ISSUES REGARDING COMPLEX COMMUNITY-BASED CARDIOVASCULAR HEALTH INTERVENTIONS

ISSUES REGARDING COMPLEX COMMUNITY-BASED CARDIOVASCULAR HEALTH INTERVENTIONS: DEVELOPING THE THEORETICAL FRAMEWORK, IMPLEMENTATION FIDELITY, ASSOCIATING OUTCOMES WITH FACTORS AT MULTIPLE LEVELS

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ABSTRACT

The thesis presents three papers discussing some of the methodological issues regarding studies investigating complex community-based cardiovascular health interventions. All three studies involved the Cardiovascular Health Awareness Program (CHAP), a standardised blood pressure and risk factor assessment and educational sessions held in pharmacies or other locally accessible areas in small to mid-sized communities in Ontario, Canada.

The first paper reviews the literature and proposes a guide on how to develop a theoretical framework for complex community-based interventions using CHAP as an example. The paper describes a stepwise process of developing a theoretical framework including challenges encountered and strategies employed to overcome them.

The second paper presents how recently published randomized controlled trials evaluating complex community-based cardiovascular health interventions monitored and reported implementation fidelity based on a structured review of the published articles and a survey of their primary authors. The results showed that fidelity reporting of included studies was better than those described in previous reviews. Fidelity was verified through self-reports by implementers and supervision by researchers. Strategies described to standardize intervention delivery were through training of implementers and use of implementation guides. The authors' survey results were consistent with the

review results though there were some gaps which could be improved to strengthen fidelity reporting.

A data analysis issue with studies investigating complex community-based interventions is that outcomes can be affected by factors from multiple levels. The third paper explores the association of individual, partnership, and community-related factors with CHAP participants' use of health-related community resources and cardiovascular risk behaviours. This was a cross-sectional analysis of an on-going cohort study. The results showed that individual factors (age and self-efficacy) had the most consistent association with the outcomes. Community and partnership level variables showed less consistent association with the outcome. Methodological and analytical challenges were presented.

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LIST OF ABBREVIATIONS

BP	Blood Pressure
CEI	Coalition Effectiveness Inventory
CHAP	Cardiovascular Health Awareness Program
CHAP-CCEC	Cardiovascular Health Awareness Program Community Coalitions, Engagement, and Cardiovascular health
CONSORT	Consolidated Standards of Reporting Trials
CV	Cardiovascular
CVD	Cardiovascular Disease
DV	Dependent Variable
GEE	Generalized Estimating Equations
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ICC	Intracluster Correlation Coefficient
IV	Independent Variable
LLO	Local Lead Organization
NCD	Non-communicable Diseases
PSAT	Partnership Assessment Tool
RCT	Randomized Controlled Trials
RIO	Rurality Index of Ontario
VIF	Variance Inflation Factor
WHO	World Health Organization

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PREFACE

This PhD thesis, which has been written for the Health Research Methodology program, takes the form of a sandwich thesis. There is a general introduction which discusses and presents problems regarding cardiovascular health, methodological issues regarding complex community-based cardiovascular health interventions, and an overview of the thesis and three papers included. The three papers follow as separate chapters. Two of the papers have been submitted separately to Health Promotion Practice and Health Promotion International journals and have been formatted to meet their requirements. The third paper, which is an analytical paper, will be reformatted to meet the Uniform Requirements for Manuscripts prior to its publication. The final conclusion chapter presents the overall implications of the three studies and future research directions.

All three papers utilize information and data connected with the Cardiovascular Health Awareness Program (CHAP). The first author for all three papers is Ricardo Angeles. The thesis supervisor (Lisa Dolovich) and committee members (Janusz Kaczorowski, Lehana Thabane) were all co-authors of the studies. Sheri Burns was a co-author for the second paper and served as the one of the study reviewers. Ricardo Angeles and Lisa Dolovich conceived the initial idea for all three papers and Janusz Kaczorowski and Lehana Thabane contributed ideas to enrich the concepts and methodology. Ricardo Angeles implemented each of the studies, including data collection, analysis, interpretation, and drafting of the manuscripts, with the guidance of

Lisa Dolovich. All co-authors contributed by providing feedback to the manuscripts prior to submission for publication.

The three papers included in this thesis are entitled:

1. *Developing a theoretical framework for complex community–based interventions*
2. *Implementation fidelity of studies investigating complex community cardiovascular health intervention: A systematic review and survey of authors*
3. *Individual, Partnership, and Community factors associated with change in cardiovascular risk factors and use of health-related resources in communities implementing the Cardiovascular Health Awareness Program (CHAP)*

INTRODUCTION

Cardiovascular diseases in Canada and worldwide

Non-communicable diseases (NCDs), comprised mostly of cardiovascular diseases, are the leading cause of death globally (Alwan, 2011). Cardiovascular disease (CVD) is expected to surpass infectious diseases as the leading cause of death in the next 10 years (Levenson, Skerrett, & Gaizano, 2002). This is influenced by increased prevalence of risk factors (tobacco use, unhealthy diet, insufficient physical activity, and harmful use of alcohol), an aging population due to improved health care, and increased identification of individuals with CVD (Alwan, 2011; Lee et al., 2009, Lavenson et al., 2001).

One of the trends observed worldwide is that CVD affects countries and populations with low income and resources (Sanderson et al., 2007; Perkovic, Huxley, Wu, Prabhakaran, & MacMahon, 2007; Kearney, et al., 2005). Within certain countries, people in the lower income strata have a higher prevalence rate of CVD, suffer its ill effects more, and consequently have higher CVD-related mortality rates (Lavenson et al., 2001, Yusuf, Reddy, Ounpuu., & Anand, 2001).

In Canada, the rates of CVD have steadily declined over the past 40 years (Heart and stroke website, 2012). However, CVD-related deaths remain the leading cause of mortality (Heart and stroke website, 2012; Manuel, Leung, Nguyen, Tanuseputro, & Johansen, 2003; Lavenson et al., 2001). Furthermore, all the trends regarding the burden

of heart disease among the low income population are also seen in Canada. Studies show that the prevalence of CVD 2 to 3 times higher in the lower income groups than in higher income groups (Lee et al., 2009). Cardiovascular diseases remain a major burden due to morbidity and mortality associated with it as well as its effects in the quality of life of those affected (Manuel et al., 2003).

Complex community-based cardiovascular health interventions

As with all NCDs in the World Health Organization's (WHO) priority list, CVD is caused by a gamut of health risk behaviours. The major CVD risk factors prevalent in Canada, which the Public Health Agency are focussing efforts on, include smoking, lack of exercise, unhealthy eating, high cholesterol, hypertension, sodium intake, and stress (Public Health Agency, 2012). These multiple risk factors require a prevention and management strategy that employs multifaceted, multicomponent, population-based, and collaborative programs, also termed complex community-based cardiovascular health interventions (Alwan, 2011, Karwalatys et al., 2010; Chambers et al., 2005; Laverack, 2006; Craig et al., 2008).

Complex interventions have been defined by the Medical Research Council as interventions with several interacting components (Craig et al., 2008). Complex interventions consist of a spectrum of possible outcomes, priority populations or communities, settings for the intervention, groups or organizational levels affected by the intervention, and a degree of flexibility or tailoring to implement the intervention (Craig

et al., 2008). Flexibility and tailoring are especially helpful when implementing across various populations including vulnerable groups or groups from different low, middle or high income countries.

Most CVD community-based health programs are complex interventions, especially those having health promotion and disease prevention components. This is because of the number and complexity of health risk behaviours targeted by these programs as well as multiple levels of action (individual education, health policy interventions, community education, etc.) required to promote healthy behaviours. The WHO advises the use of comprehensive integrated packages of interventions which consist of multiple activities expected to have a synergistic effect (Nissinen, Berrios, & Puska, 2001). Such interventions are expected to decrease the explosion of CVD globally (Levenson et al., 2001). Studies testing complex community-based cardiovascular interventions have shown them to be effective in improving proxy measures of CVD health and, in some studies, improving rates of CVD-related morbidity and mortality (Penant et al., 2010; Kaczarowski et al., 2010; Kahn, Robertson, Smith, & Eddy, 2008).

Problems in evaluating complex interventions

Though complex community-based interventions are attractive interventions to combat CVD, they can be expensive (Kahn et al., 2008) and require multiple organizations' and stakeholders' involvement (Lasker & Weiss, 2003; Provan, Nakama, Veazie, Teufel-Shone, & Huddleston, 2003). Properly evaluating these interventions is

important. However, there are several methodological issues to consider because of the nature of complex interventions. Some of these issues are discussed below.

First, it is important to consider how the components of the intervention interact empirically or theoretically to bring about its synergistic effect. Complex interventions can have multiple mutually reinforcing elements which may or may not be strategically designed or coordinated (Dearing, 2008). If intervention components are disorganized and not synergistic, the end result may be an inefficient intervention with modest effectiveness. Relevant research evidence should be used in designing the components of the intervention (Blackwood, 2005) or the intervention should apply or build on existing theories (Sinclair, 2007; Leshem & Trafford, 2007). Designing the intervention properly and having an underlying theory of how it works can help in defining and measuring the outcomes and also provides a guide in appropriately implementing, analysing and evaluating the intervention (Blackwood, 2005; Grol et al., 2007; Cresswell & Plano-Clark, 2011; Michie, 2008).

Another issue to consider with complex interventions is the actual implementation of the program. Since complex interventions are usually an aggregate of multiple components, they will have multiple implementers. Furthermore, since another possible characteristic of a complex intervention is flexibility, standardizing the intervention for evaluation and future replication can be challenging (Blackwood, 2005). Choosing what components of the interventions to standardize (Hawe, Shiell, & Riley, 2004) and using

different methods to standardize it, i.e. implementation fidelity, is a key methodologic element for studies involving complex interventions (Dumas, Prinz, Smith, & Laughlin, 1999). If strict implementation fidelity cannot be achieved or is not the goal of the study, documenting and reporting the actual implementation should be done so that appropriate conclusions and recommendations can be drawn from the study.

Issues regarding data analysis of studies investigating complex community-based interventions are numerous. In many primary care and community-based studies, there are potential participant clustering (family physicians managing the participants, geographic clustering of residence, etc.) which should be considered as a possible factor affecting the outcomes (Killip, 2004). There are also multiple factors or independent variables at different levels (individual, organizational, partnership/coalition, community, etc.) which affect individual and community level outcomes. These factors may be collinear which should be considered in the data analysis process (Fox, 1991). Having an underlying theoretical framework as a guide would be ideal (Grol, Bosch, Hulscher, Eccles, & Wensing, 2007; Cresswell & Plano-Clark, 2011; Michie, 2008). Despite this, data analysis remains challenging and complicated.

Rationale of the thesis

The data presented earlier show that CVD is and will continue to be responsible for a large proportion of morbidity and mortality in Canada and worldwide. To decrease the impact of this problem and its associated health care cost, complex community-based

cardiovascular health interventions are continuously being developed, adapted to different settings, and evaluated by governments and researchers (Perkovic et al., 2007; Provan et al., 2003). All these processes will therefore encounter the methodological issues presented in the previous section.

This thesis is composed of three papers which attempts to fill in some of the gaps regarding methodological issues concerning studies investigating complex community-based cardiovascular health interventions. Though the focus of this thesis was on community-based cardiovascular interventions, the findings of the three papers may be applicable to studies investigating complex interventions in general.

OBJECTIVES OF THE THESIS

The overall thesis objective is to examine some of the methodological challenges regarding complex community-based cardiovascular interventions. In particular, this thesis focuses on three knowledge gaps. The papers in thesis discuss and present research evidence regarding these knowledge gaps and examples of how to overcome them. The three knowledge gaps addressed in this thesis are:

- How to develop theoretical frameworks or apply theories to complex interventions
- How currently published papers monitor and report implementation fidelity
- How to analyze data associating individual, partnership and community factors with individual behaviour change

OVERVIEW OF THE THREE PAPERS

Each of the three papers include presentations and discussions about subsets of the Cardiovascular Health Awareness Program (CHAP) study. The CHAP is a multi-component, community-based, cardiovascular health intervention which has been tested and implemented in various small to mid-sized communities around Ontario since 2006 (Chambers, et al., 2005; Karwalajtys et al., 2005; Pora, Farrell, Dolovich, Kaczorowski, & Chambers, 2005, Kaczarowski et al., 2011). The program consists of 2-3 hour weekday blood pressure and cardiovascular risk factor assessment and educational sessions held in pharmacies and locally accessible areas in the community. These sessions are organized by local agencies (Local Lead Organizations or LLO) and run by trained volunteer peer health educators. Details of the program are described in all three papers of this thesis and in published articles of Kaczorowski et. al. (2008, 2011) and Carter et. al. (2009). The author has worked with the CHAP research group and used this experience with the program to elaborate and discuss the issues regarding complex community-based cardiovascular health interventions.

Paper 1: Developing a theoretical framework for complex community–based interventions

To properly begin designing research investigating complex community-based cardiovascular health interventions, theorizing the mechanisms on how the components of the intervention work separately or interact synergistically to bring about the outcome is beneficial to properly evaluate the intervention (Grol et al., 2007; Cresswell & Plano-

Clark, 2011; Sinclair, 2007). However, there are few publications that comprehensively describe how to develop theoretical frameworks for studies involving complex community-based interventions. The first paper reviews the literature and proposes a guide on how to develop a theoretical framework for complex community-based interventions using the Cardiovascular Health Awareness Program (CHAP) as an example. The paper demonstrates a stepwise process of developing a theoretical framework. The challenges encountered are described and an overview of the strategies employed to overcome these challenges are presented.

Paper 2: Implementation fidelity of studies investigating complex community cardiovascular health intervention

Monitoring and reporting implementation fidelity is important especially for studies investigating complex community-based interventions. Implementation fidelity can affect the validity of study conclusions and therefore the usefulness of the study results. The second paper presents how recently published studies evaluating complex community-based cardiovascular health interventions monitored and reported implementation fidelity based on a structured review of the published articles and a survey of the primary authors of the study.

The review consisted of full text studies in English, published within 2009 to 2011, which met the following criteria: participants were community-dwelling; intervention under investigation was a complex intervention; outcomes assessed included

cardiovascular risk factors or measures of cardiovascular morbidity or mortality; study was a RCT. Two reviewers independently assessed the quality and relevance of the full papers and extracted data. The studies were assessed on whether they described strategies to standardize the intervention, strategies used to monitor implementation of the intervention, and assessment of how deviation from the planned implementation affected the results. A survey of study authors was carried out to supplement data obtained from the structured literature review. The paper reviewed only recently published papers since the assessment was partly driven by the recommendations for publishing non-pharmacologic trials released by Consolidated Standards of Reporting Trials (CONSORT) Group in 2008. The CONSORT Group recommended reporting of all the components of the intervention, co-interventions, method of standardizing the treatment, and compliance of care providers with the protocol (Bourton, Moher, Altman, Schultz, & Rayaud, 2008).

The paper presents the adherence of the studies to the CONSORT recommendations regarding publishing details related to standardization of the intervention and its components. It also presents the different methods which the authors of the published studies used in verifying, promoting, and reporting implementation fidelity.

Part 3: Individual, Partnership, and Community factors associated with change in cardiovascular risk factors and use of health-related resources in communities implementing the Cardiovascular Health Awareness Program (CHAP)

The CHAP intervention, which relies on local community resources and partnerships, is hypothesized to affect individual and community cardiovascular outcomes. The third study explores the association individual, partnership, and community-related factors with the use of health related community resources and cardiovascular risk behaviours of community residents participating in CHAP. The paper presents methods on how to deal with some of the data analysis challenges in studies involving complex community-based cardiovascular health interventions. Data from the Cardiovascular Health Awareness Program Community Coalitions Engagement and Cardiovascular health (CHAP-CCEC) project was used to demonstrate how to correlate factors at different levels with individual level outcomes.

This was a cross sectional analysis of an on-going cohort study. The outcomes were changes in health behaviours (risk behaviours and use of health-related community resources) of participants of the CHAP which were assessed through computer assisted telephone interviews. The independent variables were categorized into three levels: individual, partnership, and community-related.

