



Applying the RE-AIM framework to the Alberta's Caring for Diabetes Project: A protocol for a comprehensive evaluation of primary care quality improvement interventions

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8 **Applying the RE-AIM framework to the Alberta's Caring for Diabetes Project: A protocol for a**
9 **comprehensive evaluation of primary care quality improvement interventions**
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42 project, primary care
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Abstract

Introduction: Diabetes represents a major public health and health system burden. As part of the Alberta's Caring for Diabetes (ABCD) Project, two quality-improvement interventions are being piloted in four Primary Care Networks in Alberta. Gaps between health research, policy, and practice have been documented and the need to evaluate the impact of public health interventions in real-world settings to inform decision-making and clinical practice is paramount. In this article, we describe the application of the RE-AIM framework to evaluate the interventions beyond effectiveness.

Methods and analysis: Two quality improvement interventions were implemented, based on previously proven effective models of care and are directed at improving the physical and mental health of patients with type-2 diabetes. Our goal is to adapt and apply the RE-AIM framework, using a mixed-methods approach, to understand the impact of the interventions to inform policy and clinical decision-making. We present the proposed measures, data sources, and data management and analysis strategies used to evaluate the interventions by RE-AIM dimension.

Ethics and dissemination: Ethics approval for the ABCD Project has been granted from the Health Research Ethics Board (HREB #PRO00012663) at the University of Alberta. The RE-AIM framework will be used to structure our dissemination activities by dimension. Results will be presented at relevant conferences and prepared for publication in peer-reviewed journals. Various products, such as presentations, briefing reports, and webinars, will be developed to inform key stakeholders of the findings. Presentation of findings by RE-AIM dimension will facilitate discussion regarding the public health impact of the two interventions within the primary care context of Alberta and lessons learned to be used in program planning and care delivery for patients with type-2 diabetes. It will also promote the application of evaluation models to better assess the impact of community-based primary health care interventions through our dissemination activities.

Article Summary

Article focus

- Diabetes represents a public health and health system burden; primary care requires collaborative team interventions and self-management support.
- Study protocol using a mixed-method approach for a comprehensive evaluation.

Key messages

- Evidence on effectiveness of public health interventions in real-world settings is needed to better inform decisions about practice and policy.
- RE-AIM model provides a framework to elicit contextual information to better interpret effectiveness of interventions.
- Dissemination activities can be structured using the RE-AIM dimensions to identify target audiences, key messages, and appropriate knowledge products.

Strengths and limitations of this study

- Application of the RE-AIM framework and a mixed-methods approach allows for a comprehensive evaluation of the ABCD Project interventions beyond clinical effectiveness.
- This represents the evaluation of a pilot study in four Primary Care Networks (PCNs), which may not be representative of other primary care models.

INTRODUCTION

Diabetes represents a major public health and health system burden. The Canadian National Diabetes Surveillance System has estimated that 6.2% of the population have diabetes [1]. In Alberta, 206,000 people were living with diabetes in 2009, representing over 5.5% of the population [2]. This signifies a doubling of affected individuals within the past decade. The majority (i.e., >90%) of these individuals have type 2 diabetes. As the number of people with diabetes increases, the number of resulting complications and co-morbidities increases, creating a greater demand on health care resources [2] [3].

The Alberta's Caring for Diabetes (ABCD) Project, funded by the Alberta Health ministry as part of the provincial diabetes strategy, was developed to improve the quality and efficiency of care for diabetes in Alberta, Canada, with a focus on supporting Primary Care Networks (PCNs) in non-metro areas of Alberta. PCNs consist of a voluntary network of family physicians (hereby referred to as "member physicians") and allied health professionals, who identify priorities and coordinate health services for patient populations [4] [5]. The PCN model is akin to the "patient-centered medical home" model emerging in the United States [6] [7].

The ABCD team has worked with participating PCNs to implement a number of quality improvement interventions. This includes an ongoing, survey-based cohort study that seeks to understand why some people with type 2 diabetes develop complications while others do not. This study involves an annual survey of individuals with type 2 diabetes over five years, to collect data on lifestyle behaviours, self-management and patient-reported outcomes and linkage with administrative databases to assess health care utilization and longer term clinical outcomes. In addition, participating PCNs will implement pilot interventions including: (1) Healthy Eating and Active Living in Diabetes (HEALD-PCN), a pedometer-based walking program [8]; and (2) TeamCare-PCN, a collaborative team-based, depression case management intervention [9]. Key features of HEALD-PCN include the provision

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3 of information in a group setting by an exercise specialist on increasing the amount and intensity of
4 physical activity (i.e., walking), the glycemic index, and individual goal setting. The HEALD-PCN program
5 also provides opportunities for participants to implement lessons learned (i.e., walking group sessions)
6 through partnerships with community recreational facilities [10]. Key features of TeamCare-PCN include
7 coordinated care by a nurse care manager (CM) to direct active patient follow-up, treat-to-target
8 principles, and specialist (i.e., psychiatrists and internists/endocrinologists) consultation [11].
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17 The efficacy of both pilot interventions has been proven in other settings [10-12], and the study
18 protocols to determine the effectiveness of HEALD-PCN and TeamCare-PCN in the PCN environment in
19 Alberta have been published [8] [9]. Our goal is to also assess the impact of the entire ABCD project
20 activities, including how these different interventions were simultaneously implemented, in Alberta's
21 PCN environment. The purpose of this paper is to describe the design of the evaluation for the different
22 elements of the ABCD project, using the RE-AIM framework [13].
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33 **Evaluating the ABCD pilot interventions using RE-AIM**

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35 The gaps between health research, policy and practice have been well documented [13-16].
36 Evaluations of health interventions are often limited to efficacy studies rather than assessment of
37 potential public health impact [17]. Efficacy studies tend to focus on the internal validity of high-
38 intensity health interventions with motivated and homogenous populations in controlled settings [13].
39 This narrow focus hinders the translation of research into practice and reduces the ability to generalize
40 findings to similar settings [13]. Evidence on the external validity of less-intensive interventions in real-
41 world settings is needed to better inform decisions about practice [13].
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51 In this context, assessment of clinical effectiveness alone is not enough to inform decisions
52 about a program's broader public health impact. The RE-AIM evaluation framework was designed to
53 assess health interventions beyond effectiveness to include multiple criteria to better identify effect and
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transferability [18]. The framework consists of five dimensions: **Reach** into the target population; **Effectiveness** of the intervention; **Adoption** by target settings, institutions and staff; **Implementation**, including consistency and cost of delivery; and **Maintenance** of intervention effects over time [13].

The RE-AIM model addresses two levels of assessment: individual (Reach, Effectiveness); organization (Adoption and Implementation); or both (Maintenance) [13]. To fit our evaluation goals, we expanded the assessment level of “reach” [13] beyond the individual assessment level (i.e., absolute number, proportion, and representativeness of *individuals* willing to participate in an intervention) to include an organization assessment level (i.e., an organization’s ability to identify the entire target population) (Table 1). An example of an organizational strategy to identify a population is the development and use of a patient registry.

Table 1: RE-AIM dimensions, definitions, and assessment levels for evaluation of the ABCD pilot interventions

Dimension	Definition	Level of Assessment
Reach	<i>The ability to identify targeted population(s) at an organizational level and the absolute number, proportion, and representativeness of individuals who are willing to participate in an intervention.</i>	Individual & Organizational
Effectiveness	The impact of an intervention on important outcomes, including potential negative effects and quality of life.	Individual
Adoption	The absolute number, proportion, and representativeness of settings and intervention agents (i.e., people who deliver the program) who are willing to initiate an intervention	Organizational
Implementation	At the individual level, implementation refers to clients' use of the intervention strategies. At the setting level, implementation refers to the intervention agents' fidelity to the various elements of an intervention's protocol, including consistency of delivery as intended, and the time and cost of the intervention.	Individual & Organizational
Maintenance	At the individual level, maintenance has been defined as the long-term effects of a program on outcomes 6 or more months after the most recent intervention contact. At the setting level, maintenance refers to the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies.	Individual & Organizational

Italicized words or phrases indicate modifications made by the ABCD Project team to the original “Reach” definition and assessment level [13]. This table was compiled and adapted from several sources [13] [17] [18].

