You give me a bunch of numbers, it means nothing to me. So unless the doctor explained it to me… I'd rather talk to my doctor" (Pt-07) |

| | | | |
|---|---|---|---|
| **Therapeutic relationship** | "If the patient gets a letter that's like 'you need to be on a statin' and we already had a conversation that they didn't need a statin. That could cause some issues in the therapeutic relationship." (GP-04) | **Provoking Anxieties** | "There are people who are coming down with every disease known to man, so for someone like that, that kind of information would just send them off the deep-end, right?" (Pt-05) |
| **Logistical concerns** | "What if a person gets a check from a walk-in clinic? My concern is then is that walk-in clinic docs are just going to ignore this letter" (MD-05)<br><br>"If it goes to the patient, sometimes you get lots of mail and they may just discard it" (MD-10) | **Lack of engagement** | "You mentioned mail outs and things like that… have they proven to be effective, though, 'cause how many people read them? How many people understand them? I don't think there would be a lot of point in it, 'cause I don't think people pay that much attention" (Pt-09) |
| | | **Sense of intimidation** | "Some will [say] 'I can't talk to my doctor like that'. There will be some people who might be intimidated to initiate that conversation" (Pt-03) |

## DISCUSSION

While statins have a more limited role in certain populations (low risk and those with limited life expectancy) (52, 53), they are important for the prevention of cardiovascular disease in patients who have previous vascular disease and in those with diabetes and kidney disease (4-6, 47). In this study, both GPs and patients acknowledged that there is the potential to improve the prescription and use of statin therapy among those at high risk for cardiovascular disease. In unprompted questions, GPs acknowledged that there was a need for improved physician education on this topic, and that tools to help identify and track patients would be helpful. Patients also suggested that if directly receiving laboratory test results and information on treatment options may result in better medical care, generally supporting our hypothesis that facilitating shared decision making was a key element of a novel intervention. When shown the proposed intervention, both groups were strongly supportive of the facilitated relay intervention. While there were clear benefits to the intervention, some potential downsides were raised by both GPs and patients. In general, all recipients would prefer letters to be succinct, yet contain high yield information and provide contact information where clarification could be sought.

Many interventions have been attempted to address the problem of statin underuse. A number of patient-centered approaches have been tried with varying success (22). While active forms of education, like cognitive education and behavioural counselling seem to work (54), more passive forms of education are often unsuccessful at changing behaviour, as in the recent ISLAND trial which found their intervention, comprised of a mail and phone education strategy to encourage patients to take prescribed medication, had no impact on adherence (55). Others have found that multifaceted interventions focusing on enhancing care provision through team-based care may be effective at increasing statin adherence (56).

However, when trying to target the problem of low statin prescribing, interventions directed only at patients are not likely to work. An alternate approach is to facilitate GPs ability to identify and prescribe

statins, to those in whom they are appropriate (57), through audit and feedback or facilitated relay. An educational audit and feedback intervention regarding dyslipidemia treatment in Italian primary care practices was shown to increase adherence to statins by approximately 10% (58). Improved communication and shared decision making, which are explicit goals of facilitated relay interventions, can improve patient adherence (59). While these and other studies have reviewed the clinical efficacy of quality improvement strategies (21), few have used detailed qualitative methods as we have done. One large qualitative study interviewed audit and feedback experts to generate hypotheses about the various factors that may contribute to the efficacy of such interventions (60). Others have used qualitative methods to highlight the barriers physicians face in encouraging adherence (61), but ours is unique in using such methods to design and develop an intervention to address these challenges. Finally, we also appreciate that as much as there is underuse of statins, there is also overuse, for example, in people with short life expectancy. Perhaps interventions to increase initiation may also include a component that conveys statin benefits are measured in years rather than months.

The fact that participants suggested elements of our facilitated relay intervention in the unprompted portion of the interviews lends credibility and face validity to the proposed intervention. However, it is notable that while GPs felt they would benefit from having internal systems to monitor patients' records, none independently suggested a strategy mediated by an independent third party (such as facilitated relay or audit and feedback), as we have proposed. Investigators who wish to implement facilitated relay interventions to enhance adherence to medical therapies can use the findings of this study to help develop interventions that are more likely to be acceptable to both GPs and patients. One of the main findings is to ensure that any information provided is brief and high yield, containing patient identifiers early to capture general practitioner's attention. Such interventions can be strengthened by incorporating education on controversial or little-known topics. Patients strongly preferred any correspondence to also contain direct suggestions or an action plan. Workflow and processing of these letters needs to be considered and interventions designed to be as minimally disruptive to clinical practice as possible – with most physicians preferring that it be embedded directly within the EMR; yet in healthcare settings (like ours) where there is marked heterogeneity in the use and type of EMRs, this may not be possible.

