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3 **Patient, family physician and community pharmacist perspectives on expanded**
4 **pharmacy scope of practice: a qualitative study**
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ABSTRACT

Background: The R_xEACH trial was a randomized trial to evaluate the efficacy of community pharmacy-based case finding and intervention in patients at high risk for cardiovascular (CV) events. Community-dwelling patients with poorly controlled risk factors were identified and their CV risk reduced through patient education, prescribing, and follow-up by their pharmacist. Perspectives of patients, family physicians (FPs) and community pharmacists (CPs) were obtained regarding pharmacists' identification and management of patients at high risk for CV events, to identify strategies to facilitate implementation of the pharmacist's expanded role in routine patient care.

Methods: We used a qualitative methodology (individual semi-structured interviews) with conventional qualitative content analysis to describe perceptions about CPs' care of patients at high risk for CV events. Perceptions were categorized into macro (structure), meso (institution) and micro (practice) health system levels, based on a conceptual framework of care for optimizing scopes of practice.

Results: 48 participants (14 patients, 13 FPs and 21 CPs) were interviewed. Patients were supportive of the expanded scope of practice of CPs. All participant groups emphasized the importance of communication, ability to share patient information, trust, and better understanding of the roles, responsibilities, accountabilities and liabilities of the pharmacist within their expanded role.

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3 Interpretation: Despite support from patients and changes to delivery of care in primary
4 care settings, ongoing efforts are needed to understand how to best harmonize FP and CP
5 roles across the health system. This will require collaboration and input from professional
6 associations, regulatory bodies, pharmacists, family physicians and patients.
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BACKGROUND

Community pharmacists (CPs) are well positioned to contribute to identification and management of chronic medical conditions such as hypertension, diabetes and cardiovascular disease (CVD) (1). In Canada, legislative and regulatory changes have supported an expansion of a pharmacist's scope of practice (2). Depending on the province, as each province has its own body for registering and regulating pharmacy practice, (2) pharmacists can renew, adjust, initiate or substitute prescriptions, as well as order and interpret laboratory tests.

The current pharmacy legislation has provided pharmacists an opportunity to overcome the 'classic' barriers (time constraints, limited remuneration models and low public expectations) to implementing the expanded scope of practice (3). Indeed, pharmacists across many provinces provide medication management and immunization services as well as change drug dosage, formulation and renewing/extending prescriptions for continuity of care since the launch of this legislation (<https://www.pharmacists.ca/pharmacy-in-canada/scope-of-practice-canada/>). Recent studies have reported effective pharmacists interventions on individual risk factors such as hypertension, diabetes and dyslipidemia (4-6). The Alberta Vascular Risk Reduction Community Pharmacy Project: R_xEACH trial (7) was recently conducted to evaluate the efficacy of a community pharmacy-based case finding and intervention program in patients at high risk for CVD. Findings of the trial indicated that compared to usual care, the pharmacist-based intervention significantly reduced the risk of CV events. In this intervention, pharmacists used a proactive case-finding strategy to identify patients based

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3 on their medications and risk factors. As a secondary objective of the R_xEACH trial we
4 sought to identify perspectives of patients, family physicians (FPs) and community
5 pharmacists (CPs) regarding pharmacists' identification and management of complex
6 patients (namely adults at high risk for CVD) to identify strategies to facilitate
7 implementation of the pharmacist's expanded role in routine patient care.
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18 **METHODS**

19 **Study design and participants**

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21 We used a qualitative descriptive design, a methodological approach that presents the
22 facts in everyday terms as reported by participants, with no deeper interpretation of their
23 experiences (8). Using purposive sampling, patients, FPs and CPs who participated in the
24 R_xEACH trial (7) were eligible to participate in an individual semi-structured telephone
25 interview. A letter was sent to CPs inviting them to participate and to identify patients
26 and FPs who were also involved in the study (to achieve a triad of patient, FP and CP
27 perspectives). After being approached by the pharmacists, interested patients and FPs
28 were sent a letter of invitation describing the study and interview process. A snowball
29 sampling strategy was also used to identify other FPs outside the R_xEACH trial, to obtain
30 adequate representation of FPs. The Conjoint Health Research Ethics Board, University
31 of Calgary, approved this study. Participants provided verbal informed consent.
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49 **Data Collection**

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51 The interview guide for each participant group was developed based on a review of the
52 literature (2, 9) and in consultation with the research team (pharmacists, nurses, family
53 physician, and researchers) (Supplementary Material), and was piloted with 4 community
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3 pharmacists. Questions generally focused on: skills and knowledge to manage patients at
4 high risk for CVD (patients, FPs, CPs); changes in practice behaviour (FPs, CPs);
5 communication/interaction (patients, FPs, CPs); and suggestions for sustainability
6 (patients, FPs, CPs). Experienced qualitative interviewers (MD; JP and PL: see
7 acknowledgements) conducted the 20 – 30 minute interviews from September 2015 to
8 May 2016. All interviews were audio-recorded and transcribed verbatim. Field notes
9 were recorded at the time of the interview and used to inform data analysis. Recruitment
10 and interviews were continued until the research team was satisfied that the data
11 indicated saturation (i.e. similar emerging themes).
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27 **Data Analysis**

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29 Conventional qualitative content analysis (10) was used. The three interviewers (MD; JP
30 and PL) independently categorized data based on a conceptual framework of care for
31 optimizing scopes of practice. The framework identifies factors at 3 health system levels:
32 macro (legal and regulatory, education and training, economic and political); meso
33 (institutional, technological and community); and micro (team composition and
34 professional cultures) (11). Transcripts were initially read to acquire an overall sense of
35 the phenomenon of interest. Words and phrases that captured key concepts were
36 highlighted to create codes, which identified evolving themes and subthemes. Data
37 analysis and collection were done iteratively so that interview questions could be altered
38 to enhance clarity of emerging themes. Final themes were determined through a series of
39 discussions with the research team members; consensus on final themes was achieved.
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RESULTS

A total of 48 participants (14 patients, 13 FPs and 21 CPs) were interviewed (Figure 1). One FP was identified by a CP, while the other 12 FPs (who care for patients at high risk for CVD but were not involved in the R_xEACH trial) were identified by key informants (members of the research team, and then subsequent FP participants). Demographics for each of the participant groups are presented in Table 1 and 2. One triad of participants (patient, FP and CP), 8 dyads (patient and CP) and the remaining CPs and patients were individuals who were not part of a FP or CP unit from the R_xEACH trial were interviewed. An overview of barriers, enablers and selected quotations are provided in Boxes 1- 5.