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3 While there are other evaluation frameworks, such as Procede-Proceed [19] and Health Impact
4 Assessment [20], we assert the RE-AIM model is well suited to evaluate the ABCD pilot interventions for
5 two reasons. First, RE-AIM is considered more appropriate for evaluation of behavioral change
6 interventions [21] than other models. Second, the dimensions of the RE-AIM model are well matched to
7 inform the specific needs of our audiences and interested parties including healthcare providers, PCN
8 management, policy makers, and funders.
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20 METHODS AND ANALYSIS

21 We will employ a mixed-methods approach [22] for our comprehensive evaluation of the ABCD
22 pilot interventions. Using the RE-AIM model, our research team developed logic models and data
23 matrices for both interventions in consultation with advisory committees (Appendix 1; Web only file).
24 The overarching questions guiding the evaluation for each intervention are: (1) Is the service delivery
25 model effective in the context of Alberta's primary care setting; and (2) What factors contribute to the
26 effectiveness (or ineffectiveness) of the intervention? The more specific evaluation questions related to
27 the RE-AIM framework that will direct the collection and analysis of data for both interventions include:
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- 38 1. **Reach:** Is the intervention reaching the intended target population?
- 39 2. **Adoption:** Has the intervention been adopted by the PCNs and staff?
- 40 3. **Implementation:** Is the intervention being implemented as intended? Is it cost-effective?
- 41 4. **Effectiveness:** What are the immediate, intermediate, and long-term impacts of the
42 intervention?
- 43 5. **Maintenance:** Is the intervention sustainable in a cost-effective way?
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53 Measurement by RE-AIM Dimensions

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55 In the following section, we outline the measures proposed for each dimension of RE-AIM to
56 evaluate the ABCD project interventions. A detailed summary is provided in Table 2 (Web file only).
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REACH

Evaluation of reach will be done at the individual (patient) and organization (PCN) assessment levels to determine if the ABCD pilot interventions are reaching those in most need. At the individual assessment level, we will examine total recruitment into the interventions and usual care groups and compare their characteristics with respect to eligibility criteria, demographic information, and other measures. As possible, we will compare characteristics between participants (i.e., intervention and usual care groups) and non-participants using aggregate demographic information accessed through PCN patient registries and Alberta Diabetes Surveillance System (ADSS) data [23]. Facilitators and barriers to individual patient recruitment and suggestions for improvement will be identified through interviews with PCN staff.

At the organization assessment level, we will document usual care in the PCNs, including the ability to *estimate* and *identify* target patient populations in the focus areas (i.e., type 2 diabetes management, depression management and lifestyle counseling) through completion of a standardized checklist. We will examine processes related to registry development and identify facilitators and barriers related to development, use, and maintenance through interviews with PCN staff. In addition, we will elicit recommendations related to the PCNs' ability to identify patient populations to actively offer targeted health services.

EFFECTIVENESS

Evaluation of effectiveness will be conducted at the individual assessment level to determine impact of the pilot interventions on important outcomes. The design and rationale for controlled evaluations of the effectiveness of the two ABCD pilot interventions have been described elsewhere [8] [9]. The primary outcome of HEALD-PCN is improvement in physical activity (i.e., brisk walking),

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3 determined by step pedometers and self-report [8]. For TeamCare-PCN, the primary outcome is
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5 improvement of depressive symptoms as measured by the Patient Health Questionnaire-9 (PHQ-9)
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7 items [9]. We will also use a variety of measures to determine the effectiveness of both interventions on
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9 important outcomes at the individual assessment level including clinical measures (e.g., improvements
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11 in glycemic control, blood pressure, lipid measurements, and body mass index), self-reported health-
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13 related quality of life [24] [25] [26], self-efficacy [27], satisfaction with care [28] [29], and process
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15 indicators. In addition, we will document unanticipated consequences (positive or negative), such as
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17 improved patient linkages with community health resources, to provide a richer understanding of
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19 effectiveness. Additional measures and data sources to assess effectiveness are provided in Table 2.
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27 *ADOPTION*

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30 We will assess adoption of the ABCD pilot interventions at the organization level, including
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32 documentation of the criteria for PCN selection and participation in the ABCD Project and PCN Board
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34 approval. Also, we will document and compare the characteristics of the participating PCNs (e.g.,
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36 number of family physicians, number of patients served, and governance structure) as well as usual care
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38 in the focus areas. Dependent on availability of secondary data, we will consider the representativeness
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40 of participating PCNs compared to non-participating PCNs. This will be accomplished through document
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42 review (e.g., ABCD project documents, PCN websites, business plans), use of a standardized usual care
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44 checklist, and interviews with PCN staff. In addition, perceptions related to the extent to which the
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46 ABCD pilot interventions have been adopted by the PCNs and modified to suit their contexts will be
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48 elicited through interviews with PCN staff. Identified facilitators and barriers to adoption of the
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50 interventions along with creative solutions or modifications will also be documented.
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IMPLEMENTATION

Evaluation of implementation of the ABCD pilot interventions will be done at the individual and organization assessment levels to determine patient adherence, consistency of implementation, and costs of delivering the pilot interventions. To address implementation at an individual assessment level, participant adherence to the intervention models will be determined for both interventions. For HEALD-PCN, attendance at group sessions, participant step logs (i.e., recording the number of steps over three days) and self-reported physical activity will be assessed. For TeamCare-PCN, adherence to treatment plans, including medication and behavioural modifications (e.g., engaging in planned pleasant activities), will be assessed. These types of data will be derived from patient outcome tracking systems employed in each PCN and/or survey items.

At the organization assessment level, consistency of implementation and the cost of delivering the ABCD pilot interventions will be evaluated to determine the practicality of the interventions. Actual versus intended implementation will be assessed through extensive documentation including development of project materials (e.g., training and resource materials), presence of systems and processes (e.g., patient registries), intervention staff recruited or hired by PCNs, and provision and quality of training in the intervention models. Additional measures and data sources to assess consistent implementation are provided in Table 2. Our implementation assessment will also include economic evaluations of the ABCD pilot interventions, which have been described in detail elsewhere [8] [9].

MAINTENANCE

For both ABCD pilot interventions, maintenance will be evaluated at the individual and organization assessment levels to measure continuation of intervention effects over time. We will use a previously developed conceptual framework that defines sustainability outcomes of health

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3 interventions [30]. At the individual level, maintenance will be evaluated based on patient-reported
4 health behaviours and self-care collected annually through the ABCD cohort study survey, and
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6 interviews with a sub-sample of HEALD-PCN intervention group participants at 6-months post
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8 intervention.
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13 At the organization assessment level, interviews with PCN staff will be conducted post-
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15 interventions to assess integration of intervention model components into practice (e.g., continued use
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17 of patient registries or screening tools), enhanced organizational capacity (e.g., maintaining
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19 partnerships), and continued focus on the interplay between diabetes, depression, and lifestyle (e.g.,
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21 incorporation of the intervention models into future business plans). In addition, interviews with
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23 specialists participating in TeamCare-PCN will be conducted with a focus on sustainability of the model
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25 in the current primary care environment, including appropriate compensation and funding approaches
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27 and potential medico-legal liability issues.
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Table 2: Measures, data sources, and data collection timeline by RE-AIM dimension and assessment level (Web file only)