There are limitations to this study. Firstly, as in most qualitative studies, the number of participants was relatively small. This concern over sample size is mitigated by the fact that physician interviews proceeded until the point of saturation. Patient data were not collected in this manner, and these themes may not be fully saturated and we appreciate this as a limitation. Furthermore, the patient sample we recruited may not be representative of the broader population, as many of them had previously stated an interest in quality improvement and research and therefore may be attuned to the importance of preventive therapies more than other members of the general public. Secondly, given the context-dependent nature of qualitative data, the applicability of these findings to other settings is not certain. Yet physicians in most settings face similar problems (i.e. time constraints, patient complexity and comorbidities and patient resistance to medical therapies) in numerous facets of medical care; therefore, it is conceivable that the findings of this study would apply to interactions between patients and GPs in other clinical settings. Due to time constraints of participants and researchers, member checking was not undertaken in this study. Finally, it is important to note that feedback was sought specifically about the proposed intervention. However, given the details reported, we feel that these findings are likely to be helpful to others proposing similar quality improvement interventions. One of the major strengths of this study is the depth and richness of the qualitative data that were collected. By asking questions in an open-ended manner, we were able to record detailed accounts and opinions.

Another strength of this work is the fact that we also sought patient input into the development of this intervention, rather than relying on physician feedback alone.

Statin therapy has been demonstrated to effectively lower cholesterol and reduce the risk of cardiovascular events and death in individuals at high risk of cardiovascular disease. Despite this, they remain underused. There are patient, provider and system factors that contribute to statin underuse. Facilitated relay interventions hold promise as a potential method to address this important care gap. Our study sought perspectives of both healthcare providers and patients, which will be incorporated into intervention design to maximize acceptability. Insights gained from qualitative data will be used to improve the likelihood of success and achieve the desired clinical impact. The insights about these interventions are also likely to be of interest to many researchers and clinicians who are considering and designing provider- and/or patient-facing interventions to improve the uptake of preventive medications.

**Contributions**

DJTC, RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, SB collaborated to develop the research question and methods. The study design was conceived by DJTC and SB. DJTC wrote the first draft of the study protocol. Data collection and analysis was completed by DJTC, RCWL and SB. KAM, TJA, HQ, AACL, GC, ML, and CN contributed to the interpretation and contextualization of study findings. The first draft of the manuscript was written by DJTC. RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, and SB contributed substantively to further revisions of the manuscript and have consented to the publication of this version.

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**Data Availability Statement**

No additional data available. Given that qualitative data are not deidentified and tell individuals' personal stories, data cannot be shared beyond the scope of this project, as per our research ethics board.

**Competing Interest Statement**

DC, RL, KAM, AL, TA, HQ, GC, SB – none. CN is a director of a private laboratory that does not currently offer testing in the jurisdiction under study.

