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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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3 **Strategies for Enhancing Cholesterol Lowering Medication Use Among Patients at High Cardiovascular**
4 **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.

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

90 **METHODS:**

92 **Study Design**

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

100 **Participant Selection**

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

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

118 **Data Collection**

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

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

1
2
3 130 explanation of facilitated relay, the proposed intervention, and shown a copy of the proposed
4 131 intervention letter (Appendix C) and asked for their feedback.

5 132
6 133 All interviews were conducted in-person (in clinician offices) or via telephone, by a female trained
7 134 research assistant (RCWL) with oversight by experienced study team members. None of the study team
8 135 were acquainted with or involved in the clinical care of the participants. Physician interviews were
9 136 continued until the point of theoretical saturation when no new information emerged from the
10 137 interviews (27). Because the research objective was relatively focused, interviews were brief and lasted
11 138 approximately 30 to 45 minutes. We convened two small focus groups of patients in our academic
12 139 medical centre which each lasted approximately 90 minutes. No one but researchers (including 1
13 140 facilitator and 2 field-note takers) and participants were present. Data was collected from September
14 141 2018 to November 2018.

15 142
16 143 Interviews and focus group proceedings were digitally audio-recorded and transcribed verbatim by a
17 144 professional transcriptionist. Field notes were taken to inform data analysis. All data were anonymized
18 145 and stored securely. Signed informed consent was received from each study participant. Gift cards were
19 146 provided to all participants. Ethics approval was granted from the University's Health Research Ethics
20 147 Board.

21 148 22 149 **Data Analysis**

23 150
24 151 Analysis was completed using conventional qualitative content analysis(28), a method of interpreting
25 152 interview data with the goal of describing the phenomenon of interest. Transcripts for the initial three
26 153 interviews were reviewed by three team members (DC, RL and SB), with the objective of inductively
27 154 establishing a preliminary coding template that was used for subsequent data analysis. All transcripts
28 155 were then analyzed by two reviewers (DC and RL). Codes were generated from the interview data and
29 156 systematically applied to identify themes and patterns. The process was iterative, reflexive, and
30 157 interactive as continual data collection and analysis shaped each other⁴. For example, code titles or
31 158 definitions identified based on earlier interviews were modified according to the data collected during
32 159 subsequent interviews. The team met together to review the coding to elicit discussion about the coding
33 160 strategy and attempted to achieve consensus to resolve coding discrepancies. NVivo 12 (Doncaster,
34 161 Australia) qualitative data analysis software was used to facilitate the coding process.

35 162 36 163 **Patient and public involvement**

37 164
38 165 Patient partners and family members from the Libin Cardiovascular Institute's established patient and
39 166 family member advisory group voiced that *prevention* was one of their top research priorities for
40 167 cardiovascular health. This work is related to prevention of cardiovascular disease. Patients were
41 168 included in focus groups.

42 169 43 170 **RESULTS**

44 171
45 172 We reached saturation after having completed 17 individual interviews with GPs (Table 1a). 4 physicians
46 173 declined participation in the interview. The majority were women (88%) with 65% having graduated
47 174 from medical school within the last ten years. All GPs spent more than 50% of their time in clinical
48 175 practice, at urban centers within Primary Care Networks (PCNs). PCNs are networks of GPs that share
49 176 interdisciplinary resources to enhance the delivery of primary care within geographical regions(29); they
50 177 are associated with improved chronic disease care and outcomes(30).

178

179 **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)

180 * Focused practice, or special interest types: care of the elderly (n = 2), emergency medicine (n = 1),
 181 urgent care (n = 1), refugee medicine (n = 1), obstetrics (n = 2), indigenous health (n = 2), lactation (n =
 182 1).

183
184
185 We hosted two focus groups for patients – one with 8 and another with 6 participants (Table 1b). There
186 were no dominant members and all participants got equal opportunity to voice their opinions. There
187 was a range of ages represented, with a similar distribution of men and women. Nearly all had a general
188 practitioner and were also followed by medical specialist(s). The conditions represented in our patient
189 group were diabetes, history of myocardial infarction and elevated cholesterol level; none reported a
190 history of stroke, chronic kidney disease, or peripheral arterial disease.

191
192 **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

193
194
195 **General suggestions for potential interventions**

196
197 Several themes arose regarding interventions to improve statin use during the unprompted portion of
198 the interviews (Table 2). General practitioner participants described that statin use may be improved by:
199 (1) enhancing aspects of physician education to promote appropriate statin prescribing; and, (2)
200 implementation of support tools to help physicians in decision-making and identification of patients for
201 whom statins are indicated. In addition, patients suggested that having access to their own laboratory
202 results may enable them to be more effective self-advocates.

203

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

Providers	Treatment of specific Sub-populations	<p>Patients with chronic kidney disease: <i>"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.</i></p> <p>Patients who previously experienced side effects with statin(s): <i>"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."</i></p> <p>Elderly patients: <i>"...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?"</i></p> <p>Patients with hypertriglyceridemia: <i>"I always find it hard to know what to do with triglycerides... more education around how to manage those [patients]."</i></p>
	Treatment to Targets	<p><i>"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".</i></p> <p><i>"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"</i></p> <p><i>"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".</i></p>
	Preferred modality of Education	<i>"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".</i>
	EMR-based tools	<i>"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".</i>
Patients	Laboratory Results	<p><i>"I would like to get a copy, in addition to the doctor. I can do with it what I want"</i></p> <p><i>"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?'"</i></p>
	Enhanced education	<i>"What if somebody was going regularly to a lab, and a clinician sort of goes: 'How are you doing on this?'"</i>

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3 204 EMR: electronic medical record
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1) General practitioner *education*:

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

213

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

218

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

223

2) General practitioner *tools*

225

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

231

3) *Patient results and information*

233

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

242

Feedback on the proposed facilitated relay intervention

244

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

249

1) *General feedback and impression*

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2
3 252 General practitioners responded with strongly positive feedback (Table 3), which included that they
4 253 found the information to be helpful and direct. They generally felt that the letter was written in a clear
5 254 fashion and with a respectful tone. Several mentioned that the information provided them with
6 255 reassurance and credibility in making recommendations to their patients.
7 256

8 257 GPs also voiced some questions and potential concerns after hearing about our proposed intervention.
9 258 These concerns included whether the introduction of a facilitated relay intervention might increase their
10 259 workload, lead to possible disclosure to patients of new diagnoses of conditions that qualified them as
11 260 high risk (i.e. diabetes), and pose a threat to their therapeutic relationships with patients. In addition,
12 261 logistical issues around how the letter will be best delivered to ordering providers and patients were
13 262 raised as concerns.
14 263

15 264 Patients generally felt that bringing their facilitated relay letter to a scheduled appointment would be
16 265 positive in their relationship by providing structure to the follow-up encounter, holding GPs to account,
17 266 and enhancing patient-provider communication. Even though most were generally positive, some
18 267 patients expressed concern about the facilitated relay intervention, including the possibility for privacy
19 268 breaches and increasing patient anxieties.
20 269

21 270 2) Suggested information to remove or add 22 271

23 272 We asked GPs specifically what they would like to see changed in the preliminary materials shown.
24 273 Almost unanimously, they suggested that the letter would be more appreciated if it were shortened to
25 274 fit on one page. Several participants suggested removing the references, mention of clinical studies, and
26 275 guideline citations to make it more reader-friendly. There was also a preference voiced for revising the
27 276 introductory paragraphs to have direct relevance to individual patient(s):
28 277

29 278 *“I’m going to read it for sure, but then when you start to read it, people might put it down and say*
30 279 *‘oh this is a study intervention’, [but] if you have the first thing at the very top: ‘you know this person*
31 280 *has been identified as being at risk’ – then it’s about the patient rather than being about the*
32 281 *studies”.*
33 282

34 283 A few GPs voiced opinions that specific additions could be made to improve the letter’s utility. These
35 284 suggestions included adding: information about health behavior change (*“the whole picture, as opposed*
36 285 *to just medication”*); adding contact information for a specialist; and details about how/why a particular
37 286 individual was flagged as eligible for the facilitated relay intervention: *“It would be helpful if I got a*
38 287 *name, condition and then the statin-indicated condition, and where the condition was pulled from”.*
39 288

40 289 Patient feedback was notable for also suggesting that the intervention provide contact information, in
41 290 case they have further questions about interpreting their results:
42 291

43 292 *“back that up with a helpline for somebody that doesn’t know what the [results] mean”.* Similar to
44 293 physicians, patients expressed a strong preference for brevity: *“If I have to go through 14 pages of*
45 294 *information to figure out what that means, I’m sorry, I don’t have time for that”.*
46 295

47 296 However, numerous patients also stressed the importance of not only providing results or diagnoses,
48 297 but also giving some basic education and an action plan to follow.
49 298

50 299 3) Intervention details 51 300

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2
3 300
4 301 In addition to general feedback, we also explicitly asked GPs whether they would prefer to receive
5 302 information about their patient in the form of facilitated relay (individual letter for each patient
6 303 identified) or 'audit and feedback' (summary report including a group of their patient panel). A summary
7 304 list or report (audit and feedback) was preferred by roughly 2/3 of the general practitioners interviewed.
8 305 Regarding receiving letters for each patient, participants stated:

9 306
10 307 *"this is going to get tiresome very quickly"*

11 308
12 309 *"Am I going to get this letter 20 times? I'm probably just going to read it once";*

13 310
14 311 *"[a list would] decrease paper burden, decrease the chance of it getting misplaced".*

15 312
16 313 While the 'audit and feedback' approach was more popular, some GPs were clearly in favor of facilitated
17 314 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*
18 315 *for it, if you have the means to do it, then why not?"*

19 316
20 317 We also asked pointedly about how providers would feel about receiving a follow-up reminder from the
21 318 study team, if patients' had not filled the prescription as recommended in the initial letter. The response
22 319 was split with roughly half of the general practitioners stating that a reminder would not be necessary.

23 320
24 321 Those who felt a reminder would be acceptable generally agreed that a 6 month window should be
25 322 sufficient to ascertain whether or not the patient would have started on therapy: *"There are people that*
26 323 *have a three-month wait list time, you may have to pick an interval more like six-months to appeal to the*
27 324 *masses...".*

28 325
29 326 Most patients felt that they would benefit from receiving a follow-up reminder. After considerable
30 327 discussion amongst the groups, consensus was achieved that follow-up should not happen prior to four
31 328 months, and possibly even as long as six months after the initial contact. One participant stated: *"close*
32 329 *enough that I vaguely remember that I meant to do something with that, but not a few weeks later, [so]*
33 330 *it's not irritating".*

34 331
35 332 We also asked patients if they had a preference for who had signed the letter. Most felt that having
36 333 letters come from a local specialist in cardiology or endocrinology would be preferable to having them
37 334 signed by another GP.

38 335 39 336 *4) Workflow processing considerations (General practitioners only)*

40 337
41 338 To each GP we asked specific details about how our intervention letter would be received in their offices
42 339 and what would happen upon receipt. The majority stated that such a letter would be opened and
43 340 processed by their front-desk staff. One participant clarified that the information on the envelope would
44 341 determine who opened it: *"if it's addressed to me then it will come to me, if it has a patient name for*
45 342 *me, then it goes through our document people [who file it]"*.

46 343
47 344 Once the letter has been opened, different offices employed a variety of different processes. In many
48 345 practices, it would be given directly to the GP; while in others it would be scanned directly into a
49 346 patient's file in an electronic medical record, yet in others, the hardcopy would be filed in a patient's
50 347 chart.

348
349 In terms of the preferred delivery modality, most GPs felt that electronic delivery directly via the EMR
350 platform would be the preferred method of receiving the intervention. However, a number still felt that
351 conventional delivery via paper mail or fax would be preferable. Even those who expressed a preference
352 for conventional delivery, many elaborated that such letters would often be scanned into a patient's
353 electronic file: "if it was to come by mail or fax, then they have to scan it onto the computer". A few GPs
354 described systems which can do this process automatically: "our office works with a new web system, so
355 everything that comes in via the fax actually goes directly into the computer and they then allocate to
356 the patient".
357

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" "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" "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" "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" "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

	<p>helpful to have some numbers around it, and strategies to address that”</p> <p>“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’”</p>		<p>things that are important and that should be covered... that we haven’t left anything out”</p>
Negative			
Increased workload	<p>“I would caution against anything that causes more documents or more paperwork... there’s already so much”</p>	Privacy concerns	<p>“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”</p> <p>“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”</p>
Disclosing new diagnoses	<p>“my concern is that they get this information from a letter... my preference would be that it came straight to me”</p>	Difficulty interpreting results	<p>“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”</p>
Therapeutic relationship	<p>“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.”</p>	Provoking Anxieties	<p>“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?”</p>
Logistical concerns	<p>“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”</p> <p>“If it goes to the patient, sometimes you get lots of mail and they may just discard it”</p>	Lack of engagement	<p>“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”</p>
		Sense of intimidation	<p>“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”</p>

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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

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3 407 applicability of these findings to other settings is not certain. Yet physicians face similar problems (i.e.
4 408 time constraints, patient complexity and comorbidities and patient resistance to medical therapies) in
5 409 numerous facets of medical care; therefore, it is conceivable that the findings of this study would apply
6 410 to interactions between patients and GPs in other clinical settings. Due to time constraints of
7 411 participants and researchers, member checking was not undertaken in this study. Finally, it is important
8 412 to note that feedback was sought specifically about the proposed intervention. However, given the
9 413 details reported, we feel that these findings are likely to be helpful to others proposing similar quality
10 414 improvement interventions. One of the major strengths of this study is the depth and richness of the
11 415 qualitative data that were collected. By asking questions in an open-ended manner, we were able to
12 416 record detailed accounts and opinions. Another strength of this work is the fact that we also sought
13 417 patient input into the development of this intervention, rather than relying on physician feedback alone.
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16 419 Statin therapy has been demonstrated to effectively lower cholesterol and reduce the risk of
17 420 cardiovascular events and death in individuals at high risk of cardiovascular disease. Despite this, they
18 421 remain underused. There are patient, provider and system factors that contribute to the underuse of
19 422 statins. Facilitated relay interventions hold promise as a potential method to address this important care
20 423 gap. Our study sought perspectives of both healthcare providers and patients, which will be
21 424 incorporated into intervention design to maximize acceptability. Insights gained from qualitative data
22 425 will be used to improve the likelihood of success and achieve the desired clinical impact.
23 426

24 427 **Contributions**

25
26 428 All study team members contribute to the development of the research question. The study design was
27 429 conceived by DJTC and SB. DJTC wrote the first draft of the study protocol. Data collection and analysis
28 430 was completed by DJTC, RCWL and SB. All study team members contribute to the interpretation and
29 431 contextualization of study findings. The first draft of the manuscript was written by DJTC. All study team
30 432 members contributed substantively to further revisions of the manuscript and have consented to the
31 433 publication of this version.
32 434

33 435 **Data Sharing**

34 436 No additional data available
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For peer review only

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)

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3 How should such an intervention either on a specific patient or about your entire practice
4 be received?
5

- 6 • Mail/Fax/EMR/combo

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9 How would such an intervention be processed in your office?