Assessment level(s)	Measures	Data sources	Timeline
REACH			
Individual	<ul style="list-style-type: none"> Eligibility criteria Demographic information 	<ul style="list-style-type: none"> Patient recruitment tracking system Survey items 	<ul style="list-style-type: none"> Ongoing <i>HEALD-PCN specific</i>: baseline, 3- & 6-months <i>TeamCare-PCN specific</i>: baseline, 6- & 12-months
	<ul style="list-style-type: none"> Identified facilitators & barriers to recruitment Identified recommendations for improvement 	<ul style="list-style-type: none"> Interview data (PCN staff and ABCD team) 	<ul style="list-style-type: none"> Baseline & midpoint
	<ul style="list-style-type: none"> Patient characteristics (participants vs. population) 	<ul style="list-style-type: none"> PCNs' patient registry AHW/ADSS data 	<ul style="list-style-type: none"> Post-intervention
Organization	<ul style="list-style-type: none"> Ability to estimate & identify targeted patient populations 	<ul style="list-style-type: none"> Document review (standardized checklist) 	<ul style="list-style-type: none"> Baseline
	<ul style="list-style-type: none"> Registry development & maintenance process issues, including identified facilitators and barriers Identified recommendations for improvement 	<ul style="list-style-type: none"> Interview data (PCN staff and ABCD team) Document review (field notes) 	<ul style="list-style-type: none"> Baseline & midpoint Ongoing
EFFECTIVENESS			
Individual	<p>Primary outcomes: A1c, blood pressure, total cholesterol, & BMI</p> <ul style="list-style-type: none"> <i>HEALD-PCN specific</i>: total # of steps <i>TeamCare-PCN specific</i>: Composite of PHQ-9 <p>Secondary outcomes: self-reported quality of life, quality of care, self-efficacy, & satisfaction with care</p> <ul style="list-style-type: none"> <i>HEALD-PCN specific</i>: nutritional behaviours & satisfaction with intervention <i>TeamCare-PCN specific</i>: process care indicators including: # of visits with health care providers, referrals, psychotherapy sessions, medication adjustments, & adherence to treatment Perceptions of impact/ consequences (positive or negative) 	<ul style="list-style-type: none"> Clinical assessment recorded in patient outcome tracking systems Survey items Interview data (PCN staff) 	<ul style="list-style-type: none"> Ongoing <i>HEALD-PCN specific</i>: baseline, 3- & 6-months <i>TeamCare-PCN specific</i>: baseline, 6- & 12-months Baseline, midpoint, & post-intervention
ADOPTION			
Individual	<ul style="list-style-type: none"> Total number of member physicians participating in ABCD project 	<ul style="list-style-type: none"> Document review (PCN and ABCD project documents) 	<ul style="list-style-type: none"> Post-intervention
Organization	<ul style="list-style-type: none"> Criteria for PCN participation in ABCD Project PCN Board agreement to participate Features of participating PCNs Comparison of characteristics between participating & non-participating PCNs, as possible Description of usual care in the focus areas Perception of extent to which ABCD Project has been adopted by PCNs and modified to fit their context(s) Identified facilitators, barriers, & recommendations at organizational level 	<ul style="list-style-type: none"> Document review (project and PCI/PCN documents –websites and business plans, availability of secondary data e.g., PCI evaluation) Standardized checklist Interview data (PCN staff) 	<ul style="list-style-type: none"> Baseline, midpoint, & post-intervention
IMPLEMENTATION			
Individual	<ul style="list-style-type: none"> <i>HEALD-PCN specific</i>: # of steps in log and self-reported physical activity <i>TeamCare-PCN specific</i>: adherence to treatment plan, including medications and behavioural modifications 	<ul style="list-style-type: none"> Patient outcome tracking systems Survey items 	<ul style="list-style-type: none"> Post-intervention

Assessment level(s)	Measures	Data sources	Timeline
Organization	Development of: <ul style="list-style-type: none"> Project materials: job descriptions for intervention staff, recruitment & data collection protocols and forms Training & resource materials: project binders, algorithms, patient resources Systems/processes: patient registries, patient recruitment & outcome tracking systems 	<ul style="list-style-type: none"> Document review (PCN and ABCD Project documents) 	<ul style="list-style-type: none"> Baseline
	<ul style="list-style-type: none"> # and type of intervention staff hired by PCNs, including turnover 	<ul style="list-style-type: none"> Document review (e.g., contracts) 	<ul style="list-style-type: none"> Ongoing
	<ul style="list-style-type: none"> Provision of and quality of training in ABCD Project and interventions: # and type of staff trained, detailing sessions, and training materials provided; attendance in training sessions; assessment of change in knowledge & satisfaction 	<ul style="list-style-type: none"> Document review (ABCD Project documents) Pre/post survey items Interviews with PCN intervention staff 	<ul style="list-style-type: none"> Baseline, midpoint, & post- intervention
	Service delivery: <ul style="list-style-type: none"> HEALD-PCN specific: # and type of group meetings & patient resources distributed; level of attendance TeamCare-PCN specific: # and type of screenings, assessments, patient management plans, follow-up sessions, specialist consultations; time of service delivery; and QI assessment through monthly teleconferences 	<ul style="list-style-type: none"> Document review:(class attendance lists) Patient outcome tracking systems 	<ul style="list-style-type: none"> Ongoing & post-intervention
	<ul style="list-style-type: none"> Perceptions of implementation as intended Identified facilitators & barriers to implementation Identified recommendations for improvement 	<ul style="list-style-type: none"> Interviews with PCN staff 	<ul style="list-style-type: none"> Baseline, midpoint, & post-intervention
	<ul style="list-style-type: none"> Economic Evaluation: Decrease in # of family physician and ER visits; reduction in complications, co-morbidities, and mortality; reduction in direct medical costs; and reduction in projected future health care costs 	<ul style="list-style-type: none"> Document review (field notes, communications, meeting minutes) Document review (budget & invoices) AHW/ADSS data 	<ul style="list-style-type: none"> Ongoing Post-intervention
MAINTENANCE			
Individual	<ul style="list-style-type: none"> Sustained awareness, knowledge, & management of type 2 diabetes and depression or lifestyle behaviours 	<ul style="list-style-type: none"> Survey items (ABCD Cohort Study) regarding health behaviours & self-care Interviews with HEALD-PCN intervention group participants 	<ul style="list-style-type: none"> Post-intervention & ongoing (minimum 4 years follow-up) Post-intervention
Organization	<ul style="list-style-type: none"> PCN level: integration of aspects of the model into usual care; and/or incorporation of models into future business planning 	<ul style="list-style-type: none"> Interviews with PCN staff 	<ul style="list-style-type: none"> Post-intervention
	<ul style="list-style-type: none"> More appropriate health care utilization: Decrease in # of family physician and ER visits; reduction in complications, co-morbidities, and mortality; reduction in direct medical costs; and reduction in projected future health care costs. 	<ul style="list-style-type: none"> AHW data 	<ul style="list-style-type: none"> Post-intervention

Data Management

Our comprehensive evaluation will involve the collection and management of a wide range and large volume of data. Primary data sources for the evaluation of the ABCD pilot interventions include: (1) clinical outcome measures; (2) patient-reported outcomes; (3) interviews (e.g., with PCN staff, HEALD-PCN intervention group participants, and specialists for TeamCare-PCN); (4) document review (e.g., usual care checklists, project documents, field notes); and (5) administrative health care datasets.

Clinical outcomes and survey data captured in the patient outcome tracking systems or standardized case forms used in each PCN will be entered into centralized, web-accessible databases. These study databases will be housed on secure servers in the research offices at the University of Alberta. Once the pilot interventions are completed, all data will be exported and merged, based on individually assigned study ID numbers, to form an analyzable dataset. Investigators, research assistants, and analysts will be masked to allocation status at all times.

Semi-structured interviews will take place at the PCN offices of the interviewees. Interviews with HEALD-PCN intervention group participants and TeamCare-PCN specialists will be conducted via telephone. Interviews will be facilitated through the use of interview guides. Interviews will be digitally recorded for subsequent analysis, transcribed verbatim by an independent transcriptionist, and verified for accuracy.