Figure 1: Laboratory-Based Facilitated-Relay Intervention

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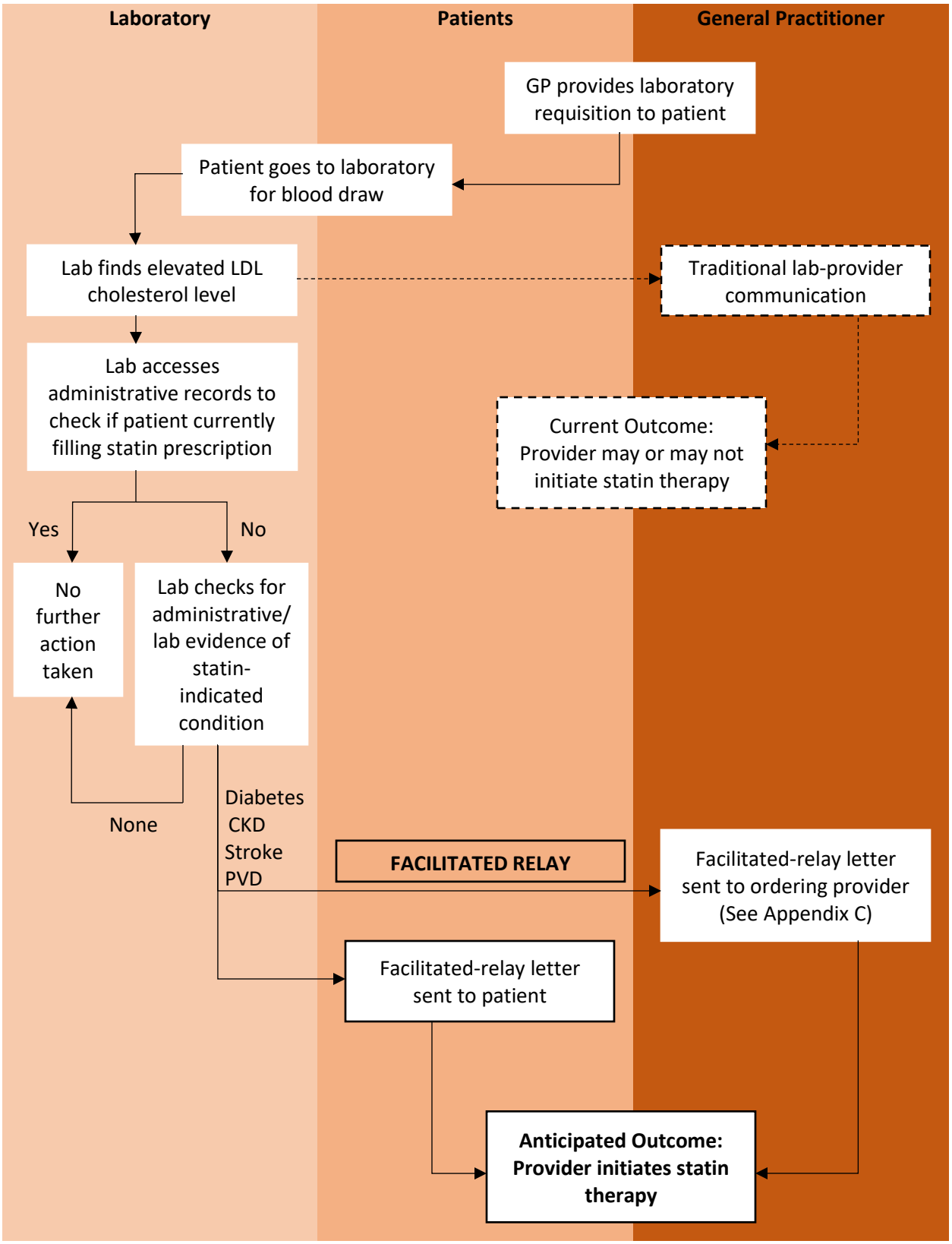


**Figure 1: Laboratory-Based Facilitated-Relay Intervention**
Dashed lines: traditional interface between lab and ordering provider

**Appendix A: Interview Guide for health care professional**

Thank you for agreeing to participate in our interview today. We wish to discuss your experience in managing dyslipidemia (or high cholesterol) in order to better understand how we might help family physicians treat dyslipidemia (or high cholesterol). We have a proposed intervention and would like your assistance in how to enrich it.

**1. Experience managing dyslipidemia**

Please describe any challenges or difficulties that you experience in identifying and managing patients with dyslipidemia?

- Do you use any resources to guide you in the management of these patients?
    - Canadian Cardiovascular Society Guidelines
    - Diabetes Canada Guidelines
    - TOP guidelines

In addition to measuring a patient's lipids, what are some other parameters that you consider when assessing a patient for dyslipidemia, and how to optimally manage this condition?

**2. Dyslipidemia-related practices**

In your practice, do you find it helpful to quantify a patient's LDL-cholesterol or get a lipid panel?

If yes,

- Are there certain populations in whom you find this test most helpful?
- What is your chosen method/diagnostic test to do so?
    - Fasting or random lipid profile
        - Total cholesterol
        - HDL-cholesterol
        - LDL-cholesterol
    - ApoB
- How does this information change your clinical practice?
- How often do you repeat cholesterol testing for patients with with conditions that puts them at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease)?