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

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16 Who should this letter be coming from in order to have it received in the most positive
17 way possible?
18

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

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

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

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

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

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51 Do you have any additional comments or suggestions for developing an intervention to
52 increase the use statins in people at high risk for cardiovascular disease (i.e. previous
53 clinical cardiovascular disease, diabetes, chronic kidney disease) in primary care?
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3 Thank you for participating in today's interview. Using the information you provided, we
4 will work on developing an intervention to improve the treatment of dyslipidemia in
5 patients who are at high risk for cardiovascular disease (i.e. previous clinical
6 cardiovascular disease, diabetes, chronic kidney disease)?
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9 **Appendix B: Focus Group Guide for patients**

10 Thank you for agreeing to participate in our focus group today. There are many risk
11 factors for heart attacks and stroke. Today we want to focus on one risk factor being high
12 cholesterol. High cholesterol is a major risk factor for heart attacks, strokes and
13 circulatory problems. There are no symptoms of high cholesterol and it is diagnosed by a
14 lab test that your doctor would order. Importantly, we work for the University of Calgary
15 and have no relationship with any medication companies.
16
17

18 We wish to discuss your experience in managing *cholesterol* with medications in order to
19 better understand how we might help family physicians (*doctors*) treat high cholesterol.
20
21

22 **1. Experience with high cholesterol**

23 Think about the last time your doctor has sent you for a cholesterol test. Did your doctor
24 talk to you about the results? Treatment? What kind of treatment was discussed (diet,
25 exercise, a medication)?
26
27

28 Put yourself in the position of being told that you need to take a medication for your
29 cholesterol. What factors would make you more likely to take it? What factors would
30 make you not want to take it? Reasons, side effects, costs
31
32

- 33 • Would you use any resources to help you decide?
 - 34 ○ Doctor
 - 35 ○ Dietician
 - 36 ○ Internet
 - 37 ○ Family, friends
 - 38
 - 39

40 What would you think if your doctor told you that your cholesterol wasn't all that high,
41 but because of your other health conditions she wanted to start you on a cholesterol
42 lowering medication to reduce your risk of heart attack and stroke?
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44

45 Do you think it would be helpful to get the actual result of your cholesterol level sent
46 directly from the lab to you?
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50 Currently, cancer screening programs send letters to patients about their results and next
51 steps. What are your thoughts for something similar for high cholesterol?
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3 What about information about recommended treatments and potential side effects?
4 Would you find this to be invasive of your privacy (i.e. info from the lab about treatment
5 and not your doctor)?
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9 How would you feel about taking a letter with these recommendations to your doctor to
10 discuss about a medication for high cholesterol?
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14 How do you feel your doctor would respond to you bringing this information?
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18 What things on the letter would make it helpful?
19

20 -length, colour, graphics,
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24 Who should this letter be coming from in order to have it received in the most positive
25 way possible?
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- 27
- 28 • A non-clinical academic researcher (Dr. XXXX)
- 29 • Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- 30 • A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- 31 • An academic family doctor (Dr. Kerry McBrien)
- 32 • A respected community family doctor
- 33 • The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- 34 • Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic
35 Disease Management, Community and Rural for Alberta Health Services
- 36 • Someone else
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41 Would it be helpful to receive a reminder or follow-up letter?
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- 43 • How much later should this be sent, so as to be useful and not annoying?
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45 Do you have any additional comments or suggestions for developing an way to increase
46 the use the treatment of people with high cholesterol?
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Appendix C: Facilitated Relay Letter



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 stroke¹⁻². As you know, in patients like [name], statins are indicated for their dyslipidemia because they are proven to reduce cardiovascular outcomes and mortality³⁻⁴. Because of numerous randomized controlled trials, guidelines recommend statin use in individuals with history of previous cardiovascular disease, diabetes, or chronic renal failure⁵.

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 2.5-5mg⁷.
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 myalgia⁸. For your reference, maximum doses of these low potency statins, and their equivalencies are:

1
2 Pravastatin 80mg = Atorvastatin 20mg = Rosuvastatin 10mg
3 Fluvastatin XL 80mg = Atorvastatin 10mg = Rosuvastatin 5mg
4

- 5
6 3. *Reducing dose or lengthening administration interval.* Studies have demonstrated that
7 greater than 70% of patients affected by myalgias were able to tolerate every other day
8 administration with no recurrence of muscle symptoms⁹.
9

10 There is a small chance that your patient may have been misclassified with a statin indicated
11 condition. We sincerely apologize for this and would be most appreciative if you can call or fax us to
12 let us know.
13

14
15 We welcome any questions or comments so please kindly contact us at 403-955-8327 (or fax 403-955-
16 8249), for more information.
17

18
19 Sincerely,
20 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? <i>E.g. PhD, MD</i>	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? <i>e.g. personal goals, reasons for doing the research</i>	Not discussed
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? <i>e.g. Bias, assumptions, reasons and interests in the research topic</i>	Not discussed
Domain 2: study design			
	Theoretical framework		
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? <i>e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis</i>	Qualitative Description – Line 98

No	Item	Guide questions/ description	Response
	Participant selection		
10.	Sampling	How were participants selected? <i>e.g. purposive, convenience, consecutive, snowball</i>	GP – Snowball (line 106-107) Patients – Convenience (line 116)
11.	Method of approach	How were participants approached? <i>e.g. face-to-face, telephone, mail, email</i>	Line 106-120
12.	Sample size	How many participants were in the study?	Line 173 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? <i>e.g. home, clinic, workplace</i>	Line 137 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? <i>e.g. demographic data, date</i>	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. <i>participant number</i>	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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3 **Strategies for Enhancing the Initiation of Cholesterol Lowering Medication Among Patients at High**
4 **Cardiovascular Disease Risk: A Qualitative Descriptive Exploration of Patient and General**
5 **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).

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3 83 There are clearly many challenges that lead to the observed clinical treatment gap for patients who have
4 84 indications for statin treatment. However, some studies have shown that such treatment gaps, in
5 85 related conditions like hypertension, can be closed using quality improvement strategies (20-22).
6 86 Integrated quality improvement strategies that target both patients and healthcare providers are more
7 87 likely to achieve quality indicators than strategies which only target one aspect in isolation (21). One
8 88 such strategy is facilitated relay. Facilitated relay is a quality improvement strategy whereby information
9 89 about individual patients is sent directly to healthcare providers through a means other than the usual
10 90 clinical encounter (23). Despite the establishment and promotion of facilitated relay and other quality
11 91 improvement strategies, there remain significant treatment gaps in hypertension (24) and other chronic
12 92 conditions (25). Furthermore, while facilitated relay has been shown to be effective in improving a
13 93 number of cardiovascular risk factors (21, 26), it remains among the least commonly used quality
14 94 improvement strategies (27) and has not been explored in the management of dyslipidemia.
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18 96 For an intervention to have the potential to maximum impact, it is important to have the input of key
19 97 stakeholders prior to the application of any intervention with a qualitative study being suited to do so
20 98 (28). This allows for the development of a higher quality intervention, rather than one that relies on
21 99 physician feedback alone (29). As such, the objective of our study was to explore the perspectives of
22 100 patients and GPs regarding interventions to increase cholesterol lowering medication (or statin)
23 101 prescription, including specific feedback on a proposed laboratory-based facilitated relay intervention.
24 102

25 103 **METHODS:**

26 104

27 105 **Study Design**

28 106
29 107 We conducted a qualitative descriptive study (28) to explore patients' and general practitioners' (GPs)
30 108 perspectives on interventions to increase initiation of statins for cardiovascular risk reduction and
31 109 treatment of high cholesterol. In addition to generic thoughts on potential hypothetical interventions,
32 110 we specifically sought directed feedback and perceptions on the acceptability of the proposed facilitated
33 111 relay intervention from both patients and GPs (30). We used the consolidated criteria for reporting
34 112 qualitative research (COREQ) as the reporting framework for this study (31).
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38 114 **Proposed Intervention**

39 115
40 116 We drew from behaviour change theory to develop a facilitated relay intervention to increase statin
41 117 prescriptions (32-34) (Figure 1). Our proposed intervention partners with our province's single
42 118 laboratory system to identify individuals who have elevated cholesterol levels, statin-indicated
43 119 conditions, and who are not currently filling prescriptions for statins. Our lab system has access to
44 120 province-wide administrative databases, including labs, pharmacy dispensations, and hospitalization
45 121 data. For every elevated LDL-cholesterol level, the lab would have an algorithm that would check the
46 122 patients' records for evidence of statin-indicated conditions (administrative markers of myocardial
47 123 infarction, stroke, diabetes, or chronic kidney disease), and would then identify if they have recently
48 124 filled a statin prescription. This is possible because of province-wide, linkable databases. For patients
49 125 who are not filling statins, but who should be, their GP who had ordered the cholesterol levels and the
50 126 patient, will then each receive a letter outlining the indication for treatment and the potential to benefit
51 127 from statin therapy. The patient letter will encourage them to speak to their GP, and the GP letter will
52 128 encourage them to make an appointment to discuss directly with the patient - both with the objective to
53 129 initiate or renew statin prescriptions. We felt that it was important to include patients in the facilitated
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3 130 relay to empower them in discussions with their GP and to enable shared decision-making (35), which
4 131 has been demonstrated to improve adherence with statins (36).

5 132
6 133 **Participant Recruitment**
7 134

8 135 *General Practitioners:* We recruited general practitioners to participate in individual interviews, using a
9 136 snowball sampling approach. First, we asked key stakeholders in areas of primary care, endocrinology,
10 137 nephrology and cardiology affiliated with the university medical centre, to recommend community-
11 138 based (non-academic) GPs to participate in the study. Individuals were then contacted by telephone and
12 139 email with a formal invitation to participate. GPs who met the following criteria were enrolled: (1)
13 140 currently practicing in community general practice settings; and, (2) have at least one year of experience
14 141 as a GP. We sampled participants purposively based on several key demographic characteristics in order
15 142 to achieve representation across a range of ages, genders and practice types.
16 143

17 144 *Patients:* We recruited patients who would qualify as recipients of the proposed intervention.
18 145 Specifically, we were interested in recruiting those at high risk of cardiovascular disease, who self-
19 146 reported a prior history of high cholesterol, preferably with co-existing vascular disease (myocardial
20 147 infarction, stroke or peripheral vascular disease), diabetes, or chronic kidney disease. Using a
21 148 convenience sampling approach, we invited patients who were part of an established advisory panel and
22 149 previously agreed to be contacted about research opportunities for study participation (37, 38). In
23 150 addition, patients were recruited using poster advertisements placed throughout the academic health
24 151 sciences centre and in various clinical care areas where care is provided to patients with diabetes, heart
25 152 disease and kidney disease.
26 153

27 154 **Data Collection**
28 155

29 156 Data was collected from September 2018 to November 2018 using both qualitative semi-structured
30 157 interviews (with GPs) and focus groups (with patients). We chose focus groups for patients as rich
31 158 personal disclosures are more likely to occur in this setting than in individual interviews (39). However,
32 159 we purposely used individually scheduled interviews to offset potential aversion to focus groups by
33 160 community-based GPs due to their competing clinical demands. Furthermore, we wanted to recruit
34 161 from both urban and rural locales which is more challenging to do in a focus group.
35 162

36 163 *Question Guides:* Both focus groups and interviews were guided by question guides (Appendix A & B)
37 164 which were developed based on a review of the literature (40, 41) and discussion with the research
38 165 team. These were designed so that they initially asked study participants what they thought would be
39 166 effective strategies or interventions to improve statin uptake (i.e. prescribing, patient use and
40 167 adherence). After they had given their unprompted views, participants were then given a brief
41 168 explanation of facilitated relay, the specifics of the proposed intervention (Figure 1), and they were
42 169 shown a copy of the proposed intervention letter for GPs (Appendix C). After briefing participants on the
43 170 principles and practices of facilitated relay and showing them our preliminary documents for the
44 171 intervention, we asked for feedback. They were then asked for their specific feedback on this
45 172 intervention.
46 173

47 174 *Provider Interviews:* All interviews were conducted in-person (in clinician offices) or via telephone, by a
48 175 female trained research assistant (RCWL) with oversight by experienced study team members. Physician
49 176 interviews were continued until the point of theoretical saturation when no new information emerged
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3 177 from the interviews (42). Because the research objective was relatively focused, interviews were brief
4 178 and lasted approximately 30 to 45 minutes.

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6 180 *Patient Focus Groups:* None of the study team were acquainted with or involved in the clinical care of
7 181 the patients who participated. We convened two focus groups in our academic medical centre which
8 182 each lasted approximately 90 minutes. No one but researchers (including 1 facilitator and 2 field-note
9 183 takers) and participants were present. Focus group facilitators tried to ensure that there were no
10 184 dominant members and provide all participants with equal opportunity to voice their opinions.

11 185
12 186 Interviews and focus group proceedings were digitally audio-recorded and transcribed verbatim by a
13 187 professional transcriptionist. Field notes were taken to inform data analysis. All data were anonymized
14 188 and stored securely. Signed informed consent was received from each study participant. Gift cards were
15 189 provided to all participants. Ethics approval was granted from the University's Health Research Ethics
16 190 Board.

17 191 18 192 **Data Analysis**

19 193
20 194 Analysis was completed using conventional qualitative content analysis (43), a method of interpreting
21 195 interview data with the goal of describing the phenomenon of interest. Transcripts for the initial three
22 196 interviews were reviewed by three team members (DC, RL and SB), with the objective of inductively
23 197 establishing a preliminary coding template that was used for subsequent data analysis. All transcripts
24 198 were then analyzed by two reviewers (DC and RL). Codes were generated from the interview data and
25 199 systematically applied to identify themes and patterns. The process was iterative, reflexive, and
26 200 interactive as continual data collection and analysis shaped each other. For example, code titles or
27 201 definitions identified based on earlier interviews were modified according to the data collected during
28 202 subsequent interviews. The team met together to review the coding to elicit discussion about the coding
29 203 strategy and attempted to achieve consensus to resolve coding discrepancies. NVivo 12 (Doncaster,
30 204 Australia) qualitative data analysis software was used to facilitate the coding process.