Regarding document review, we will develop a standardized usual care checklist by adapting themes from the Change Process Capability Questionnaire [31] and the Organizational Readiness to Change Scale [32] to be validated by staff of the participating PCNs. Topic areas include: usual care for people with type-2 diabetes; existing PCN diabetes, depression and lifestyle programming; and organizational factors and strategies related to PCN patient care. Also, we will document how the ABCD pilot interventions unfolded in each PCN through field notes, communications, and meeting minutes. All

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3 qualitative data sources, including interview transcripts and documents, will be compiled and managed
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5 using Nvivo 9.0 software.
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8 Patients enrolled in the pilot interventions and the ABCD Cohort study will be asked for
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10 permission to access their medical records by providing their personal health number, thus allowing
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12 linkage to provincial health care administrative data from Alberta Health for physician, hospital, and
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14 emergency department billing, and pharmaceutical data (for patients 65 years and older). This linkage
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16 will allow health care utilization and health care costs to be included in the evaluation.
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20 21 **Data Analysis**

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23 We are undertaking a broad mixed-methods approach to analysis. In terms of quantitative data,
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25 the approach to power, sample size calculations, assessment and statistical modeling of clinical
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27 effectiveness have been previously detailed [8] [9]. In terms of qualitative data, we will take a general
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29 inductive approach [33] with the evaluation questions related to the RE-AIM framework directing the
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31 analysis of data. Findings will be derived directly through a content analysis [34] of the raw data without
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33 preconceived notions about specific findings.
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40 **ETHICS AND DISSEMINATION**

41 **Ethical Considerations**

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43 Ethics approval for the entire ABCD Project and its associated interventions has been granted from
44
45 the Health Research Ethics Board (HREB #PRO00012663) at the University of Alberta. However, the
46
47 Board deemed this component of the ABCD Project as evaluation and not research; therefore, it did not
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49 require ethics review and approval. Regardless, the requirements outlined in the Canadian Tri-Council
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51 Policy Statement: Ethical Conduct of Research Involving Humans [35] will be followed.
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Discussion and Dissemination

The ABCD Project was developed to improve the quality and efficiency of diabetes care in non-metro Alberta. In order to address the gap between research, policy, and practice, we have adapted and expanded the RE-AIM model to conduct a comprehensive evaluation of the ABCD pilot interventions. This will contribute to our knowledge of the broader impact of the two interventions within the evolving primary care context of Alberta beyond effectiveness, as outlined in the study trial designs [8] [9]. The purpose of this article was to present the proposed measures and data sources to be used to evaluate the interventions by RE-AIM dimension. Using the RE-AIM evaluation framework will allow us to systematically identify facilitators, challenges, opportunities and lessons learned to be used in program planning and care delivery for patients with type-2 diabetes. In addition, our application of the RE-AIM evaluation framework may encourage others to use similar models to determine the impact of community-based primary health care interventions. The RE-AIM model will also be used to structure our dissemination activities. For example, each RE-AIM dimension will inform the development of products (such as academic manuscripts for peer-review publication, presentations at relevant conferences and workshops, and briefing reports) and identification of relevant target audiences.

Authors' contributions

LW developed the evaluation framework for the Alberta's Caring for Diabetes (ABCD) Project and drafted the manuscript. SR, AS, STJ actively contributed to the development of the evaluation framework and critically reviewed and revised the manuscript. FA provided feedback on the manuscript. SRM provided expert feedback on the study design and critically reviewed the manuscript. JAJ conceived of the study, participated in its design, and helped draft the manuscript. All authors read and approved the final manuscript.

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Competing interests

The authors have no competing interests to declare.

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6 role in the conduct, analysis or reporting of the studies or evaluation, nor access to the data.
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14 15 **Data Sharing Statement**

16 No additional data are available.
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Appendix 1: HEALD-PCN and TeamCare-PCN Logic Models and Data Matrices

HEALD-PCN Logic Model

1.0 Inputs/ Resources	2.0 Key activities	3.0 Outputs (products & services)	4.0 Immediate outcomes	5.0 Intermediate outcomes	6.0 Ultimate outcomes
<p>1.1 Funding</p> <ul style="list-style-type: none"> AHW (\$5.2M over 5 years for ABCD) Lawson Foundation (\$150K over 2 years) <p>1.2 Direction/ guidance</p> <ul style="list-style-type: none"> ABCD Advisory Committee ABCD Implementation & Evaluation Steering Committee <p>1.3 HR</p> <ul style="list-style-type: none"> ABCD project staff (Co-PIs, Program Manager, project coordinators, RAs, data analyst, and admin staff) <p>1.4 Partners & supports</p> <ul style="list-style-type: none"> PCNs (non-metro) Community recreational facilities AHS AHW 	<p>2.1 Engagement</p> <ul style="list-style-type: none"> Establish relationships w/ and <i>btwn</i> key partners (e.g., non-metro PCNs, & community rec facilities, others) Establish communication strategy w/ partners <p>2.2 Intervention adaptation</p> <p>Collaborate with PCNs & rec facilities to adapt intervention to local PCN environment</p> <ul style="list-style-type: none"> Develop job descriptions (e.g., exercise specialist) Set up systems to ID newly diagnosed T2D (e.g., registry/database, referral process) Develop training materials for exercise specialists Enhance resource manual for participants Set up PCN patient recruitment and tracking system Develop recruitment & data collection protocols Develop class schedule template <p>2.3 HR</p> <ul style="list-style-type: none"> Recruit ES in PCNs (0.4 FTE) 	<p>HEALD-PCN intervention</p> <p>3.1 Exercise Specialist Training</p> <ul style="list-style-type: none"> HEALD-PCN intervention Recruitment protocols Data collection (e.g., protocols, recruitment/ screening script & patient tracking) Conduct detailing w/ ES Class schedule set-up <p>3.2 Recruitment (reach/ coverage)</p> <ul style="list-style-type: none"> Patients recruited into intervention & usual care using criteria <p>3.3 Service Delivery</p> <p>Lifestyle counseling/24-week walking program</p> <ul style="list-style-type: none"> Group meetings (x4) Patient resources (i.e., pedometers, stopwatch, & workbook - resource manual & log book) Clinical assessments (x3) 	<p>4.1 Exercise specialists</p> <ul style="list-style-type: none"> Increased awareness, knowledge, & skills related to lifestyle/ self- management <p>4.2 Patients</p> <ul style="list-style-type: none"> Increased awareness, knowledge, & skills related to lifestyle/ self- management <p>4.3 PCNs/Community</p> <ul style="list-style-type: none"> Necessary system requirements & resources are in place & adequate to implement & sustain HEALD-PCN Organizational factors & systems/ strategies are in place to facilitate CDM care 	<p>5.1 Exercise specialists</p> <ul style="list-style-type: none"> Increased confidence in managing pts w/ T2D, esp in PA & diet <p>5.2 Patients</p> <p>Improved behavioural outcomes (self-reported):</p> <ul style="list-style-type: none"> Increase in PA (i.e., # of steps/day) (P1) Increase in intensity of PA (P2) Increased consumption & exchange of low-GI foods (P2) Increased use of PCN &/or community resources <p>5.3 PCNs/Community</p> <ul style="list-style-type: none"> More effective use of resources (i.e., recently diagnosed T2D patients received enhanced lifestyle counseling through available community resources, relieving the burden on the PCNs) 	<p>6.1 Exercise specialists</p> <ul style="list-style-type: none"> Increased job satisfaction Improved retention of staff <p>6.2 Patients</p> <p>Improved cardio-metabolic measures:</p> <ul style="list-style-type: none"> Improved control of A1c, BP, lipids, & resting heart rate Improved anthropometrics (i.e., weight, height, waist & hip circumference) <p>Satisfaction w/ HEALD-PCN</p> <ul style="list-style-type: none"> Self-reported satisfaction <p>6.3 PCNs</p> <ul style="list-style-type: none"> Improved decision making ability/inform future business planning Meets PCI agenda, esp increasing the emphasis on care of pts w/ chronic disease Sustained partnerships w/ community resources <p>6.4 PCN/Community/HCS</p> <p>Improved health care utilization (economic evaluation)</p> <ul style="list-style-type: none"> Decreased # of FP & ER visits Reduction in complications, co-morbidities, & mortality Reduction in direct medical costs Reduction in projected future health care costs