If no,

- Why is it not particularly helpful?
    - Don't know which test to do
    - Don't know how to order it
    - Don't know in whom it is indicated

- Don't know what to do with the results

In thinking about your practice, what proportion of your patients with conditions that put them at high risk for cardiovascular disease (i.e. previous myocardial infarction, stroke, diabetes, and/or chronic kidney disease) have had their lipid profile assessed in the past 12 months?

What are some of the reasons this does not happen (in your practice and in others')?

- Didn't think it was indicated/for whom it is indicated
- Too many things to attend to
- Not perceived to be an important issue amongst all other disease/conditions that FPs manage
- Patient factors (doesn't go for test)

**3. Intervention**

If we wanted to increase the use of statins among people at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease), what might be done? What tools, resources, prompts may help facilitate increased treatment of dyslipidemia?

In your opinion, what type of educational intervention is most effective in disseminating clinical practice guidelines to family physicians? (i.e. conferences, local lectures, treatment recommendations on lab results).

We are considering the use of a facilitated relay strategy, where patient's information from Calgary Laboratory Services is used to identify those who have indications for statin therapy. Those who are not currently filling statin prescriptions at the pharmacy would receive a letter from the lab indicating that they may benefit from statins. They will be encouraged to bring this letter in to discuss this with you.

How would family physicians respond to receiving a letter from the lab prompting them to consider starting their patient on statin treatment?

- What would be the characteristics of such a letter that would make it more likely to succeed?
    - Short/Pictorial/Colorful

Would it be more helpful to have this information specific about one named patient, or rather have an audit of your entire practice that would indicate what proportion of eligible patients with statin-indicated conditions are currently being treated with statins? (i.e. Audit and Feedback)

How should such an intervention either on a specific patient or about your entire practice be received?

- Mail/Fax/EMR/combo

How would such an intervention be processed in your office?

- Who would open the envelope?
- What would they do with it? (give it to you, put it in the patient's chart)
- How likely would you be to see this information?

Who should this letter be coming from in order to have it received in the most positive way possible?

- A non-clinical academic researcher (Dr. XXXX)
- Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- An academic family doctor (Dr. Kerry McBrien)
- A respected community family doctor
- The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- Dr. Cello Tonelli, Associate Vice-President (Research) at the University of Calgary
- Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic Disease Management, Community and Rural for Alberta Health Services
- Someone else

Would it be helpful to receive a reminder or follow-up letter?

- How much later should this be sent, so as to be useful and not annoying?

If the intervention provided you with patient-oriented material about this subject, and asked you to share it with your patients, how would you feel about doing so?

- What content should be included in this patient-oriented material to enhance statin use?
- What format should this material be in? Electronic, hard-copy? How should it be delivered? Mail, email?
- Would you share it in a clinical setting?
- Would you be willing to mail it to patients directly?

Do you have any additional comments or suggestions for developing an intervention to increase the use statins in people at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease) in primary care?

Thank you for participating in today's interview. Using the information you provided, we will work on developing an intervention to improve the treatment of dyslipidemia in patients who are at high risk for cardiovascular disease (i.e. previous clinical cardiovascular disease, diabetes, chronic kidney disease)?

**Appendix B: Focus Group Guide for patients**

Thank you for agreeing to participate in our focus group today. There are many risk factors for heart attacks and stroke. Today we want to focus on one risk factor being high cholesterol. High cholesterol is a major risk factor for heart attacks, strokes and circulatory problems. There are no symptoms of high cholesterol and it is diagnosed by a lab test that your doctor would order. Importantly, we work for the University of Calgary and have no relationship with any medication companies.

We wish to discuss your experience in managing *cholesterol* with medications in order to better understand how we might help family physicians (*doctors)* treat high cholesterol.

1. **Experience with high cholesterol**

Think about the last time your doctor has sent you for a cholesterol test. Did your doctor talk to you about the results? Treatment? What kind of treatment was discussed (diet, exercise, a medication)?

Put yourself in the position of being told that you need to take a medication for your cholesterol. What factors would make you more likely to take it? What factors would make you not want to take it? Reasons, side effects, costs

- Would you use any resources to help you decide?
    - Doctor
    - Dietician
    - Internet
    - Family, friends

What would you think if your doctor told you that your cholesterol wasn't all that high, but because of your other health conditions she wanted to start you on a cholesterol lowering medication to reduce your risk of heart attack and stroke?