Macro (Structure) Level

Health care professional accountability/liability

All 3-participant groups identified concerns about liability and “lack of clarity” regarding who was responsible and ultimately accountable for adverse patient outcomes, should they occur. FPs expressed concern that they may be left “holding the bag” if a patient problem arose. FPs and CPs were concerned about possible differences between standards of practice based on their regulatory bodies and jurisdictions. Participants identified strategies to overcome this including education of healthcare professionals and the public regarding the pharmacists’ expanded scope of practice and providing a quality assurance framework for healthcare professionals.

Health care compensation and funding models

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3 Some FPs and CPs felt the current model did not support co-management, with potential
4 duplication of services and “potential waste of health care dollars”. They thought both
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6 parties should not be compensated for the same service to a patient (e.g., comprehensive
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8 annual care plan for chronic disease management). To address this barrier, participants
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10 recommended that funding for services should be monitored and standardized across
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12 jurisdictions, with an audit process to reduce potential duplication.
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20 *Professional education needs and requirements*

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22 Both FPs and CPs identified that not all pharmacists “embrace the expanded scope of
23
24 practice”. However, those who did demonstrated higher clinical confidence and have
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26 typically established a “network of support”. CPs also identified the need for continuing
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28 education, particularly in management of patients with multiple co-morbidities. Both FPs
29
30 and CPs supported inter-professional education.
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38 *Community pharmacy business model*

39 CPs reported difficulties balancing their requirements to “perform as an employee”
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41 within an often corporate business model with the capacity to deliver high-quality
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43 expanded services. FPs questioned whether there may be conflict of interest for
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45 pharmacists who prescribe and dispense medications, “pushing products due to business
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47 agenda”. CPs reflected on the importance of having the support of the larger pharmacy
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49 chains as a mechanism to enable pharmacists to function in their expanded role.
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55 *Professional and regulatory bodies*

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3 Both FPs and CPs identified lack of engagement, guidance and support from their
4 representative professional colleges and associations. They expressed the need for all
5 parties to promote a team-based approach for patient care. Similarly, a key enabler
6 identified was having support of their professional organizations and regulatory bodies
7 for inter-professional practice.
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18 **Meso (Institutional) Level**

19 *Patient information management across multiple care settings*

20 All 3-participant groups identified the need for sharing patient information across care
21 settings, ideally through an electronic health record (EMR). Patients reported that access
22 to their health information would allow them to take more responsibility for their health.
23 FPs expressed concern that patients may be at risk when CPs made medication changes
24 without a complete patient history. All groups identified that “mixed messaging” may
25 occur and result in patient confusion and “eroding” of the care plan. Patients, FPs and
26 CPs uniformly agree that implementation of shared EMRs would facilitate an integrated
27 model of care.
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44 **Micro (Practice) Level**

45 *Patient satisfaction*

46 Patients reported appreciation for care from a team, highlighting the pharmacist’s pivotal
47 role. They indicated that pharmacists allowed them to take more responsibility in their
48 care as well as spent time explaining their treatment plan and answering questions.
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55 Patients appreciated the compassion that pharmacists demonstrated.
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6 *Communication between FPs and CPs*
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8 All 3-participant groups identified absence of effective communication between FPs and
9 CPs. FP and CP groups reported the importance of a “consistent and effective” means of
10 communication, whether face to face, or through fax, phone or electronic means. Some
11 patients also perceived that FPs and CPs did not communicate well based on “mixed
12 messages” about recommended medications. Potential enablers included the importance
13 of FPs and CPs collaboration via timely and effective communication.
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24 *Role clarity*
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26 Patients and FPs reported lack of clearly defined roles and understanding of the expanded
27 scope of practice for CP. Patient and FP participants that had a better understanding
28 reported a “greater appreciation” of the potential benefits. Recognizing that CPs can
29 contribute to the inter-disciplinary care of patients in the community setting was
30 identified as an enabler.
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41 *Trusting relationships*
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43 Patients’ trust in their CP stemmed from their “existing, long term relationship” with the
44 CP. Patients and FPs identified the need to be aware of CPs able to provide expanded role
45 services. This information could be made public by “creating a registry of certified
46 pharmacists”. The importance of “investing time and effort in forming relationships” with
47 each other was also highlighted. FPs considered personal contact with pharmacists as a
48 starting point for a collaborative relationship.
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Access

Both patients and FPs commented on the importance of close proximity and timely access to CPs. FPs reported that when the pharmacist was located nearby it lent itself to convenient, brief and frequent consults about patients – “the pharmacy next door” or “in-house” pharmacist (in team setting). Patients appreciated not having to make an appointment with the CP to get medication adjustments or laboratory results, and the time CPs spent with them.

Workplace environment and workforce

CPs reported the importance of having “up-to-date medical equipment, computers with adequate software, as well as support staff and counseling rooms” to assist them in their expanded scope.