HEALD-PCN Data Matrix

RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
2.0 KEY ACTIVITIES: Is the HEALD-PCN intervention adapted to the local PCN context? Is the intervention set up for successful implementation?				
A (R at system level)	<p>Engagement</p> <p>2.1 Have relationships with key partners been established and with whom (i.e., 4 non-metro PCNs and community recreational facilities)?</p> <p>What is the rationale/criteria for engaging the specific partners (i.e., the 4 chosen PCNs, and rec facilities), and not others?</p> <p>How representative are the participating PCNs compared to non-participating PCNs?</p> <p>Has a communication strategy been established in collaboration with each partner (i.e., 4 non-metro PCNs and community recreational facilities)?</p> <p>What aspects of the partnerships have been successful? What aspects have been problematic and need to be addressed? What are the critical factors/features of a successful partnership?</p>	<p>List, description, & contribution (e.g., role & resources contributed) of key partners</p> <p>Description of rationale/criteria for engaging specific partners, including PCNs approached who declined participation</p> <p>Comparison of characteristics btwn participating & non-participating PCNs</p> <p>Communication strategies are identified</p> <p># and type of communications/meetings</p> <p>Facilitators and barriers to successful partnerships</p> <p>Recommendations/suggestions for improvement</p>	<p>Document review:</p> <ul style="list-style-type: none"> HEALD-PCN project documents (e.g., LOAs/contracts, ABCD Contacts & Organizational Chart for PCNs document, calendars) PCI/PCN program documents (e.g., websites, business plans) Secondary data from PCI on characteristics of PCNs, if available & feasible <p>Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs</p> <p>Interviews with HEALD-PCN project staff and key partners (e.g. rec centre program directors)</p> <p>Participant observation (e.g., meetings, communications)</p>	Ongoing
A & I	<p>Intervention Adaptation</p> <p>2.2 Is the intervention adapted to the local PCN context?</p> <p>Has this been a collaborative process among:</p> <ul style="list-style-type: none"> ABCD project team 4 non-metro PCNs? Community rec facilities? <p>Are the systems needed developed and in place to adapt & implement HEALD-PCN?</p>	<p>Job description for exercise specialist drafted</p> <p>System for identifying newly diagnosed T2D patients created (e.g., registry, database from existing program(s), referral process, other)</p> <p>Training manual for exercise specialists developed</p> <p>Resource manual for participants enhanced (graphic designer)</p> <p>Facilities (e.g., rec centre walking track/classrooms) secured/booked</p> <p>PCN patient recruitment and tracking system developed</p> <p>Perception of collaboration and the extent to which the intervention is adapted to local PCN context</p> <p>Perception to which the systems needed have been developed and are in place</p>	<p>Document review:</p> <ul style="list-style-type: none"> HEALD-PCN project documents (e.g., job descriptions, training and resource manuals, contracts/ LOA) PCN project documents (e.g., databases to ID and track participants) Audit(s) <p>Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs</p> <p>Interviews with HEALD-PCN project staff and key partners (e.g., rec centre program directors)</p> <p>Participant observation (e.g., meetings, communications)</p>	Ongoing

RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
2.0 KEY ACTIVITIES: Is the HEALD-PCN intervention adapted to the local PCN context? Is the intervention set up for successful implementation?				
A (R at system level)	<p>Human Resources</p> <p>2.3 Are the right level, type & mix of staff (i.e., exercise specialists) available to implement and track/monitor the intervention?</p> <p>Are the resources sufficient (e.g., FTE)? What additional human resources, if any, are needed to implement the program (as intended)?</p>	<p>Job descriptions</p> <p># and type of exercise specialists hired/ recruited at each PCN</p> <p># and type of PCN staff turnover (i.e., exercise specialists and other PCN staff, such as CDM team, leadership, receptionist)</p> <p>Perception of right human resource level, type, and mix (e.g., hired internally vs. externally, professional designation/ experience/ qualifications)</p> <p>Perception of impact of PCN staff turnover on intervention</p>	<p>Document review:</p> <ul style="list-style-type: none"> Job descriptions Contracts/ToA PCN stats on PCN HR environment, if feasible & appropriate <p>Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs</p> <p>Interviews with HEALD-PCN staff and rec centre program directors</p> <p>Participant observation (e.g., meetings, communications, visits)</p>	Ongoing
3.0 Outputs (products & services): Has HEALD-PCN been implemented in each PCN/community? Is the HEALD-PCN intervention being implemented as intended?				
I	<p>Exercise Specialist training</p> <p>3.1 Have PCN staff (e.g., ES and DAA) been trained in the intervention components: HEALD-PCN intervention, recruitment protocols/scripts, data collection protocols, & patient tracking?</p>	<p># and type of staff trained for each component</p> <p># of detailing sessions</p> <p># and type of training/reference materials provided to staff</p> <p>Training activities, materials/resources, & on-going support identified</p> <p>Perceived quality/adequacy of training, materials provided, & on-going support received (i.e., satisfaction)</p>	<p>Document review:</p> <ul style="list-style-type: none"> HEALD-PCN project documents (e.g., training schedule) Training/reference materials <p>Interviews with exercise specialists who participate in the training session(s)</p> <p>Participant observation (e.g., meetings, communications, training)</p>	End of study
R & I	<p>Recruitment (reach/coverage)</p> <p>3.2 How many participants are referred to the intervention and usual care?</p> <p>How do the characteristics of participants in the intervention compare to those in usual care?</p> <p>How do the characteristics of participants (i.e., intervention and usual care) compare to non-participants?</p>	<p># / % of type of participants (e.g., demographics) screened & recruited to <u>intervention</u> in each PCN/community</p> <p># / % of type of participants (e.g., demographics) screened & recruited to <u>usual care</u> in each PCN</p> <p># / % of type of <u>non-participants</u> (e.g., demographics)</p> <p>Sample size calculations</p>	<p>Document review:</p> <ul style="list-style-type: none"> PCN patient/ diabetes registry (aggregate characteristics of participants & <u>non-participants, if feasible & appropriate</u>) Patient recruitment tracking system (reasons for non-participation) <p>Survey instrument:</p> <ul style="list-style-type: none"> Short screening survey (reasons for 	Screen, baseline, & FUs

RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
3.0 Outputs (products & services): Has HEALD-PCN been implemented in each PCN/community? Is the HEALD-PCN intervention being implemented as intended?				
	How is the target population of participants defined?	Rationale for definition of target population (i.e., inclusion/exclusion criteria) Facilitators & barriers to recruitment are identified Recommendations/ suggestions to improve recruitment are identified	exclusion) <ul style="list-style-type: none"> HEALD-PCN Survey items (demographics) PCN reports <ul style="list-style-type: none"> Report for ABCD (monthly) ABCD Bulletin (quarterly) 	
I	Service Delivery 3.3 Has the intervention been implemented as intended? What is usual care at each PCN for patients requiring lifestyle counseling? What are the facilitators/ barriers to implementation? What adaptations to the intervention have been made/required, if any? What suggestions/ recommendations are there to the implementation process?	# & type of group meetings Level of attendance at group meetings # & type of patient resources distributed # / % clinical assessments (baseline, 3 months, & 6 months) # / % of actual participants who completed in the intervention (consider ON tx) Time of service delivery (i.e., service delivery of education/group meetings, and clinical mgmt as delivered by the ES) Description of usual care at each PCN Description & perception of the quality and degree of implementation Facilitators & barriers to implementation, as intended, are identified Recommendations/suggestions to improve the implementation process are identified	Document review: <ul style="list-style-type: none"> HEALD-PCN project documents (e.g., group meeting/counseling session schedule) PCN patient/ diabetes registry Patient recruitment/ tracking system PCN documents (e.g., website, program brochures) ABCD Bulletin (quarterly) Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs Interviews with HEALD-PCN project staff, exercise specialists, & rec centre program directors Participant observation (e.g., meetings, communications, visits)	Baseline & ongoing/ end of study

RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
4.0 IMMEDIATE OUTCOMES: What is the immediate impact of the HEALD-PCN intervention? What are the necessary system requirements & resources to implement and sustain this type of intervention?				
I (A in the future)	Exercise specialists 4.1 Do exercise specialists demonstrate increased awareness, knowledge, and skills related to lifestyle/self-management	Perception of increased awareness, knowledge, and skills related to lifestyle/self management (i.e., confidence)	Interviews/survey with exercise specialists who participated in HEALD-PCN training re: adequacy of training Participant observation (e.g., meetings, communications, visits to PCN, training)	End of study