Do you think it would be helpful to get the actual result of your cholesterol level sent directly from the lab to you?

Currently, cancer screening programs send letters to patients about their results and next steps. What are your thoughts for something similar for high cholesterol?

What about information about recommended treatments and potential side effects? Would you find this to be invasive of your privacy (i.e. info from the lab about treatment and not your doctor)?

How would you feel about taking a letter with these recommendations to your doctor to discuss about a medication for high cholesterol?

How do you feel your doctor would respond to you bringing this information?

What things on the letter would make it helpful?

-length, colour, graphics,

Who should this letter be coming from in order to have it received in the most positive way possible?

- A non-clinical academic researcher (Dr. XXXX)
- Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- An academic family doctor (Dr. Kerry McBrien)
- A respected community family doctor
- The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic Disease Management, Community and Rural for Alberta Health Services
- Someone else

Would it be helpful to receive a reminder or follow-up letter?

- How much later should this be sent, so as to be useful and not annoying?

Do you have any additional comments or suggestions for developing an way to increase the use the treatment of people with high cholesterol?

## Appendix C: Facilitated Relay Letter

UNIVERSITY OF CALGARY

Date: XXXX-XX-XX

Dear Dr. [Physician Last Name],

RE: [Patient Name]

As you may recall, your Primary Care Network is involved in a study with the University of Calgary. This is an investigator-initiated study with public funding from the [*Canadian Institutes of Health Research*].

Dyslipidemia is a major risk factor for myocardial infarction and stroke[1-2]. As you know, in patients like [name], statins are indicated for their dyslipidemia because they are proven to reduce cardiovascular outcomes and mortality[3-4]. Because of numerous randomized controlled trials, guidelines recommend statin use in individuals with history of previous cardiovascular disease, diabetes, or chronic renal failure[5].

We are writing to you to consider initiating a statin in your patient. We know the importance of the therapeutic relationship that you have with your patients and know that we do not know your patient like you do. The purpose of this letter is to assist in you in your discussion with [name], about using a statin medication.

[Name] may not be taking a statin because of underestimation of their personal risk of cardiovascular disease, fear of side-effects, previous side-effects, or cost. If cost is a concern, compassionate programs are available for several statin medications. Please kindly call our study telephone number to assist in facilitating this.

The most common side effect from statins is muscle aches, and the frequency of statin-induced rhabdomyolysis is very rare (i.e. < 1 in 10,000 patients per year on statins)[6]. Studies suggest that there are several proven methods for managing people who have experienced muscle aches. For those unable to tolerate daily high intensity statins, some statin is still better than none, and the following strategies can be considered:

1. *Reducing the dose of statin*. i.e. Atorvastatin 10-20mg or Rosuvastatin 2.5-5mg[7].

2. *Trying a low potency statin medication.* Lower potency statins seem to be less strongly associated with muscle aches. Fluvastatin and Pravastatin were much less likely than Simvastatin and Atorvastatin to cause myalgia[8]. For your reference, maximum doses of these low potency statins, and their equivalencies are:

Pravastatin 80mg = Atorvastatin 20mg = Rosuvastatin 10mg
Fluvastatin XL 80mg = Atorvastatin 10mg = Rosuvastatin 5mg

3. *Reducing dose or lengthening administration interval.* Studies have demonstrated that greater than 70% of patients affected by myalgias were able to tolerate every other day administration with no recurrence of muscle symptoms[9].

There is a small chance that your patient may have been misclassified with a statin indicated condition. We sincerely apologize for this and would be most appreciative if you can call or fax us to let us know.

We welcome any questions or comments so please kindly contact us at 403-955-8327 (or fax 403-955-8249), for more information.