The individual risk factors included participants age, gender, self-efficacy and number of CHAP sessions attended. The partnership factors included two measures of

partnership strength: the Coalition Effectiveness Inventory (CEI) (Butterfoss et al., 2006) and Partnership Self-Assessment Tool (PSAT) (Weiss, Anderson, & Lasker, 2002; Lasker & Weiss, 2003). These were scales based on structured questionnaires which were assessed through computer assisted interviews with representatives of the LLO and partners running the CHAP program in each community. The community related variables included the Rurality Index of Ontario (RIO) score, the proportion of pharmacies and family physicians involved in CHAP, and the type of CHAP community (whether the community was part of the original set of the community where CHAP was initiated or a community which adopted CHAP later after its randomized controlled trial).

The analysis followed a systematic process of initially determining if data clustering affected the outcome, identifying multicollinearity among the independent variables and coming up with a final regression model, summarizing the data as composite score and binary composite and comparing the results, and assessing the impact of missing data. Generalized Estimating Equations, Linear Regression with multiple imputation, and Logistic regression were used in the analyses. The study showed the complexity of analyzing data from multiple levels and dealing with it through a theory-based approach. The study also showed the methodological challenges encountered and how limitations in the design and sample possibly affected the results.

METHODOLOGICAL CHALLENGES

Identifying relevant literature for reviews of specific aspects of the methods

In conducting a literature review, whether it be for a formal study or reviewing the background of a research topic, a systematic approach is advised (Guyatt, Rennie, Meade, & Cook, 2008). However there are several instances when the use of standard search terms separately or in combination yields very little about the topic the researcher is interested in (McGowan & Sampson, 2005). This is especially true when the search is not about the standard population, intervention, comparison, and outcome (PICO) aspects about the study but rather specific aspects of the methodology.

In the case of paper 1 of this thesis, the literature search was regarding how to formulate/apply a theoretical framework for complex interventions. Guyatt et. al. (2008) considers this topic as a background question which was more general and advises the use of standard textbooks and the internet for such topics. A search through standard textbooks and internet resources yielded few sources which describe how to formulate/apply a theoretical framework, none of which were specific to complex interventions. A search through bibliographic databases was challenging.

A broad search is usually the approach in this scenario so as not to miss important literature (Guyatt et al., 2008; McGowan & Sampson, 2005). As expected, this yielded a large amount of literature, few were relevant. Reference scanning was done for both the relevant textbooks and journal article to supplement the general search strategy.

Evaluating study implementation based on the published literature

Evaluating studies based on the published report is the standard method for systematic reviews. However, inadequate reporting remains common (Augestad et al., 2012; Bourton et al., 2008; Piggott, McGee, & Feurer, 2004) especially regarding implementation of the study (Glasziou, Meats, Heneghan, & Shepperd, 2008). This may be partly due to journal requirements, authors' reporting bias (Guyatt et al., 2008) or other factors. Assessing aspects of study implementation thus requires more effort than evaluation of outcomes.

Paper 2 of the thesis assessed implementation fidelity of RCTs investigating complex community-based cardiovascular health interventions. The author did not want to equate failure to report implementation fidelity to lack of it. To overcome this, an authors' survey was done to supplement information obtained from the published article. All authors responded to the survey making the study results more informative.

Data analysis challenges

There were some challenges in analyzing the data for paper 3 (Individual, Partnership, and Community factors associated with change in cardiovascular risk factors and use of health-related resources in communities implementing the CHAP). These included (1) the data came from communities which implemented the CHAP and by nature were clustered data (Killip, 2004); (2) there was a single value of partnership and community factors for each community; (3) there were many independent variables to

combine in a single model; (4) composites were used as outcomes; and (5) there were missing data.

Analyzing clustered data

Textbooks and other resources advise not to treat cluster observations as if they were independent (Hanley, 2003) since similarity among subjects within pre-existing clusters reduces the variability of responses (Killip, 2004). Therefore, correlating community level variables with individual level outcomes should be avoided if similarity within clusters is high (Hardin & Hilbe, 2003). This is measured using the Intracluster Correlation Coefficient (ICC) (Killip, 2004). To overcome this issue, Generalized Estimating Equations with exchangeable correlation structures (Ziegler & Vens, 2010) were used to measure the ICC to see if overlooking the clustering and creating a model including the community-level variables was possible. In paper 3 since the ICC was negligible, linear and logistic regression were used in analyzing the data.

Dealing with multiple independent variables

Since there were a number of independent variables to include in a regression model associating them with the outcomes, a valid method of prioritizing the independent variables was needed. A common approach is the use of stepwise (forward or backward) regression modelling to reduce the regressors in the model to a less correlated set (Fox, 1991). However, this has been discouraged as an approach to prioritizing variables (O'Brien, 2007; Fox, 1991). The Variance Inflation Factor (VIF) and tolerance, which are

measures of multicollinearity among the variables, has also been used to reduce the number of variables by removing variables which are correlated or collinear. Though this is also not ideal, at times it is reasonable to eliminate correlated variables, but doing so should be theoretically motivated (O'Brien, 2007). Variable selection was therefore done to reduce the set of variables to those which were not collinear (VIF <2.5) (Allison, 1999; Meloun, Militký, Hill, & Brereton, 2002; Fox, 1991) and prioritizing based on the theoretical framework of the CHAP-CCEC study.

Using composite outcomes

Paper 3 used a composite score to summarize the outcomes (change in CVD risk behaviours and use of health-related community resources). Though there are issues regarding the use of composite outcomes (Ferreira-Gonzalez et al., 2007; Berger, 2002; Freemantle, Calvert, Wood, Eastaugh, & Griffin, 2003), the author believed that the advantages were clear and intuitive (Ferreira-Gonzalez et al., 2007). The score was simple to compute and interpret. Details regarding the composite score are in paper 3. The main advantage was that it increased the power to detect associations. Sensitivity analysis was done comparing the composite score and a binary composite (Sampson, Metcalfe, Pfeffer, Solomon, & Zou, 2010). Analysis of the individual outcomes was also presented.

Missing Data

As common with most population health studies, missing data was also a problem in the CHAP-CCEC study (Paper 3). The missing data for the individual outcomes ranged from 6.6 to 12%. Multiple imputation was done as a sensitivity analysis for the composite score (Harrell, 2001; Norman & Streiner, 2008).

Summary statement

Overall, there are many challenges encountered in the conduct of the three papers which are not necessarily unique to studies regarding complex community-based cardiovascular interventions. Presenting these methodological challenges and demonstrating ways to overcome them will hopefully increase the awareness of the research community regarding them, stimulate discussions to provide more solutions to overcome them, and improve the research practice.

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Developing a theoretical framework for complex community–based interventions

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ABSTRACT

Applying existing theories to research, in the form of a theoretical framework, is necessary to advance knowledge from what is already known towards the next steps to be taken. This article proposes a guide on how to develop a theoretical framework for complex community-based interventions using the Cardiovascular Health Awareness Program (CHAP) as an example. Developing a theoretical framework starts with identifying the intervention's essential elements. Subsequent steps include: 1) Identifying and defining the different variables (independent, dependent, mediating/intervening, moderating, and control); 2) Postulating mechanisms how the independent variables will lead to the dependent variables; 3) Identifying existing theoretical models supporting the theoretical framework under development; 4) Scripting the theoretical framework into a figure or set of statements as a series of hypotheses, if-then logic statements, or a visual model; 5) Content and face validation of the theoretical framework; and 6) Revising the theoretical framework. In our example, we combined the "Diffusion of innovation theory" and the "Health belief model" to develop our framework. Using CHAP as the model, we demonstrated a stepwise process of developing a theoretical framework. The challenges encountered were described and an overview of the strategies employed to overcome these challenges were presented.

INTRODUCTION

Applying existing theories to any research, in the form of a theoretical framework, is necessary to advance knowledge based on what is already known about the area being studied (Sinclair, 2007; Leshem, 2007) and the next steps to be taken. Using a theoretical framework provides a guide to appropriately implement, analyse and evaluate future studies (Grol et al., 2007; Cresswell and Plano-Clark, 2011; Michie, 2008). The theoretical framework can also guide adaptation and application of the research intervention (Sinclair, 2007).

There is little literature discussing how to develop theoretical frameworks for studies involving complex community interventions. Complex interventions have been defined by the Medical Research Council as interventions with several interacting components (Craig et al., 2008). Complex interventions will often include a spectrum of possible outcomes, priority populations or communities, settings for the intervention, groups or organizational levels affected by the intervention, and degree of flexibility or tailoring permitted as part of the intervention (Craig et al., 2008). Most programs with health promotion and disease prevention components are complex interventions. This is because of the number and complexity of health risk behaviours targeted by these programs as well as multiple levels of action (individual education, health policy interventions, community education, etc.) required to promote healthy behaviours. Developing theoretical frameworks for such interventions may not be as straightforward as with single component interventions. It may require more reflection and discussion

with experts, research team members, and stakeholders to understand the interaction between different aspects of the intervention and the setting in which it is applied (Grol et al., 2007).

The Cardiovascular Health Awareness Program (CHAP) is an example of a complex community intervention with several interacting components affecting multiple behaviours and populations. It has been designed to be flexible enough so that it can be tailored to fit the local context. Briefly, CHAP is a community-based, primary care centered, volunteer peer-led, free of charge, cardiovascular disease risk assessment and blood pressure (BP) monitoring program for community dwelling older adults (Kaczorowski et al., 2008). The CHAP intervention consists of regularly scheduled, community-based 3-hour BP and cardiovascular risk factor assessments combined with education sessions conducted by trained volunteer peer health educators measuring BP using a validated, automated instrument (BpTRU^{TM}). Blood pressure readings and data on cardiovascular risk factors are recorded and, with participants' consent, sent to their family physician and usual pharmacist. Volunteer peer educators promote self-management by providing participants with a copy of their risk profile, risk-specific educational materials, and information on the availability of and access to local community resources. A community health nurse or on-site pharmacist ensures immediate follow-up of participants identified as being at high risk based on their systolic BP level. Fax-to-database technology is used to compile and send individual patient data to family physicians and pharmacists. Comparative audit and feedback results are sent to

participating family physicians. Local lead organizations (LLO) use opinion leaders and peers to gain the support and participation of family physicians and pharmacists. The research team provided central support and a networking function for communities delivering the intervention. The CHAP website (www.chapprogram.ca) provides easily accessible, comprehensive and practical information and tools supporting CHAP implementation and on-going functioning. A 39 community cluster randomized trial showed that CHAP significantly decreased annual hospitalization rates at the community level for a combined composite of myocardial infarction, stroke and congestive heart failure (Kaczorowski et al., 2011).

CHAP was developed to become a standardized program through a series of pilot and demonstration studies. The different components were evaluated through empirical testing based on challenges encountered in the field. Studies were undertaken to assess participants' perception of CHAP and develop strategies to enhance peer educator retention (Pora et al., 2005), determine how to best invite community residents to participate in CHAP (Karwalajtys et al., 2005), and understand the roles and experiences of peer volunteers delivering the CHAP sessions (Karwalajtys et al., 2009). However, a comprehensive theoretical framework was not developed or formally articulated at the time the project was initiated.

This article proposes a guide on how to develop a theoretical framework for complex interventions. This guide is meant for researchers who are involved in

developing, implementing and evaluating health promotion and disease prevention programs. It was prepared based on an extensive literature review of journal articles and books regarding developing a conceptual or theoretical framework with a special emphasis on complex interventions. The author applied the guide, using the Cardiovascular Health Awareness Program (CHAP) as an example, and in the process did validation of the theoretical framework by stakeholders involved in CHAP.

PROCESS IN DEVELOPING A THEORETICAL FRAMEWORK

Identifying the essential elements of CHAP

Before developing a theoretical framework for complex interventions like CHAP, its essential elements (also called core elements or active ingredients) need to be identified and described (Greenhalgh et al., 2004; Craig et al., 2008). These elements give the intervention it's theoretical and pragmatic basis and are thought to account for the intervention's effectiveness (Gearing et al., 2011). Essential elements are characteristics that define the intervention or the minimum requirements for the intervention, without which it cannot be labelled as that specified intervention. For CHAP we have categorised these elements into process, organization, and contextual components (Table 1).

Developing the theoretical framework for CHAP

Developing a theoretical framework is usually a prospective process that is done prior to implementation of the study or intervention. Although the intervention example highlighted in this article has already been tested, the steps taken can still ably illustrate

this process. This article presents a general systematic process which is not meant to be a rigid guide but rather a reflective process so that important aspects in developing the theoretical framework will not be missed.

Step 1: Identifying the variables and the context

Initially, the different variables (independent, dependent, mediating/intervening, moderating, and control) to be included in the model need to be identified and defined. Standard definitions of these variables based on the literature will be applied. A number of resources can be used to provide standard definitions (Cresswell and Plano-Clark, 2009; Ogilvie et al., 2011 ; Baron and Kenny, 1986) however, a few key points will be emphasized below.

The independent variable (complex intervention) can be taken as a whole or broken down into its key components (or essential elements)—if component evaluation is desired (Craig et al., 2008). Component evaluation may not be feasible or necessary for complex interventions in which the various components are packaged together. Nevertheless, itemising them individually may be beneficial to determine if the developers have considered all the mechanisms of the intervention.

Another issue to consider is that the dependent variables may be multiple in the case of complex interventions (Craig et al., 2008). There may also be several mediating variables or outcomes in the process which need to be identified.

In addition, the importance of the context especially when dealing with complex community interventions (Wang et al., 2006) need to be described. This includes population base (culture, personal, social characteristics) context (Gearing et al., 2011), within systems organization and external neighbouring organization context (Greenhalgh et al., 2004; Denis et al., 2002), socio-political context (Fleuren et al., 2004), and others. Some context aspects can be considered moderating (including clustering or nesting variables) or control variables.

In this step, we use Table 2 as a template to help visualize the many variables involved in the program.

Step 2: List postulated mechanisms, mediating variables and postulated outcomes

A second useful step is to establish the postulated mechanisms of how the IV will lead to the DV while specifying the different mediating variables. Each essential element can be viewed separately to see how it contributes to influencing the outcome. For certain complex interventions, the effects of each element cannot be separated from the other elements but instead the elements exist as uncoordinated cumulative effects (Dearing, 2008).

The main postulated mechanisms of CHAP are that it enhances the awareness of the importance of BP monitoring, management and reduction of modifiable cardiovascular risk factors (Kaczorowski et al., 2008, Pora et al., 2005); raises the

participants' awareness of their high blood pressure; and informs their pharmacists and physicians about their CVD risk profiles and current BP status (Pora et al., 2005). This and other postulated mechanisms are outlined in Table 3.

Step 3: Identify existing theoretical models supporting the Theoretical Framework under development

Identifying and selecting existing theoretical models can be a challenging step. Grol et al (2007) provides a comprehensive list of theories related to patient care. Researchers can also review related literature and determine if theoretical frameworks in these studies apply to their planned study.

In the area of complex interventions, combining theories may be useful to explain the entire mechanism of how the intervention can work (Ogilvie et al., 2011). This depends on how complex the intervention is, how proximal the relationship of the IV is to the DV. In the case of the CHAP intervention, none of the essential elements are proximally related to the outcome of interest. Our team identified the "Diffusion of innovation theory" and the "Health belief model" as most applicable to CHAP and combined them to develop our framework.

The *diffusion of innovation theory*, whose earlier version was based on rural sociology (Rogers and Scott, 1997; Rogers, 2003; Dearing, 2008), has evolved and its application has expanded to include diffusion of health information. It states that the

process of adoption of innovation (new knowledge or information, practice, behaviour) goes through 4 main stages - dissemination, adoption, implementation, and continuation (Fleuren et al., 2004; Dingfelder and Mandell, 2011) - and there are specific determinants in each stage which promotes or discourages the adoption of the innovation. Furthermore, individuals go through processes of awareness, persuasion, decision, implementation, continuation (Fleuren et al., 2004; Dingfelder and Mandell, 2011) which is important to understand so that appropriate interventions can influence adoption of the innovation. Numerous studies regarding the diffusion theory attempted to identify the determinants of diffusion at different levels (individual, social, organizational, professional, community, country). Greenhalgh et al (2004) conducted an extensive review of evidence of the determinants of diffusion and summarized the different factors affecting the adoption process based on the user context and outer context (factors related to the Innovation, Diffusion and Dissemination Process). This theory was chosen to explain how the multiple interventions and strategies used in CHAP mutually influences and reinforces individuals to attend the CHAP sessions (the innovation).