I & E & M	<p>Patients</p> <p>4.2 Do patients demonstrate increased awareness, knowledge, and skills related to lifestyle/self-management</p> <p>Overtime, do patients demonstrate sustained awareness, knowledge, & skill in goal setting?</p>	<p>Survey items</p> <p>Perception of self-efficacy in relation to PA & diet</p> <p>Perception of sustained awareness, knowledge, & skill in goal setting over time</p>	<p>HEALD-PCN survey instrument (baseline, 3 months, and 6 months), Cohort survey instrument (self care & health behaviours)</p> <p>Comparison of intervention and usual care groups</p> <p>Interviews w/ HEALD-PCN ON group participants (sampling 10%)</p>	<p>Baseline & FU (12 months after baseline enrolment)</p>
I & E	<p>PCNs/Community</p> <p>4.3 Are the necessary system requirements and resources in place & adequate to implement & sustain HEALD-PCN?</p>	<p>Perception of establishment & adequacy of system requirements and resources to implement & sustain HEALD-PCN</p>	<p>Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs</p> <p>Interviews with PCN staff (e.g., ES) and rec centre program directors</p> <p>Participant observation (e.g., meetings, communications, visits)</p>	<p>Baseline & end of study</p>

RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
5.0 INTERMEDIATE OUTCOMES (Intervention arm): What is the intermediate impact of the HEALD-PCN intervention?				
I	<p>Exercise Specialists (I)</p> <p>5.1 Increased confidence in managing patients with T2D, especially in relation to PA and diet</p>	<p>Perception of increased confidence in providing lifestyle counseling to patients with T2D</p>	<p>Interviews with exercise specialists</p>	<p>Post intervention</p>
E & M	<p>Patients</p> <p>5.2 Are participants' self-reporting improvement in lifestyle behaviours (i.e., increased PA; increased intensity of PA, and increased consumption and exchange of low-GI foods)?</p> <p>Are participants self-reporting increased use of PCN and/or community resources?</p> <p>What additional lifestyle programs or disciplines are needed to better manage T2D, as identified by participants?</p>	<p>Survey items</p> <p>Self-reported PA, intensity of PA, & consumption of low-GI foods</p> <p>Self-reported use of PCN/community resources</p> <p>Add'l lifestyle management programs/disciplines are identified</p>	<p>HEALD-PCN survey instrument – GODIN items (baseline, 3 months, and 6 months), Cohort survey instrument (self care & health behaviours)</p> <p>STEPS (3-day step logs)</p> <p>Interviews w/ HEALD-PCN ON group participants (sampling 10%)</p>	<p>End of study (12 months after baseline enrolment)</p>
E	<p>PCNs</p> <p>5.3 Are community resources being (effectively) used, thereby reducing the burden on the PCNs (i.e., PCN staff, resources, programming; & family physicians)?</p>	<p>Perception of use of community resources</p>	<p>Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs</p> <p>Interviews with PCN staff (e.g., ES) and rec center program directors</p>	<p>End of study</p>

RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
6.0 ULTIMATE OUTCOMES (Intervention arm): What is the long-term impact of the HEALD-PCN intervention? Can a lifestyle program like HEALD-PCN be implemented and sustained in the PCN environment in a cost-effective way?				
E	6.1 Exercise Specialists (E) Do exercise specialists experience increased job satisfaction and willingness to stay/work at PCNs?	Self-reported job satisfaction Self-reported willingness to work at a PCN	Interviews with exercise specialists	Post intervention
E	Patients 6.2 Is there an improvement in participants' cardio-metabolic measures (i.e., A1c, blood pressure, lipids, & resting heart rate)? Is there an improvement in participants' anthropomorphic measurements (i.e., weight, height, waist & hip circumference)? How satisfied are participants with the HEALD-PCN intervention (e.g., materials provided)?	Clinical assessment (baseline, 3 months, and 6 months) Perceived satisfaction with the intervention	Document review • Access/Filemaker database Interviews with HEALD-PCN ON group participants (sampling 10%)	End of study
M	PCNs 6.3 Did this intervention help PCNs make decisions around their business planning? Did this intervention help PCNs meet the objectives set out by the PCI, especially increasing the emphasis on care of patients with chronic disease?	Decisions around business planning (e.g., will intervention model be part of business plan and why/why not; where does this intervention model fall in comparison to other initiatives/ competing priorities)? Perceptions of meeting the PCI objectives	Interviews with PCN staff (e.g., ES, ED, CDMs) and rec center program directors Document review: • PCN business plan • PCI documents • PCI evaluation	End of study
A & M	Did this intervention result in sustained partnerships with community resources? Has a relationship btwn the PCN & community rec facility been established beyond facilitation by the research group? What is the quality of this relationship? Is this relationship sustainable?	Decisions around business planning (e.g., include staff & community services contracts) Perceptions of the establishment & sustainability of relationship/ partnership	Interviews with key partners (e.g., PCN EDs, & CDMs; and rec centre program directors)	End of study
E & M	PCNs/Community/Health care system 6.4 Did the intervention result in improved health care utilization?	AHW and ADSS items: • Decreased # of FP & ER visits • Reduction in complications, co-morbidities, & mortality	Document review: • AHW and ADSS datasets	End of study

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RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
6.0 ULTIMATE OUTCOMES (Intervention arm): What is the long-term impact of the HEALD-PCN intervention? Can a lifestyle program like HEALD-PCN be implemented and sustained in the PCN environment in a cost-effective way?				
		<ul style="list-style-type: none"> • Reduction in direct medical costs • Reduction in projected future health care costs 		

For peer review only

TeamCare-PCN Logic Model

1.0 Inputs/ Resources	2.0 Key activities	3.0 Outputs (products & services)	4.0 Immediate outcomes	5.0 Intermediate outcomes	6.0 Ultimate outcomes
<p>1.1 Funding</p> <ul style="list-style-type: none"> • AHW (\$5.2M over 5 years) <p>1.2 Direction/ guidance</p> <ul style="list-style-type: none"> • ABCD Advisory Committee • Implementation & Evaluation Steering Committee • Depression Working Group <p>1.3 HR</p> <ul style="list-style-type: none"> • ABCD project staff (lead researcher, Medical Lead, Project Manager, project coordinators, RAs, data analyst, and admin staff) <p>1.4 Partners & supports</p> <ul style="list-style-type: none"> • PCNs (non-metro) • Katon Group • AHS • AHW • HQCA • AMA • RxA 	<p>2.1 Engagement</p> <ul style="list-style-type: none"> • Establish relationships w/ key partners (e.g., non-metro PCNs, & Katon group) • Establish communication strategy w/ PCNs • Identify physician champions in PCNs <p>2.2 Intervention adaptation</p> <p>Collaborate with PCNs and Katon group to adapt intervention to local PCN environment</p> <ul style="list-style-type: none"> • Draft job descriptions • Develop tx algorithms (e.g., working group) • Draft training & resource manual(s) • Set up systems to ID T2D (e.g., patient/ diabetes registry) • Set up patient recruitment & tracking system (i.e., on-line or Access) • Draft recruitment & data collection protocols • CMTS tailored <p>2.3 HR</p> <ul style="list-style-type: none"> • Recruit intervention staff (PCNs) 	<p>TeamCare-PCN intervention</p> <p>3.1 Provider Training</p> <ul style="list-style-type: none"> • TeamCare-PCN model/ team care approach • Tx Algorithms • Recruitment protocols • Data collection (e.g., protocols, recruitment/ screening script & patient tracking) <p>3.2 Recruitment (reach/ coverage)</p> <ul style="list-style-type: none"> • Patients recruited into intervention (& usual care) using criteria <p>3.3 Service Delivery</p> <ul style="list-style-type: none"> • Screening (PHQ-8 component of short screening survey) • Assessment (baseline) • Management of conditions (treat to target/stepped care; CBT) • Follow-up (1-2 sessions/pt/month) • Reassessment (every 10-12 weeks) • Team consultations (wkly) • Katon consultations (mthly) 	<p>4.1 Providers</p> <p>Increased awareness & knowledge of:</p> <ul style="list-style-type: none"> • Collaborative team care approach; • Diagnosis & pharmacotherapy of depression; • Psychotherapeutic techniques (CBT); • Mgmt of diabetes (lipids, BP, glucose) <p>4.2 Patients</p> <ul style="list-style-type: none"> • Patients receive right medications +/- or therapies, in right amount <p>Increased awareness & knowledge of:</p> <ul style="list-style-type: none"> • Mgmt of depression (CBT) (P1); • Mgmt of diabetes (lipids, BP, glucose) (P2); • Lifestyle behaviours (P3) <p>4.3 PCNs/AHS</p> <ul style="list-style-type: none"> • Organizational factors & systems/ strategies in place to improve diabetes/ depression care 	<p>5.1 Providers</p> <ul style="list-style-type: none"> • Increased confidence in managing pt w/ diabetes & depression • Increased collaboration/ team approach to care <p>5.2 Patients</p> <p>Behaviour change</p> <ul style="list-style-type: none"> • Improved mgmt of depression (e.g., 50% reduction in PHQ-8 score/remission of depression PHQ-8>10) • Improved control of A1c, BP, & lipids (target or 10% improvement) • Improved lifestyle behaviours (e.g., smoking cessation) <p>Satisfaction</p> <ul style="list-style-type: none"> • Increased satisfaction w/ care/QoC • Improved self-reported health status/QoL <p>5.3 PCNs/AHS</p> <ul style="list-style-type: none"> • More efficient use of resources for diabetes/ depression care 	<p>6.1 Providers</p> <ul style="list-style-type: none"> • Increased job satisfaction • Improved retention of staff <p>6.2 Patients</p> <ul style="list-style-type: none"> • Decreased # of FP & ER visits • Reduction in complications, co-morbidities, & mortality <p>6.3 PCNs</p> <p>Assists in decisions around business planning</p> <p>Meets PCI agenda, esp:</p> <ul style="list-style-type: none"> • Increasing the emphasis on care of pts with medically complex problems & with chronic disease • Fostering a team approach to providing PHC <p>6.4 AHS</p> <p>More appropriate health care utilization</p>