Sincerely,
Sonia Butalia MD, FRCPC, MSc and the study team



References

1. Yusuf S, Hawken S, Ôunpuu S, et al. *The Lancet.* 2004;364(9438):937-952.
2. O'Donnell MJ, Xavier D, Liu L, et al. *The Lancet.* 2010;376(9735):112-123.
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5. Anderson TJ, Grégoire J, Pearson GJ, et al. 2016 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult. *Canadian Journal of Cardiology.* 2016;32(11):1263-1282.
6. Graham DJ, Staffa JA, Shatin D, et al. *JAMA.* 2004;292(21):2585-2590.
7. Arca M, Pigna G. *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy.* 2011;4:155-166.
8. Bruckert E, Hayem G, Dejager S, Yau C, Bégaud B. *Cardiovascular Drugs and Therapy.* December 01 2005;19(6):403-414.
9. Bellosta S, Paoletti R, Corsini A. *Circulation.* June 15, 2004 2004;109(23 suppl 1):III-50-III-57.

# Strategies for Enhancing Cholesterol Lowering Medication Use Among Patients at High Cardiovascular Disease Risk: Patient and General Practitioners' Perspectives on a Facilitated Relay Intervention

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| **Domain 1: Research team and reflexivity** | | | |
| Personal Characteristics | | | |
| 1. | Interviewer/facilitator | Which author/s conducted the interview or focus group? | Line 137 |
| 2. | Credentials | What were the researcher's credentials? *E.g. PhD, MD* | Author information |
| 3. | Occupation | What was their occupation at the time of the study? | Line 137 |
| 4. | Gender | Was the researcher male or female? | Line 137 |
| 5. | Experience and training | What experience or training did the researcher have? | Line 137 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Relationship with participants | | | |
| 6. | Relationship established | Was a relationship established prior to study commencement? | Line 138-139 |
| 7. | Participant knowledge of the interviewer | What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research* | Not discussed |
| 8. | Interviewer characteristics | What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic* | Not discussed |
| **Domain 2: study design** | | | |
| Theoretical framework | | | |
| 9. | Methodological orientation and Theory | What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis* | Qualitative Description – Line 98 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Participant selection | | | |
| 10. | Sampling | How were participants selected? *e.g. purposive, convenience, consecutive, snowball* | GP – Snowball (line 106-107)<br>Patients – Convenience (line 116) |
| 11. | Method of approach | How were participants approached? e.*g. face-to-face, telephone, mail, email* | Line 106-120 |
| 12. | Sample size | How many participants were in the study? | Line 173<br>Line 186 |
| 13. | Non-participation | How many people refused to participate or dropped out? Reasons? | Line 176-177 |
| Setting | | | |
| 14. | Setting of data collection | Where was the data collected? e.*g. home, clinic, workplace* | Line 137<br>Line 142 |
| 15. | Presence of non-participants | Was anyone else present besides the participants and researchers? | Line 143 |
| 16. | Description of sample | What are the important characteristics of the sample? *e.g. demographic data, date* | Line 174-195 |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Data collection | | | |
| 17. | Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Appendix A& B |
| 18. | Repeat interviews | Were repeat interviews carried out? If yes, how many? | No |
| 19. | Audio/visual recording | Did the research use audio or visual recording to collect the data? | Line 146 |
| 20. | Field notes | Were field notes made during and/or after the interview or focus group? | Line 143-144 |
| 21. | Duration | What was the duration of the interviews or focus group? | Line 142-143 |
| 22. | Data saturation | Was data saturation discussed? | Line 140 + limitations section |
| 23. | Transcripts returned | Were transcripts returned to participants for comment and/or correction? | No |
| **Domain 3: analysis and findings** | | | |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| Data analysis | | | |
| 24. | Number of data coders | How many data coders coded the data? | Line 156-160 |
| 25. | Description of the coding tree | Did authors provide a description of the coding tree? | Line 157 |
| 26. | Derivation of themes | Were themes identified in advance or derived from the data? | Line 157-158 (inductive) |
| 27. | Software | What software, if applicable, was used to manage the data? | Line 164-165 |
| 28. | Participant checking | Did participants provide feedback on the findings? | Line 414-415 |
| Reporting | | | |
| 29. | Quotations presented | Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number* | In-text and Table 3 |
| 30. | Data and findings consistent | Was there consistency between the data presented and the findings? | Yes |

| No | Item | Guide questions/ description | Response |
|---|---|---|---|
| 31. | Clarity of major themes | Were major themes clearly presented in the findings? | Results section |
| 32. | Clarity of minor themes | Is there a description of diverse cases or discussion of minor themes? | Table 2 & 3 |