INTERPRETATION

Changes to the scope of practice of pharmacists are changing the way primary care is delivered in Canada. Using qualitative methodology, we identified key issues to optimizing the pharmacist’s expanded scope of practice for patients at high risk for CVD. To facilitate the delivery of patient-centered care it is important to understand perceptions of patients, FPs and CPs. Patient participants were very supportive of the CPs expanded scope of practice model, and reported that they received timely access to a qualified professional that they trusted. At all levels of the health care system (macro, meso and micro) the importance of communication, ability to share patient information, trust, and

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3 better understanding of the roles, responsibilities, accountabilities and liabilities of the CP
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5 within their expanded role of practice was emphasized. FPs and CPs recognized that
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7 shared care should be patient-centered, and that in order to implement this model of care
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9 effectively all parties will need to embrace the notion of a collaborative care model.
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15 As previously reported (9), a core concept that evolved was the need for better
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17 communication, with enhanced two-way electronic communications through electronic
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19 health records to facilitate real-time and reciprocal relay of information about patient
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21 care. Effective and shared communication would enable FPs to be notified about
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23 modifications or initiation of therapy, and similarly for CPs to be aware of changes to
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25 patients' health status and therapy as provided by the FP. The potential for
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27 communication to be facilitated through co-location has also been recognized (12, 13).
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34 At the micro level the importance of role clarity and trusting relationships was
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36 highlighted. Hatah and colleagues also reported lack of understanding by general
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38 practitioners regarding pharmacists' roles (14). We found that some of the R_xEACH
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40 patients were cautious about the pharmacist's role initially, but with ongoing interaction
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42 they were receptive to this model of care. While CPs hold liability insurance (2), the lack
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44 of a clear understanding of accountability and liability was identified as a potential
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46 barrier by patients and FPs in our study. The Canadian Medical Protective Association
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48 have outlined liability issues, and indicate that each member of the healthcare team in an
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50 inter-professional model of care is potentially liable for their actions (15). The
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52 importance of trust and mutual respect between FPs and CPs was emphasized by
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3 participants, with similar findings from Saskatchewan (16) and Australia (14, 17).

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5 Gregory and Austin identified that pharmacists and FPs have different concepts of trust
6 and that they are inherently different (18). Strategies to achieve trust and mutual respect
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8 may include the use of inter-professional education between FPs and CPs (19). Indeed,
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10 universities across Canada are beginning to offer opportunities where students from
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12 across health care faculties train together to prepare for collaborative and inter-
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14 professional roles in the clinical setting (2).
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22 Our study has limitations. We identified participants from Alberta using purposive and
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24 snowball sampling strategies, thus their experiences are reflective of health care delivery
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26 in Alberta, which may limit generalizability. However considering the universal nature of
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28 health care in Canada, there is no reason to believe these results are not relevant to other
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30 Canadian provinces, and in particular those with similar expanded pharmacist roles.
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34 While attempts were made to include FPs who were involved in the care of patients in the
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36 R_xEACH trial (7), consent was obtained from only one physician who fulfilled this
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38 criterion. The remainder of the FPs were identified through a purposive, snowball
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40 sampling technique. However, all interviewed FPs were practicing in a setting that
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42 included patients at high risk of CVD, and thus their perspectives would be relevant and
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44 representative of FPs, although they would not have the benefit of seeing firsthand the
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46 experience of patients managed through the R_xEACH trial. Patient participants were
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48 identified by the pharmacists, as requested by our ethics board. While pharmacists may
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50 have selected patients who were more satisfied with the expanded scope of practice, the
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52 wide range of patient responses suggests this is unlikely. As is common in all studies of
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3 this nature, the results are representative of those who responded and completed the
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5 interviews. The family physicians who participated had all been in practice for at least 10
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7 years. The extent to which this incorporates the perceptions of family physicians who
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9 have just completed their training and are starting their practice cannot be determined.
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15 Optimizing the scope of practice of health care professionals is key to transforming our
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17 health care system, and delivering high quality, patient-centered care. The expanded
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19 scope of pharmacists' practice is one such example where we can support patients in the
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21 community setting. Despite the support from the patients and the current regulations to
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23 enable the integration of pharmacists into routine clinical care, ongoing efforts are needed
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25 to understand how to best harmonize FP and CP roles across the health system. This will
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27 require collaboration and input from professional associations, regulatory bodies,
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29 practicing pharmacists, family physicians and the patients (2).
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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS

All authors fulfill the criteria for authorship of ICMJE. Brenda Hemmelgarn, Braden Manns, Marcello Tonelli, Ross Tsuyuki, Kathryn King-Shier, Wendy Tink, Nairne Scott-Douglas, Charlotte Jones and Yazid Al Hamarneh were involved in the conception, design and oversight of the study. Maoliosa Donald, Kathryn King-Shier and Brenda Hemmelgarn were responsible for acquisition, analysis and interpretation of the data. All authors contributed to the drafting of the manuscript and critical revision of the manuscript for important intellectual content. Brenda Hemmelgarn, Braden Manns, Marcello Tonelli, Nairne Scott-Douglas and Ross Tsuyuki obtained funding.

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CONFLICT OF INTEREST STATEMENT

The results presented in this paper have not been published previously in whole or part, except in abstract format. This research was supported by a team grant funded by Alberta Innovates-Health Solutions.

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ABSTRACT

Background: **The R_xEACH trial was** a randomized trial to evaluate the efficacy of community pharmacy-based case finding and intervention in patients at high risk for cardiovascular (CV) events. **Community-dwelling** patients with poorly controlled risk factors **were** identified and their CV risk reduced **through patient education, prescribing, and follow-up by their pharmacist**. Perspectives of patients, family physicians (FPs) and community pharmacists (CPs) **were obtained regarding pharmacists'** identification and management of patients at **high risk for CV events**, to identify strategies to facilitate implementation of the pharmacist's expanded role in routine patient care.

Methods: We used a qualitative methodology (individual semi-structured interviews) with conventional qualitative content analysis to describe perceptions about CPs' care of patients at high risk for CV events. Perceptions were categorized into macro (structure), meso (institution) and micro (practice) health system **levels**, based on a conceptual framework of care for optimizing scopes of practice.

Results: 48 participants (14 patients, 13 FPs and 21 CPs) were interviewed. **Patients were supportive of the expanded scope of practice of CPs**. All participant groups emphasized the importance of communication, ability to share patient information, trust, and better understanding of the roles, responsibilities, accountabilities and liabilities of the pharmacist within their expanded role.