The *health belief model* on the other hand was chosen to explain how individuals attending CHAP were influenced to adopt healthy behaviours. The health belief model states that health related action/behavior depends on 3 classes of factors: i) existence of sufficient motivation (health concern), ii) belief that one is susceptible to a serious problem (vulnerability), and iii) belief that a health recommendation would be beneficial in reducing the threat at a subjectively-acceptable cost. This also depends on perceived

self-efficacy to adopt the health related actions. (Rosenstock et al., 1998) Other theorists coin the factors as perceived threat (susceptibility and severity), perceived benefit, perceived barriers, and cues to action (motivation) (Dennison, 2004; Janz and Becker, 1984).

Step 4: Script the theoretical model into either a figure or sets of statements

Based on Table 3 (Step 2) and with the background knowledge of the theories explaining the mechanisms, the theoretical framework can then be constructed. The theoretical model can be written in different ways but the common practice is to draft it as a series of hypothesis, if-then logic statements, or a visual model (Cresswell and Plano-Clark, 2009). For CHAP, a visual model was chosen to represent its theoretical framework (Figure 1).

The CHAP framework can be visualised as a series of inter-related steps. CHAP participants (adopters) undergo stages of awareness, persuasion, and adoption of the innovation (attendance to CHAP sessions) which is initially influenced (information and persuasion) through CHAP promotion activities by the LLO and Family Physicians/Pharmacists. Once the participants attends the CHAP sessions, this leads to a series of actions (information sent to family physicians and referral to community health resources) which in turn leads to mediating outcomes (improved awareness of susceptibility, improved awareness of consequences, awareness of benefits of attending CHAP, improved self-efficacy in management of risk factors) reshaping the health belief

system of the participants. The combination of the activities during CHAP sessions, actions by Family Physicians, Pharmacists and Partner Organizations, will improve health awareness/self-efficacy and will lead to individual patient outcomes (increased use of community resources, decreased modifiable risk behaviours, better BP control) as well as community level outcomes (decrease in hospitalization and deaths due to stroke, MI, and CHF). All these actions and outcomes loop back to make more community residents aware of CHAP and persuade more residents to attend the CHAP sessions either through early adopters influencing the social environment or social pressure to adopt an innovation which others have done.

Step 5: Content and face validation of the theoretical model

After drafting a theoretical framework, this can be presented to different stakeholders for validation. This can be done through a Delphi approach (Pikora et al., 2003) or through interviews with stakeholders affected by the intervention or involved in its development and delivery (Craig et al., 2008). Regardless of the method, it is important to present the entire framework to key stakeholders to validate the theory and to elicit middle range theories (Ogilvie et al., 2011) previously unidentified by the developers.

The CHAP framework was presented to the researchers and LLO program coordinators to solicit their views. Data gathered from previous interviews of CHAP

patients and family physicians working in CHAP communities were also explored to determine if their views supported the theoretical framework.

All information from the different sources supports the framework. The LLO coordinators agreed that the main mechanism of CHAP was that it increased awareness of participants regarding their blood pressure status. Accordingly, some participants were keen on learning more from the CHAP sessions about ways to manage their blood pressure and get connected with community resources, while others just wanted their blood pressure monitored. Personalized feedback of cardiovascular risk and health status with tailored education is a proven cost-effective tool in improving health behaviours (Artinian et al., 2010; Erikson et al., 2006; Sohn et al., 2012; Yates, et al. 2011). In addition, participation of physician/pharmacist and partner organizations varied across the different communities. So although they agreed with the framework as a whole, the different mechanisms varied in terms of their influence on individual and community level outcomes.

The CHAP researchers considered additional mechanisms. One researcher stated that social interaction between CHAP participants and other family members may increase participation rates. Another stated that CHAP also leads to a gamut of local health services outcome (increased community capacity to prevent chronic disease, new networks that assist in mobilizing organizations and individuals in health promotion activities, and improved integration of service delivery across sectors).

Information from previous interviews with physicians/pharmacists and CHAP participants supported the fact that many previously undiagnosed hypertensive patients were detected to have high BP through CHAP. Diagnosed hypertensive patients who had poor BP control were better monitored and medications were adjusted as needed. The physicians stated that the BP monitoring added to their information in making decisions regarding patient treatment and made patients more compliant to their diagnosis and treatment plan.

Step 6: Revise the theoretical framework based on Step 5

Comments and ideas of stakeholders generated during Step 5 should be incorporated where relevant. In the case of the CHAP theoretical framework, none of the stakeholders disagreed with any of the mechanisms presented. They presented additional mechanisms which were added to the explanation of the framework. Some changes in the wordings and arrows in the diagram were also incorporated.

DISCUSSION

An understanding of theoretical assumptions and hypothesis behind the interaction of factors influencing the success or failure of a program is necessary since it enables development, evaluation, and adaptation of theory-based interventions or programs (Grol et al., 2007; Cresswell and Plano-Clark, 2011, Sinclair, 2007).

Challenges to consider in developing theoretical models for complex community interventions have been raised earlier.

One issue is that complex interventions can have multiple mutually reinforcing elements which may or may not be strategically designed or coordinated (Dearing, 2008). Determining which part of the complex intervention causes which effect in the hope of explaining causality or improving effectiveness can be difficult especially if different aspects of the intervention are hypothesized to result in the same outcomes. Decomposing the intervention to its component parts may disregard the system effects or interactions of the components (Hawe et al., 2004). From a pragmatic standpoint, explaining causality of complex interventions at the component level may not be crucial. Improving effectiveness can be done by strengthening each component based on operational evaluation.

Another methodological issue in framework development is the determination of which components are essential, fixed or flexible (Greenhalgh et al., 2004). Identifying the components which are the "active ingredients" influencing the outcome is important. However, if the intervention is a multi-faceted program, as is usually the case with complex community interventions, the entire program with its interacting components should be considered as the essential element. More importantly, the theoretical framework should focus on describing how these components interact with each other to create a mutually reinforcing intervention (Dearing, 2008; Hawe et al., 2004). For

community interventions which are implemented by different stakeholders in different settings, true fixed elements (implemented exactly as recommended) may not be realistic other than equipment used. Instead core principles of the interventions are fixed but actual implementation are context dependent. As for CHAP, Carter (2009) stated that "standardization needs to be balanced with adequate flexibility to deliver it within the context and resources of individual communities." CHAP's fixed core principles is that the intervention uses a reliable and accurate method to measure BP in a familiar environment, it taps into underutilized local resources such as volunteers and community pharmacies, and 'closes the loop' by communicating up-to-date BP and CVD risk information to family physicians, pharmacists and patients (Kaczorowski et al., 2008).

Using CHAP as the model, we were able demonstrate a stepwise process of developing a theoretical framework for complex community interventions. The challenges encountered were described as well as an overview of the strategies employed to overcome them. The process of designing a theoretical framework is developmental and experiential (Sinclair, 2007). It is not enough to develop a framework as part of the protocol the set it aside. It is important to revisit the framework, synthesize the data outcomes at each stage of the research process to further develop, test or confirm relationships between variables (Sinclair, 2007). Since CHAP has produced measurable results and outcomes through the years, a retrospective look at the intervention and outcome gave us a unique perspective of having people who have experience implementing CHAP review the framework and give their opinions regarding its

mechanism. Future CHAP research and implementation can use this framework and make subsequent adaptation, operationalization, and evaluation more systematic.

CONCLUSION

In this article we have proposed a guide on how to develop theoretical framework for complex community interventions. We have combined previous literature regarding developing theoretical frameworks and highlighted issues with complex interventions as well as developed our own tools to guide researchers in developing theoretical models. We have given an actual example of how to use our proposed guide using our experience with the CHAP. This guide and other similar tools can be adopted or adapted to improve the practice of theory-based research practice in areas that demand complex interventions.

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Table 1: Essential elements of CHAP (Kaczorowski 2011, Carter 2009, CHAP implementation guide)

Process components	**Organization components**	**Contextual components**
• Regular scheduled cardiovascular risk assessment and education sessions using an accurate BP measurement device and global cardiovascular risk factor assessment and education • Sessions held at an accessible community-based location (e.g. pharmacy) • Referral of BP and chronic disease risk profile result according to protocol to ensure appropriate referral to health providers and resources • Health care providers within reach for cases needing urgent care (on-call or present during CHAP sessions) • Process/Program evaluation • Integrated with primary health care workers (CHAP information sent to physician, nurse, pharmacist) • Support for staff and volunteers (training and implementation needs)	• Implemented by Local Lead Organization and trained volunteer peer health educators • Coordinated action (centrally supported) • Participation of primary health care providers (or practitioners) (family physicians and pharmacist) • Community mobilization/ Partnership with local stakeholders	• Community-wide scope • Priority populations: older adults (65 years and older) • Small to mid-sized communities • Publicly funded healthcare system

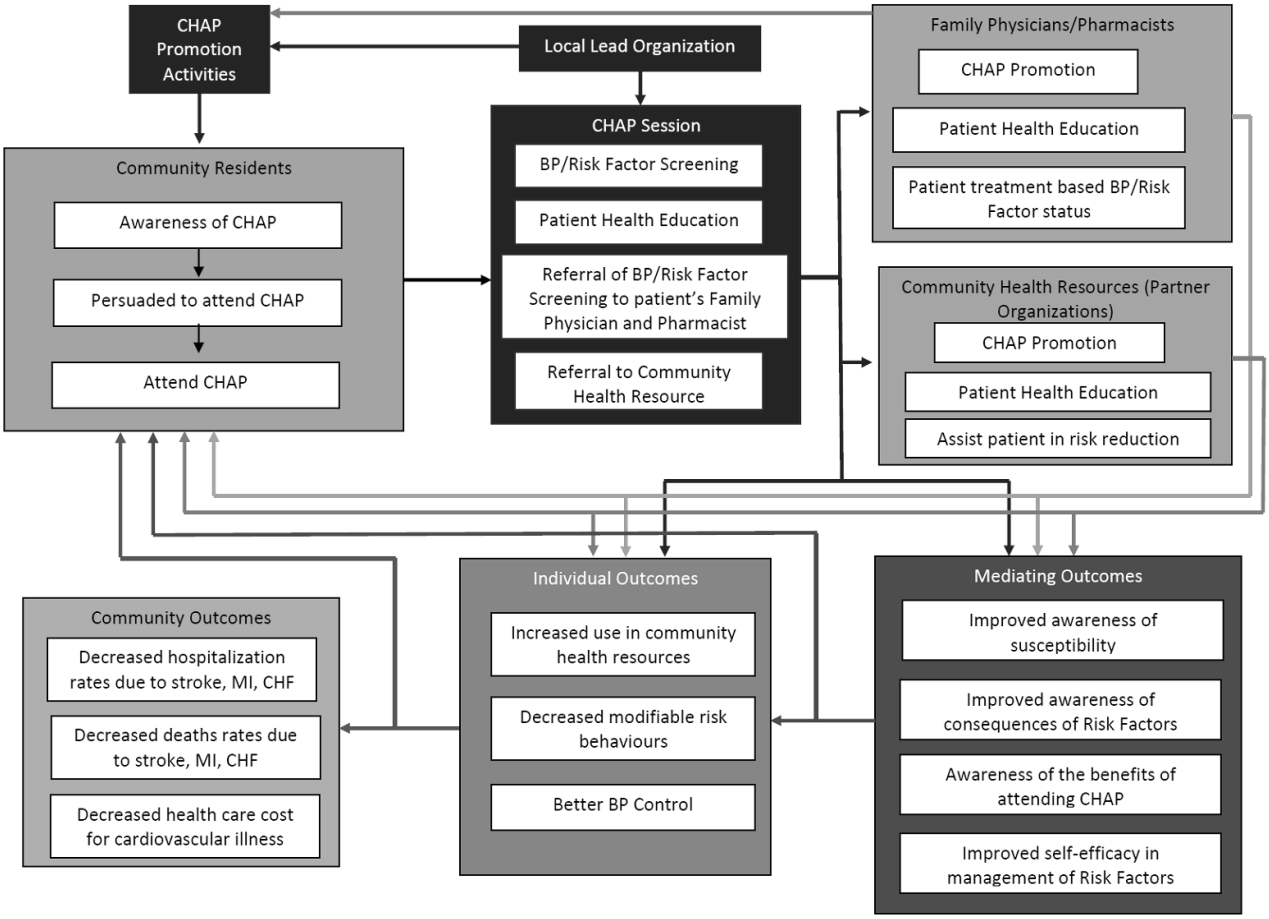
Table 2: List of variables in the CHAP study

Independent Variable	**Mediating Variables**	**Dependent Variable**	**Context**	
			Variable	**Type**
CHAP Session • BP/Risk factor screening • Health education • Referral of BP/risk factor screening results to family physicians • Referral of patient to community health resources (partner organizations) Family Physician/ Pharmacist interventions • Health education • Initiate or adjust patient treatment based on BP/Risk factors status • Adherence to management guideline Partner Organization interventions • Health education • Provide resources to assist in risk factor reduction	Knowledge/ awareness regarding risk of developing CV complications Knowledge/ awareness regarding management of CV factors Perceived self-efficacy in managing CV risk factors	Individual • Use of community health resources • Modifiable CV risk behaviours • BP Control Community • Hospitalization and death rates due to stroke, MI and CHF • Health care cost related to management of CV illness	Number of participating physicians/ pharmacists Number of partner organizations in the community Community size Health Resources available	Moderating Moderating Control/ Moderating Control/ Moderating

Table 3: Postulated mechanisms and possible associated mediating/moderating and dependent variables

Postulated mechanism	**Mediating Outcomes**	**Postulated Outcomes**
Education regarding CV risk factors through the CHAP sessions and referrals to Family Physicians/ Pharmacists and Partner Organizations	Improved awareness regarding susceptibility for CV complications Improved awareness regarding consequences and management of CV risk factors Awareness regarding the benefit of CHAP Improved self-efficacy in the management of risk factors	Changes in modifiable risk behaviours Increased use of community health resources Better BP control
Regular BP monitoring through CHAP sessions	Improved awareness regarding susceptibility for CV complications Improved self-efficacy in the management of risk factors	Better BP control
BP and CV risk information sent to Family Physicians/Pharmacists leading them to initiate medications or adjust therapy for patients with high BP, and adhere to prescribed management guidelines		Better BP control
Partner organization assisting CHAP participants in managing specific risk factors	Improved self-efficacy in the management of risk factors	Changes (or improvements) in modifiable risk behaviours

Figure 1 : CHAP Theoretical Framework



Implementation fidelity of studies investigating complex community cardiovascular health intervention

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ABSTRACT

Background: Implementation fidelity can affect the validity of study conclusion and the usefulness of the result especially for studies investigating complex interventions.

Objective: This review described how randomized-controlled trials (RCT) investigating complex community-based cardiovascular health interventions monitor and report implementation fidelity.

Study eligibility criteria: Full text studies in English, published within 2009 to 2011, were included if they met the following criteria: participants were community-dwelling; intervention under investigation was a complex intervention; outcomes assessed included cardiovascular risk factors or measures of cardiovascular morbidity or mortality; study was a RCT.

Study appraisal and synthesis: Two reviewers independently assessed the quality and relevance of the full papers and extracted data. The studies were assessed whether they described strategies to standardize the intervention, strategies used to monitor implementation of the intervention, and attempts to assess how deviation from the planned implementation affected the results. A survey of study authors was carried out to supplement data obtained from the structured review.