TeamCare-PCN Data Matrix

RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
2.0 KEY ACTIVITIES: Has the TeamCare-PCN intervention been adapted to the local PCN context?				
A (R at system level)	Engagement 2.1 Have relationships with key partners been established and with whom? <ul style="list-style-type: none"> • 4 non-metro PCNs • Katon What is the rationale/criteria for engaging the specific partners (i.e., the 4 chosen PCNs, and Katon), and not others? How representative are the participating PCNs compared to non-participating PCNs? Has a communication strategy been established in collaboration with each PCN? Has a physician champion or equivalent been identified for each PCN? What aspects of the partnerships have been successful? What aspects have been problematic and need to be addressed? What are the critical factors/features of a successful partnership?	List and description of key partners Description of rationale/criteria for engaging specific partners, including PCNs approached who declined participation Comparison of characteristics btwn participating & non-participating PCNs Communication strategies are identified List of physician champions # and type of communications/meetings Facilitators and barriers to successful partnerships Recommendation/suggestions for improvement	Document review: <ul style="list-style-type: none"> • ABCD project documents (e.g., LOAs/contracts, ABCD Contacts & Organizational Chart for PCNs document) • PCI/PCN program documents (e.g., websites, business plans) • Secondary data from PCI on characteristics of PCNs, if available & feasible Interviews with ABCD project staff; Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs; Interviews w/ other key partners (e.g., Katon group) Participant observation (e.g., meetings, communications)	Ongoing
A & I	Intervention Adaptation 2.2 Is the intervention adapted to the: <ul style="list-style-type: none"> • ABCD project? • Local PCN context? Has this been a collaborative process among: <ul style="list-style-type: none"> • ABCD project team • Katon • 4 non-metro PCNs Are the systems needed developed and in place?	Job descriptions for intervention staff drafted (e.g., CM, data admin assistant & specialists) Tx algorithms developed Training and resource manual(s) developed Patient/ diabetes registry created Patient recruitment & tracking system established Draft recruitment & data collection protocols Perception of collaboration & extent to which the intervention is adapted to the needs of the ABCD project Perception of collaboration and the extent to	Document review: <ul style="list-style-type: none"> • ABCD project documents (e.g., job descriptions, Algorithm Working Group minutes, training & resource manual(s), on-line patient tracking system, recruitment & data collection protocols) • PCN project documents (e.g., patient/ diabetes registry, patient recruitment/ tracking database) • Audit(s) Interviews with ABCD project staff; Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs; Interviews w/ other key partners	Ongoing

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		which the intervention is adapted to local PCN context Perception to which the systems needed have been developed and are in place	(e.g., Katon group) Participant observation (e.g., meetings, communications, reflections)	
A (R at system level)	Human Resources 2.3 Are the right level, type & mix of PCN intervention staff available to implement and track/monitor the intervention? Are the resources sufficient (e.g., FTE)? What additional human resources, if any, are needed to implement the program (as intended)?	Job descriptions # and type of PCN intervention staff hired/ recruited at each PCN # and type of PCN staff turnover (i.e., intervention staff and other PCN staff, such as CDM team, leadership, receptionist) Perception of right human resource level, type, and mix (e.g., hired internally vs. externally, professional designation/experience/qualifications of CM) Perception of impact of PCN staff turnover on intervention	Document review: • Job descriptions • Contracts/ToA • PCN stats on PCN HR environment, if feasible & appropriate Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs; Interviews with ABCD and PCN staff (ED, CDM, CM, FP, specialists & physician champions) Participant observation (e.g., meetings, communications, visits)	Ongoing

RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
3.0 Outputs (products & services): Is the TeamCare-PCN intervention being implemented as intended?				
I	Provider training 3.1 Have PCN staff been trained in the intervention components: TeamCare-PCN model/collaborative care approach, tx algorithms, recruitment protocols/scripts, & data collection?	# and type of staff trained for each component # and type of training/reference materials provided to staff Assessment of change in knowledge Training activities, materials/ resources, & on-going support identified Perceived quality/adequacy of training, materials provided, & on-going support received (i.e., satisfaction)	Document review: • ABCD/PCN project documents (e.g., attendance sheet) • Training/reference materials (training package) Survey instrument: • Pre/post survey Interviews with PCN staff who participate in training on the intervention components & ABCD project team Participant observation (e.g., meetings, communications, training)	Sept./ Oct. 2010 & end of study
R & I	Recruitment (reach/coverage) 3.2 How many patients are referred to the	# / % of type of participants (e.g., demographics, PHQ-8 score) screened & recruited to the <u>intervention</u> in each PCN	Document review: • PCN patient/ diabetes registry (aggregate characteristics of participants & <u>non-</u>	Screen, baseline, & FUs