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3 Interpretation: Despite support from patients and changes to delivery of care in primary
4 care settings, ongoing efforts are needed to understand how to best harmonize FP and CP
5 roles across the health system. This will require collaboration and input from professional
6 associations, regulatory bodies, pharmacists, family physicians and patients.
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BACKGROUND

Community pharmacists (CPs) are well positioned to contribute to identification and management of chronic medical conditions such as hypertension, diabetes and cardiovascular disease (CVD) (1). In Canada, legislative and regulatory changes have supported an expansion of a pharmacist's scope of practice (2). Depending on the province, as each province has its own body for registering and regulating pharmacy practice, (2) pharmacists can renew, adjust, initiate or substitute prescriptions, as well as order and interpret laboratory tests.

The current pharmacy legislation has provided pharmacists an opportunity to overcome the 'classic' barriers (time constraints, limited remuneration models and low public expectations) to implementing the expanded scope of practice (3). Indeed, pharmacists across many provinces provide medication management and immunization services as well as change drug dosage, formulation and renewing/extending prescriptions for continuity of care since the launch of this legislation (<https://www.pharmacists.ca/pharmacy-in-canada/scope-of-practice-canada/>). Recent studies have reported effective pharmacists interventions on individual risk factors such as hypertension, diabetes and dyslipidemia (4-6). The Alberta Vascular Risk Reduction Community Pharmacy Project: R_xEACH trial (7) was recently conducted to evaluate the efficacy of a community pharmacy-based case finding and intervention program in patients at high risk for CVD. Findings of the trial indicated that compared to usual care, the pharmacist-based intervention significantly reduced the risk of CV events. In this intervention, pharmacists used a proactive case-finding strategy to identify patients based

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3 on their medications and risk factors. As a secondary objective of the R_xEACH trial we
4 sought to identify perspectives of patients, family physicians (FPs) and community
5 pharmacists (CPs) regarding pharmacists' identification and management of complex
6 patients (namely adults at high risk for CVD) to identify strategies to facilitate
7 implementation of the pharmacist's expanded role in routine patient care.
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17 **METHODS**

18 **Study design and participants**

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20 We used a qualitative descriptive design, a methodological approach that presents the
21 facts in everyday terms as reported by participants, with no deeper interpretation of their
22 experiences (8). Using purposive sampling, patients, FPs and CPs who participated in the
23 R_xEACH trial (7) were eligible to participate in an individual semi-structured telephone
24 interview. A letter was sent to CPs inviting them to participate and to identify patients
25 and FPs who were also involved in the study (to achieve a triad of patient, FP and CP
26 perspectives). After being approached by the pharmacists, interested patients and FPs
27 were sent a letter of invitation describing the study and interview process. A snowball
28 sampling strategy was also used to identify other FPs outside the R_xEACH trial, to obtain
29 adequate representation of FPs. The Conjoint Health Research Ethics Board, University
30 of Calgary, approved this study. Participants provided verbal informed consent.
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49 **Data Collection**

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51 The interview guide for each participant group was developed based on a review of the
52 literature (2, 9) and in consultation with the research team (pharmacists, nurses, family
53 physician, and researchers) (Supplementary Material), and was piloted with 4 community
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3 **pharmacists**. Questions generally focused on: skills and knowledge to manage **patients at**
4 **high risk for CVD** (patients, FPs, CPs); changes in practice behaviour (FPs, CPs);
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6 communication/interaction (patients, FPs, CPs); and suggestions for sustainability
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8 (patients, FPs, CPs). Experienced qualitative interviewers (MD; JP and PL: see
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10 acknowledgements) conducted the 20 – 30 minute interviews from September 2015 to
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12 May 2016. All interviews were audio-recorded and transcribed verbatim. Field notes
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14 were recorded at the time of the interview and used to inform data analysis. **Recruitment**
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16 **and interviews were continued until the research team was satisfied that the data**
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18 **indicated saturation (i.e. similar emerging themes).**
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27 **Data Analysis**

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29 Conventional qualitative content analysis (10) was used. The three interviewers (MD; JP
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31 and PL) independently categorized data based on a conceptual framework of care for
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33 optimizing scopes of practice. The framework identifies factors at 3 health system levels:
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35 macro (legal and regulatory, education and training, economic and political); meso
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37 (institutional, technological and community); and micro (team composition and
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39 professional cultures) (11). Transcripts were initially read to acquire an overall sense of
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41 the phenomenon of interest. Words and phrases that captured key concepts were
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43 highlighted to create codes, which identified evolving themes and subthemes. Data
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45 analysis and collection were done iteratively so that interview questions could be altered
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47 to enhance clarity of emerging themes. Final themes were determined through a series of
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49 discussions with the research team members; consensus on final themes was achieved.
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RESULTS

A total of 48 participants (14 patients, 13 FPs and 21 CPs) were interviewed (Figure 1). One FP was identified by a CP, while the other 12 FPs (who care for patients at high risk for CVD but were not involved in the R_xEACH trial) were identified by key informants (members of the research team, and then subsequent FP participants). Demographics for each of the participant groups are presented in Table 1 and 2. One triad of participants (patient, FP and CP), 8 dyads (patient and CP) and the remaining CPs and patients were individuals who were not part of a FP or CP unit from the R_xEACH trial were interviewed. An overview of barriers, enablers and selected quotations are provided in Boxes 1- 5.

Macro (Structure) Level

Health care professional accountability/liability

All 3-participant groups identified concerns about liability and “lack of clarity” regarding who was responsible and ultimately accountable for adverse patient outcomes, should they occur. FPs expressed concern that they may be left “holding the bag” if a patient problem arose. FPs and CPs were concerned about possible differences between standards of practice based on their regulatory bodies and jurisdictions. Participants identified strategies to overcome this including education of healthcare professionals and the public regarding the pharmacists’ expanded scope of practice and providing a quality assurance framework for healthcare professionals.