Results: Overall, 342 potential articles were screened; 10 were included in the final review. Weighted Kappa for relevance and quality were 1 and 0.28. Implementation fidelity of included studies was better than those described in previous reviews. Fidelity was verified through regular self-reports by implementers and/or supervision by researchers. Standardizing delivery of the intervention was done through training of

implementers and use of implementation guide or standardized algorithms. All study authors responded to the electronic survey. The survey results were consistent with the review results.

Key findings: Recently published RCT reported details regarding implementation fidelity better than what was reported in previous reviews. However, there were some gaps which could be improved to further strengthen reporting of implementation fidelity.

INTRODUCTION

Implementation fidelity, especially in randomized controlled trials (RCT), is a key methodologic requirement. (Dumas et al., 2001) Also called program integrity, implementation fidelity can affect the credibility or validity of the study conclusion and therefore the usefulness of the study results. (Dane and Schneider, 1998; Dumas et al., 2001; Carroll et al., 2007). Implementation fidelity is defined as the degree to which interventions or programs were delivered as planned or intended (Carroll et al., 2007; Dusenbury et al., 2003). Although the value of promoting strict fidelity versus adapting interventions or programs to the implementing site can be debated (Dane and Schneider, 1998), documenting the actual implementation of the program, including how well it's essential elements were delivered, is important to draw proper conclusions regarding the validity of its success or avoiding a Type III error, identify the reasons for its possible failure, and identify ways of improving the program (Carroll et al., 2007; Dusenbury et al., 2003).

There has been considerable effort to promote implementation fidelity as a fundamental methodological aspect of study design. Research methodologists have focussed their attention on developing theoretical models explaining the role of various elements of fidelity on the outcome (Carroll et al., 2007; Hasson, 2010), incorporating and considering fidelity safeguards during protocol development (Gearing et al., 2011), and suggesting ways of measuring and documenting it (Hulscher et al., 2003; Breitenstein et al., 2010; Wickersham et al., 2011; Dane and Schneider, 1998). However, previous

reviews have found that less than 25% of published studies described procedures that verify and promote fidelity (Dane and Schneider, 1998; Perepletchicova et al., 2007).

In the case of complex interventions, attempting to standardize the intervention and documenting its actual delivery may be all the more important. Complex interventions have multiple components, multiple implementers, and include a degree of tailoring to intervention site and recipient which may affect the delivery of the intervention and its actual impact (Craig et al., 2008; Lipsey and Corday, 2000; Dane and Schneider, 1998; Dumas et al., 2001). The lack of details in reporting the actual delivery of the intervention, adherence of implementers to the protocol, or methods of standardization may contribute to slow uptake of research findings (Bourton et al., 2008; Glasziou et al., 2008). This may be due to difficulty in replicating the actual intervention on the basis of information provided (Glasziou et al., 2008) or lack of confidence in the research results because of the possibility of poor implementation fidelity. The Consolidated Standards of Reporting Trials (CONSORT) Group has released its recommendations for publishing non-pharmacologic trials which require reporting of all the components of the intervention, co-interventions, method of standardizing the treatment, and compliance of care providers with the protocol (Bourton et al., 2008).

Monitoring the actual implementation of a program is important whether or not there was strict adherence to the intervention protocol. Understanding how an intervention was delivered in relation to the results can assist researchers and decision

makers in identifying how an intervention can be best introduced into everyday practice and how to further improve the intervention.

Using the example of community cardiovascular health promotion and prevention programs, the goal of this review is to identify how RCTs investigating health interventions monitor and report fidelity of intervention. Specifically, the objectives are to describe the reporting of the methods of promoting fidelity, verify actual implementation of study intervention, and to assess the reporting of the problems related to implementation fidelity.

METHODS

Search Strategy

This was a systematic overview followed by survey of study authors. Relevant studies were identified from databases (Medline, EMBASE, Psyche Info, Global Health, and CINAHL). The study search was restricted to studies published between January 2009 to December 2011 so as to only examine studies published after the CONSORT recommendations for publishing non-pharmacologic trials was released in 2008. The main search terms used were: *cardiovascular, community-based,* and *health promotion*. The search terms were both exploded and used as key terms. The Medical Subject Headings equivalents for these terms were also used. Additional search terms were used depending on the database. (Box 1)

Inclusion/Exclusion criteria

Only full text papers published in English were included to make the review feasible. This overview included studies that met the following criteria: target participants included community-dwelling residents; the intervention under investigation was a complex community intervention, that is, interventions with multiple components, multiple groups or organizational levels involved, flexible or tailored interventions (Craig et al., 2008); outcomes assessed included cardiovascular risk factors such as blood pressure, physical activity, diet, BMI/weight, vegetables and fruit intake, salt intake, smoking, or measures of cardiovascular morbidity or mortality; study was a randomized-controlled trial (RCT). Initial identification of qualified studies based on the titles and abstract was done by one reviewer. The review flow diagram is shown in Figure 1.

Data abstraction

Two reviewers independently assessed the full papers as to relevance and quality and extracted data. A structured data collection form was developed and pilot tested to gather information regarding the relevance, quality, and reporting of fidelity/standardization strategies among included studies. Quality of included studies was assessed based on a 4-point adjectival scale assessing the use of randomization, concealment of allocation, blinding, accounting for losses to follow up, possibility confounding bias and co-intervention. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system (Schünemann et al., 2008; Guyatt et al., 2008) was used to rate the overall methodologic quality. Factors that increase quality

based on GRADE are large magnitude of effect, control of all plausible confounders, and dose response gradient. Factors that decrease quality based on GRADE are high likelihood of bias, inconsistency of results, indirectness of evidence, imprecision of results, high probability of publication bias. The tool was assessed by both reviewers and modified based on consensus.

Discrepancies in the reviewers' assessment of the full papers were resolved by consensus. Weighted Kappa was computed to measure for agreement in assessment of relevance (include, uncertain, not include), and assessment of overall quality based on GRADE (very low, low, moderate, high).

Fidelity reporting assessments were based on previous literature regarding implementation fidelity (Carroll et al., 2007; Breitstein et al., 2010; Dane and Schneider, 1998; Dumas et al., 2009). Assessments were made about whether the studies described attempts to standardize the intervention (strategies to assure essential elements were delivered, use of implementation guide/manuals for delivering and tailoring the intervention), strategies used to monitor the implementation of the intervention (e.g. presence of a supervisor or external evaluator, use of questionnaires/checklists for self-reports), and attempts to assess deviation in the implementation of the intervention from the original plan (e.g. description of problems related to fidelity and how these affected the outcome, subgroup analysis among groups receive more or less standardized interventions). The studies included were also assessed whether they stated if they were

more pragmatic or explanatory since trials which are more pragmatic are expected to be less standardized than those that are explanatory.

A survey of study authors was also carried out to supplement data obtained through structured article review and to compare results available from structured published paper review and authors' responding to the survey. An electronic survey was sent to all of the corresponding authors of included studies in the current review to request further information regarding what methods were put in place to implement the strategies to assure fidelity of the intervention.

Analysis/synthesis

The characteristics of included studies are reported using frequency counts. The analysis of included and reviewed study findings are reported qualitatively. Weighted Kappas were computed for agreement for assessment of relevance and quality. Information obtained from the review was cross-tabulated against the results of the authors' survey.

RESULTS

The search yielded 342 potentially relevant articles for consideration. After a review of titles and abstracts, 28 studies were included for full text review, and 10 studies were included in the final list of studies. Table 1 shows a summary description of these studies.

Based on information from the structured review of published articles, all included studies were investigating multicomponent interventions, seven were implemented by two or more groups of implementers, and five described some flexibility in the delivery of the intervention tailored to the implementation site or recipients. All interventions had two or more of these characteristics of a complex intervention.

Seven of the 10 studies were implemented for over a year. All the studies had usual care as a comparison but some included active controls or a set of interventions in a factorial design. Two of the studies indicated that they were pragmatic trials. Eight of the studies used intention-to-treat analysis possibly indicating that these trials may be more pragmatic. The interventions included a combination of different strategies, most of which involved education, screening/monitoring, counselling/cognitive-behavioural strategies and medication management. All studies involved clinicians (physician, nurse, pharmacist, etc.) as one of the implementers. Three studies involved self-management while 1 included volunteers as implementers. One of the studies involved multiple organizations in the implementation of the interventions. One study concentrated on females while the rest targeted both genders. Two studies indicated the use of a theoretical framework; however this was clearly described in only one of the studies. The most common cardiovascular (CVD) related outcomes assessed were blood pressure and physical activity status. Some of the included studies focused more on clinical outcomes

such as morbidity and hospitalization with varying success in causing positive changes in these outcomes.

The estimated weighted Kappa for assessment of relevance was 1 while it was 0.28 for assessment of quality. Most of the disagreement on the grading of quality was between the moderate and low quality classification. Five of the studies were considered to be of high quality, two were moderate and three were low quality.

Table 2 provides descriptions of the interventions in the included studies, how the researchers verified and promoted fidelity based on their descriptions in the study and the CVD related outcome indicators. Based on the published articles, fidelity was verified by a combination of regular self-reports (submitted documents, face-to-face, or other forms of communication) by implementers, and supervision which was either regular, gradually tapered, or random. Most of the studies relied on self-reports rather than supervision/observation during implementation. In assuring standardized delivery of the intervention, training of implementers and use of implementation guide was most commonly described in the published articles (7 out of 10 studies). In two studies, the use of standardized algorithms was used for phone and web-based interventions. In some of the studies, meetings between researchers and implementers were used to discuss issues regarding implementation of the interventions. There were variations however in the details presented in the published articles.

All the lead authors of the 10 studies were contacted and all responded to the electronic survey. The results of the literature overview were compared with the survey (Table 3). In general, the literature review was consistent with the survey results. For example, eight authors responding to the survey (five provided a clear description) of the studies described standardization methods based on the review while nine authors indicated that standardization strategies were fully implemented. However there were also clear disparities. For example, four authors stated that implementation guides for tailoring the intervention were used but the reviewers did not find descriptions of how the interventions were tailored within the published paper, nor were there descriptions of any guide unless it was assumed to be in the implementation guide. Another contrast observed was the fact that one study reported a subgroup analysis between groups which received a more standardized versus less standardized intervention while 4 authors stated that this was fully implemented.

In addition to the results seen in the Table 3, the review identified that 6 of the studies discussed concerns about fidelity/standardization though two clearly articulated this. None of the included studies described lack of monitoring of the intervention and control of its implementation as a limitation. Two studies described problems related to fidelity during the implementation of the intervention but only 1 described how this deviation could have affected the outcome. Most of these reports related to fidelity were found in the methods section and few in the results and discussion.

The authors' survey also disclosed that 8 of the 10 studies were intended to be more pragmatic than explanatory though only 2 clearly indicated this in the published articles. Only 1 author stated that there may have been problems related to implementation fidelity during the course of the study and none stated that this issue could have affected their study results.

DISCUSSION

The results of this study showed that promotion of implementation fidelity in recent studies regarding community cardiovascular health promotion and prevention programs was better than expected. Documentation of strategies to promote intervention fidelity was described in 8 of the 10 included studies. Given the heterogeneity of the interventions studied, a variety of strategies to promote fidelity was seen including the use of computer assisted algorithms for the phone and web-based interventions. Implementation guides were also described by most of the studies though not all were freely accessible. Guides for tailoring of the study intervention or a description of how some of the interventions were to be tailored to the site or patient were not clearly presented. This may be available in the full implementation guide but was not indicated in the published articles. This is important since tailoring of interventions may undermine implementation fidelity and this has implications in the way the results should be interpreted.

Six articles presented methods of verifying implementation fidelity. Although 9 of the authors stated they did this in the survey, the fact that this wasn't documented in the published articles may cause some doubts among readers as to the possibility of a Type III error (Dusenbury et al., 2003). This may again be linked to poor adoption of positive findings as Glasziou et al. (2008) suggested. Most studies relied on self-report which is time and cost efficient. However, validity using self-reports are unknown and prone to social desirability bias (Breitenstein et al., 2010). Some studies used actual observations. Video and audio recording were not used in any of the studies (Breitenstein et al., 2010).

Given that the interventions under study were complex interventions, it was notable that the different essential elements of the interventions were clearly described by eight of the studies and the two remaining provided some descriptions of the components. However only 1 of the studies described a clear conceptual/theoretical framework on how these components interact to bring about the effect. Most of the studies described packaged interventions and therefore the adoption of the entire intervention is needed for the expected effect to take place. Increasing the effectiveness of the interventions would therefore require improving all its components. The presence of a theoretical framework could offer more approaches of improving the interventions and theoretical interactions of the elements could be investigated further.

In his conceptual framework for measuring fidelity, Carroll et al. (2007) described that measurement of fidelity involved assessment and descriptions of adherence to an

intervention (content, coverage, frequency, duration) and potential moderators (quality of delivery, participant responsiveness, intervention complexity, facilitation strategies). In the studies included, both descriptions of adherence and potential moderators were seen at varying degrees. However, the dose-response relationship of intervention and outcome, which is included under adherence, was not seen in most of the studies. Assessment of dose-response relationship can be prospective when researchers control for the duration or intensity of intervention across different participant groupings, or retrospective through subgroup analysis comparing participants who received more or less standardized intervention. Five authors stated that they did a subgroup analysis but only one presented this in the published article. In addition, descriptions regarding quality of delivery was mostly methodological, i.e., how the delivery of the intervention was verified. Only 2 studies provided this description in the results and discussion of the actual quality of delivery.

Based on the results of both the review and authors' survey, it is clear that implementation fidelity was considered important by the investigators studying the community cardiovascular health promotion and prevention programs selected for review. The findings are more encouraging than originally expected since most prior reviews suggested that documentation of strategies to verify and promote intervention fidelity were uncommon (Dane and Schneider, 1998; Perepletchicova et al., 2007). Given that these studies were RCTs, authors may have been more meticulous to assure that the

interventions were properly carried out. Strategies to assure fidelity and documentation can be improved based on the findings from this study.

There was however a gap between what was published in the literature and what was reported by authors of the studies. The authors reported a more rigorous process in verifying and promoting fidelity of intervention in the survey than what was found in the published article. If what the authors reported were more accurate than what was presented in the articles, this shows some problems in reporting which can be improved in adherence to the CONSORT statement for reporting Non-pharmacologic interventions (Bourton et al., 2008).

This study had some limitations. Due to resource limitations, we only included studies which were published in English. The results of this study therefore cannot be generalizable to those published in other languages. There were only 10 studies which met our criteria during our study period. This study should be repeated later to determine whether monitoring and reporting of implementation fidelity will further improve or decline.

CONCLUSION

In this review we found that recent published RCTs which investigated complex community CVD interventions reported a variety of strategies to verify and promote implementation fidelity in contrast to past reviews. The common strategies to verify

fidelity was based on self-report. Reporting of actual quality of delivery, based on results verifying the fidelity, was however lacking. For promoting fidelity, common strategies reported were training of implementers, use of implementation guides and algorithms.

There were some gaps in reporting implementation fidelity in the published articles when compared to what the authors reported in the survey. We therefore recommend further strengthening of fidelity reports by presenting more detailed information strategies to verify and promote fidelity in published articles.