31 205 32 206 **Patient and public involvement**

33 207
34 208 Patient partners and family members from the Libin Cardiovascular Institute's established patient and
35 209 family member advisory group (44) voiced that *prevention* was one of their top research priorities for
36 210 cardiovascular health. This work is related to prevention of cardiovascular disease. Patients were
37 211 included in focus groups.

38 212 39 213 **RESULTS**

40 214
41 215 In total, we eventually reached out to 27 GPs to invite them to participate, 4 declined to participate, 3
42 216 didn't respond to the invitation, 19 were scheduled for interviews, with 2 cancelling. We reached
43 217 saturation after having completed 17 individual GP interviews (Table 1a). The majority were women
44 218 (88%) with 65% having graduated from medical school within the last ten years. All GPs spent more
45 219 than 50% of their time in clinical practice, most were in urban centers within Primary Care Networks
46 220 (PCNs). PCNs are networks of GPs that share interdisciplinary resources to enhance the delivery of
47 221 primary care within geographical regions(45); they are associated with improved chronic disease care
48 222 and outcomes(46).

49 223
50 224 **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% Range 10-75%
Proportion of high-risk patients who have a current LDL-level on file (n=9)	Mean: 82% Range 70-90%

225 * Focused practice, or special interest types: care of the elderly (n = 2), emergency medicine (n = 1),
 226 urgent care (n = 1), refugee medicine (n = 1), obstetrics (n = 2), indigenous health (n = 2), lactation (n =
 227 1).
 228

229
230 Our patient focus groups had 8 and 6 participants, respectively (Table 1b). There was a range of ages
231 represented among patients, with a similar number of men and women. Nearly all had a general
232 practitioner and were also followed by medical specialist(s). The conditions represented in our patient
233 group were diabetes, history of myocardial infarction and elevated cholesterol level; none reported a
234 history of stroke, chronic kidney disease, or peripheral arterial disease.

235
236 **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

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239 **General suggestions for potential interventions**

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241 Several themes arose regarding interventions to improve statin initiation during the unprompted
242 portion of the interviews (Table 2). General practitioner participants described that statin prescribing
243 may be improved by: (1) enhancing aspects of physician education to promote appropriate statin
244 prescribing; and, (2) implementation of support tools to help physicians in decision-making and
245 identification of patients for whom statins are indicated. In addition, patients suggested that having
246 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 initiation of statins

Providers	Treatment of specific Sub-populations	<p>Patients with chronic kidney disease: <i>"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."</i> (GP-05)</p> <p>Patients who previously experienced side effects with statin(s): <i>"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."</i> (GP-13)</p> <p>Elderly patients: <i>"...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?"</i> (GP-10)</p> <p>Patients with hypertriglyceridemia: <i>"I always find it hard to know what to do with triglycerides... more education around how to manage those [patients]."</i> (GP-15)</p>
	Treatment to Targets *	<p><i>"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"</i>. (GP-02)</p> <p><i>"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"</i>. (GP-09)</p> <p><i>"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"</i>. (GP-08)</p>
	Preferred modality of Education	<p><i>"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"</i>. (GP-04)</p>
	EMR-based tools	<p><i>"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"</i>. (GP-06)</p>
Patients	Laboratory Results	<p><i>"I would like to get a copy, in addition to the doctor. I can do with it what I want"</i> (Pt-09)</p> <p><i>"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?'"</i> (Pt-02)</p>

	Enhanced education	<i>“What if somebody was going regularly to a lab, and a clinician sort of goes: ‘How are you doing on this?’”. (Pt-08)</i>
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248 EMR: electronic medical record

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

255

256

257 1) General practitioner *education*:

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

264

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

269

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

274

275 2) General practitioner *tools*

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

282

283 3) *Patient results and information*

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

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3 293 information about patient education, shared decision-making, and clinical decision support tools are
4 294 described in our other report from this work (16).

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6 296 **Feedback on the proposed facilitated relay intervention**

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8 298 Emerging themes regarding our proposed intervention were organized into four major categories: (1)
9 299 general feedback and impression; (2) suggested changes; (3) intervention details; and, (4) workflow
10 300 processing considerations.

11 301

12 302 *1) General feedback and impression*

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14 304 General practitioners responded with strongly positive feedback (Table 3), which included that they
15 305 found the information to be helpful and direct. They generally felt that the letter was written in a clear
16 306 fashion and with a respectful tone. Several mentioned that the information provided them with
17 307 reassurance and credibility in making recommendations to their patients.

18 308

19 309 GPs also voiced some questions and potential concerns after hearing about our proposed intervention.

20 310 These concerns included whether the introduction of a facilitated relay intervention might increase their
21 311 workload, lead to possible disclosure to patients of new diagnoses of conditions that qualified them as
22 312 high risk (i.e. diabetes), and pose a threat to their therapeutic relationships with patients. In addition,
23 313 logistical issues around how the letter will be best delivered to ordering providers and patients were
24 314 raised as concerns.

25 315

26 316 Patients generally felt that bringing their facilitated relay letter to a scheduled appointment would be
27 317 positive in their relationship by providing structure to the follow-up encounter, holding GPs to account,
28 318 and enhancing patient-provider communication. Even though most were generally positive, some
29 319 patients expressed concern about the facilitated relay intervention, including the possibility for privacy
30 320 breaches and increasing patient anxieties.

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32 322 *2) Suggested information to remove or add*

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34 324 We asked GPs specifically what they would like to see changed in the preliminary materials shown.
35 325 Almost unanimously, they suggested that the letter would be more appreciated if it were shortened to
36 326 fit on one page. Several participants suggested removing the references, mention of clinical studies, and
37 327 guideline citations to make it more reader-friendly. There was also a preference voiced for revising the
38 328 introductory paragraphs to have direct relevance to individual patient(s):

39 329

40 330 *"I'm going to read it for sure, but then when you start to read it, people might put it down and say*
41 331 *'oh this is a study intervention', [but] if you have the first thing at the very top: 'you know this person*
42 332 *has been identified as being at risk' – then it's about the patient rather than being about the*
43 333 *studies". (GP-16)*

44 334

45 335 A few GPs voiced opinions that specific additions could be made to improve the letter's utility. These
46 336 suggestions included adding: information about health behavior change (*"the whole picture, as opposed*
47 337 *to just medication"* (GP-04)); adding contact information for a specialist; and details about how/why a
48 338 particular individual was flagged as eligible for the facilitated relay intervention: *"It would be helpful if I*
49 339 *got a name, condition and then the statin-indicated condition, and where the condition was pulled*
50 340 *from". (GP-01)*

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4 342 Patient feedback was notable for also suggesting that the intervention provide contact information, in
5 343 case they have further questions about interpreting their results:
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7 345 *“back that up with a helpline for somebody that doesn’t know what the [results] mean”* (Pt-10).
8 346 Similar to physicians, patients expressed a strong preference for brevity: *“If I have to go through 14*
9 347 *pages of information to figure out what that means, I’m sorry, I don’t have time for that”* (Pt-07).
10 348

11 349 However, numerous patients also stressed the importance of not only providing results or diagnoses,
12 350 but also giving some basic education and an action plan to follow.
13 351

14 352 3) Intervention details

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16 354 In addition to general feedback, we also explicitly asked GPs whether they would prefer to receive
17 355 information about their patient in the form of facilitated relay (individual letter for each patient
18 356 identified) or ‘audit and feedback’ (summary report including a group of their patient panel). A summary
19 357 list or report (audit and feedback) was preferred by roughly 2/3 of the general practitioners interviewed.
20 358 Regarding receiving letters for each patient, participants stated:
21 359

22 360 *“this is going to get tiresome very quickly”* (GP-05)

23 361
24 362 *“Am I going to get this letter 20 times? I’m probably just going to read it once”* (GP-03)

25 363
26 364 *“[a list would] decrease paper burden, decrease the chance of it getting misplaced”*. (GP-13)
27 365

28 366 While the ‘audit and feedback’ approach was more popular, some GPs were clearly in favor of facilitated
29 367 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*
30 368 *for it, if you have the means to do it, then why not?”* (GP-10)
31 369

32 370 We also asked pointedly about how providers would feel about receiving a follow-up reminder from the
33 371 study team, if patients’ had not filled the prescription as recommended in the initial letter. The response
34 372 was split with roughly half of the general practitioners stating that a reminder would not be necessary.
35 373

36 374 Those who felt a reminder would be acceptable generally agreed that a 6 month window should be
37 375 sufficient to ascertain whether or not the patient would have started on therapy: *“There are people that*
38 376 *have a three-month wait list time, you may have to pick an interval more like six-months to appeal to the*
39 377 *masses...”*. (GP-13)
40 378

41 379 Most patients felt that they would benefit from receiving a follow-up reminder. After considerable
42 380 discussion amongst the groups, consensus was achieved that follow-up should not happen prior to four
43 381 months, and possibly even as long as six months after the initial contact. One participant stated: *“close*
44 382 *enough that I vaguely remember that I meant to do something with that, but not a few weeks later, [so]*
45 383 *it’s not irritating”*. (GP-17)
46 384

47 385 We also asked patients if they had a preference for who had signed the letter. Most felt that having
48 386 letters come from a local specialist in cardiology or endocrinology would be preferable to having them
49 387 signed by another GP.
50 388

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

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

396
397 Once the letter has been opened, different offices employed a variety of different processes. In many
398 practices, it would be given directly to the GP; while in others it would be scanned directly into a
399 patient’s file in an electronic medical record, yet in others, the hardcopy would be filed in a patient’s
400 chart.

401
402 In terms of the preferred delivery modality, most GPs felt that electronic delivery directly via the EMR
403 platform would be the preferred method of receiving the intervention. However, a number still felt that
404 conventional delivery via paper mail or fax would be preferable. Even those who expressed a preference
405 for conventional delivery, many elaborated that such letters would often be scanned into a patient’s
406 electronic file: *“if it was to come by mail or fax, then they have to scan it onto the computer”* (GP-11). A
407 few GPs described systems which can do this process automatically: *“our office works with a new web
408 system, so everything that comes in via the fax actually goes directly into the computer and they then
409 allocate to the patient”*. (GP-11)

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

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

	<p>“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)</p>		<p>their information at their disposal”. (Pt-14)</p>
Direct	<p>“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)</p> <p>“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)</p>	Increases patient accountability	<p>“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)</p>
Information	<p>“[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)</p> <p>“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)</p>	Provides peace of mind	<p>“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)</p>
Negative			
Increased workload	<p>“I would caution against anything that causes more documents or more paperwork... there’s already so much” (GP-16)</p>	Privacy concerns	<p>“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)</p> <p>“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)</p>
Disclosing new diagnoses	<p>“my concern is that they get this information from a letter... my preference would be that it came straight to me” (GP-01)</p>	Difficulty interpreting results	<p>“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)</p>

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)	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)
	“If it goes to the patient, sometimes you get lots of mail and they may just discard it” (MD-10)	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

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3 441 statins, to those in whom they are appropriate (57), through audit and feedback or facilitated relay. An
4 442 educational audit and feedback intervention regarding dyslipidemia treatment in Italian primary care
5 443 practices was shown to increase adherence to statins by approximately 10% (58). Improved
6 444 communication and shared decision making, which are explicit goals of facilitated relay interventions,
7 445 can improve patient adherence (59). While these and other studies have reviewed the clinical efficacy of
8 446 quality improvement strategies (21), few have used detailed qualitative methods as we have done. One
9 447 large qualitative study interviewed audit and feedback experts to generate hypotheses about the
10 448 various factors that may contribute to the efficacy of such interventions (60). Others have used
11 449 qualitative methods to highlight the barriers physicians face in encouraging adherence (61), but ours is
12 450 unique in using such methods to design and develop an intervention to address these challenges. Finally,
13 451 we also appreciate that as much as there is underuse of statins, there is also overuse, for example, in
14 452 people with short life expectancy. Perhaps interventions to increase initiation may also include a
15 453 component that conveys statin benefits are measured in years rather than months.
16 454

17 455 The fact that participants suggested elements of our facilitated relay intervention in the unprompted
18 456 portion of the interviews lends credibility and face validity to the proposed intervention. However, it is
19 457 notable that while GPs felt they would benefit from having internal systems to monitor patients'
20 458 records, none independently suggested a strategy mediated by an independent third party (such as
21 459 facilitated relay or audit and feedback), as we have proposed. Investigators who wish to implement
22 460 facilitated relay interventions to enhance adherence to medical therapies can use the findings of this
23 461 study to help develop interventions that are more likely to be acceptable to both GPs and patients. One
24 462 of the main findings is to ensure that any such information is brief and high yield, containing patient
25 463 identifiers early to capture general practitioner's attention. Such interventions can be strengthened by
26 464 incorporating education on controversial or little-known topics. Patients strongly preferred any
27 465 correspondence to also contain direct suggestions or an action plan. Workflow and processing of these
28 466 letters needs to be considered and interventions designed to be as minimally disruptive to clinical
29 467 practice as possible – with most physicians preferring that it be embedded directly within the EMR; yet
30 468 in healthcare settings (like ours) where there is marked heterogeneity in the use and type of EMRs, this
31 469 may not be possible.
32 470

33 471 There are limitations to this study. Firstly, as in most qualitative studies, the number of participants was
34 472 relatively small. This limitation is mitigated by the fact that physician interviews proceeded until the
35 473 point of saturation. Patient data were not collected in this manner, and these themes may not be fully
36 474 saturated and we appreciate this as a limitation. Furthermore, the patient sample we recruited may not
37 475 be representative of the broader population, as many of them had previously stated an interest in
38 476 quality improvement and research and therefore may be attuned to the importance of preventive
39 477 therapies more than other members of the general public. Secondly, given the context-dependent
40 478 nature of qualitative data, the applicability of these findings to other settings is not certain. Yet
41 479 physicians face similar problems (i.e. time constraints, patient complexity and comorbidities and patient
42 480 resistance to medical therapies) in numerous facets of medical care; therefore, it is conceivable that the
43 481 findings of this study would apply to interactions between patients and GPs in other clinical settings.
44 482 Due to time constraints of participants and researchers, member checking was not undertaken in this
45 483 study. Finally, it is important to note that feedback was sought specifically about the proposed
46 484 intervention. However, given the details reported, we feel that these findings are likely to be helpful to
47 485 others proposing similar quality improvement interventions. One of the major strengths of this study is
48 486 the depth and richness of the qualitative data that were collected. By asking questions in an open-ended
49 487 manner, we were able to record detailed accounts and opinions. Another strength of this work is the
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3 488 fact that we also sought patient input into the development of this intervention, rather than relying on
4 489 physician feedback alone.