Health care compensation and funding models

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3 Some FPs and CPs felt the current model did not support co-management, with potential
4 duplication of services and “potential waste of health care dollars”. They thought both
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6 parties should not be compensated for the same service to a patient (e.g., comprehensive
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8 annual care plan for chronic disease management). To address this barrier, participants
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10 recommended that funding for services should be monitored and standardized across
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12 jurisdictions, with an audit process to reduce potential duplication.
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20 *Professional education needs and requirements*

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22 Both FPs and CPs identified that not all pharmacists “embrace the expanded scope of
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24 practice”. However, those who did demonstrated higher clinical confidence and have
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26 typically established a “network of support”. CPs also identified the need for continuing
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28 education, particularly in management of patients with multiple co-morbidities. Both FPs
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30 and CPs supported inter-professional education.
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38 *Community pharmacy business model*

39 CPs reported difficulties balancing their requirements to “perform as an employee”
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41 within an often corporate business model with the capacity to deliver high-quality
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43 expanded services. FPs questioned whether there may be conflict of interest for
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45 pharmacists who prescribe and dispense medications, “pushing products due to business
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47 agenda”. CPs reflected on the importance of having the support of the larger pharmacy
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49 chains as a mechanism to enable pharmacists to function in their expanded role.
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55 *Professional and regulatory bodies*

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3 Both FPs and CPs identified lack of engagement, guidance and support from their
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5 representative professional colleges and associations. They expressed the need for all
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7 parties to promote a team-based approach for patient care. Similarly, a key enabler
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9 identified was having support of their professional organizations and regulatory bodies
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11 for inter-professional practice.
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14 15 16 17 18 **Meso (Institutional) Level**

19 20 *Patient information management across multiple care settings*

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22 All 3-participant groups identified the need for sharing patient information across care
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24 settings, ideally through an electronic health record (EMR). Patients reported that access
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26 to their health information would allow them to take more responsibility for their health.
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28 FPs expressed concern that patients may be at risk when CPs made medication changes
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30 without a complete patient history. All groups identified that “mixed messaging” may
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32 occur and result in patient confusion and “eroding” of the care plan. Patients, FPs and
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34 CPs uniformly agree that implementation of shared EMRs would facilitate an integrated
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36 model of care.
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43 44 **Micro (Practice) Level**

45 46 *Patient satisfaction*

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48 Patients reported appreciation for care from a team, highlighting the pharmacist’s pivotal
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50 role. They indicated that pharmacists allowed them to take more responsibility in their
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52 care as well as spent time explaining their treatment plan and answering questions.
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55 Patients appreciated the compassion that pharmacists demonstrated.
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6 *Communication between FPs and CPs*
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8 All 3-participant groups identified absence of effective communication between FPs and
9 CPs. FP and CP groups reported the importance of a “consistent and effective” means of
10 communication, whether face to face, or through fax, phone or electronic means. Some
11 patients also perceived that FPs and CPs did not communicate well based on “mixed
12 messages” about recommended medications. Potential enablers included the importance
13 of FPs and CPs collaboration via timely and effective communication.
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24 *Role clarity*
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26 Patients and FPs reported lack of clearly defined roles and understanding of the expanded
27 scope of practice for CP. Patient and FP participants that had a better understanding
28 reported a “greater appreciation” of the potential benefits. Recognizing that CPs can
29 contribute to the inter-disciplinary care of patients in the community setting was
30 identified as an enabler.
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41 *Trusting relationships*
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43 Patients’ trust in their CP stemmed from their “existing, long term relationship” with the
44 CP. Patients and FPs identified the need to be aware of CPs able to provide expanded role
45 services. This information could be made public by “creating a registry of certified
46 pharmacists”. The importance of “investing time and effort in forming relationships” with
47 each other was also highlighted. FPs considered personal contact with pharmacists as a
48 starting point for a collaborative relationship.
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Access

Both patients and FPs commented on the importance of close proximity and timely access to CPs. FPs reported that when the pharmacist was located nearby it lent itself to convenient, brief and frequent consults about patients – “the pharmacy next door” or “in-house” pharmacist (in team setting). Patients appreciated not having to make an appointment with the CP to get medication adjustments or laboratory results, and the time CPs spent with them.

Workplace environment and workforce

CPs reported the importance of having “up-to-date medical equipment, computers with adequate software, as well as support staff and counseling rooms” to assist them in their expanded scope.

INTERPRETATION

Changes to the scope of practice of pharmacists are changing the way primary care is delivered in Canada. Using qualitative methodology, we identified key issues to optimizing the pharmacist’s expanded scope of practice for patients at high risk for CVD. To facilitate the delivery of patient-centered care it is important to understand perceptions of patients, FPs and CPs. Patient participants were very supportive of the CPs expanded scope of practice model, and reported that they received timely access to a qualified professional that they trusted. At all levels of the health care system (macro, meso and micro) the importance of communication, ability to share patient information, trust, and