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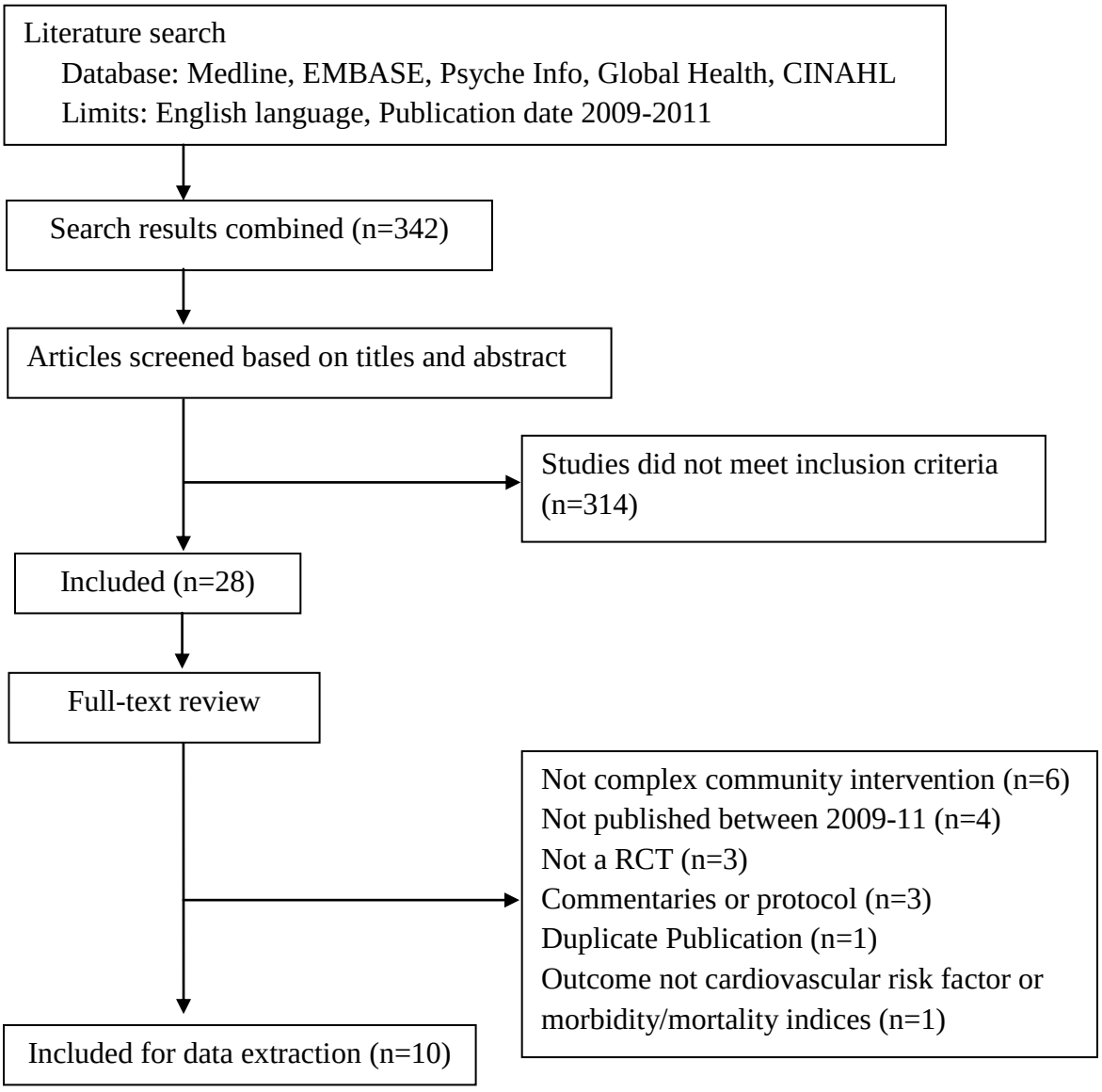

Figure 1: Review Process

Table 1: Summary description of included studies based on the review of published article

Study Description	Frequency n=10
Type of complex intervention	
• 2 or more intervention strategies	10
• 2 or more groups/levels of implementers	7
• Flexible/tailored intervention	5
Comparison Group	
• Usual Care	7
• Active Comparison	0
• Usual Care and Active Comparison	3
Purpose of the study	
• Pragmatic	2
• Explanatory	0
• Not indicated	8
Type of Analysis	
• Intention-to-treat	8
• Per protocol	2
Intervention	
• Health Education	9
• Counselling/Cognitive Behavioural strategies	6 8
• Screening/Monitoring	3
• Exercise Program	6
• Medication	1
• Physician Education	2
• Tailored patient management	
Implementers	
• Participants (self-management)	3
• Clinicians	10
• Community volunteers	1

Table 2: Study intervention and methods of how intervention fidelity was verified and promoted based on the published article

Study	Intervention	How Fidelity was verified	How Fidelity was promoted	CV indices and risk related outcomes
Kaczarowski 2010	Regular BP and CV risk factor assessment sessions with education regarding CV risk factors and available community resources offered to older adults. Sessions are held in local pharmacies, managed by local lead organizations and peer volunteers. Risk factor information are sent to participants' primary physician.	Regular reporting of operational activities, supervision by researchers during initial implementation	Training of implementers, Teleconference between implementers and the central team, use of an implementation guide	*CV morbidity, hospitalization rate †Medication use
Svetky 2009	Physician intervention: internet-based training, self-monitoring, and quarterly feedback reports. Patient Intervention: 20 weekly group sessions followed by 12 monthly telephone counselling contacts and focused on weight loss, Dietary Approaches to Stop Hypertension dietary pattern, exercise, and reduced sodium intake.	Quarterly submission of self-reports by physicians	Training of implementers, Standardized algorithm, strict guidelines to follow	*BP, weight, vegetable and fruit intake †Physical activity, salt intake, medication use
Folta 2009	24 sessions involving physical activity component (moderate-vigorous aerobic exercises) and dietary component (didactic and hands-on training) combined with behavioural strategies (self-monitoring, goal setting).	Spot checking of implementation, process evaluation (attendance, participation, etc.)	Training of implementers, use of an implementation guide	*Physical activity, weight, BMI †Vegetable & fruit intake, waist circumference, diet

Von Korff 2011	Combined self-management support, monitoring of indicators of disease control, and drugs to control depression, hyperglycaemia, hypertension, and hyperlipidaemia.	Nurse met weekly with other HCP/researchers to review new cases and progress of patients	Nurse (implementer) met weekly with other HCP/researchers to review new cases and progress of patients, use of an implementation guide	*BP † LDL, ADL
Rinfert 2009	Intervention participants received a BP monitor and access to an information technology–supported adherence and BP monitoring system providing nurses, pharmacists, and physicians with monthly reports.	Electronic collection of self-reported data by participants	Computer Generated Algorithm	*BP †Medication adherence
Bosworth 2009	Behavioural intervention (bimonthly tailored, nurse-administered telephone intervention targeting hypertension-related behaviours), home BP monitoring 3 times weekly, or the Behavioural intervention plus home BP monitoring	Patient self-reports	Use of an implementation guide	*BP †Physical activity
Jafar 2009	Patient Intervention: Family-based home health education (HHE) from lay health workers every 3 months. Physician Intervention: Annual training regarding hypertension management.		Training of Home Health Educators	*Body Mass Index †BP, physcial activity, smoking, medication use

Ferrante 2010	Education booklet with telephone interventions by specialized nurses to improve diet and treatment compliance, to promote exercise, to regularly monitor symptoms, weight, and to promote early visits if signs of clinical deterioration were detected.		Use of an implementation guide, computer software with specified algorithm	*Physical activity, CV morbidity, hospitalization Rate †BP, function, compliance
Hogg 2009	Home-based multidisciplinary team management involving a nurse practitioner, a pharmacist, and a general practitioner working collaboratively within a family practice and focusing on providing care to at-risk community-dwelling patients			†BP, hospitalization rate, quality of care
Hotu 2010	Monthly visits by community-based culturally appropriate Health Care Assistants who monitors BP, medication compliance, and reports back to the nurse and physician regarding problems related to BP, compliance and clinical events.			*BP †Echocardiogram, number of medications

Note: Outcomes presented in the tables are those related to cardiovascular risk factors. These studies have other outcomes not presented here.

CV= Cardiovascular; BP= Blood pressure; *Positive outcomes; †No significant findings

Table 3: Implementation fidelity based on results of the review and survey with authors

Elements of Fidelity	Review Results* (n=10)		Author survey† (n=10)		
	Clearly Described	Somewhat Described	Fully Implemented	Partially Implemented	Not implemented
Standardization of the intervention across implementers/sites	5	3	9	0	1
Strategies to assure delivery of essential elements of intervention	5	2	9	1	0
Use of a manual or implementation guide	6	0	7	1	2
Tailoring of intervention	3	1	3	2	4
Use of a guide for tailoring of intervention	0	0	4	2	2
Supervised/monitored the implementation of the intervention	6	0	8	1	0
External evaluator supervising the implementation	6	0	4	4	0
Tools (questionnaire/ checklist) for monitoring	3	0	--	--	--
Subgroup analysis among participants who received more vs. less standardized intervention	1	0	4	1	4

*A third category is “Not described” which is not included in the table.

† A third category is “Not applicable” which is not included in the table.

Box 1: Search Strategy

1. exp cardiovascular disease/ or cardiovascular.mp. or exp cardiovascular risk/
2. exp community/ or exp health program/ or exp community care/ or community-based.mp.
3. health promotion.mp. or exp health promotion/
4. 1 and 2
5. 2 and 3
6. 1 and 3
7. 1 and 2 and 3
8. limit 7 to english language
9. limit 7 to human
10. limit 7 to full text

Individual, Partnership, and Community factors associated with change in cardiovascular risk factors and use of health-related resources in communities implementing the Cardiovascular Health Awareness Program (CHAP)

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ABSTRACT

The Cardiovascular Health Awareness Program (CHAP) is a standardised blood pressure and risk factor assessment and educational sessions held in pharmacies or other locally accessible areas in the communities. CHAP has been implemented and tested in 20 small to mid-sized communities across Ontario, Canada. CHAP relies on local community partnerships to implement the program. This study explores the association of individual, partnership, and community-related factors on the use of health related community resources and cardiovascular risk behaviours of community residents participating in CHAP. This study is a cross-sectional analysis of an on-going cohort study. Participants of CHAP sessions from 8 Ontario communities currently implementing CHAP were recruited to participate in a telephone survey. The primary outcomes were composite scores of participants' use of health-related community resources and change in cardiovascular risk factors. Independent variables included age, gender, self-efficacy, and number of CHAP sessions attended for individual level variables; the Partnership Self-Assessment Tool (PSAT) and Coalition Effectiveness Inventory (CEI) for partnership level variables; and Rurality Index of Ontario score, proportion of pharmacies and family physicians involved with CHAP, and type of CHAP community (original or expansion community) for community level variables. Data analysis included assessment of intracluster correlation using Generalized Estimating Equations, and regression modelling with collinearity assessment. The results showed that age and self-efficacy were negatively correlated with the composite score for use of community resources while proportion of pharmacies was positive correlation with it.

Age and the synergy domain of PSAT were negatively correlated with the composite score for change in cardiovascular risk factors. Methodological and analytical challenges were also presented. Overall, this study showed that individual factors, specifically age and self-efficacy, had the most consistent association with the outcomes. Future repeated measurements in this on-going cohort may provide more inference regarding partnership strength and the outcomes.

INTRODUCTION

The Cardiovascular Health Awareness Program (CHAP) is a standardised program which has been implemented and tested in 20 small to mid-sized communities across Ontario, Canada (Kaczorowski et al., 2008, 2011). The CHAP was developed and refined through several pilot studies, scientific trials and community-wide demonstration projects (Chambers et al., 2005; Karwalajtys et al., 2005; Pora, Farrell, Dolovich, Kaczorowski, & Chambers, 2005). The program consists of 3 hour weekday blood pressure and cardiovascular risk factor assessment and educational sessions held in pharmacies or other locally accessible areas in the communities. These sessions are organized by local agencies (Local Lead Organizations or LLO) and staffed by trained volunteer peer health educators. The volunteers help participants measure their blood pressure, using a validated automated blood pressure device (BpTRU), assess their cardiovascular risk factors. Information gathered at the CHAP sessions are recorded and, with participants' consent, shared with participants themselves and sent to their family physician and regular pharmacist. CHAP volunteers provide participants with personalized risk profiles, risk specific educational materials, and information about availability and access to local community resources around modifiable risk factors. A community health nurse is on standby to ensure immediate follow-up of participants identified as being at high risk on the basis of their systolic blood pressure, and an on-site pharmacist is available for drug related consultations (Kaczorowski et al., 2011).

In a 39 community cluster-randomized trial, communities implementing CHAP showed a 9% relative reduction in the composite end point (rate ratio 0.91,95% confidence interval 0.86 to 0.97; P=0.002) or 3.02 fewer annual hospital admissions for cardiovascular events per 1000 people aged 65 and over (Kaczorowski et al., 2011). There were also statistically significant reductions in hospital admissions for acute myocardial infarction (rate ratio 0.87, 0.79 to 0.97; P=0.008) and congestive heart failure (0.90, 0.81 to 0.99; P=0.029).

One of the reasons why CHAP was developed and implemented is the belief that community empowerment and participation, linked with primary care providers and other community organisations and agencies, and resource mobilisation, can lead to improvement in health outcomes for residents at the population level (Kaczorowski et al., 2008; Laverack, 2006; Butterfoss, Goodman, & Wandersman, 1993; Roussos & Fawcett, 2000). This belief lead to development of partnerships and coalitions within the communities implementing CHAP. At the end of the CHAP project funding in 2010, some of the communities involved in the CHAP program continued implementing the program through the initiative of the local lead organization and the partnerships developed.

To continue monitoring the effects of CHAP in the community and to explore the role of community engagement on the effectiveness of CHAP, funding was obtained from the Canadian Institutes of Health Research. The CHAP Community Coalitions

Engagement and Cardiovascular health (CHAP-CCEC) project aimed to assess the effectiveness of coalitions and partnerships in communities implementing CHAP on policies, programs, and practices implemented by partner organizations in the community as well as to assess the overall effect of CHAP on participants' use of health-related resources and their cardiovascular health (McDonough et al., 2012). The theories of collaboration underlying this evaluation were derived from the partnership synergy (Lasker & Weiss, 2003; Lasker, Weiss, & Miller, 2001) and stages of coalition development (Butterfoss, Lachance, & Orians, 2006; Butterfoss et al., 2006) frameworks.

The power to combine the perspectives, resources, and skills of a group of people and organizations, or synergy, has been hypothesized as a key mechanism which determines the success of partnerships (Lasker et al., 2001). Partnership synergy leads to collaborative actions and activities accomplishing more than any of its individual participants thus becoming a whole that is greater than the sum of its parts (Lasker et al., 2003). On the other hand, the stages of coalition development state that coalitions go through cycles of *formation, implementation, maintenance, and institutionalization* and that at each stage, specific interventions need to be in place in order to improve the coalition (Butterfoss et al., 2006). Coalitions in more advanced stages are expected to perform better. The Partnership Self-Assessment Tool (PSAT, 2012) and the Coalition Effectiveness Inventory (Butterfoss et al., 2006) were adapted and used to assess the partnership synergy and stages of coalition development, respectively.

Based on the literature search we found few empirical studies which assessed the association of partnerships and coalitions on community outcomes (Butterfoss et al., 1993; Kreuter, 2000; Provan, Nakama, Veazie, Teufel-Shone, & Huddleston, 2003; Clark et al., 2006), but none which assessed its association with individual level outcomes. The current study explores the association of individual, partnership, and community related factors on the use of health related community resources and cardiovascular risk behaviours of community residents participating in CHAP. This study also assesses methodological and analytical considerations in associating factors at multiple levels with the individual level outcomes. We hypothesized that the strength of community partnerships is associated with health care outcomes at the individual and community level. This is an initial report of the on-going CHAP-CCEC project.

METHODS

Study design

This is a cross-sectional analysis of an on-going prospective cohort. A survey was administered to community dwelling residents who attended CHAP, and representatives of local lead organizations and partner institutions involved in running the CHAP sessions in the communities.

Population

Community dwelling residents who attended CHAP sessions were recruited to participate in a telephone survey. Peer volunteers assisting in the CHAP sessions

gathered consent forms and contact information residents who were willing to participate in the survey.

The local lead organizations (LLO) from each of the 8 communities implementing CHAP were asked to identify 2 representatives from their organization to complete self-administered partnership surveys. They were also asked to identify and list community organizations that were considered as partners in delivering CHAP in the community. These partner organizations were asked to identify a representative to complete self-administered survey for partner organizations.