	<p>intervention and usual care?</p> <p>How do the characteristics of participants in the intervention compare to those in usual care?</p> <p>How do the characteristics of participants (i.e., intervention and usual care) compare to non-participants?</p> <p>How is the target population of participants defined?</p>	<p># / % of type of participants (e.g., demographics, PHQ-8 score) screened & recruited to <u>usual care</u> in each PCN</p> <p># / % of type of <u>non-participants</u> (e.g., demographics)</p> <p>Sample size calculations</p> <p>Rationale for definition of target population (i.e., inclusion/exclusion criteria)</p> <p>Facilitators & barriers to recruitment are identified</p> <p>Recommendations/ suggestions to improve recruitment are identified</p>	<p><u>participants, if feasible & appropriate</u></p> <ul style="list-style-type: none"> • Patient recruitment tracking system (reasons for non-participation) <p>Survey instrument:</p> <ul style="list-style-type: none"> • Short screening survey (reasons for exclusion) • TeamCare-PCN Survey items (demographics) <p>PCN reports</p> <ul style="list-style-type: none"> • Report for ABCD (monthly) • ABCD Bulletin (quarterly) <p>Interviews w/ ABCD project team</p>	
<p>I</p>	<p>Service Delivery</p> <p>3.3 Has the intervention been implemented as intended?</p> <p>What is usual care at each PCN for patients with T2D and/or depression?</p> <p>How does physician buy-in influence implementation, if at all?</p> <p>How does the relationship btwn the PCN Board & physicians (i.e., degree of autonomy) influence implementation, if at all?</p> <p>What are the facilitators/ barriers to implementation? What adaptations to the intervention have been made/required, if any?</p> <p>What suggestions/ recommendations are there to the implementation process?</p>	<p># / % of screening</p> <p># & type of assessment</p> <p># & type of patient management plans</p> <p># & type of follow-up sessions w/ pts</p> <p># & type of reassessment sessions w/ pts</p> <p># & type of team consultations</p> <p># & type of Katon consultations</p> <p>Time of service delivery</p> <p>QI assessment (e.g., Katon's benchmarks of implementation/mthly meetings; and levels of service delivery)</p> <p>Description of usual care at each PCN</p> <p>Description & perception of the quality & degree of implementation as intended</p> <p>Perception of impact of physician buy-in on implementation, as intended</p> <p>Perception of impact of relationship btwn PCN & physicians on implementation, as intended</p> <p>Facilitators & barriers to implementation, as intended, are identified</p> <p>Recommendations/suggestions to improve the implementation process are identified</p>	<p>Document review:</p> <ul style="list-style-type: none"> • PCN patient/ diabetes registry • Patient recruitment/tracking system • PCN documents (e.g., website, program brochures) • ABCD Bulletin (quarterly) <p>Usual Care Checklist/Interview (pre-intervention & post) w/ EDs & CDMs</p> <p>Survey instruments (usual care):</p> <ul style="list-style-type: none"> • PACIC (short form) • TeamCare-PCN Survey items (satisfaction) <p>Interviews with PCN staff (CDM, CM, FP, & specialists)</p> <p>Participant observation (e.g., Katon's consultation meetings, other meetings, communications, visits)</p>	<p>Baseline and ongoing FU @ regular intervals</p>

RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
4.0 IMMEDIATE OUTCOMES: What is the immediate impact of the TeamCare-PCN intervention? What are the necessary system requirements and resources to implement and sustain this type of intervention?				
I (A in the future)	Providers 4.1 Do providers demonstrate increased awareness and knowledge of: <ul style="list-style-type: none"> TeamCare-PCN model/collaborative care approach? Diagnosis & pharmacotherapy of depression? Psychotherapeutic techniques (CBT)? Mgmt of diabetes (lipids, BP, & glucose)? 	Pre/Post knowledge test of intervention components Perception of increased awareness & knowledge of intervention components (i.e., confidence)	Survey instrument: <ul style="list-style-type: none"> Pre/Post survey Interviews/survey with PCN staff who participated in TeamCare-PCN training re: confidence in applying intervention model into practice Participant observation (e.g., meetings, communications, visits to PCN, training)	Sept./Oct. 2010 & end of study
I & E & M	Patients 4.2 Are patients receiving the right medications and/or therapies (e.g., CBT)? Do patients demonstrate an increased awareness and knowledge of the management of depression, diabetes (lipids, BP, & glucose), and/or lifestyle behaviours? Overtime, do patients demonstrate sustained awareness and knowledge of the mgmt of depression, diabetes, and/or lifestyle behaviours?	Patient management plans Survey items (baseline, 3-, 6-, & 12- months, and over 5 years)	Document review: <ul style="list-style-type: none"> Patient tracking database (e.g., PHQ-9 scores, lab, anthropometric values) Survey instrument: <ul style="list-style-type: none"> TeamCare-PCN Survey items Comparison of intervention and usual care groups	Baseline & FU or as needed for patient care
I & E	PCNs/AHS 4.3 Are there organizational factors & systems/strategies in place to improve diabetes/depression care?	Perception of organizational factors/priorities and systems/strategies in place to improve diabetes/depression care (as compared to usual care)	Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs Interviews with PCN staff (ED, CM, FP, specialists) Participant observation (e.g., meetings, communications, visits)	Baseline & FU
5.0 INTERMEDIATE OUTCOMES: What is the intermediate impact of the TeamCare-PCN intervention?				
I	Providers 5.1 Increased confidence in managing patients with diabetes and depression	Perceptions of confidence in managing patients with diabetes and depression # & type of team consultations	Survey instrument: <ul style="list-style-type: none"> Pre/Post survey Usual Care Checklist/Interview (pre & post)	Sept./Oct. 2010 & end of study

	Do providers perceive an increase in collaborative care? What are the facilitators or barriers to collaborative care? What are the critical success factors/recommendations for collaborative care?	Perception of increased collaborative care as compared to usual care	intervention, incl Q#18 of CPCQ) w/ EDs & CDMs Interviews/survey with PCN staff (CM, FP, specialists) Document review: <ul style="list-style-type: none"> • Patient tracking database Participant observation (e.g., meetings, communications, training)	
E & M	Patients 5.2 Are patients demonstrating improved management of depression; diabetes (lipids, BP, and glucose); and lifestyle behaviours (e.g., cessation of smoking)? Are patients more satisfied with their care/quality of care? Are patients self-reporting improved health status/QoL?	Patient management plans (e.g., adherence) Survey items (baseline, 3-, 6-, & 12- months, and over 5 years)	Document review: <ul style="list-style-type: none"> • Patient tracking database (e.g., lab, anthropometric values) Survey instruments: <ul style="list-style-type: none"> • Patient Assessment of Chronic Illness Care (PACIC) survey (baseline & 12-mths only) • TeamCare-PCN Survey items Comparison of intervention and usual care groups	Baseline & FU
E	PCNs/AHS 5.3 Are the PCNs demonstrating more efficient use of resources to improve diabetes and depression care?	Perception of adequacy of and efficient use of PCN resources as compared to usual care Economic evaluation: <ul style="list-style-type: none"> • # of GP visits • # of ER visits • # of psychiatric admissions 	Usual Care Checklist/Interview (pre & post intervention) w/ EDs & CDMs Interviews with PCN staff (CM, FP, & specialists) ADSS and AHW datasets	Baseline & FU

RE-AIM	Possible Questions	Indicators/Metrics	Potential data sources & methods	Timeframe
6.0 ULTIMATE OUTCOMES: What is the long-term impact of the TeamCare-PCN intervention?				
E	Providers 6.1 Do providers experience increased job satisfaction and a willingness to stay at the PCNs?	Self-reported job satisfaction Self-reported willingness to work at a PCN	Document review: <ul style="list-style-type: none"> • PCN stats on PCN HR environment (e.g., staff turnover), if feasible & appropriate Interviews w/ CM	End of study
E & M	Patients 6.2 Is there a decrease in the number of family physician and ER visits among the patients? Is there a reduction in complications, co-morbidities, and mortality among these patients?	AHW and ADSS items: <ul style="list-style-type: none"> • Decreased # of FP & ER visits • Reduction in complications, co-morbidities, & mortality 	AHW and ADSS datasets	End of study & continued FU

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M	<p>PCNs</p> <p>6.3 Did this intervention help PCNs make decisions around their business planning?</p> <p>Did this intervention help PCNs meet the objectives set out by the PCI, especially in relation to:</p> <ul style="list-style-type: none"> Increasing the emphasis on care of patients with medically complex problems & with chronic disease? Fostering a team approach to health care utilization? 	<p>Decisions around business planning (e.g., will intervention model be part of business plan and why/why not; where does this intervention model fall in comparison to other initiatives/competing priorities; is model transferable to other CDM)?</p> <p>Perceptions of meeting the PCI objectives</p>	<p>Interviews with PCN staff (e.g., ED)</p> <p>Document review:</p> <ul style="list-style-type: none"> PCN business plan PCI documents PCI evaluation 	End of study
E & M	<p>AHS/Health care system</p> <p>6.4 Did this intervention have an impact on more appropriate health care utilization?</p>	<p>AHW and ADSS items:</p> <ul style="list-style-type: none"> Reduction in direct medical costs Reduction in projected future health care costs 	AHW and ADSS datasets	End of study & continued FU