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3 better understanding of the roles, responsibilities, accountabilities and liabilities of the CP
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5 within their expanded role of practice was emphasized. FPs and CPs recognized that
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7 shared care should be patient-centered, and that in order to implement this model of care
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9 effectively all parties will need to embrace the notion of a collaborative care model.
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15 As previously reported (9), a core concept that evolved was the need for better
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17 communication, with enhanced two-way electronic communications through electronic
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19 health records to facilitate real-time and reciprocal relay of information about patient
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21 care. Effective and shared communication would enable FPs to be notified about
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23 modifications or initiation of therapy, and similarly for CPs to be aware of changes to
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25 patients' health status and therapy as provided by the FP. The potential for
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27 communication to be facilitated through co-location has also been recognized (12, 13).
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34 At the micro level the importance of role clarity and trusting relationships was
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36 highlighted. Hatah and colleagues also reported lack of understanding by general
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38 practitioners regarding pharmacists' roles (14). We found that some of the R_xEACH
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40 patients were cautious about the pharmacist's role initially, but with ongoing interaction
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42 they were receptive to this model of care.
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48 While CPs hold liability insurance (2), the lack of a clear understanding of accountability
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50 and liability was identified as a potential barrier by patients and FPs in our study. The
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52 Canadian Medical Protective Association have outlined liability issues, and indicate that
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54 each member of the healthcare team in an inter-professional model of care is potentially
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3 liable for their actions (15). The importance of trust and mutual respect between FPs and
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5 CPs was emphasized by participants, with similar findings from Saskatchewan (16) and
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7 Australia (14, 17). Gregory and Austin identified that pharmacists and FPs have different
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9 concepts of trust and that they are inherently different (18). Strategies to achieve trust and
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11 mutual respect may include the use of inter-professional education between FPs and CPs
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13 (19). Indeed, universities across Canada are beginning to offer opportunities where
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15 students from across health care faculties train together to prepare for collaborative and
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17 inter-professional roles in the clinical setting (2).
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24 Our study has limitations. We identified participants from Alberta using purposive and
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26 snowball sampling strategies, thus their experiences are reflective of health care delivery
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28 in Alberta, which may limit generalizability. However considering the universal nature of
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30 health care in Canada, there is no reason to believe these results are not relevant to other
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32 Canadian provinces, and in particular those with similar expanded pharmacist roles.
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35 While attempts were made to include FPs who were involved in the care of patients in the
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37 R_xEACH trial (7), consent was obtained from only one physician who fulfilled this
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39 criterion. The remainder of the FPs were identified through a purposive, snowball
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41 sampling technique. However, all interviewed FPs were practicing in a setting that
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43 included patients at high risk of CVD, and thus their perspectives would be relevant and
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45 representative of FPs, although they would not have the benefit of seeing firsthand the
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47 experience of patients managed through the R_xEACH trial. Patient participants were
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49 identified by the pharmacists, as requested by our ethics board. While pharmacists may
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51 have selected patients who were more satisfied with the expanded scope of practice, the
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3 wide range of patient responses suggests this is unlikely. As is common in all studies of
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5 this nature, the results are representative of those who responded and completed the
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7 interviews. The family physicians who participated had all been in practice for at least 10
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9 years. The extent to which this incorporates the perceptions of family physicians who
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11 have just completed their training and are starting their practice cannot be determined.
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18 Optimizing the scope of practice of health care professionals is key to transforming our
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20 health care system, and delivering high quality, patient-centered care. The expanded
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22 scope of pharmacists' practice is one such example where we can support patients in the
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24 community setting. Despite the support from the patients and the current regulations to
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26 enable the integration of pharmacists into routine clinical care, ongoing efforts are needed
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28 to understand how to best harmonize FP and CP roles across the health system. This will
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30 require collaboration and input from professional associations, regulatory bodies,
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32 practicing pharmacists, family physicians and the patients (2).
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COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS

All authors fulfill the criteria for authorship of ICMJE. Brenda Hemmelgarn, Braden Manns, Marcello Tonelli, Ross Tsuyuki, Kathryn King-Shier, Wendy Tink, Nairne Scott-Douglas, Charlotte Jones and Yazid Al Hamarneh were involved in the conception, design and oversight of the study. Maoliosa Donald, Kathryn King-Shier and Brenda Hemmelgarn were responsible for acquisition, analysis and interpretation of the data. All authors contributed to the drafting of the manuscript and critical revision of the manuscript for important intellectual content. Brenda Hemmelgarn, Braden Manns, Marcello Tonelli, Nairne Scott-Douglas and Ross Tsuyuki obtained funding.

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CONFLICT OF INTEREST STATEMENT

The results presented in this paper have not been published previously in whole or part, except in abstract format. This research was supported by a team grant funded by Alberta Innovates-Health Solutions.

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The sponsors of the study had no role in study design, data collection, data analysis, data interpretation or writing of the report.

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Figure 1: Participant recruitment flow chart