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6 491 Statin therapy has been demonstrated to effectively lower cholesterol and reduce the risk of
7 492 cardiovascular events and death in individuals at high risk of cardiovascular disease. Despite this, they
8 493 remain underused. There are patient, provider and system factors that contribute to the underuse of
9 494 statins. Facilitated relay interventions hold promise as a potential method to address this important care
10 495 gap. Our study sought perspectives of both healthcare providers and patients, which will be
11 496 incorporated into intervention design to maximize acceptability. Insights gained from qualitative data
12 497 will be used to improve the likelihood of success and achieve the desired clinical impact. The insights
13 498 about these interventions are also likely to be of interest to many researchers and clinicians who are
14 499 considering and designing provider- and/or patient-facing interventions to improve the uptake of
15 500 preventive medications.

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17 502
18 503 **Contributions**

19 504 DJTC, RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, SB collaborated to develop the research question and
20 505 methods. The study design was conceived by DJTC and SB. DJTC wrote the first draft of the study
21 506 protocol. Data collection and analysis was completed by DJTC, RCWL and SB. KAM, TJA, HQ, AACL, GC,
22 507 ML, and CN contributed to the interpretation and contextualization of study findings. The first draft of
23 508 the manuscript was written by DJTC. RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, and SB contributed
24 509 substantively to further revisions of the manuscript and have consented to the publication of this
25 510 version.

26 511
27 512 **Data Availability Statement**

28 513 No additional data available. Given that qualitative data are not deidentified and tell individuals'
29 514 personal stories, data cannot be shared beyond the scope of this project, as per our research ethics
30 515 board.

31 516
32 517 **Competing Interest Statement**

33 518 DC, RL, KAM, AL, TA, HQ, GC, SB – none. CN is a director of a private laboratory that does not currently
34 519 offer testing in the jurisdiction under study.

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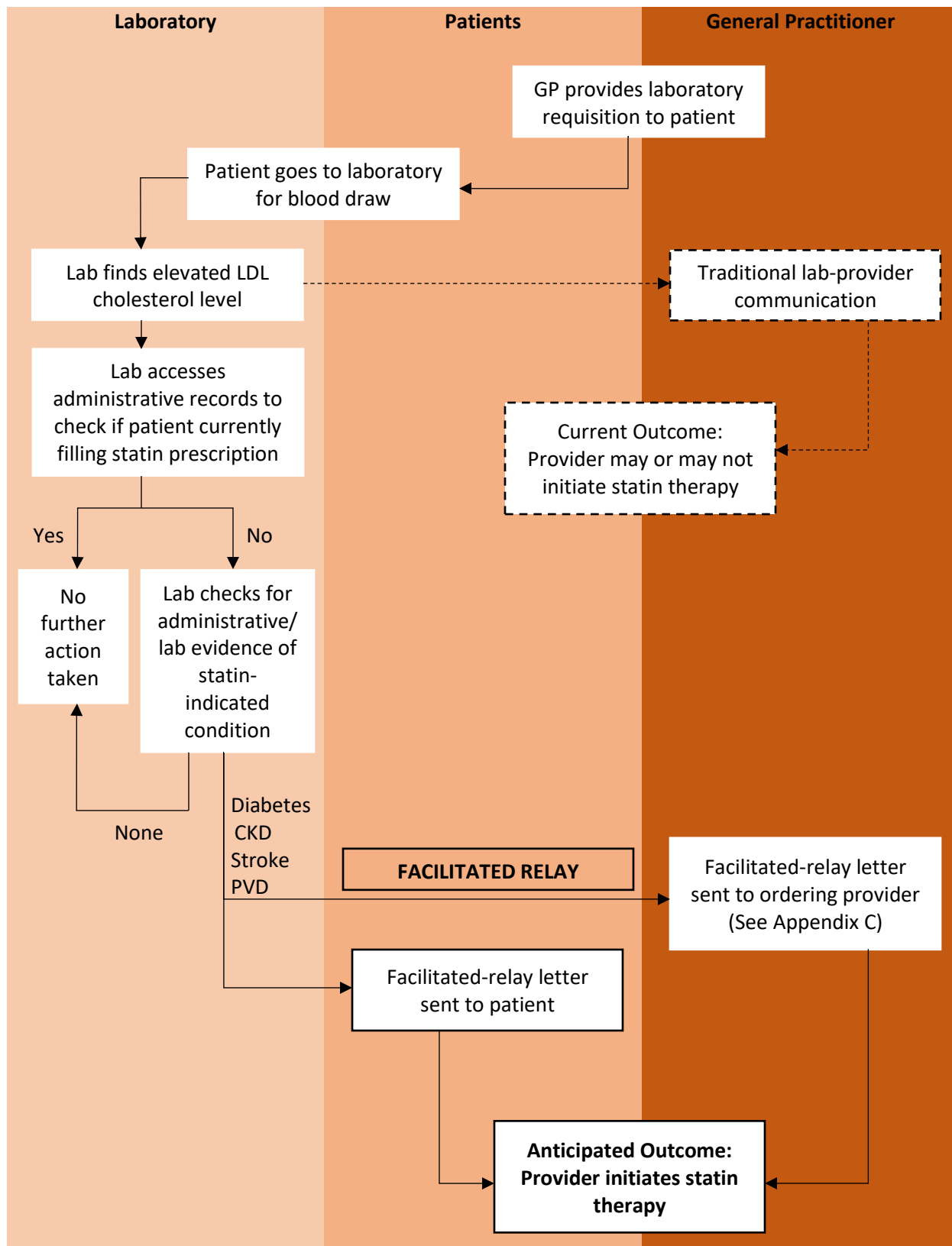


Figure 1: Laboratory-Based Facilitated-Relay Intervention
 Dashed lines: traditional interface between lab and ordering provider

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)

1
2
3 How should such an intervention either on a specific patient or about your entire practice
4 be received?
5

- 6 • Mail/Fax/EMR/combo

7
8
9 How would such an intervention be processed in your office?

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

13
14
15
16 Who should this letter be coming from in order to have it received in the most positive
17 way possible?
18

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

30
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34
35 Would it be helpful to receive a reminder or follow-up letter?

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

37
38
39 If the intervention provided you with patient-oriented material about this subject, and
40 asked you to share it with your patients, how would you feel about doing so?

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

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51 Do you have any additional comments or suggestions for developing an intervention to
52 increase the use statins in people at high risk for cardiovascular disease (i.e. previous
53 clinical cardiovascular disease, diabetes, chronic kidney disease) in primary care?
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3 Thank you for participating in today's interview. Using the information you provided, we
4 will work on developing an intervention to improve the treatment of dyslipidemia in
5 patients who are at high risk for cardiovascular disease (i.e. previous clinical
6 cardiovascular disease, diabetes, chronic kidney disease)?
7
8

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

10 Thank you for agreeing to participate in our focus group today. There are many risk
11 factors for heart attacks and stroke. Today we want to focus on one risk factor being high
12 cholesterol. High cholesterol is a major risk factor for heart attacks, strokes and
13 circulatory problems. There are no symptoms of high cholesterol and it is diagnosed by a
14 lab test that your doctor would order. Importantly, we work for the University of Calgary
15 and have no relationship with any medication companies.
16
17

18 We wish to discuss your experience in managing *cholesterol* with medications in order to
19 better understand how we might help family physicians (*doctors*) treat high cholesterol.
20
21

22 **1. Experience with high cholesterol**

23 Think about the last time your doctor has sent you for a cholesterol test. Did your doctor
24 talk to you about the results? Treatment? What kind of treatment was discussed (diet,
25 exercise, a medication)?
26
27

28 Put yourself in the position of being told that you need to take a medication for your
29 cholesterol. What factors would make you more likely to take it? What factors would
30 make you not want to take it? Reasons, side effects, costs
31
32

- 33 • Would you use any resources to help you decide?
 - 34 ○ Doctor
 - 35 ○ Dietician
 - 36 ○ Internet
 - 37 ○ Family, friends
 - 38
 - 39

40 What would you think if your doctor told you that your cholesterol wasn't all that high,
41 but because of your other health conditions she wanted to start you on a cholesterol
42 lowering medication to reduce your risk of heart attack and stroke?
43
44

45 Do you think it would be helpful to get the actual result of your cholesterol level sent
46 directly from the lab to you?
47
48

49
50 Currently, cancer screening programs send letters to patients about their results and next
51 steps. What are your thoughts for something similar for high cholesterol?
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3 What about information about recommended treatments and potential side effects?
4 Would you find this to be invasive of your privacy (i.e. info from the lab about treatment
5 and not your doctor)?
6
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10 How would you feel about taking a letter with these recommendations to your doctor to
11 discuss about a medication for high cholesterol?
12

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14 How do you feel your doctor would respond to you bringing this information?
15
16

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18 What things on the letter would make it helpful?
19

20 -length, colour, graphics,
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25 Who should this letter be coming from in order to have it received in the most positive
26 way possible?
27

- 28 • A non-clinical academic researcher (Dr. XXXX)
- 29 • Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- 30 • A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- 31 • An academic family doctor (Dr. Kerry McBrien)
- 32 • A respected community family doctor
- 33 • The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- 34 • Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic
35 Disease Management, Community and Rural for Alberta Health Services
- 36 • Someone else
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41 Would it be helpful to receive a reminder or follow-up letter?
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- 43 • How much later should this be sent, so as to be useful and not annoying?
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45 Do you have any additional comments or suggestions for developing an way to increase
46 the use the treatment of people with high cholesterol?
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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 stroke¹⁻². As you know, in patients like [name], statins are indicated for their dyslipidemia because they are proven to reduce cardiovascular outcomes and mortality³⁻⁴. Because of numerous randomized controlled trials, guidelines recommend statin use in individuals with history of previous cardiovascular disease, diabetes, or chronic renal failure⁵.

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 2.5-5mg⁷.
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 myalgia⁸. For your reference, maximum doses of these low potency statins, and their equivalencies are:

1
2 Pravastatin 80mg = Atorvastatin 20mg = Rosuvastatin 10mg
3 Fluvastatin XL 80mg = Atorvastatin 10mg = Rosuvastatin 5mg
4

- 5
6 3. *Reducing dose or lengthening administration interval.* Studies have demonstrated that
7 greater than 70% of patients affected by myalgias were able to tolerate every other day
8 administration with no recurrence of muscle symptoms⁹.
9

10 There is a small chance that your patient may have been misclassified with a statin indicated
11 condition. We sincerely apologize for this and would be most appreciative if you can call or fax us to
12 let us know.
13

14
15 We welcome any questions or comments so please kindly contact us at 403-955-8327 (or fax 403-955-
16 8249), for more information.
17

18
19 Sincerely,
20 Sonia Butalia MD, FRCPC, MSc and the study team
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32 References

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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? <i>E.g. PhD, MD</i>	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? <i>e.g. personal goals, reasons for doing the research</i>	Not discussed
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? <i>e.g. Bias, assumptions, reasons and interests in the research topic</i>	Not discussed
Domain 2: study design			
	Theoretical framework		
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? <i>e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis</i>	Qualitative Description – Line 98

No	Item	Guide questions/ description	Response
	Participant selection		
10.	Sampling	How were participants selected? <i>e.g. purposive, convenience, consecutive, snowball</i>	GP – Snowball (line 106-107) Patients – Convenience (line 116)
11.	Method of approach	How were participants approached? <i>e.g. face-to-face, telephone, mail, email</i>	Line 106-120
12.	Sample size	How many participants were in the study?	Line 173 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? <i>e.g. home, clinic, workplace</i>	Line 137 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? <i>e.g. demographic data, date</i>	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. <i>participant number</i>	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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3 **Strategies for Enhancing the Initiation of Cholesterol Lowering Medication Among Patients at High**
4 **Cardiovascular Disease Risk: A Qualitative Descriptive Exploration of Patient and General**
5 **Practitioners' Perspectives on a Facilitated Relay Intervention in Alberta, Canada**
6

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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).

1
2
3 83 There are clearly many challenges that lead to the observed clinical treatment gap for patients who have
4 84 indications for statin treatment. However, some studies have shown that such treatment gaps, in
5 85 related conditions like hypertension, can be closed using quality improvement strategies (20-22).
6 86 Integrated quality improvement strategies that target both patients and healthcare providers are more
7 87 likely to achieve quality indicators than strategies which only target one aspect in isolation (21). One
8 88 such strategy is facilitated relay. Facilitated relay is a quality improvement strategy whereby information
9 89 about individual patients is sent directly to healthcare providers through a means other than the usual
10 90 clinical encounter (23). Despite the establishment and promotion of facilitated relay and other quality
11 91 improvement strategies, there remain significant treatment gaps in hypertension (24) and other chronic
12 92 conditions (25). Furthermore, while facilitated relay has been shown to be effective in improving a
13 93 number of cardiovascular risk factors (21, 26), it remains among the least commonly used quality
14 94 improvement strategies (27) and has not been explored in the management of dyslipidemia.
15 95

16 96 For an intervention to have the potential to yield maximum impact, it is important to qualitatively seek
17 97 the input of key stakeholders prior to the application of any intervention (28). This allows for the
18 98 development of a higher quality intervention, rather than one that relies on physician feedback alone
19 99 (29). As such, the objective of our study was to explore the perspectives of both patients and general
20 100 practitioners' (GPs) regarding interventions to increase cholesterol lowering medication (or statin)
21 101 prescription, including specific feedback on a proposed laboratory-based facilitated relay intervention.
22 102

23 103 **METHODS:**

24 104 **Study Design**

25 105
26 106
27 107 We conducted a qualitative descriptive study (28) to explore patients' and GPs' perspectives on
28 108 interventions to increase initiation of statins for cardiovascular risk reduction and treatment of high
29 109 cholesterol in those at high cardiovascular risk. In addition to generic thoughts on potential hypothetical
30 110 interventions, we specifically sought directed feedback and perceptions on the acceptability of the
31 111 proposed facilitated relay intervention from both patients and GPs (30). We used the consolidated
32 112 criteria for reporting qualitative research (COREQ) as the reporting framework for this study (31).
33 113

34 114 **Proposed Intervention**

35 115
36 116 We drew from behaviour change theory to develop a facilitated relay intervention to increase statin
37 117 prescriptions (32-34) (Figure 1). Our proposed intervention partners with our province's single unified
38 118 laboratory system to identify individuals who have elevated cholesterol levels, statin-indicated
39 119 conditions, and who are not currently filling prescriptions for statins. Our lab system has access to
40 120 province-wide administrative databases, including labs, pharmacy dispensations, and hospitalization
41 121 data. For every elevated LDL-cholesterol level, the lab would have an algorithm that would check the
42 122 patients' records for evidence of statin-indicated conditions (administrative markers of myocardial
43 123 infarction, stroke, diabetes, or chronic kidney disease), and would then identify if the patient has
44 124 recently filled a statin prescription. This is possible because of province-wide, linkable databases. For
45 125 patients who are not filling statins, but who should be, their GP (who had ordered the cholesterol level)
46 126 and the patient, will then each receive a letter outlining the indication for treatment and the potential to
47 127 benefit from statin therapy. The patient letter will encourage them to speak to their GP, and the GP
48 128 letter will encourage them to make an appointment to discuss directly with the patient - both with the
49 129 objective to initiate or renew statin prescriptions. We felt that it was important to include patients in the
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130 facilitated relay to empower them in discussions with their GP and to enable shared decision-making
131 (35), which has been demonstrated to improve adherence with statins (36).