Primary outcomes

The two main outcomes were self-reported use of health-related community resources (health care, social support, physical activity, education, food & nutrition) and change in cardiovascular risk factors (fatty food, fruit & vegetable intake, salt use, stress, physical activity, weight, blood pressure) since the participants started attending the CHAP sessions. These outcomes were based on information gathered during the phone interviews with participants. The participants were asked to report whether there was an increase, no change or decrease in each of the activities since they last attended a CHAP session. These responses were subsequently dichotomized. For use of health-related community resources, "increased" use was considered a positive outcome (improved), while "no change" and "decreased" were considered negative outcomes (no improvement). This was operationalized differently for change in cardiovascular risk

factor. For fruit & vegetable intake and physical activity, “increased” was considered a positive outcome; for fatty food, salt use, stress, weight, and blood pressure, “decreased” was considered the positive outcome.

A composite score was developed for use of health-related community resources and for change in cardiovascular risk factors. This was done to increase the statistical power to detect associations with the independent variables (Sampson, Metcalfe, Pfeffer, Solomon, & Zou, 2010; Ferreira-Gonzalez et al., 2007). Each positive outcome was given 1 point and a negative outcome was scored as 0. For use of health-related community resources, each participant could get a score of 0 to 5 depending on the number of resources they reported an increase in use. For the cardiovascular risk factors, the score ranged from 0 to 7 depending on the number of risk factors improved.

Community level outcomes were the number of programs, policies and practices implemented in the communities related to cardiovascular health. This was based on reviews of documents submitted by the LLO regarding cardiovascular health-related programs and policies implemented by their organizations and partners. Reviews of public documents were also done by research assistants.

Independent Variables

The independent variables were divided into three levels: individual, partnership, and community variables. Individual variables included demographic variables (age and

gender), number of CHAP sessions the participant attended in the last 6 months, and a 10-point scale measuring the participants' self-efficacy to perform activities to manage their blood pressure.

We used the Partnership Self-Assessment Tool (PSAT) and Coalition Effectiveness Inventory (CEI) to discriminate between CHAP communities with strong and weak partnerships. The PSAT measures partnership strength in terms of 6 domains: s*ynergy, leadership effectiveness, efficiency, administration and management, use of financial and other capital resources, and use of non-financial resources* (PSAT, 2012). Each domain has a set of questions, each scored from 1 to 5, and the average score across all the questions serves as the score for the domain. There is no overall PSAT score but the synergy is considered most important among the domains assessed (Weiss, Anderson, & Lasker, 2002; Lasker et al., 2003). The average PSAT scores for each domain from the representatives of the LLO and the partners were considered as the score for each community.

The CEI has subdomains based on the stages of coalition development: *formation, implementation, maintenance, and institutionalization.* Each subdomain has a set of questions which assesses whether a characteristic of each stage is fully present (2-points), present but limited (1-point), or not at all present (0-points). The number of questions varies by domain (4-formation, 4-implementation, 7-maintainance, 6-institutionalization)

and a coalition can receive a maximum score of 42 (Butterfoss et al., 2006). The scores of 2 representatives of the LLO were averaged to obtain the CEI of each community.

The community-related variables included the Rurality Index of Ontario (RIO) score, the proportion of pharmacies and family physicians involved, and the type of CHAP community (whether the community was part of the original CHAP trial or a community which adopted CHAP after the trial). The RIO score is an indicator used by the government of Ontario to rate a community's rurality based on travel time to an advanced referral centre, travel time to a basic referral centre, and population (count and density) (Kralj, 2008). Higher scores indicate that the community is more rural. The number of community pharmacies and family physicians' involvement was part of the CHAP program. The proportion of involvement (number involved with CHAP over total number existing in the community) of pharmacies and family physicians was computed based on reports by local lead organization. Three of the 8 communities in this study started implementing CHAP in 2006 while the others started in 2008 when the second wave of funding was available to expand CHAP to other communities. This was therefore considered as a factor since some of the initial communities may be more advanced than others in terms of implementing CHAP.

Data gathering procedures

Participant Survey

The lists of CHAP participants who consented to participate were obtained from the local lead organizations. These surveys were conducted through computer assisted telephone interviews. Trained research assistants conducted the interviews. Fifty participants were recruited consecutively from each of the large communities and 30 from smaller communities. The sample size was computed based on an alpha, beta, and effect size of 0.05, 0.20, and 30% or more (participants were going to report a change in their health behavior due to CHAP), respectively.

Partnership Survey

Partnership survey forms were sent to CHAP LLO for their 2 representatives to complete. The partnership surveys to the LLO included the CEI and PSAT. The community partner agencies identified by the LLO were also sent partnership survey forms to complete which contained the PSAT only. Responses to the surveys were collected through a combination of an electronic survey and computer-assisted telephone interviews. The LLO and partner agencies were sent emails with a link to the electronic survey form where they could enter their responses. For those who did not do this, trained research assistants contacted them to go through the forms and collect their responses to the questions using the electronic survey.

Document Review

The LLO and partners were requested to submit documents of programs and policies they were implementing regarding cardiovascular health. Research assistants also reviewed public documents and websites of the LLO and partners to gather this information. All programs and policies identified were assessed as to stage of development. The individual programs were scored using an adjectival scale as to whether they were (1) at the community needs assessment level, (2) currently under programming or being modified, (3) currently being developed with community participation or undergoing pilot testing, (4) being delivered to the community, or (5) undergoing impact/process evaluation. The individual policies were scored as to whether they were at the level of (1) agenda setting, (2) policy formulation, (3) initial adoption, (4) implementation of less than 1 year, (5) implementation of over 1 year, or (6) impact evaluation.

Data analysis

The community level outcomes were presented using descriptive statistics. The main goal in analysing the data was to determine if there was an association between individual, partnership, and community factors with composites of increased use of health-related resources and positive change in risk factors. Several steps were taken to process and analyse the data (Figure 1).

Assessing the effect of clustering

Since the participants came from 8 communities, making sure that factors related to potential clustering effect were taken into account. Generalized Estimating Equations (GEE) using exchangeable error structure correlating the individual factors to the composite outcomes was done with community as a clustering/panel variable (Hanley, 2003; Ziegler, 2010; Hardin & Hilbe, 2003). An Intracluster Correlation (ICC) of <18.75% for the 8 clusters, which was equivalent to a variance inflation factor (VIF) of less than 2.5 (Allison, 1999; Meloun, Militký, Hill, & Brereton, 2002; Fox, 1991), was considered acceptable. This meant that analysis ignoring the effect of clustering in the regression analysis could be conducted.

Multicollinearity Assessment

Since there were several independent variables assessed at different levels, assessment of multicollinearity was done to reduce the number of variables while testing the main hypothesis, i.e. whether strength of the partnership was associated with the composite outcomes. Multicollinearity was initially assessed by factor level (individual, partnership, community). A VIF of less than 2.5 was set as the cut-off (Allison, 1999; Meloun, Militký, Hill, & Brereton, 2002 2002; Fox, 1991) to select the variables from different levels into regression model. Assessment of multicollinearity was repeated in this regression model using the same VIF criteria to come up with the set of independent variables for the final regression model. Linear regression (complete case analysis) was

subsequently done to assess which of the independent variables were associated with the composite outcomes.

Sensitivity analysis assessing the impact of missing data and the use of a binary composite

Since the proportion of missing data for increased use of community resources and positive change in risk factors were 6.6% and 12.1% respectively, multiple-imputation was done to assess the impact of missing data in the analysis. The individual level factors and outcomes used in computing the composite were used as predictors of the composite outcomes.

To evaluate the outcomes differently, the composite scores were converted to binary composites (Quan, Zhang, Zhang, & Devlamynck, 2007; Ferreira-Gonzalez et al., 2007). A composite score of one or more was considered a positive outcome and a zero a negative outcome. The results of multiple imputation and analysis using a binary composite were compared to the complete case analysis.

Assessing the correlation of the independent variables and individual behaviour outcomes

The last analysis presented was assessed which independent variables were associated with the individual behaviour outcomes. Using the final regression model, logistic regression was used to determine which of the variables were associated with

increased use of each of the resources (health care, social support, physical activity, education, food & nutrition) and positive change in each of the cardiovascular risk factors (fatty food intake, fruit & vegetable intake, salt use, physical activity, weight, blood pressure).

RESULTS

Descriptive Analysis

A total of 366 participants were interviewed from 8 communities. The community profile and community level outcomes included in the study are presented in table 1. The community characteristics varied widely. Some communities were quite large (population >30,000) while others were small (<5,000). The RIO score ranged from 11 to 80 (mean of 40.5). The proportion of family physicians and pharmacies involved ranged from 0 to100% (mean of 41.2% and 46.7%, respectively). The smaller communities had fewer physicians and pharmacies and had a higher proportion of involvement compared to the larger communities. The number of programs and policies varied considerably.

Assessment of partnership strength varied depending on the measures used. The overall CEI ranged from 6.0 to 36.2 (mean=25.6). The mean CEI formation, implementation, and maintenance scores were high while the mean institutionalization score was low. The scores for the domains were highly correlated ($r \geq 0.7$) with each other. Only the overall CEI score was used for further analysis (Table 2).

The PSAT scores varied by domains and were less correlated with each other (Table 2). The mean score for synergy was 3.4 (SD=0.2). The domains with the highest mean score were efficiency, use of non-financial resources, and use of financial and other capital resources. The domain with the lowest mean score was that of administration and management.

There were between 26 to 73 participants recruited from each community. The mean age of the participants was 71.6 (Table 2). A majority of the participants were female (75.1%). The self-efficacy to engage in activities to lower blood pressure was high among the participants (mean=8.54).

Table 3 summarizes the outcomes in terms of proportion of positive change. For use of community resources, the highest reported positive change was in use of food and nutrition resources (22.1%) and use of physical activity resources (20.5%). For change in cardiovascular risk factors, the highest reported positive change was increased intake of fruits and vegetables (49.6%) followed by increased physical activity (23.9%) and decreased blood pressure level (23.1%). Few participants reported decreased stress (5.2%) compared to the other risk factors. There were varying levels of non-response and missing data among the reported outcomes. The mean composite score for increased use of community resources was 0.87 (SD=1.33) and 1.63 (SD=1.56) for improvement in risk factor.

Assessing the effect of clustering

The GEE analysis revealed that within community correlation was low for the model assessing the association of individual factors with each composite outcome (Table 4). For association of individual factors with composite of increased use of community resources, the ICC was 0.02. For the composite of positive change in cardiovascular risk factors, the ICC was 0.004. In both analyses, age and self-efficacy score were negatively correlated with the composite outcomes. This meant that age and self-efficacy were inversely related with the composite scores for both outcomes. Since the ICC for both outcomes was low, linear and logistic regression ignoring within community clustering was used in further data analysis.

Multicollinearity Assessment

Multicollinearity assessment for the individual factors (age, gender, number of CHAP sessions attended, self-efficacy score) indicated that collinearity was low. Linear regression was done to assess the association of these factors with the composite outcomes as well as investigate for interactions among them. In these analyses, only age and self-efficacy were associated ($p<0.05$) with the composite outcomes. None of the interaction terms were statistically significant. Age, self-efficacy, and number of CHAP sessions attended were included for further analysis, the latter being included since it was of theoretical interest.

For the partnership related variables, there was multicollinearity between the PSAT domains and the CEI. The analysis was therefore separated into 2 models, one including the PSAT domains and the other including the CEI, since we were interested in how both measures of partnership strength were associated with the outcomes. There was also multicollinearity among the PSAT domains. Synergy was prioritized over the other domains in variable selection (Weiss et al., 2002; Lasker et al., 2003). The other domains included together with synergy (VIF<2.5 in collinearity diagnostics) were efficiency and administration and management.

Among the community related variables, the proportion of family physicians involved, proportion of pharmacies involved, and the RIO score displayed multicollinearity. Excluding either proportion of family physicians involved or the proportion of pharmacies involved decreased the VIF to an acceptable level. Since both were considered equally important, these variables were alternately used in the analysis eventually excluding proportion of family physicians involved since this yielded less significant findings.

Combining all the factor levels into one model, RIO score was excluded since it displayed collinearity when used in combination with the partnership variables. The final models therefore included age, number of CHAP sessions attended, self-efficacy score, proportion of pharmacies involved, type of CHAP community, and the PSAT domains

(synergy, efficiency, administration and management) in one model and the CEI in another (Figure 1).

Association of individual, partnership, and community related variables with the composite outcomes

The results of regression analysis evaluating the association of individual, partnership and community related variables with the composite of increased use of community resources and positive change in risk factors are shown in Tables 5 and 6. Model 1 included the PSAT domains for the partnership variables while Model 2 included CEI.

The complete case analysis results in Table 5 show that age and self-efficacy were negatively correlated with increased use of health related community resources, while the proportion of pharmacies involved was positively correlated with it. This was true in both Models 1 and 2. None of the partnership related variables were significantly associated with composite score. The sensitivity analysis using multiple imputation revealed similar results except that PSAT-administration and management was negatively correlated with the composite outcome ($p=0.03$) in Model 1. Converting the composite to a binary outcome yielded the same result as the composite score in Model 1. In Model 2, proportion of pharmacies' variable did not reach a significant value.

Table 6 shows the association of the independent variables with the composite for positive change in cardiovascular risk factors. Age was negatively correlated with composite outcome in both models. The only other variable which was significant was PSAT-synergy which was negatively correlated with the outcome. The multiple-imputation results were similar to the complete case analysis. On the other hand, the analysis using the binary outcome showed that only PSAT-synergy was significant in Model 1 while only age was significant in Model 2.

Association of individual, partnership, and community related variables with the individual behaviour outcomes

Table 7 shows the independent variables included in the final model which were significantly associated with the different individual outcomes. For most of the outcomes, individual factors, specifically age and self-efficacy, were most frequently significant factors. The odds were lower as the age and self-efficacy increased.

Some measures of partnership strength were significantly associated with some of the outcomes. Higher values of PSAT-synergy and the CEI were associated with higher odds of participants reporting increased use of food and nutrition resources. Higher values of PSAT-efficiency also increased the odds of participants reporting decreased blood pressure. Higher PSAT-administration and management scores lowered the odds of reporting increased use of food and nutrition resources. Higher values of PSAT-synergy and the CEI also lowered the odds of reporting increased fruits and vegetable intake.

Both community-related variables were associated with some of the individual outcomes. The proportion of pharmacies involved was associated with higher odds of reporting increased use education resource, increased use of food and nutrition resource, and decreased fatty food intake. Participants who were from the original CHAP communities had higher odds of reporting decreased fatty food intake.

DISCUSSION

Among the different independent variables assessed, individual factors, specifically age and self-efficacy, had the strongest and most consistent association with the participants' health behaviours. Depending on the model, some partnership and community related variables were also found to be significantly correlated with the outcomes. However, the association of partnership variables with the outcomes did not show a consistent (positive or negative) correlation.

Age and self-efficacy were negatively correlated with the composite outcomes. The negative correlation between age and improved health behaviours may be due to the fact that older participants have a harder time adapting new behaviours because of physical limitations or negative views regarding their ability to change their behaviour (Pedersen, Rothenberg, & Maria, 2002; Zanjani & Vens, 2006). The observed negative correlation between self-efficacy and the outcomes (composite and certain individual outcomes) contradicts usual expectations that high self-efficacy leads to better health

behaviour and health outcomes (Grembowki et al., 1993; Strecher, De Vellis, Becker, & Rosenstock, 1986). It is possible that participants who reported higher self-efficacy felt that they needed to use community resources less frequently or that they have already used these resources prior to the survey and therefore reported no change in this behaviour.

The main focus of this exploratory study was to determine whether the strength of the partnership implementing CHAP was associated with positive outcomes. Associating community level variables with community level outcomes is usually the initial step in the process. Since only 8 communities implemented CHAP at the time of the study, there was not enough data and information to assess this association using statistical inferences. This study therefore theorized that community level factors, such as strength of partnership, which affected community level outcomes for CHAP would also affect individual outcomes such as health behaviour changes similar to theoretical assumptions of previous studies (Angeles, Guilkey, & Mroz, 2005; Blakely & Woodward, 2000). A stepwise analytical procedure was followed assuming this scenario.