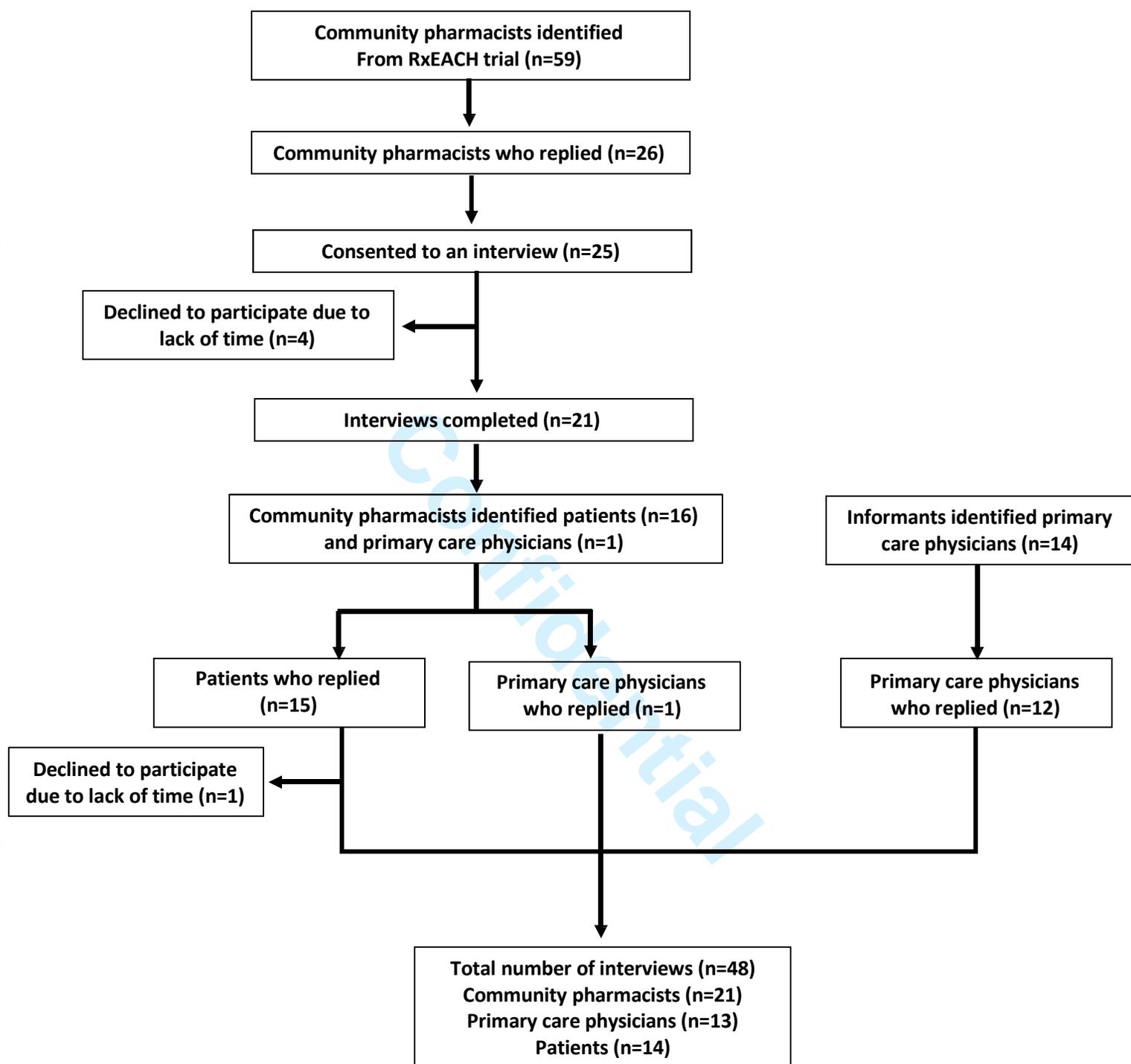


Table 1. Characteristics of community pharmacists (n = 21) and family physicians (n = 13)

Community Pharmacists Characteristics	N	(%)
Sex		
Male	9	(43)
Age group (years)		
≤ 35	7	(33)
36 – 45	9	(43)
46 – 64	5	(24)
≥ 65	0	(0)
Years in practice		
≤ 10	9	(43)
11 – 20	7	(33)
21 – 30	4	(19)
≥ 31	1	(5)
Practice location		
Urban	12	(57)
Rural	9	(43)
Practice type		
Independent (not affiliated with any corporately run banner)	9	(43)
Banner (independent pharmacy affiliated with a central office)	2	(9)
Chain (head office directs pharmacy practice)	10	(48)
Employment status		
Full time	17	(81)
Part time	4	(19)
Pharmacist status		
Owner	7	(33)
Employee	14	(67)
Family Physician Characteristics		
Sex		
Male	7	(54)
Years in practice		
≤ 10	0	(0)
11 – 20	3	(23)
21 – 30	7	(54)
≥ 31	3	(23)
Practice location		
Urban	10	(77)
Rural	3	(23)

Table 2. Characteristics of patients (n = 14)

Characteristic	N	(%)
Sex		
Male	7	(50)
Female	7	(50)
Age group (years)		
≤ 50	2	(14)
51 – 60	4	(29)
61 - 70	6	(43)
71 - 80	1	(7)
≥ 81	1	(7)
Residence location		
Urban	8	(57)
Rural	6	(43)
Comorbidities		
Diabetes	12	(86)
Chronic kidney disease	8	(57)
Previous cardiovascular disease	5	(36)
Hypertension	14	(100)
Smoking	2	(14)

Box 1. Macro (Structure) level issues reported by patients, family physicians (FP) and community pharmacists (CP)

- **Health care professional accountability/liability:** “you recognize things that you wanted to change and it was hard to sometimes get the doctors on board to make the change, to let either myself be in control of it or they want to be in control of it” (CP)

“unclear and simply don’t know what guidelines pharmacists adhere to” (FP)

- **Health care compensation/funding models:** “duplication of comprehensive care plans are seen as particularly wasteful, as is the involvement of a diabetic educator at the pharmacy when diabetic education has already been provided” (FP)

“expanded scope, the added services, they (pharmacists) were doing it because they wanted to, because it is the right thing to do, felt patients would benefit from it, and now there is a big push basically do it so that you can bill” (CP)

- **Professional education needs/requirements:** “they don’t feel adequately trained, I don’t think they feel competent to be doing this and my worry is that it’ll be the people (pharmacists) who don’t know what they don’t know” (FP)

“wonderful thing to have the pharmacist do it as long as they know what they’re doing and that they’re educated” (Patient)

- **Community pharmacy business models:** “It’s very difficult to do this (clinical) work because you still have to dispense medication, income comes from dispensing” (CP)

- **Professional and regulatory bodies:** “it’s going to take undeniably, leadership from both the College of Physicians and Surgeons and the College of Pharmacists” (CP)

Box 2. Macro (Structure) level enablers reported by patients, family physicians (FP) and community pharmacists (CP)

- **Educate professionals and public on changes to pharmacists expanded scope of practice; provide guidance regarding quality assurance framework for all professionals; ensure professional accountability:** “we have to communicate that we’re not trying to take their (FP) jobs, we’re just trying to do a better job for the patients’ (CP)

“prove to the public what their pharmacists are making a difference, especially in cardiovascular” (CP)

“have the pharmacists do it as long as they know what they’re doing, he has gone through what they need to do” (Patient)

- **Standardize funded services across all jurisdictions; implement audit process:** “I think right from the get go there should be some Blue Cross audits, professional services billing, which initially when they came out there wasn’t – the government was paying for all this stuff” (CP)

“being a pharmacy owner, call backs and audits and the challenge I have is making sure that the work I’m doing pleases everybody involved” (CP)

- **Provide continuing professional development for pharmacists; implement inter-professional education:** “more confidence and respect for recommendations that I would be making, whereas maybe a year ago they (physicians) would be like, well I’m not sure if I believe that, whereas now I have a physician standing beside me” (CP)

“more pharmacist directed-maybe some sort of basic diagnostic type courses or ongoing that would help focus or specialize in other areas” (CP)

“learning it in school, but in real life you have to just get out and do it, and even just a couple of programs that would be available – get a useful skill” (CP)

- **Support pharmacists to provide higher quality clinical services:** “we had to convince head office ... prove that this time and med review services actually benefits them” (CP)

“the patient is the most important person, the patient is the driver – marrying clinical services with production” (CP)

- **Representation of the interests of the professionals to support inter-professional practice:** “we need somebody to advocate, we need avocation, we need someone to say you’re not there yet” (CP)

“I think in the future definitely recommend shared learning and brainstorming about strategies and things, on a quarterly or twice yearly basis just to keep everybody engaged” (CP)