132

133 **Participant Recruitment**

134

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

144

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

154

155 **Data Collection**

156

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

163

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

173

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

1
2
3 177 from the interviews (42). Because the research objective was relatively focused, interviews were brief
4 178 and lasted approximately 30 to 45 minutes.

5 179
6 180 *Patient Focus Groups:* None of the study team were acquainted with or involved in the clinical care of
7 181 the patients who participated. We convened two focus groups in our academic medical centre which
8 182 each lasted approximately 90 minutes. No one but researchers (including 1 facilitator and 2 field-note
9 183 takers) and participants were present. Focus group facilitators tried to ensure that there were no
10 184 dominant members and provide all participants with equal opportunity to voice their opinions.

11 185
12 186 Interviews and focus group proceedings were digitally audio-recorded and transcribed verbatim by a
13 187 professional transcriptionist. Field notes were recorded to inform data analysis. All data were
14 188 anonymized and stored securely. Signed informed consent was received from each study participant.
15 189 Gift cards were provided to all participants. Ethics approval was granted from the University's Health
16 190 Research Ethics Board.

17 191

18 192 **Data Analysis**

19 193

20 194 Analysis was completed using conventional qualitative content analysis (43), a method of interpreting
21 195 interview data with the goal of describing the phenomenon of interest. Transcripts for the initial three
22 196 interviews were reviewed by three team members (DJTC, RCWL and SB), with the objective of
23 197 inductively establishing a preliminary coding template that was used for subsequent data analysis. All
24 198 transcripts were then analyzed by two reviewers (DJTC and RCWL). Codes were generated from the
25 199 interview data and systematically applied to identify themes and patterns. The process was iterative,
26 200 reflexive, and interactive as continual data collection and analysis shaped each other. For example, code
27 201 titles or definitions identified based on earlier interviews were modified according to the data collected
28 202 during subsequent interviews. The team met together to review the coding to elicit discussion about the
29 203 coding strategy and attempted to achieve consensus to resolve coding discrepancies. NVivo 12
30 204 (Doncaster, Australia) qualitative data analysis software was used to facilitate the coding process.

31 205

32 206 **Patient and public involvement**

33 207

34 208 Patient partners and family members from the Libin Cardiovascular Institute's established patient and
35 209 family member advisory group (44) voiced that *prevention* was one of their top research priorities for
36 210 cardiovascular health. This work is related to prevention of cardiovascular disease. Patients were
37 211 included in focus groups.

38 212

39 213 **RESULTS**

40 214

41 215 In total, we eventually reached out to 27 GPs to invite them to participate, 4 declined to participate, 4
42 216 didn't respond to the invitation, 19 were scheduled for interviews, with 2 cancelling. We reached
43 217 saturation after having completed 17 individual GP interviews (Table 1a). The majority were women
44 218 (88%) with 65% having graduated from medical school within the last ten years. All GPs spent more
45 219 than 50% of their time in clinical practice, most were in urban centers within Primary Care Networks
46 220 (PCNs). PCNs are networks of GPs that share interdisciplinary resources to enhance the delivery of
47 221 primary care within geographical regions (45); they are associated with improved chronic disease care
48 222 and outcomes(46).

49 223

50 224 **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% Range 10-75%
Proportion of high-risk patients in their practice who have a current LDL-level on file (n=9)	Mean: 82% Range 70-90%

225 * Focused practice, or special interest types: care of the elderly (n = 2), emergency medicine (n = 1),
 226 urgent care (n = 1), refugee medicine (n = 1), obstetrics (n = 2), indigenous health (n = 2), lactation (n =
 227 1).

228
229
230 Our patient focus groups had 8 and 6 participants, respectively (Table 1b). There was a range of ages
231 represented among patients, with a similar number of men and women. Nearly all had a general
232 practitioner and were also followed by medical specialist(s). The conditions represented in our patient
233 group were diabetes, history of myocardial infarction and elevated cholesterol level; none reported a
234 history of stroke, chronic kidney disease, or peripheral arterial disease.

235
236 **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

237

238

239 **General suggestions for potential interventions**

240

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

247

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

Providers	Treatment of specific Sub-populations	<p>Patients with chronic kidney disease: <i>"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."</i> (GP-05)</p> <p>Patients who previously experienced side effects with statin(s): <i>"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."</i> (GP-13)</p> <p>Elderly patients: <i>"...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?"</i> (GP-10)</p> <p>Patients with hypertriglyceridemia: <i>"I always find it hard to know what to do with triglycerides... more education around how to manage those [patients]."</i> (GP-15)</p>
	Treatment to Targets *	<p><i>"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."</i> (GP-02)</p> <p><i>"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"</i>. (GP-09)</p> <p><i>"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"</i>. (GP-08)</p>
	Preferred modality of Education	<p><i>"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"</i>. (GP-04)</p>
	EMR-based tools	<p><i>"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"</i>. (GP-06)</p>
Patients	Laboratory Results	<p><i>"I would like to get a copy, in addition to the doctor. I can do with it what I want"</i> (Pt-09)</p> <p><i>"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?'"</i> (Pt-02)</p>

	Enhanced education	<i>“What if somebody was going regularly to a lab, and a clinician sort of goes: ‘How are you doing on this?’”. (Pt-08)</i>
--	--------------------	---

248 EMR: electronic medical record

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

255

256

257 1) General practitioner *education*:

258

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

264

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

269

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

274

275 2) General practitioner *tools*

276

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

282

283 3) *Patient results and information*

284

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

290

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

294 able to discuss results and treatment options. Further information about patient education, shared
295 decision-making, and clinical decision support tools are described in our other report from this work
296 (16).

297

298 **Feedback on the proposed facilitated relay intervention**

299

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

303

304 *1) General feedback and impression*

305

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

311

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

318

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

324

325 *2) Suggested information to remove or add*

326

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

333

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

338

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

1
2
3 342 particular individual was flagged as eligible for the facilitated relay intervention: *"It would be helpful if I*
4 343 *got a name, condition and then the statin-indicated condition, and where the condition was pulled*
5 344 *from"*. (GP-01)
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7 345

8 346 Patient feedback was notable for also suggesting that the intervention provide contact information, in
9 347 case they have further questions about interpreting their results: *"back that up with a helpline for*
10 348 *somebody that doesn't know what the [results] mean"* (Pt-10). Similar to physicians, patients expressed
11 349 a strong preference for brevity: *"If I have to go through 14 pages of information to figure out what that*
12 350 *means, I'm sorry, I don't have time for that"* (Pt-07).
13 351

14 352 However, numerous patients also stressed the importance of not only providing results or diagnoses,
15 353 but also giving some basic education and an action plan to follow.
16 354

17 355 3) Intervention details

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19 357 In addition to general feedback, we also explicitly asked GPs whether they would prefer to receive
20 358 information about their patient in the form of facilitated relay (individual letter for each patient
21 359 identified) or 'audit and feedback' (summary report including a group of their patient panel). A summary
22 360 list or report (audit and feedback) was preferred by roughly 2/3 of the general practitioners interviewed.
23 361 Regarding receiving letters for each patient, participants stated:
24 362

25 363 *"this is going to get tiresome very quickly"* (GP-05)
26 364

27 365 *"Am I going to get this letter 20 times? I'm probably just going to read it once"* (GP-03)
28 366

29 367 *"[a list would] decrease paper burden, decrease the chance of it getting misplaced"*. (GP-13)
30 368

31 369 While the 'audit and feedback' approach was more popular, some GPs were clearly in favor of facilitated
32 370 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*
33 371 *for it, if you have the means to do it, then why not?"* (GP-10)
34 372

35 373 We also asked pointedly about how providers would feel about receiving a follow-up reminder from the
36 374 study team, if patients had not filled the prescription as recommended in the initial letter. The response
37 375 was split with roughly half of the general practitioners stating that a reminder would not be necessary.
38 376

39 377 Those who felt a reminder would be acceptable generally agreed that a 6 month window should be
40 378 sufficient to ascertain whether or not the patient would have started on therapy: *"There are people that*
41 379 *have a three-month wait list time, you may have to pick an interval more like six-months to appeal to the*
42 380 *masses..."*. (GP-13)
43 381

44 382 Most patients felt that they would benefit from receiving a follow-up reminder. After considerable
45 383 discussion amongst the groups, consensus was achieved that follow-up should not happen prior to four
46 384 months, and possibly even as long as six months after the initial contact. One participant stated: *"close*
47 385 *enough that I vaguely remember that I meant to do something with that, but not a few weeks later, [so]*
48 386 *it's not irritating"*. (GP-17)
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388 We also asked patients if they had a preference for who had signed the letter. Most felt that having
 389 letters come from a local specialist in cardiology or endocrinology would be preferable to having them
 390 signed by another GP.

391
 392 *4) Workflow processing considerations (General practitioners only)*

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

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

405 In terms of the preferred delivery modality, most GPs felt that electronic delivery directly via the EMR
 406 platform would be the preferred method of receiving the intervention. However, a number still felt that
 407 conventional delivery via paper mail or fax would be preferable. Even those who expressed a preference
 408 for conventional delivery, many elaborated that such letters would often be scanned into a patient's
 409 electronic file: *"if it was to come by mail or fax, then they have to scan it onto the computer"* (GP-11). A
 410 few GPs described systems which can do this process automatically: *"our office works with a new web*
 411 *system, so everything that comes in via the fax actually goes directly into the computer and they then*
 412 *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	<p>"Overall I thought it was worded quite well and was very clear" (GP-08)</p> <p>"I think it's appropriate, it didn't take me very long to get through" (GP-16)</p>	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	<p>"it's written in a way that doesn't make you feel stupid, I guess" (GP-11)</p> <p>"it's good because [it's] not telling you to do this [start statin therapy], but telling you to have a conversation]." (GP-17)</p>	Enhances communication	"I think that's good 'cause these doctors, some guys don't communicate." (Pt-13)

Credibility	<p>“it gives family physicians more confidence to do those things and know the specialists are behind them in that recommendation” (GP-02)</p> <p>“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)</p>	Increases doctor accountability	<p>“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)</p>
Direct	<p>“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)</p> <p>“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)</p>	Increases patient accountability	<p>“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)</p>
Information	<p>“[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)</p> <p>“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)</p>	Provides peace of mind	<p>“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)</p>
Negative			
Increased workload	<p>“I would caution against anything that causes more documents or more paperwork... there’s already so much” (GP-16)</p>	Privacy concerns	<p>“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)</p> <p>“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)</p>

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)	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)
	“If it goes to the patient, sometimes you get lots of mail and they may just discard it” (MD-10)	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

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3 438 prescribed medication, had no impact on adherence (55). Others have found that multifaceted
4 439 interventions focusing on enhancing care provision through team-based care may be effective at
5 440 increasing statin adherence (56).

6 441
7 442 However, when trying to target the problem of low statin prescribing, interventions directed only at
8 443 patients are not likely to work. An alternate approach is to facilitate GPs ability to identify and prescribe
9 444 statins, to those in whom they are appropriate (57), through audit and feedback or facilitated relay. An
10 445 educational audit and feedback intervention regarding dyslipidemia treatment in Italian primary care
11 446 practices was shown to increase adherence to statins by approximately 10% (58). Improved
12 447 communication and shared decision making, which are explicit goals of facilitated relay interventions,
13 448 can improve patient adherence (59). While these and other studies have reviewed the clinical efficacy of
14 449 quality improvement strategies (21), few have used detailed qualitative methods as we have done. One
15 450 large qualitative study interviewed audit and feedback experts to generate hypotheses about the
16 451 various factors that may contribute to the efficacy of such interventions (60). Others have used
17 452 qualitative methods to highlight the barriers physicians face in encouraging adherence (61), but ours is
18 453 unique in using such methods to design and develop an intervention to address these challenges. Finally,
19 454 we also appreciate that as much as there is underuse of statins, there is also overuse, for example, in
20 455 people with short life expectancy. Perhaps interventions to increase initiation may also include a
21 456 component that conveys statin benefits are measured in years rather than months.

22 457
23 458 The fact that participants suggested elements of our facilitated relay intervention in the unprompted
24 459 portion of the interviews lends credibility and face validity to the proposed intervention. However, it is
25 460 notable that while GPs felt they would benefit from having internal systems to monitor patients'
26 461 records, none independently suggested a strategy mediated by an independent third party (such as
27 462 facilitated relay or audit and feedback), as we have proposed. Investigators who wish to implement
28 463 facilitated relay interventions to enhance adherence to medical therapies can use the findings of this
29 464 study to help develop interventions that are more likely to be acceptable to both GPs and patients. One
30 465 of the main findings is to ensure that any information provided is brief and high yield, containing patient
31 466 identifiers early to capture general practitioner's attention. Such interventions can be strengthened by
32 467 incorporating education on controversial or little-known topics. Patients strongly preferred any
33 468 correspondence to also contain direct suggestions or an action plan. Workflow and processing of these
34 469 letters needs to be considered and interventions designed to be as minimally disruptive to clinical
35 470 practice as possible – with most physicians preferring that it be embedded directly within the EMR; yet
36 471 in healthcare settings (like ours) where there is marked heterogeneity in the use and type of EMRs, this
37 472 may not be possible.