The results showed inconsistent relationships between partnership indicators and the outcomes. For the composite outcomes, PSAT-synergy showed a significant negative correlation which was contrary to the hypothesized relationship. PSAT-synergy, PSAT-efficiency, and CEI were associated with higher odds of reporting positive changes in some of the individual outcomes (use of food and nutrition resources, decreased blood

pressure). At the same time PSAT-synergy, CEI, and PSAT-administration and management were associated with lower odds of reporting positive changes in other individual outcomes (increased fruits and vegetables intake, use of food and nutrition resources). The lack of consistency in the results may be due to a number of reasons, some of which are discussed below.

The findings may be due to design limitations. The use of self-reported measures for some independent variables and the dependent variables may have led to biased data. These biases associated with self-report (Streiner & Norman, 2008) may have led to the misleading findings in the analysis.

Another possible reason for the inconsistent findings may be due to small sample size. This study was only able to assess 8 communities with varying sizes and characteristics. The small number of communities assessed for partnership strength and community characteristics may have limited the statistical power to detect associations. Furthermore, the evaluation may have been done too early since partnerships are still developing in the sample.

The third possibility is that a correlation between partnership strength and individual outcomes may be weak or non-existent. The presence of the CHAP activities, which is visible to the population of interest, may be the driving force for participants to change health behaviours. The strength of the partnership may have less of a role in

promoting behaviour change but is more important for sustaining the program (Jagosh et al., 2012). The sustained program implementation may eventually have an effect on individual level outcomes and can be captured through repeated measurements.

A community related variable which can also be an indicator of the strength of partnership, the proportion of pharmacies involved, was positively associated with the composite score for increased use of health related community resources. It was also associated with higher odds of participants' reporting changes in some of the individual outcomes. This shows that involving more pharmacies in the communities where CHAP was implemented, which probably resulted in increased community awareness regarding the CHAP program, was an important indicator of positive behaviour change among participants.

Though partnerships and coalitions is a popular strategy to implement community-based health interventions, there have been few attempts to systematically correlate characteristics of the partnerships and their effects on the outcomes (Clark et al., 2006, Provan, et al., 2003, Roussos et al., 2000). The CHAP-CCEC study attempted to examine this relationship. This investigation was made possible because the existing partnerships have gathered enough synergy to sustain their goals even beyond the project period (Jagosh et al., 2012), which in itself was already a success. This was a unique opportunity which allowed us to conceptualize and apply methods to test theories regarding the CHAP community coalitions and partnerships.

The evidence in this on-going study however provides little evidence regarding the correlation of partnership strength and individual health behaviours. Jagosh et al. (2012) suggest that there is evidence that partnership synergy and outcomes build-up over time. Future repeated measurements in this study will provide additional information to make the research findings more conclusive. Furthermore, a more improved design should be implemented recognizing the limitations identified in this study.

CONCLUSIONS

Overall, this study showed that among the individual, partnership, and community factors hypothesized to affect use of community resources and cardiovascular risk behaviours of participants of CHAP, the individual factors, specifically age and self-efficacy, have been observed to have the most consistent association with the outcomes. Both age and self-efficacy were negatively correlated with the outcomes indicating participants who are older and have higher self-efficacy report less improvement in their use of health related resources and cardiovascular risk behaviours. The correlation between partnership strength and the outcomes were less consistent. The proportion of pharmacies involved with CHAP, which can also be an indicator of the extent of partnership, was positively correlated with increased use of health related community resources. Future measurements and repeated analysis may provide more evidence regarding the relationship of partnership strength and changes in individual health behaviour.

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Table 1: Profile of the 8 communities implementing CHAP

Community	Population	Rurality Index Score	CEI Score	PSAT Synergy Score	% Physician participating in CHAP	% Pharmacy participating in CHAP	Number of Programs	Mean (SD) Program Formation Score	Number of Policies & Practices	Mean (SD) Program Formation Score
1	54237	11	29.0	3.4	9.1	25.0	33	3.6 (1.0)	5	2.3 (1.1)
2	30461	23	36.0	3.7	81.5	100	3	4.3 (0.5)	7	4.9 (0.8)
3	15177	73	6.0	3.4	0	0	39	3.1 (1.5)	26	2.2 (1.4)
4	6617	35	34.5	3.7	0	33.3	2	4.0 (0.0)	2	4.5 (0.7)
5	5905	42	27.4	3.3	100	100	3	4.0 (0.0)	7	4.0 (1.0)
6	4022	43	36.2	3.3	12.5	0	2	4.3 (0.6)	2	5.0 (1.0)
7	3082	51	19.0	3.3	100	50.0	9	4.0 (0.0)	5	4.55 (0.5)
8	1803	38	26.5	3.4	100	100	2	4.0 (0.0)	0	--

CEI - Coalition Effectiveness Inventory; PSAT - Partnership Self-Assessment Tool

Table 2: Summary of independent variables

Variable Level	Variables	Descriptive summary
Individual (n=366)	Age in years – Mean (SD)	71.6 (14.1)
	Number of CHAP sessions attended in the recent 6 months (%) • 0-2 • 3-4 • ≥5	 43.1 21.1 35.8
	% Males	24.9
	Self-efficacy score – Mean (SD)	8.54 (1.6)
Partnership (n=8)	Coalition Effectiveness Inventory score – Mean (SD)	25.6 (10.9)
	PSAT-Synergy – Mean (SD)	3.4 (0.2)
	PSAT-Leadership Effectiveness – Mean (SD)	3.4 (0.3)
	PSAT-Efficiency – Mean (SD)	3.6 (0.3)
	PSAT-Administration and management – Mean (SD)	3.0 (0.4)
	PSAT-Non-financial resources – Mean (SD)	3.6 (0.2)
	PSAT-Financial and other capital resources – Mean (SD)	3.6 (0.3)
Community (n=8)	Proportion of Family Physicians involved – Mean (SD)	41.2 (44.3)
	Proportion of Pharmacies involved – Mean (SD)	46.7 (40.8)
	%Original CHAP community	37.5
	Rurality Index of Ontario (RIO) score – Mean (SD)	40.5 (22.9)

SD - Standard Deviation; PSAT-Partnership self-assessment test

Table 3: Frequency of outcomes

Outcome		n	Reported positive change Count (%)	95%CI* %
Use of health-related community resources	Health care resource	348	44 (12.6)	9.1-16.1
	Social service resource	352	59 (16.8)	12.8-20.6
	Physical activity resource	351	72 (20.5)	16.2-24.7
	Education resource	349	55 (15.8)	11.9-19.6
	Food and nutrition resource	349	81 (22.1)	18.7-27.6
Change in cardiovascular risk factors	Fatty food intake	352	70 (19.9)	15.6-24.07
	Salt use	353	63 (17.8)	13.8-21.8
	Stress	363	19 (5.2)	2.9-7.5
	Physical activity	351	84 (23.9)	19.4-28.4
	Fruits and vegetables intake	343	170 (49.6)	44.2-54.8
	Weight	356	72 (20.2)	16.0-24.4
	Blood Pressure	350	81 (23.1)	18.7-27.5

*CI - Confidence Intervals

Table 4: Generalized Estimating Equations (Error structure: Exchangeable) correlating individual level predictors to composite outcome with "community" as grouping variable

Outcome	Predictors (Units)	**Estimated β (95% CI)**	p-value	ICC
Increased use of health-related resources composite score (0-5 points)	Age (years)	*-0.01 (-0.02, -0.00)*	*<0.01*	0.020
	Gender (1 =Male, 2=Female)	0.09 (-0.23,0.41)	0.58	
	Number of CHAP sessions (#)	-0.02 (-0.06, 0.02)	0.34	
	Self-Efficacy (score of 1-10)	*-0.20 (-0.32, -0.08)*	*<0.01*	
Positive change in cardiovascular risk factors composite score (0-7 points)	Age (years)	*-0.02 (-0.03,-0.01)*	*<0.01*	0.004
	Gender (1 =Male, 2=Female)	-0.02 (-0.55, 0.51)	0.94	
	Number of CHAP sessions (#)	-0.03 (-0.08, 0.01)	0.18	
	Self-Efficacy (score of 1-10)	*-0.09 (-0.17,-0.00)*	*0.03*	

CI – Confidence Intervals; ICC – Intra Cluster Correlation

Figure 1: Modelling procedure - Correlating individual, partnership and community related variables to use of health-related community variables and change in cardiovascular risk factors

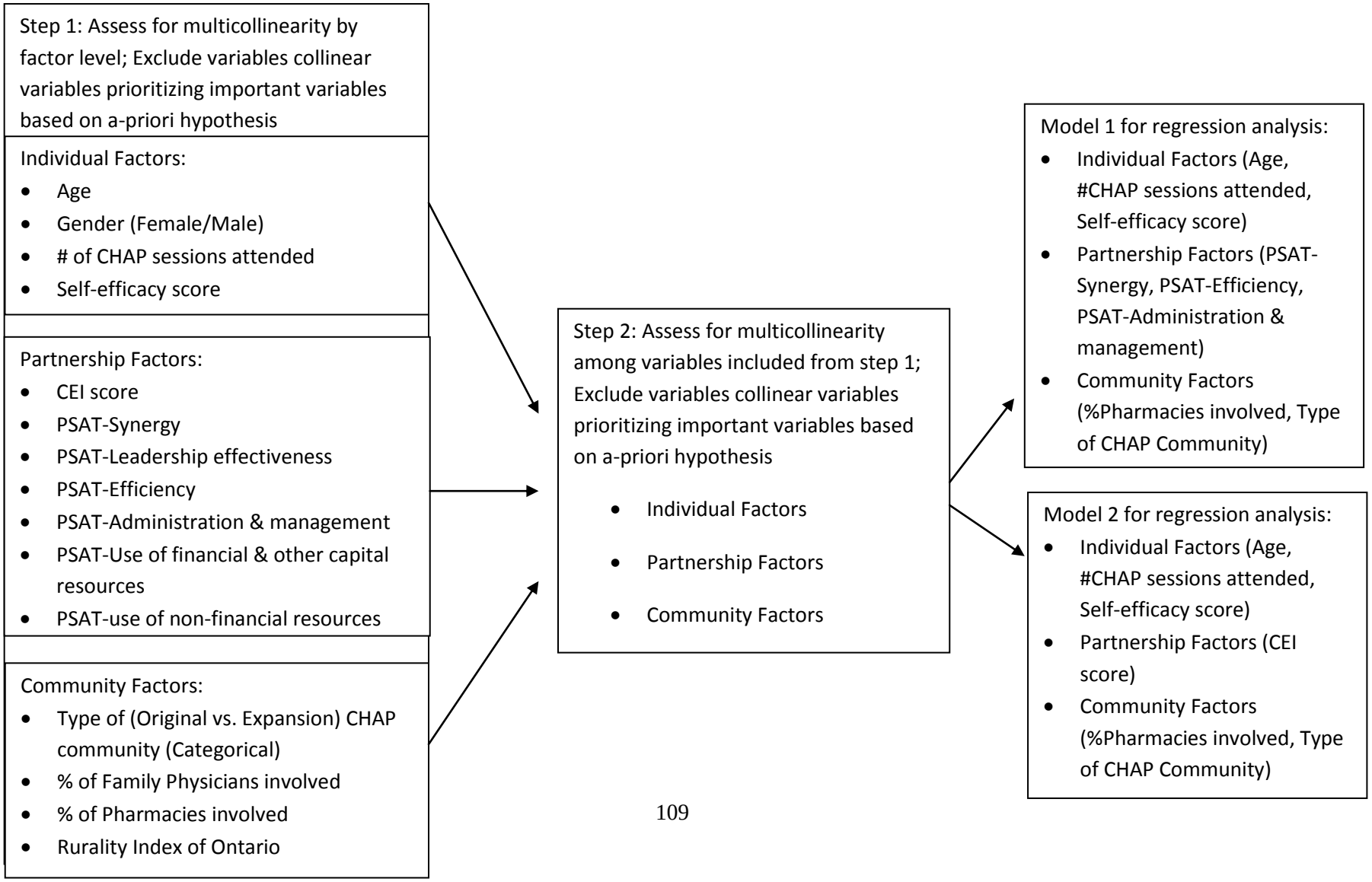

Table 5: Sensitivity analysis comparing the results of complete case analysis, multiple imputation, and using a binary outcome in correlating individual, partnership and community related variables with composite for increased use of community resources

Outcome (Analysis)	**Model 1**			**Model 2**		
	Factors	**Estimated *β* (95% CI)**	**p-value**	**Factors**	**Estimated *β* (95% CI)**	**p-value**
Use of health-related resources composite score (Complete Case)	Age*	*-0.19 (-0.30, -0.07)*	*<0.01*	Age*	*-0.19 (-30, -0.08)*	*<0.01*
	#CHAP sessions attended†	0.06 (-0.10, 0.23)	0.47	#CHAP sessions attended†	0.07 (-0.09, 0.24)	0.36
	Self-efficacy score	*-0.20 (-0.29, -0.11)*	*<0.01*	Self-efficacy score	*-0.20 (-0.29, -0.11)*	*<0.01*
	PSAT-Synergy	0.61 (-0.44, 1.67)	0.25	CEI Score	0.01 (-0.005, 0.02)	0.20
	PSAT-Efficiency	0.23 (-0.27, 0.76)	0.37	%Pharmacies involved	*0.004 (0.000, 0.008)*	*0.03*
	PSAT-Administration & management	-0.41 (-0.82, 0.00*)*	0.05	Original CHAP Community	0.26 (-0.03, 0.56)	0.07
	%Pharmacies involved	*0.005 (0.001, 0.008)*	*0.01*			
	Original CHAP Community	0.03 (-0.32, 0.40)	0.83			
Use of health-related resources composite score (Multiple Imputation-pooled results)	Age*	*-0.17 (-0.28, -0.05)*	*<0.01*	Age*	*-0.17 (-0.29, -0.06)*	*<0.01*
	#CHAP sessions attended†	-0.03 (-0.22, 0.16)	0.75	#CHAP sessions attended†	-0.01 (-0.20, 0.17)	0.85
	Self-efficacy score	*-0.18 (-0.27, -0.09)*	*<0.01*	Self-efficacy score	*-0.18 (-0.27, -0.09)*	*<0.01*
	PSAT-Synergy	0.72 (-0.31, 1.77)	0.17	CEI Score	0.001 (-0.005, 0.02)	0.16
	PSAT-Efficiency	0.26 (-0.25, 0.78)	0.32	%Pharmacies involved	*0.005 (0.001, 0.009)*	*0.01*
	PSAT-Administration & management	*-0.46 (-0.88, -0.03)*	*0.03*	Original CHAP Community	0.13 (-0.18, 0.44)	0.41
	%Pharmacies involved	*0.005 (0.002, 0.009)*	*<0.01*			
	Original CHAP Community	-0.11 (-0.49, 0.26)	0.55			
Use of health-related resources binary composite (Complete Case)	Age*	*-0.22 (-0.42, -0.02)*	*0.02*	Age*	*-0.21 (-0.41, -0.25)*	*0.02*
	#CHAP sessions attended†	0.009 (-0.28, 0.30)	0.95	#CHAP sessions attended†	0.04 (-0.25,0.33)	0.78
	Self-efficacy score	*-0.33 (-0.50, -0.17)*	*<0.01*	Self-efficacy score	*-0.32 (-0.48, -16)*	*<0.01*
	PSAT-Synergy	1.42 (-0.43, 3.28)	0.13	CEI Score	0.01 (-0.01, 0.03)	0.47
	PSAT-Efficiency	-0.08 (-1.09, 0.92)	0.86	%Pharmacies involved	0.006 (0.00, 0.01)	0.06
	PSAT-Administration & management	-0.66 (-1.38, 0.05)	0.06	Original CHAP Community	0.34 (-0.16, 0.85)	0.18
	%Pharmacies involved	*0.007 (0.000, 0.013)*	*0.04*			
	Original CHAP Community	0.08 (-0.57, 0.74)	0.79			

*Age: <40, 40-49, 50-59, 60-69, 70-79, 80-89, ≥90; †#CHAP sessions attended: <3, 3-4, ≥5

CI – Confidence Intervals; CEI - Coalition Effectiveness Inventory; PSAT – Partnership Self-Assessment Tool