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Box 3. Meso (Institutional) level issues and enablers reported by family physicians (FP)

- **Information management across multiple care settings:** “find that errors get propagated in the electronic medical records (EMR) so I’ve changed writing records, I’ve had a lot more queries and feedback just because of EMR problems” (FP)
- **Implement and upkeep of shared EMRs:** “always a bit of a search when it comes to clinical data, moving forward it would be nice if we had EMRs built into pharmacy software” (FP)

Confidential

Box 4. Micro (Practice) level issues reported by patients, family physicians (FP) and community pharmacists (CP)

- **Communication between pharmacists and FPs:** “in the absence of effective communication we (FPs) can feel overwhelmed by the large volumes of faxes, notes” (FP)
- **Role clarity:** “I had great concerns when it (expanded scope of practice) came on the radar, sounded as though they would be presuming to diagnose and initiate therapy and medication which I wasn’t sure that was appropriate” (FP)

“this is a little beyond what I thought they do, but I know they are well educated and stuff” (Patient)

- **Trusting relationships:** “we had that relationship going into it (expanded scope of practice) and we continue that relationship, there’s mutual respect for what we can do” (CP)

“...I have a number of people that are looking after me which gives a lot of confidence and relaxation when you know your being taken care of” (Patient)

- **Access:** “the closer they (pharmacist) are the more regular the interaction is – hallway consultations, the more relationship you have built, the more trust each other and the less friction there is around decision making” (FP)

“...a lot more closer contact with your pharmacist than you do with your doctor...can get in to see your pharmacist without an appointment...” (Patient)

- **Workplace environment and workforce:** “I couldn’t imagine being in a pharmacy with 10 people with only one person doing this (expanded scope of practice), I think it would be very difficult” (CP)

Box 5. Micro (Practice) level enablers reported by patients, family physicians (FP) and community pharmacists (CP)

- **Ensure adequate, timely and reciprocal communication:** “you need to work on your relationships, communicate with them (FPs) in a way that they like, send them follow-ups when you promise” (CP)

“they (FP, pharmacist) connect back and forth by whatever it is, by email or faxes, so they’re both aware of what is going on” (Patient)

- **Acknowledge that pharmacists have expertise and provide valuable services; function as team to co-manage patient:** “they are consulted often, appreciated for their expertise, and provide numerous educational services since their credentials, training and scope of practice are well known and well defined” (FP)

“doctors can’t be experts on everything, refer to somebody that is more knowledgeable” (Patient)

“...he (Pharmacist) didn't just prescribe drugs for us, he explained them and explained things that we could do the help ourselves...he keeps us very involved and knowledgeable.” (Patient)

- **Recognize pharmacist’s qualifications and training; invest time and effort in getting to know each other:** “we have more and more trust with each other and communication and from patient’s feedback, they get more information about the problem and self-management, also about testing” (FP)

“doctors should diagnose and pharmacists should prescribe – they (pharmacists) know their drugs, know interactions, so I want their opinion, knowledge” (Patient)

- **Co-locate or identify pharmacy/pharmacist in close physical proximity; easy and open access to pharmacist:** “a lot more closer contact with your pharmacist than you do with your doctor... can get in to see your pharmacist without an appointment” (Patient)

- **Support for pharmacist autonomy for expanded scope of practice; provide appropriate space and equipment to do clinical assessments:** “I am the owner/manager, so I redesigned my workflow so the technical work is being handled by technicians, I’m just getting involved in the clinical part of interacting with the patient” (CP)

“Going forward having a bit more pre-population of information, some better tools that work on computers” (CP)

Supplementary File – Interview Guide

Broad introduction question: (patients, family physicians, community pharmacists)

- I would like to learn about your experience being involved in the Rx EACH project?
 - Could you tell me about how you found out about the project?
 - What did you think when you heard about the project?
- How satisfied were you with the intervention/care?

Intervention related questions:

Skills and knowledge to manage patients with chronic disease in the community- (Community pharmacists):

- Did you feel that you had the skills and knowledge to manage complex patients with many problems in your practice?
- I want to understand what you found helpful regarding the training to manage patients with chronic disease in your community practice?
 - Content/materials? Methods used?
- I want to understand what was not helpful?
- How has this training made a difference in how you practice?
- What additional training could have been provided to facilitate your ability to manage these patients?

Case finding - (Community pharmacists):

- I want to learn about your experience identifying patients with the chronic conditions of interest in your pharmacy.
 - What approach do you use to identify patients?
 - What was helpful?
 - What was not helpful?
 - How has case finding made a difference in how you practice?

Management - (Community pharmacists):

- Please tell me about the resources/mechanisms in your everyday clinical practice that assists or enables you to manage patients with chronic conditions?
- Please tell me about the resources/mechanisms in your everyday clinical practice that inhibits (challenges) or is a barrier to you in managing patients with chronic conditions?

Treatment - (Patients):

- Tell me about the care you have received from your pharmacist?
 - What was helpful?
 - What was not helpful?
 - What would you change?

Practice behavior – (Community pharmacist):

- How has participation in this project changed your practice behavior?

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5 **Barriers and facilitators related questions:**

6 *Communication/interaction between participants – (patients, family physicians, community*
7 *pharmacists):*

- 8 ○ I want to understand if the RxEACH project has changed how community pharmacists,
9 family physicians and patients interact and communicate about managing cardiovascular
10 risk -
11
12 ➤ Has this relationship changed and if so, how has this relationship changed?
13 ➤ What kind of help do you need to overcome any challenges?
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16 **Sustainability related questions:**

17 *Sustainability - (patient, family physician, community pharmacists):*

- 18 ○ We are looking at innovative ways to assist you, and other pharmacists/family
19 physicians/patients like you, with managing cardiovascular risk in the community
20 setting. Tell me about some ideas that might help you?
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23 **Closing question:**

24 My main purpose in the interview today was to try and understand the barriers and facilitators to
25 identifying and managing complex patients in your practice. Is there anything else you would
26 feel is important that we haven't discussed?
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COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.