38 473
39 474 There are limitations to this study. Firstly, as in most qualitative studies, the number of participants was
40 475 relatively small. This concern over sample size is mitigated by the fact that physician interviews
41 476 proceeded until the point of saturation. Patient data were not collected in this manner, and these
42 477 themes may not be fully saturated and we appreciate this as a limitation. Furthermore, the patient
43 478 sample we recruited may not be representative of the broader population, as many of them had
44 479 previously stated an interest in quality improvement and research and therefore may be attuned to the
45 480 importance of preventive therapies more than other members of the general public. Secondly, given the
46 481 context-dependent nature of qualitative data, the applicability of these findings to other settings is not
47 482 certain. Yet physicians in most settings face similar problems (i.e. time constraints, patient complexity
48 483 and comorbidities and patient resistance to medical therapies) in numerous facets of medical care;
49 484 therefore, it is conceivable that the findings of this study would apply to interactions between patients
50 485 and GPs in other clinical settings. Due to time constraints of participants and researchers, member

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3 486 checking was not undertaken in this study. Finally, it is important to note that feedback was sought
4 487 specifically about the proposed intervention. However, given the details reported, we feel that these
5 488 findings are likely to be helpful to others proposing similar quality improvement interventions. One of
6 489 the major strengths of this study is the depth and richness of the qualitative data that were collected. By
7 490 asking questions in an open-ended manner, we were able to record detailed accounts and opinions.
8 491 Another strength of this work is the fact that we also sought patient input into the development of this
9 492 intervention, rather than relying on physician feedback alone.
10 493

11 494 Statin therapy has been demonstrated to effectively lower cholesterol and reduce the risk of
12 495 cardiovascular events and death in individuals at high risk of cardiovascular disease. Despite this, they
13 496 remain underused. There are patient, provider and system factors that contribute to statin underuse.
14 497 Facilitated relay interventions hold promise as a potential method to address this important care gap.
15 498 Our study sought perspectives of both healthcare providers and patients, which will be incorporated
16 499 into intervention design to maximize acceptability. Insights gained from qualitative data will be used to
17 500 improve the likelihood of success and achieve the desired clinical impact. The insights about these
18 501 interventions are also likely to be of interest to many researchers and clinicians who are considering and
19 502 designing provider- and/or patient-facing interventions to improve the uptake of preventive
20 503 medications.
21 504

22 505 **Contributions**

23 506 DJTC, RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, SB collaborated to develop the research question and
24 507 methods. The study design was conceived by DJTC and SB. DJTC wrote the first draft of the study
25 508 protocol. Data collection and analysis was completed by DJTC, RCWL and SB. KAM, TJA, HQ, AACL, GC,
26 509 ML, and CN contributed to the interpretation and contextualization of study findings. The first draft of
27 510 the manuscript was written by DJTC. RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, and SB contributed
28 511 substantively to further revisions of the manuscript and have consented to the publication of this
29 512 version.
30 513

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33 516

34 517 **Data Availability Statement**

35 518 No additional data available. Given that qualitative data are not deidentified and tell individuals'
36 519 personal stories, data cannot be shared beyond the scope of this project, as per our research ethics
37 520 board.
38 521

39 522 **Competing Interest Statement**

40 523 DC, RL, KAM, AL, TA, HQ, GC, SB – none. CN is a director of a private laboratory that does not currently
41 524 offer testing in the jurisdiction under study.
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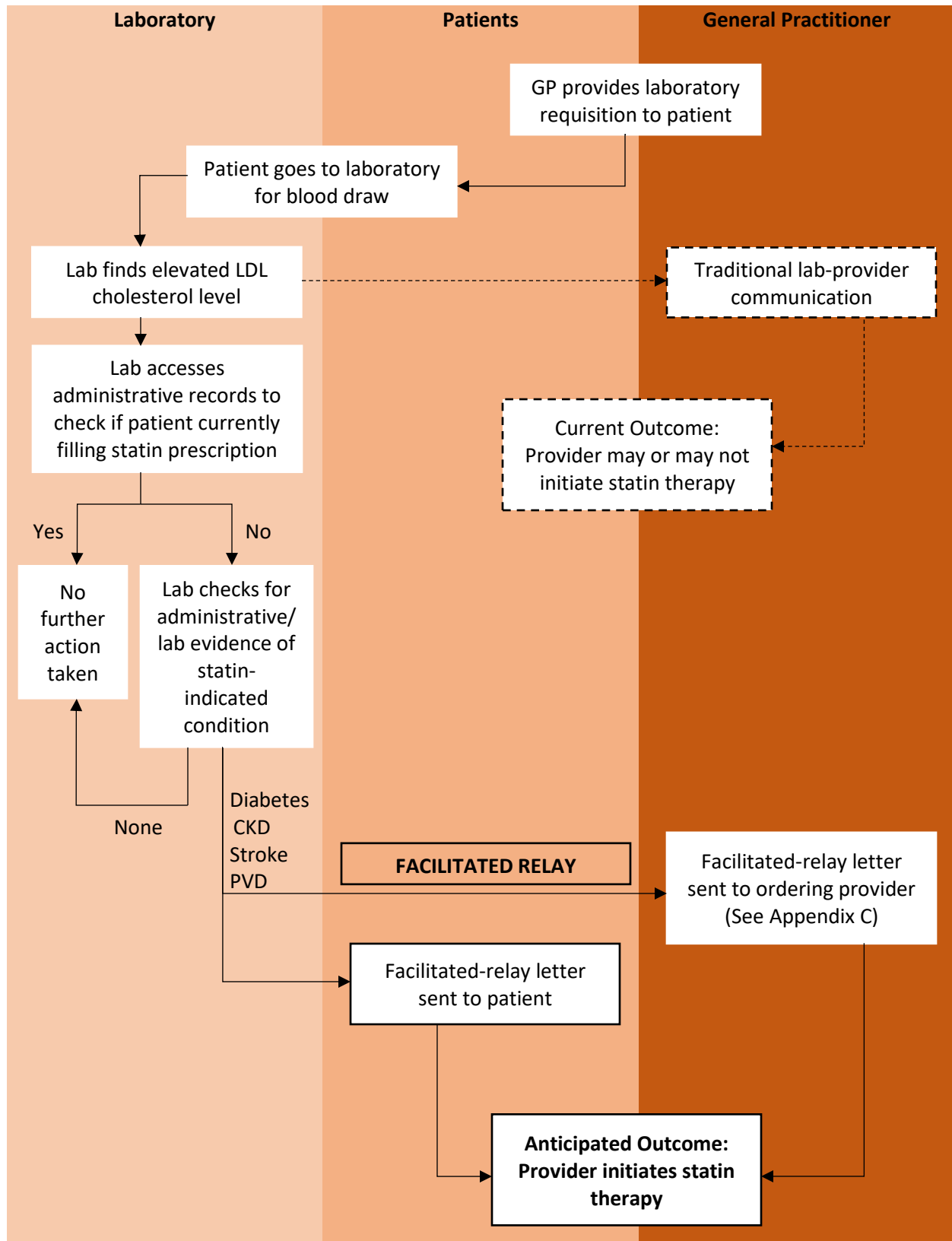


Figure 1: Laboratory-Based Facilitated-Relay Intervention
 Dashed lines: traditional interface between lab and ordering provider

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 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)

1
2
3 How should such an intervention either on a specific patient or about your entire practice
4 be received?
5

- 6 • Mail/Fax/EMR/combo

7
8
9 How would such an intervention be processed in your office?

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

13
14
15
16 Who should this letter be coming from in order to have it received in the most positive
17 way possible?
18

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

30
31
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33
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35 Would it be helpful to receive a reminder or follow-up letter?

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

37
38
39 If the intervention provided you with patient-oriented material about this subject, and
40 asked you to share it with your patients, how would you feel about doing so?

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

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51 Do you have any additional comments or suggestions for developing an intervention to
52 increase the use statins in people at high risk for cardiovascular disease (i.e. previous
53 clinical cardiovascular disease, diabetes, chronic kidney disease) in primary care?
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3 Thank you for participating in today's interview. Using the information you provided, we
4 will work on developing an intervention to improve the treatment of dyslipidemia in
5 patients who are at high risk for cardiovascular disease (i.e. previous clinical
6 cardiovascular disease, diabetes, chronic kidney disease)?
7
8

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

10 Thank you for agreeing to participate in our focus group today. There are many risk
11 factors for heart attacks and stroke. Today we want to focus on one risk factor being high
12 cholesterol. High cholesterol is a major risk factor for heart attacks, strokes and
13 circulatory problems. There are no symptoms of high cholesterol and it is diagnosed by a
14 lab test that your doctor would order. Importantly, we work for the University of Calgary
15 and have no relationship with any medication companies.
16
17

18 We wish to discuss your experience in managing *cholesterol* with medications in order to
19 better understand how we might help family physicians (*doctors*) treat high cholesterol.
20
21

22 **1. Experience with high cholesterol**

23 Think about the last time your doctor has sent you for a cholesterol test. Did your doctor
24 talk to you about the results? Treatment? What kind of treatment was discussed (diet,
25 exercise, a medication)?
26
27

28 Put yourself in the position of being told that you need to take a medication for your
29 cholesterol. What factors would make you more likely to take it? What factors would
30 make you not want to take it? Reasons, side effects, costs
31
32

- 33 • Would you use any resources to help you decide?
 - 34 ○ Doctor
 - 35 ○ Dietician
 - 36 ○ Internet
 - 37 ○ Family, friends
 - 38
 - 39

40 What would you think if your doctor told you that your cholesterol wasn't all that high,
41 but because of your other health conditions she wanted to start you on a cholesterol
42 lowering medication to reduce your risk of heart attack and stroke?
43
44

45 Do you think it would be helpful to get the actual result of your cholesterol level sent
46 directly from the lab to you?
47
48

49
50 Currently, cancer screening programs send letters to patients about their results and next
51 steps. What are your thoughts for something similar for high cholesterol?
52
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3 What about information about recommended treatments and potential side effects?
4 Would you find this to be invasive of your privacy (i.e. info from the lab about treatment
5 and not your doctor)?
6
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9
10 How would you feel about taking a letter with these recommendations to your doctor to
11 discuss about a medication for high cholesterol?
12

13
14 How do you feel your doctor would respond to you bringing this information?
15
16

17
18 What things on the letter would make it helpful?
19

20 -length, colour, graphics,
21
22

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24
25 Who should this letter be coming from in order to have it received in the most positive
26 way possible?
27

- 28 • A non-clinical academic researcher (Dr. XXXX)
- 29 • Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- 30 • A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- 31 • An academic family doctor (Dr. Kerry McBrien)
- 32 • A respected community family doctor
- 33 • The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- 34 • Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic
35 Disease Management, Community and Rural for Alberta Health Services
- 36 • Someone else
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41 Would it be helpful to receive a reminder or follow-up letter?
42

- 43 • How much later should this be sent, so as to be useful and not annoying?
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45 Do you have any additional comments or suggestions for developing an way to increase
46 the use the treatment of people with high cholesterol?
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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 stroke¹⁻². As you know, in patients like [name], statins are indicated for their dyslipidemia because they are proven to reduce cardiovascular outcomes and mortality³⁻⁴. Because of numerous randomized controlled trials, guidelines recommend statin use in individuals with history of previous cardiovascular disease, diabetes, or chronic renal failure⁵.

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 2.5-5mg⁷.
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 myalgia⁸. For your reference, maximum doses of these low potency statins, and their equivalencies are:

1
2 Pravastatin 80mg = Atorvastatin 20mg = Rosuvastatin 10mg
3 Fluvastatin XL 80mg = Atorvastatin 10mg = Rosuvastatin 5mg
4

- 5
6 3. *Reducing dose or lengthening administration interval.* Studies have demonstrated that
7 greater than 70% of patients affected by myalgias were able to tolerate every other day
8 administration with no recurrence of muscle symptoms⁹.
9

10 There is a small chance that your patient may have been misclassified with a statin indicated
11 condition. We sincerely apologize for this and would be most appreciative if you can call or fax us to
12 let us know.
13

14
15 We welcome any questions or comments so please kindly contact us at 403-955-8327 (or fax 403-955-
16 8249), for more information.
17

18
19 Sincerely,
20 Sonia Butalia MD, FRCPC, MSc and the study team
21
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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? <i>E.g. PhD, MD</i>	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? <i>e.g. personal goals, reasons for doing the research</i>	Not discussed
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? <i>e.g. Bias, assumptions, reasons and interests in the research topic</i>	Not discussed
Domain 2: study design			
	Theoretical framework		
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? <i>e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis</i>	Qualitative Description – Line 98

No	Item	Guide questions/ description	Response
	Participant selection		
10.	Sampling	How were participants selected? <i>e.g. purposive, convenience, consecutive, snowball</i>	GP – Snowball (line 106-107) Patients – Convenience (line 116)
11.	Method of approach	How were participants approached? <i>e.g. face-to-face, telephone, mail, email</i>	Line 106-120
12.	Sample size	How many participants were in the study?	Line 173 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? <i>e.g. home, clinic, workplace</i>	Line 137 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? <i>e.g. demographic data, date</i>	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. <i>participant number</i>	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
Secondary Subject Heading:	Diabetes and endocrinology, General practice / Family practice, Health services research, Qualitative research, Renal medicine
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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3 **Strategies for Enhancing the Initiation of Cholesterol Lowering Medication Among Patients at High**
4 **Cardiovascular Disease Risk: A Qualitative Descriptive Exploration of Patient and General**
5 **Practitioners' Perspectives on a Facilitated Relay Intervention in Alberta, Canada**
6

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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).