Table 6: Sensitivity analysis comparing the results of complete case analysis, multiple imputation, and using a binary outcome in correlating individual, partnership and community related variables with composite for positive change in cardiovascular risk factors

Outcome (Analysis)	**Model 1**			**Model 2**		
	Factors	**Estimated *β* (95% CI)**	**p-value**	**Factors**	**Estimated *β* (95% CI)**	**p-value**
Change in Cardiovascular risk factors composite score (Complete Case)	Age*	*-0.25 (-0.38, -0.12)*	*<0.01*	Age*	*-0.28 (-0.41, -0.15)*	*<0.01*
	#CHAP sessions attended†	0.04 (-0.15, 0.23)	0.67	#CHAP sessions attended†	0.05 (-0.14, 0.25)	0.57
	Self-efficacy score	-0.08 (-0.19, 0.16)	0.09	Self-efficacy score	-0.09 (-0.19, 0.01)	0.08
	PSAT-Synergy	*-1.13 (-2.23, -0.003)*	*0.04*	CEI Score	-0.009 (-0.02, 0.009)	0.33
	PSAT-Efficiency	-0.32 (-1.04, 0.40)	0.38	%Pharmacies involved	-0.000 (-0.004,0.004)	0.97
	PSAT-Administration & management	0.22 (-0.39, 0.84)	0.47	Original CHAP Community	0.19 (-0.14, 0.54)	0.25
	%Pharmacies involved	0.000 (-0.004,0.005)	0.96			
	Original CHAP Community	0.415 (-0.005, 0.84)	0.05			
Change in Cardiovascular risk factors composite score (Multiple Imputation-pooled results)	Age*	*-0.23 (-0.36, -0.11)*	*<0.01*	Age*	*-0.26 (-0.39, -0.14)*	*<0.01*
	#CHAP sessions attended†	0.03 (-0.15, 0.23)	0.69	#CHAP sessions attended†	0.07 (0.12, 0.26)	0.46
	Self-efficacy score	-0.06 (-0.13,0.03)	0.17	Self-efficacy score	-0.07 (-0.16, 0.02)	0.16
	PSAT-Synergy	-1.15 (-2.28, -0.03)	0.04	CEI Score	-0.008 (-0.02, 0.009)	0.35
	PSAT-Efficiency	0.17 (-0.39, 0.74)	0.54	%Pharmacies involved	0.000 (-0.004, 0.005)	0.82
	PSAT-Administration & management	-0.19 (-0.66, 0.26)	0.40	Original CHAP Community	0.17 (-0.15, 0.49	0.30
	%Pharmacies involved	0.001 (-0.003, 0.005)	0.52			
	Original CHAP Community	0.20 (-0.19, 0.60)	0.30			
Change in Cardiovascular risk factors binary composite (Complete Case)	Age*	-0.20 (-0.42, 0.01)	0.07	Age*	*-0.23 (-0.45, -0.01)*	*0.03*
	#CHAP sessions attended†	0.25 (-0.06, 0.56)	0.11	#CHAP sessions attended†	0.25 (-0.06, 0.56)	0.11
	Self-efficacy score	0.05 (-0.10, 0.21)	0.49	Self-efficacy score	0.05 (-0.10, 0.21)	0.50
	PSAT-Synergy	*-2.45 (-4.35, -0.55)*	*0.01*	CEI Score	-0.02 (-0.05, 0.01)	0.21
	PSAT-Efficiency	0.74 (-0.59, 2.07)	0.27	%Pharmacies involved	-0.005 (-0.12, 0.002)	0.16
	PSAT-Administration & management	0.49 (-0.38, 1.37)	0.26	Original CHAP Community	-0.03 (0.56, 0.50)	0.91
	%Pharmacies involved	-0.006 (-0.01, 0.001)	0.10			
	Original CHAP Community	0.02 (-0.73,0.78)	0.95			

*Age: <40, 40-49, 50-59, 60-69, 70-79, 80-89, ≥90; †#CHAP sessions attended: <3, 3-4, ≥5

CI – Confidence Intervals; CEI - Coalition Effectiveness Inventory

Table 7: Correlating individual, partnership and community related variables with increased use of health-related community resources and positive change in cardiovascular risk factors

Outcomes	**Significant (p<0.05) independent variables in Model 1**	**Odds Ratio (95%CI)**	**Significant (p<0.05) independent variables in Model 2**	**Odds Ratio (95%CI)**
Increased use of health care resource	Self-efficacy score	0.78 (0.64, 0.97)	Self-efficacy score	0.78 (0.64, 0.96)
Increased use social service resource	Age Self-efficacy score	0.72 (0.56, 0.93) 0.72 (0.60, 0.87)	Age Self-efficacy score	0.70 (0.55, 0.89) 0.72 (0.60, 0.87)
Increased use physical activity resource	Age Self-efficacy score	0.69 (0.55, 0.87) 0.75 (0.63, 0.90)	Age Self-efficacy score	0.69 (0.55, 0.86) 0.75 (0.63,0.90)
Increased use education resource	Age Self-efficacy score	0.67 (0.51, 0.89) 0.77 (0.62, 0.95)	Age Self-efficacy score % Pharmacies involved	0.70 (0.53, 0.90) 0.78 (0.63, 0.96) 1.01 (1.00, 1.02)
Increased use food and nutrition resource	Self-efficacy score PSAT-Synergy PSAT-Administration and management % Pharmacies involved Original CHAP community	0.72 (0.60, 0.86) 39.97 (4.34, 376.19) 0.25 (0.09, 0.74) 1.01 (1.00, 1.02) 0.39 (0.15, 0.99)	Self-efficacy score % Pharmacies involved CEI	0.76 (0.61, 0.87) 1.01 (1.00, 1.02) 1.05 (1.01, 1.09)
Decreased fatty food intake	Age Self-efficacy score % Pharmacies involved Original CHAP Community	0.69 (0.54, 0.89) 0.82 (0.68, 0.98) 1.01 (1.00, 1.02) 5.78 (1.84, 18.12)	Age Self-efficacy score % Pharmacies involved Original CHAP Community	0.68 (0.54, 0.86) 0.81 (0.68, 0.97) 1.01 (1.00, 1.02) 2.69 (1.38, 5.26)
Decreased salt intake	Self-efficacy score	0.70 (0.58, 0.83)	Self-efficacy score	0.70 (0.58, 0.83)
Increased physical activity	Age	0.64 (0.50, 0.80)	Age	0.61 (0.49, 0.77)
Increased fruits & vegetables intake	Age PSAT-Synergy	0.82 (0.67, 0.99) 0.06 (0.01, 0.35)	Age CEI	0.80 (0.66, 0.96) 0.97 (0.94, 0.99)
Decreased Blood Pressure	PSAT-Efficiency	3.00 (1.06, 8.48)	Age	0.76 (0.61, 0.95)

CI – Confidence Intervals; PSAT – Partnership Self-Assessment Tool; CEI – Coalition Effectiveness Inventory

CONCLUSIONS OF THE THESIS

The three papers in this thesis contribute useful knowledge about complex community-based cardiovascular interventions. The findings provide some new information that can guide researchers and program implementers as well as providing some directions for future research.

Theory-based development of complex community cardiovascular health interventions

Theory-based development is important for complex interventions. The literature review in paper 1 asserts that having a theoretical framework, (1) helps in advancing knowledge based on what is already known about the area being studied (Sinclair, 2007; Leshem et al., 2007); (2) provides a guide to appropriately implement, analyse and evaluate interventions (Grol et al., 2007; Cresswell et al., 2011; Michie, 2008); and (3) provides guidance in how to adapt and apply the interventions tested through research endeavours (Sinclair, 2007).

Among the 10 studies included in the review in paper 2, two mentioned about a theoretical/conceptual framework related to the intervention and 1 discussed it adequately. Though it was unclear whether the 8 other papers described interventions that utilized theoretical frameworks as their basis but did not describe this in the paper, this finding indicates the lack of emphasis placed on having or highlighting a framework. Many complex interventions are developed through progressive phases of testing through a series of pilot studies and therefore many programs have not been defined at the outset

(Campbell et al., 2000). However, this is an inefficient way to develop complex interventions. Given the number of primary studies and systematic reviews regarding public health interventions and the current ease in retrieving literature, identifying or developing appropriate theories justifying the intervention should be easier than it once was. This has been identified as an important step by the Medical Research Council in developing complex interventions (Craig et al., 2008).

Paper 1 provides a guide for researchers to develop a conceptual framework or apply existing theoretical frameworks to their planned intervention. The work described in paper 1 was based on a review of textbooks and journal articles. There was no one resource that comprehensively described the steps to apply or develop a theoretical framework for complex interventions. This thesis therefore contributes to the literature by combining the different resources and coming up with a comprehensive stepwise process and demonstrated this process using the Cardiovascular Health Awareness Program (CHAP) as a model.

One of the advantages of having a theoretical framework for a complex intervention is that it guides the analysis process by defining the expected outcomes of the intervention (Cresswell et al., 2011; Michie, 2008). This was demonstrated in paper 3 when independent variable selection was needed to be done. The Community Coalition Action Theory provided a basis for the prioritization of independent variables based on the theory of how the intervention was proposed to have worked and which variables

were important. Furthermore, the framework of multicomponent interventions can be the basis for designing studies to evaluate the effect of each component if desired. Studies can utilize factorial designs, parallel single component intervention RCT, or step-wedged RCT, or other applicable designs (Craig et al., 2008; Trochim, 2000).

Implementation fidelity for complex community-based interventions

Recently published RCTs investigating complex community-based cardiovascular health interventions have shown better documentation of intervention fidelity compared to previous reports (Dane & Schneider, 1998; Perepletchicova, Treat, & Kazdin, 2007). Eight of the 10 studies included in the review in paper 2 described strategies related to promoting intervention fidelity. This may be in response to the CONSORT Group's recommendations (Bourton et el., 2008) or a more knowledgeable cohort of researchers. Either way, this is a step forward in improving the use or reporting of intervention fidelity.

One of the issues regarding intervention fidelity is how to standardize the intervention across implementation site (Blackwood, 2005). Replicating the intervention exactly as it was delivered in a different site may be difficult especially with complex interventions since there will be multiple components of the interventions, multiple communities with different resources, and multiple implementers (Craig et al., 2008). Hawe et al. (2004) suggests selecting the elements to standardize which is the intervention's core or essential elements. Therefore, a good practice for studies

investigating complex interventions is to always indicate its core components since this will be the basis of measuring intervention fidelity. This may be based on the studies' theoretical framework or simply presented as part of a packaged intervention believed to have synergistic effects.

Another issue regarding implementation fidelity is how it should be monitored/verified or controlled. The studies in paper 2 used a variety of self-reporting strategies to verify implementation fidelity. There were few studies where actual observation of study implementation was done to assess fidelity. Self-reports were more common possibly due to feasibility especially when dealing with complex interventions with multiple sites and multiple implementers. Though it is more advisable to use objective evaluation strategies such as observation compared to self-report (Breitenstein et al., 2010; Perepletchickova et al., 2007), it should be balanced with the possibility that the observation essentially becomes part of the intervention or biases the results. For controlling implementation fidelity, training of implementers and the use of manuals or implementation guides has been a standard method for most studies (Gearing et al., 2011). For some interventions, it can be more advanced such as the use of computer-based algorithms. However, details regarding the actual intervention training have not been given emphasis in the published articles as was recommended by previous literature (Gearing et al., 2011).

Finally, reporting implementation fidelity should be an important element included in publications of studies investigating complex community-based cardiovascular health interventions. In paper 2, a gap was noted between what was published and what the authors of these articles stated in the survey regarding how the study verified and promoted intervention fidelity. The authors reported a more rigorous process compared to what was published. This may be true since journal publications have space limitations and specific expectations which may lead to a publication with fewer details on methodological concerns. However, the CONSORT (2012) Extension Checklist of Items for Reporting Trials of Nonpharmacologic Treatments requires reporting of actual implementation in the results section. This checklist also requires a more detailed information of the intervention including descriptions of the different components of the interventions, descriptions of the procedure for tailoring the interventions to individual participants (if applicable), details of how the interventions were standardized, and details of how adherence of care providers with the protocol was assessed or enhanced. The published articles reviewed in paper 2 presented most of the descriptions of implementation fidelity in the methods section. There were few descriptions in the results section regarding the actual intervention implementation and how fidelity was assured. The author of this thesis suggests that reporting intervention fidelity should emphasize the actual implementation of the intervention. The manuscripts should meet the items listed in the CONSORT (2012) Extension checklist and the study authors should also make the reviewers and readers confident enough to believe that the

actual implementation followed the intervention plan. If this did not happen, the studies should adequately report how the intervention was actually delivered.

Associating outcomes with factors at multiple levels

Paper 3 demonstrated how to determine the association of factors at multiple levels with composite outcomes. The initial step was to determine if the clustered nature of the data might affect the outcome (Killip, 2004; Hanley, 2003). Generalized Estimating Equation (GEE) using exchangeable error structure (Hanley, 2003; Hardin et al., 2003) was used to assess the ICC with community as the cluster. Heirarchical Linear Modelling (HLM) could have also been used given the data and analysis plan (Hardin et al., 2003). The data analyzed in paper 3 had a low ICC which allowed the use of linear and logistic regression to correlate individual, partnership, and community level variables with the outcomes overlooking the clustered nature of the data. If the ICC was high, overlooking the clustered nature of the data would have led to biased analysis (Hardin et al., 2003).

Among the different methods of managing multicollinearity across the variables, excluding variables with significant collinearities (VIF >2.5) was used in paper 3. This was the method chosen since the study had a theoretical framework as a basis for the selection of variables (O'Brien, 2007). Assessment of collinearity was initially done by factor level (individual, partnership, community) then as a single multilevel model.

To assess whether the missing data might have affected the results of complete case analysis, sensitivity analysis was done using multiple imputations. The multiple imputations result was consistent with the complete case analysis in terms of which factors were associated with the outcomes. The composite score was also converted to a binary composite as a sensitivity analysis since previous literature suggested that using a composite score required 10% larger sample size to achieve the same power as a binary composite (Sampson et al., 2010). Though the results were consistent in the analyses using a composite score and binary composite, the one using a composite score was more sensitive in detecting associated factors.

The results generated in paper 3 were not as expected based on the hypotheses proposed. Possible reasons discussed in paper 3 were design limitations (use of self-reported factors and outcomes) and issues related to the characteristics of the sample (few communities included, partnership in the communities may be at the early stages and assessment was too early). However, using the same analysis method in the repeated measurements for the on-going research in paper 3 may provide more information to confirm or contradict the current study results.

Overall thesis recommendations

The thesis provided rationale based on literature review and provided a concrete example regarding the benefit of having a theoretical framework for studies investigating complex community based cardiovascular health interventions. Paper 1 provided a step

by step process on how to develop or apply a theoretical framework to complex interventions. This guide can be utilized or improved upon by other researchers to increase the practice of having theoretical frameworks for studies investigating complex interventions.

Most recently published studies investigating complex community-based intervention cardiovascular health interventions described how they verified and controlled intervention fidelity as part of the description of the intervention in the methods section. Actual implementation was less reported and most methods of verifying implementation fidelity was based on self-report. The thesis therefore recommends more reporting of actual implementation and the use of actual observation methods in verifying implementation fidelity.

Finally, the thesis demonstrated one way of correlating individual, partnership and community level variables with individual level outcomes. The process began by assessing the ICC to determine if the clustering of participants by community affected the outcome. If the ICC was high (>18.75%) then it would not be rational to proceed with linear and logistic regression modelling. Since the ICC in the data of paper 3 was low (<18.75%), linear and logistic regression was used in to assess the correlation of the factors from multiple levels with individual outcomes. To deal with the multicollinearity of the factors in the model, factor selection was done based on the VIF (<2.5) and the theoretical framework. Since there were missing data, sensitivity analysis was done

comparing complete case analysis and multiple imputations. In addition, sensitivity analysis was also done to compare the result if the composite score and a binary composite. Though the results of the data analyses in paper 3 were not as expected, the process was rigorous and could be replicated by other studies with similar analysis objectives.

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