1
2
3 83 Integrated quality improvement strategies that target both patients and healthcare providers are more
4 84 likely to achieve quality indicators than strategies which only target one aspect in isolation (21). One
5 85 such strategy is facilitated relay. Facilitated relay is a quality improvement strategy whereby information
6 86 about individual patients is sent directly to healthcare providers through a means other than the usual
7 87 clinical encounter (23). Despite the establishment and promotion of facilitated relay and other quality
8 88 improvement strategies, there remain significant treatment gaps in hypertension (24) and other chronic
9 89 conditions (25). Furthermore, while facilitated relay has been shown to be effective in improving a
10 90 number of cardiovascular risk factors (21, 26), it remains among the least commonly used quality
11 91 improvement strategies (27) and has not been explored in the management of dyslipidemia.
12 92

13 93 For an intervention to have the potential to yield maximum impact, it is important to qualitatively seek
14 94 the input of key stakeholders prior to the application of any intervention (28). This allows for the
15 95 development of a higher quality intervention, rather than one that relies on physician feedback alone
16 96 (29). As such, the objective of our study was to explore the perspectives of both patients and general
17 97 practitioners' (GPs) regarding interventions to increase cholesterol lowering medication (or statin)
18 98 prescription, including specific feedback on a proposed laboratory-based facilitated relay intervention.
19 99

100 **METHODS:**

101 **Study Design**

102
103
104 We conducted a qualitative descriptive study (28) to explore patients' and GPs' perspectives on
105 interventions to increase initiation of statins for cardiovascular risk reduction and treatment of high
106 cholesterol in those at high cardiovascular risk. In addition to generic thoughts on potential hypothetical
107 interventions, we specifically sought directed feedback and perceptions on the acceptability of the
108 proposed facilitated relay intervention from both patients and GPs (30). We used the consolidated
109 criteria for reporting qualitative research (COREQ) as the reporting framework for this study (31).
110

111 **Proposed Intervention**

112
113 We drew from behaviour change theory to develop a facilitated relay intervention to increase statin
114 prescriptions (32-34) (Figure 1). Our proposed intervention partners with our province's single unified
115 laboratory system to identify individuals who have elevated cholesterol levels, statin-indicated
116 conditions, and who are not currently filling prescriptions for statins. Our lab system has access to
117 province-wide administrative databases, including labs, pharmacy dispensations, and hospitalization
118 data. For every elevated LDL-cholesterol level, the lab would have an algorithm that would check the
119 patients' records for evidence of statin-indicated conditions (administrative markers of myocardial
120 infarction, stroke, diabetes, or chronic kidney disease), and would then identify if the patient has
121 recently filled a statin prescription. This is possible because of province-wide, linkable databases. For
122 patients who are not filling statins, but who should be, their GP (who had ordered the cholesterol level)
123 and the patient, will then each receive a letter outlining the indication for treatment and the potential to
124 benefit from statin therapy. The patient letter will encourage them to speak to their GP, and the GP
125 letter will encourage them to make an appointment to discuss directly with the patient - both with the
126 objective to initiate or renew statin prescriptions. We felt that it was important to include patients in the
127 facilitated relay to empower them in discussions with their GP and to enable shared decision-making
128 (35), which has been demonstrated to improve adherence with statins (36).
129

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.

177 *Patient Focus Groups:* None of the study team were acquainted with or involved in the clinical care of
 178 the patients who participated. We convened two focus groups in our academic medical centre which
 179 each lasted approximately 90 minutes. No one but researchers (including 1 facilitator and 2 field-note
 180 takers) and participants were present. Focus group facilitators tried to ensure that there were no
 181 dominant members and provide all participants with equal opportunity to voice their opinions.
 182

183 Interviews and focus group proceedings were digitally audio-recorded and transcribed verbatim by a
 184 professional transcriptionist. Field notes were recorded to inform data analysis. All data were
 185 anonymized and stored securely. Signed informed consent was received from each study participant.
 186 Gift cards were provided to all participants. Ethics approval was granted from the University's Health
 187 Research Ethics Board.
 188

189 **Data Analysis**

191 Analysis was completed using conventional qualitative content analysis (43), a method of interpreting
 192 interview data with the goal of describing the phenomenon of interest. Transcripts for the initial three
 193 interviews were reviewed by three team members (DJTC, RCWL and SB), with the objective of
 194 inductively establishing a preliminary coding template that was used for subsequent data analysis. All
 195 transcripts were then analyzed by two reviewers (DJTC and RCWL). Codes were generated from the
 196 interview data and systematically applied to identify themes and patterns. The process was iterative,
 197 reflexive, and interactive as continual data collection and analysis shaped each other. For example, code
 198 titles or definitions identified based on earlier interviews were modified according to the data collected
 199 during subsequent interviews. The team met together to review the coding to elicit discussion about the
 200 coding strategy and attempted to achieve consensus to resolve coding discrepancies. NVivo 12
 201 (Doncaster, Australia) qualitative data analysis software was used to facilitate the coding process.
 202

203 **Patient and public involvement**

205 Patient partners and family members from the Libin Cardiovascular Institute's established patient and
 206 family member advisory group (44) voiced that *prevention* was one of their top research priorities for
 207 cardiovascular health. This work is related to prevention of cardiovascular disease. Patients were
 208 included in focus groups.
 209

210 **RESULTS**

212 In total, we eventually reached out to 27 GPs to invite them to participate, 4 declined to participate, 4
 213 didn't respond to the invitation, 19 were scheduled for interviews, with 2 cancelling. We reached
 214 saturation after having completed 17 individual GP interviews (Table 1a). The majority were women
 215 (88%) with 65% having graduated from medical school within the last ten years. All GPs spent more
 216 than 50% of their time in clinical practice, most were in urban centers within Primary Care Networks
 217 (PCNs). PCNs are networks of GPs that share interdisciplinary resources to enhance the delivery of
 218 primary care within geographical regions (45); they are associated with improved chronic disease care
 219 and outcomes(46).
 220

221 **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% Range 10-75%
Proportion of high-risk patients in their practice who have a current LDL-level on file (n=9)	Mean: 82% 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

234

235

236 General suggestions for potential interventions

237

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

244

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

Providers	Treatment of specific Sub-populations	<p>Patients with chronic kidney disease: <i>"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."</i> (GP-05)</p> <p>Patients who previously experienced side effects with statin(s): <i>"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."</i> (GP-13)</p> <p>Elderly patients: <i>"...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?"</i> (GP-10)</p> <p>Patients with hypertriglyceridemia: <i>"I always find it hard to know what to do with triglycerides... more education around how to manage those [patients]."</i> (GP-15)</p>
	Treatment to Targets *	<p><i>"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"</i>. (GP-02)</p> <p><i>"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"</i>. (GP-09)</p> <p><i>"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"</i>. (GP-08)</p>
	Preferred modality of Education	<p><i>"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"</i>. (GP-04)</p>
	EMR-based tools	<p><i>"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"</i>. (GP-06)</p>
Patients	Laboratory Results	<p><i>"I would like to get a copy, in addition to the doctor. I can do with it what I want"</i> (Pt-09)</p> <p><i>"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?'"</i> (Pt-02)</p>
	Enhanced education	<p><i>"What if somebody was going regularly to a lab, and a clinician sort of goes: 'How are you doing on this?'"</i>. (Pt-08)</p>

245 EMR: electronic medical record

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

252

253

254 1) General practitioner *education*:

255

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

261

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

266

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

271

272 2) General practitioner *tools*

273

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

279

280 3) *Patient results and information*

281

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

287

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

292 decision-making, and clinical decision support tools are described in our other report from this work
293 (16).

294

295 **Feedback on the proposed facilitated relay intervention**

296

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

300

301 *1) General feedback and impression*

302

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

308

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

315

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

321

322 *2) Suggested information to remove or add*

323

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

330

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

335

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

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

342
343 Patient feedback was notable for also suggesting that the intervention provide contact information, in
344 case they have further questions about interpreting their results: *“back that up with a helpline for*
345 *somebody that doesn’t know what the [results] mean” (Pt-10)*. Similar to physicians, patients expressed
346 a strong preference for brevity: *“If I have to go through 14 pages of information to figure out what that*
347 *means, I’m sorry, I don’t have time for that” (Pt-07)*.

348
349 However, numerous patients also stressed the importance of not only providing results or diagnoses,
350 but also giving some basic education and an action plan to follow.

351 352 *3) Intervention details*

353
354 In addition to general feedback, we also explicitly asked GPs whether they would prefer to receive
355 information about their patient in the form of facilitated relay (individual letter for each patient
356 identified) or ‘audit and feedback’ (summary report including a group of their patient panel). A summary
357 list or report (audit and feedback) was preferred by roughly 2/3 of the general practitioners interviewed.
358 Regarding receiving letters for each patient, participants stated:

359
360 *“this is going to get tiresome very quickly” (GP-05)*

361
362 *“Am I going to get this letter 20 times? I’m probably just going to read it once” (GP-03)*

363
364 *“[a list would] decrease paper burden, decrease the chance of it getting misplaced”. (GP-13)*

365
366 While the ‘audit and feedback’ approach was more popular, some GPs were clearly in favor of facilitated
367 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*
368 *for it, if you have the means to do it, then why not?” (GP-10)*

369
370 We also asked pointedly about how providers would feel about receiving a follow-up reminder from the
371 study team, if patients had not filled the prescription as recommended in the initial letter. The response
372 was split with roughly half of the general practitioners stating that a reminder would not be necessary.

373
374 Those who felt a reminder would be acceptable generally agreed that a 6 month window should be
375 sufficient to ascertain whether or not the patient would have started on therapy: *“There are people that*
376 *have a three-month wait list time, you may have to pick an interval more like six-months to appeal to the*
377 *masses...”. (GP-13)*

378
379 Most patients felt that they would benefit from receiving a follow-up reminder. After considerable
380 discussion amongst the groups, consensus was achieved that follow-up should not happen prior to four
381 months, and possibly even as long as six months after the initial contact. One participant stated: *“close*
382 *enough that I vaguely remember that I meant to do something with that, but not a few weeks later, [so]*
383 *it’s not irritating”. (GP-17)*

384
385 We also asked patients if they had a preference for who had signed the letter. Most felt that having
386 letters come from a local specialist in cardiology or endocrinology would be preferable to having them
387 signed by another GP.

388
389 *4) Workflow processing considerations (General practitioners only)*
390

391 To each GP we asked specific details about how our intervention letter would be received in their offices
392 and what would happen upon receipt. The majority stated that such a letter would be opened and
393 processed by their front-desk staff. One participant clarified that the information on the envelope would
394 determine who opened it: *"if it's addressed to me then it will come to me, if it has a patient name for*
395 *me, then it goes through our document people [who file it]"*. (GP-09)
396

397 Once the letter has been opened, different offices employed a variety of different processes. In many
398 practices, it would be given directly to the GP; while in others it would be scanned directly into a
399 patient's file in an electronic medical record, yet in others, the hardcopy would be filed in a patient's
400 chart.
401

402 In terms of the preferred delivery modality, most GPs felt that electronic delivery directly via the EMR
403 platform would be the preferred method of receiving the intervention. However, a number still felt that
404 conventional delivery via paper mail or fax would be preferable. Even those who expressed a preference
405 for conventional delivery, many elaborated that such letters would often be scanned into a patient's
406 electronic file: *"if it was to come by mail or fax, then they have to scan it onto the computer"* (GP-11). A
407 few GPs described systems which can do this process automatically: *"our office works with a new web*
408 *system, so everything that comes in via the fax actually goes directly into the computer and they then*
409 *allocate to the patient"*. (GP-11)
410

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

General Practitioners		Patients	
Positive			
Composition	<p>"Overall I thought it was worded quite well and was very clear" (GP-08)</p> <p>"I think it's appropriate, it didn't take me very long to get through" (GP-16)</p>	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	<p>"it's written in a way that doesn't make you feel stupid, I guess" (GP-11)</p> <p>"it's good because [it's] not telling you to do this [start statin therapy], but telling you to have a conversation]." (GP-17)</p>	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

	<p>“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)</p>		<p>problem with a patient having all their information at their disposal”. (Pt-14)</p>
Direct	<p>“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)</p> <p>“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)</p>	Increases patient accountability	<p>“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)</p>
Information	<p>“[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)</p> <p>“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)</p>	Provides peace of mind	<p>“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)</p>
Negative			
Increased workload	<p>“I would caution against anything that causes more documents or more paperwork... there’s already so much” (GP-16)</p>	Privacy concerns	<p>“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)</p> <p>“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)</p>
Disclosing new diagnoses	<p>“my concern is that they get this information from a letter... my preference would be that it came straight to me” (GP-01)</p>	Difficulty interpreting results	<p>“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)</p>

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)	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)
	“If it goes to the patient, sometimes you get lots of mail and they may just discard it” (MD-10)	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

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3 441 statins, to those in whom they are appropriate (57), through audit and feedback or facilitated relay. An
4 442 educational audit and feedback intervention regarding dyslipidemia treatment in Italian primary care
5 443 practices was shown to increase adherence to statins by approximately 10% (58). Improved
6 444 communication and shared decision making, which are explicit goals of facilitated relay interventions,
7 445 can improve patient adherence (59). While these and other studies have reviewed the clinical efficacy of
8 446 quality improvement strategies (21), few have used detailed qualitative methods as we have done. One
9 447 large qualitative study interviewed audit and feedback experts to generate hypotheses about the
10 448 various factors that may contribute to the efficacy of such interventions (60). Others have used
11 449 qualitative methods to highlight the barriers physicians face in encouraging adherence (61), but ours is
12 450 unique in using such methods to design and develop an intervention to address these challenges. Finally,
13 451 we also appreciate that as much as there is underuse of statins, there is also overuse, for example, in
14 452 people with short life expectancy. Perhaps interventions to increase initiation may also include a
15 453 component that conveys statin benefits are measured in years rather than months.
16 454

17 455 The fact that participants suggested elements of our facilitated relay intervention in the unprompted
18 456 portion of the interviews lends credibility and face validity to the proposed intervention. However, it is
19 457 notable that while GPs felt they would benefit from having internal systems to monitor patients'
20 458 records, none independently suggested a strategy mediated by an independent third party (such as
21 459 facilitated relay or audit and feedback), as we have proposed. Investigators who wish to implement
22 460 facilitated relay interventions to enhance adherence to medical therapies can use the findings of this
23 461 study to help develop interventions that are more likely to be acceptable to both GPs and patients. One
24 462 of the main findings is to ensure that any information provided is brief and high yield, containing patient
25 463 identifiers early to capture general practitioner's attention. Such interventions can be strengthened by
26 464 incorporating education on controversial or little-known topics. Patients strongly preferred any
27 465 correspondence to also contain direct suggestions or an action plan. Workflow and processing of these
28 466 letters needs to be considered and interventions designed to be as minimally disruptive to clinical
29 467 practice as possible – with most physicians preferring that it be embedded directly within the EMR; yet
30 468 in healthcare settings (like ours) where there is marked heterogeneity in the use and type of EMRs, this
31 469 may not be possible.
32 470

33 471 There are limitations to this study. Firstly, as in most qualitative studies, the number of participants was
34 472 relatively small. This concern over sample size is mitigated by the fact that physician interviews
35 473 proceeded until the point of saturation. Patient data were not collected in this manner, and these
36 474 themes may not be fully saturated and we appreciate this as a limitation. Furthermore, the patient
37 475 sample we recruited may not be representative of the broader population, as many of them had
38 476 previously stated an interest in quality improvement and research and therefore may be attuned to the
39 477 importance of preventive therapies more than other members of the general public. Secondly, given the
40 478 context-dependent nature of qualitative data, the applicability of these findings to other settings is not
41 479 certain. Yet physicians in most settings face similar problems (i.e. time constraints, patient complexity
42 480 and comorbidities and patient resistance to medical therapies) in numerous facets of medical care;
43 481 therefore, it is conceivable that the findings of this study would apply to interactions between patients
44 482 and GPs in other clinical settings. Due to time constraints of participants and researchers, member
45 483 checking was not undertaken in this study. Finally, it is important to note that feedback was sought
46 484 specifically about the proposed intervention. However, given the details reported, we feel that these
47 485 findings are likely to be helpful to others proposing similar quality improvement interventions. One of
48 486 the major strengths of this study is the depth and richness of the qualitative data that were collected. By
49 487 asking questions in an open-ended manner, we were able to record detailed accounts and opinions.
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3 488 Another strength of this work is the fact that we also sought patient input into the development of this
4 489 intervention, rather than relying on physician feedback alone.
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6 491 Statin therapy has been demonstrated to effectively lower cholesterol and reduce the risk of
7 492 cardiovascular events and death in individuals at high risk of cardiovascular disease. Despite this, they
8 493 remain underused. There are patient, provider and system factors that contribute to statin underuse.
9 494 Facilitated relay interventions hold promise as a potential method to address this important care gap.
10 495 Our study sought perspectives of both healthcare providers and patients, which will be incorporated
11 496 into intervention design to maximize acceptability. Insights gained from qualitative data will be used to
12 497 improve the likelihood of success and achieve the desired clinical impact. The insights about these
13 498 interventions are also likely to be of interest to many researchers and clinicians who are considering and
14 499 designing provider- and/or patient-facing interventions to improve the uptake of preventive
15 500 medications.
16 501

17 502 **Contributions**

18 503 DJTC, RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, SB collaborated to develop the research question and
19 504 methods. The study design was conceived by DJTC and SB. DJTC wrote the first draft of the study
20 505 protocol. Data collection and analysis was completed by DJTC, RCWL and SB. KAM, TJA, HQ, AACL, GC,
21 506 ML, and CN contributed to the interpretation and contextualization of study findings. The first draft of
22 507 the manuscript was written by DJTC. RCWL, KAM, TJA, HQ, AACL, GC, ML, CN, and SB contributed
23 508 substantively to further revisions of the manuscript and have consented to the publication of this
24 509 version.
25 510

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28 513

29 514 **Data Availability Statement**

30 515 No additional data available. Given that qualitative data are not deidentified and tell individuals'
31 516 personal stories, data cannot be shared beyond the scope of this project, as per our research ethics
32 517 board.
33 518

34 519 **Competing Interest Statement**

35 520 DC, RL, KAM, AL, TA, HQ, GC, SB – none. CN is a director of a private laboratory that does not currently
36 521 offer testing in the jurisdiction under study.
37 522

38 523 Figure 1: Laboratory-Based Facilitated-Relay Intervention
39 524

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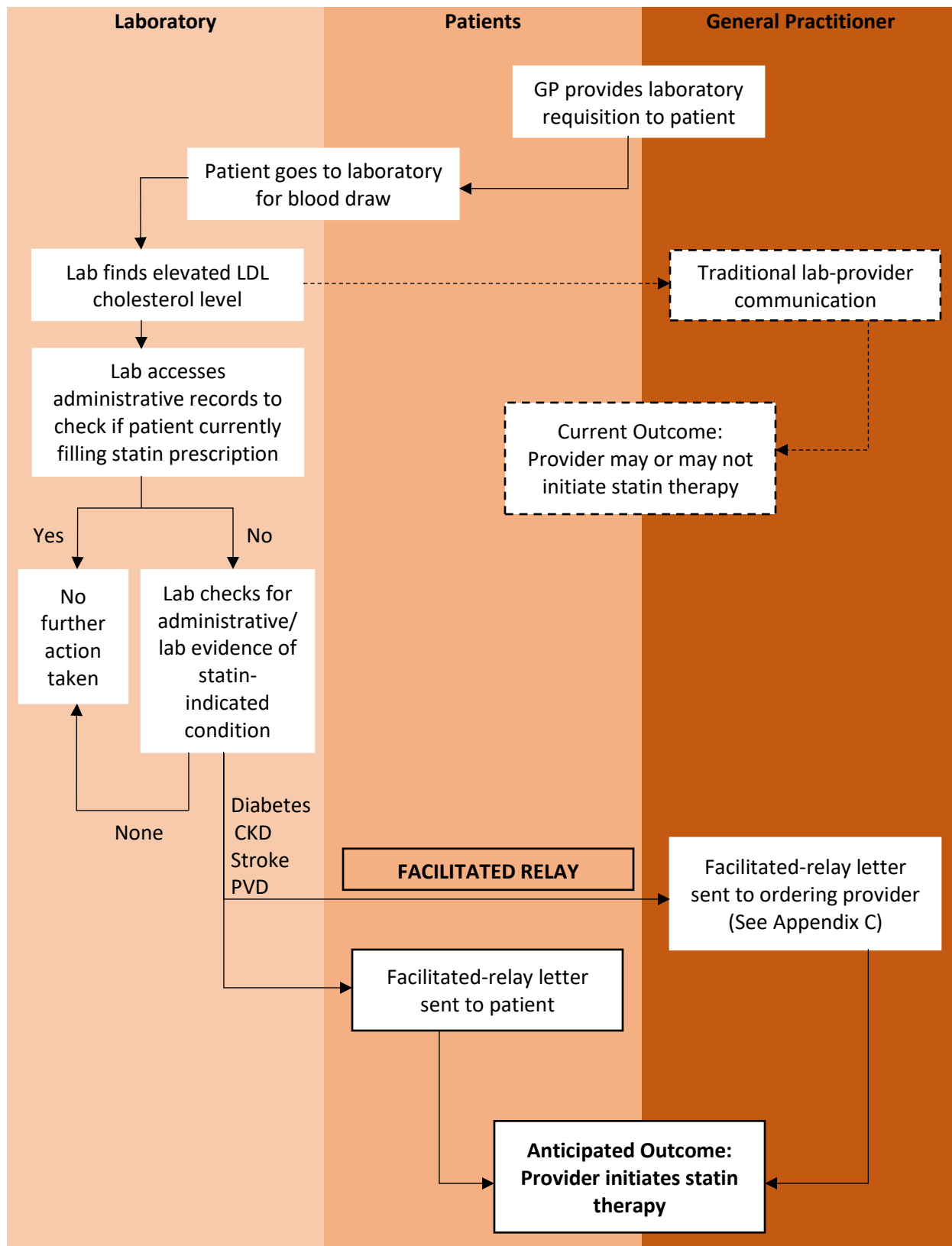


Figure 1: Laboratory-Based Facilitated-Relay Intervention
 Dashed lines: traditional interface between lab and ordering provider

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 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)

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3 How should such an intervention either on a specific patient or about your entire practice
4 be received?
5

- 6 • Mail/Fax/EMR/combo
7

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9 How would such an intervention be processed in your office?
10

- 11 • Who would open the envelope?
- 12 • What would they do with it? (give it to you, put it in the patient's chart)
- 13 • How likely would you be to see this information?
14
15

16 Who should this letter be coming from in order to have it received in the most positive
17 way possible?
18

- 19 • A non-clinical academic researcher (Dr. XXXX)
- 20 • Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- 21 • A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- 22 • An academic family doctor (Dr. Kerry McBrien)
- 23 • A respected community family doctor
- 24 • The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- 25 • Dr. Cello Tonelli, Associate Vice-President (Research) at the University of
26 Calgary
- 27 • Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic
28 Disease Management, Community and Rural for Alberta Health Services
- 29 • Someone else
30
31
32
33

34
35 Would it be helpful to receive a reminder or follow-up letter?
36

- 37 • How much later should this be sent, so as to be useful and not annoying?
38

39 If the intervention provided you with patient-oriented material about this subject, and
40 asked you to share it with your patients, how would you feel about doing so?
41

- 42 • What content should be included in this patient-oriented material to enhance statin
43 use?
- 44 • What format should this material be in? Electronic, hard-copy? How should it be
45 delivered? Mail, email?
- 46 • Would you share it in a clinical setting?
- 47 • Would you be willing to mail it to patients directly?
48
49

50
51 Do you have any additional comments or suggestions for developing an intervention to
52 increase the use statins in people at high risk for cardiovascular disease (i.e. previous
53 clinical cardiovascular disease, diabetes, chronic kidney disease) in primary care?
54
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2
3 Thank you for participating in today's interview. Using the information you provided, we
4 will work on developing an intervention to improve the treatment of dyslipidemia in
5 patients who are at high risk for cardiovascular disease (i.e. previous clinical
6 cardiovascular disease, diabetes, chronic kidney disease)?
7
8

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

10 Thank you for agreeing to participate in our focus group today. There are many risk
11 factors for heart attacks and stroke. Today we want to focus on one risk factor being high
12 cholesterol. High cholesterol is a major risk factor for heart attacks, strokes and
13 circulatory problems. There are no symptoms of high cholesterol and it is diagnosed by a
14 lab test that your doctor would order. Importantly, we work for the University of Calgary
15 and have no relationship with any medication companies.
16
17

18 We wish to discuss your experience in managing *cholesterol* with medications in order to
19 better understand how we might help family physicians (*doctors*) treat high cholesterol.
20
21

22 **1. Experience with high cholesterol**

23 Think about the last time your doctor has sent you for a cholesterol test. Did your doctor
24 talk to you about the results? Treatment? What kind of treatment was discussed (diet,
25 exercise, a medication)?
26
27

28 Put yourself in the position of being told that you need to take a medication for your
29 cholesterol. What factors would make you more likely to take it? What factors would
30 make you not want to take it? Reasons, side effects, costs
31
32

- 33 • Would you use any resources to help you decide?
 - 34 ○ Doctor
 - 35 ○ Dietician
 - 36 ○ Internet
 - 37 ○ Family, friends
 - 38
 - 39

40 What would you think if your doctor told you that your cholesterol wasn't all that high,
41 but because of your other health conditions she wanted to start you on a cholesterol
42 lowering medication to reduce your risk of heart attack and stroke?
43
44

45 Do you think it would be helpful to get the actual result of your cholesterol level sent
46 directly from the lab to you?
47
48

49
50 Currently, cancer screening programs send letters to patients about their results and next
51 steps. What are your thoughts for something similar for high cholesterol?
52
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2
3 What about information about recommended treatments and potential side effects?
4 Would you find this to be invasive of your privacy (i.e. info from the lab about treatment
5 and not your doctor)?
6
7

8
9
10 How would you feel about taking a letter with these recommendations to your doctor to
11 discuss about a medication for high cholesterol?
12

13
14 How do you feel your doctor would respond to you bringing this information?
15
16

17
18 What things on the letter would make it helpful?
19

20 -length, colour, graphics,
21
22

23
24
25 Who should this letter be coming from in order to have it received in the most positive
26 way possible?
27

- 28 • A non-clinical academic researcher (Dr. XXXX)
- 29 • Head of the Calgary Laboratory Services (Dr. Christopher Naugler)
- 30 • A lipid specialist (Dr. Sonia Butalia, Alex Leung)
- 31 • An academic family doctor (Dr. Kerry McBrien)
- 32 • A respected community family doctor
- 33 • The lead of Dyslipidemia Guidelines (Dr. Todd Anderson)
- 34 • Dr. Richard Lewanczuk, Senior Medical Director for Primary Care, Chronic
35 Disease Management, Community and Rural for Alberta Health Services
- 36 • Someone else
37
38
39

40
41 Would it be helpful to receive a reminder or follow-up letter?
42

- 43 • How much later should this be sent, so as to be useful and not annoying?
44

45 Do you have any additional comments or suggestions for developing an way to increase
46 the use the treatment of people with high cholesterol?
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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 stroke¹⁻². As you know, in patients like [name], statins are indicated for their dyslipidemia because they are proven to reduce cardiovascular outcomes and mortality³⁻⁴. Because of numerous randomized controlled trials, guidelines recommend statin use in individuals with history of previous cardiovascular disease, diabetes, or chronic renal failure⁵.

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 2.5-5mg⁷.
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 myalgia⁸. For your reference, maximum doses of these low potency statins, and their equivalencies are:

1
2 Pravastatin 80mg = Atorvastatin 20mg = Rosuvastatin 10mg
3 Fluvastatin XL 80mg = Atorvastatin 10mg = Rosuvastatin 5mg
4

- 5
6 3. *Reducing dose or lengthening administration interval.* Studies have demonstrated that
7 greater than 70% of patients affected by myalgias were able to tolerate every other day
8 administration with no recurrence of muscle symptoms⁹.
9

10 There is a small chance that your patient may have been misclassified with a statin indicated
11 condition. We sincerely apologize for this and would be most appreciative if you can call or fax us to
12 let us know.
13

14
15 We welcome any questions or comments so please kindly contact us at 403-955-8327 (or fax 403-955-
16 8249), for more information.
17

18
19 Sincerely,
20 Sonia Butalia MD, FRCPC, MSc and the study team
21
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32 References

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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? <i>E.g. PhD, MD</i>	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? <i>e.g. personal goals, reasons for doing the research</i>	Not discussed
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? <i>e.g. Bias, assumptions, reasons and interests in the research topic</i>	Not discussed
Domain 2: study design			
	Theoretical framework		
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? <i>e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis</i>	Qualitative Description – Line 98

No	Item	Guide questions/ description	Response
	Participant selection		
10.	Sampling	How were participants selected? <i>e.g. purposive, convenience, consecutive, snowball</i>	GP – Snowball (line 106-107) Patients – Convenience (line 116)
11.	Method of approach	How were participants approached? <i>e.g. face-to-face, telephone, mail, email</i>	Line 106-120
12.	Sample size	How many participants were in the study?	Line 173 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? <i>e.g. home, clinic, workplace</i>	Line 137 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? <i>e.g. demographic data, date</i>	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. <i>participant number</i>	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