The Development of a Conceptual Framework for Understanding Financial Barriers to Care for Patients with Cardiovascular-Related Chronic Disease: A Protocol for a Grounded Theory (Qualitative) Study

Running Title: Understanding Financial Barriers: A Grounded Theory

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Abstract

Background: Patients with cardiovascular%related chronic diseases often face financial barriers to optimizing their health; even in Canada where a universal healthcare insurance plan is in place. As many as 12 of Canadians with chronic diseases experience a financial barrier to care. Unfortunately, no current theory or framework adequately describes the process of striving to achieve optimal health in the face of financial barriers. The overall objective of the proposed study is to develop a framework to understand how financial barriers impact patients' lives and the mechanisms they use to cope with financial barriers.

Methods: We plan to undertake an inductive qualitative grounded theory study to develop a framework to understand the role of financial barriers on patients with chronic disease. We will use semi%structured interviews (telephone and face%to%face) with a purposive sample of participants with chronic disease (at least one of hypertension, diabetes, heart disease or stroke) from Alberta, Canada. Interview transcripts will be analyzed in triplicate using grounded theory coding techniques including open, focused and axial coding following the principle of constant comparison. Interviews and analysis will be done iteratively to theoretical saturation. Member checking will be used to enhance rigor.

Interpretation: The development of a novel comprehensive framework for understanding financial barriers is instrumental for both researchers and clinicians who care for patients with chronic diseases. Such a framework would enable a better understanding of patient behavior and non%adherence to medical therapies and lifestyle modifications.

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Background

Cardiovascular-related chronic diseases such as hypertension, diabetes, stroke and coronary artery disease are among the leading causes of morbidity and mortality in Canada [1-2]. Hospital services and medically necessary physician services are covered by Canada's universal public health insurance [3]. Despite the increasingly important role of medication use and allied health care providers' services in managing outpatients with chronic diseases [4], these are not universally included within Canadian health care insurance. For example, public insurance plans for outpatient prescription medications vary by province, but no province offers universal public medication insurance [5]. Those fortunate enough to qualify for public medication insurance are still faced with considerable copayments and/or deductibles [6]. Thus, financial constraints can have a significant impact on the care required to optimize outcomes in people with cardiovascular-related chronic diseases [7]. In fact, many patients face barriers to obtaining adequate health care, such as necessary prescription medications, due to the costs associated with these services [8] (henceforth called financial barriers).

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There are several types of financial barriers that might reduce accessibility to necessary care and impact health outcomes. Some people may not be able to afford the direct costs associated with medications (such as insurance premiums or user charges), self-monitoring supplies, rehabilitation or home care. While others may struggle to access care that is fully funded by the public system because of an inability to pay for the indirect costs associated with these appointments (e.g. lost income from taking time off work; paying for transportation and parking costs; or childcare). A previous survey conducted by our group revealed that 12 of Canadians with cardiovascular-related chronic diseases experience financial barriers, and these people are 70 more likely to have hospitalizations or emergency department visits related to

their ambulatory care%sensitive condition [9]. These adverse outcomes may be potentially avoidable if the financial barrier which contributed to it could be addressed. It is therefore important to understand how an individual comes to perceive a financial barrier and the role and impact of financial barriers on their lives.

Researchers often use theories or frameworks to understand how a social phenomenon is operationalized. In preparing to design a survey focused on financial barriers, we were unable to identify a theory or framework which adequately described how financial barriers are experienced or how they impact care and outcomes. Rather, we found a number of frameworks which touch on relevant aspects of care seeking. There are three types of frameworks that relate to understanding financial barriers to care: [1] frameworks related to access to care in a general sense, [2] health economics frameworks for understanding health decision making and health behaviour and [3] frameworks focusing on the impact of social determinants of health, or socioeconomic status on health resource utilization.

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Several authors have attempted to create frameworks to comprehensively understand access to care for patients with chronic diseases. Finances are often considered as an aspect of access to care in these frameworks, but the focus of attention is not on how patients experience financial barriers. Some of these include: the Health Behavior Model [10] and the Health Care Access Barriers Model [11]. The breadth of these frameworks is often viewed as a strength as they are able to consider a variety of potential barriers at many different levels. However, taking such a broad perspective on the overarching topic of 'access' also limits the depth to which they can devote to fully comprehending a construct such as financial barriers.

Grossman's health production model is an economic approach to understanding individuals' health decision making [12]. There are limitations and criticisms of the Grossman

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theory, primarily based on the economic practice of simplifying the complexities of the human condition to a point where theories can be tested empirically [13]. A number of frameworks, including that proposed by Brown, focus on the impact and role of social determinants of health or socioeconomic status on health care access [14]. These frameworks are troubled by their complexity and the significant interconnectedness of a multitude of individual and community factors, making them difficult to apply in practice. Furthermore, it is feasible that even those who may typically be considered to have higher socioeconomic status may encounter financial barriers to care under certain circumstances (ie. lacking health insurance).

Methods

Objectives:

Given that none of the frameworks or models that we have found are ideal for understanding the impact of financial barriers on people with cardiovascular‑related chronic disease, nor how patients experience financial barriers, a novel model or framework is required. Inductive qualitative research has as its goal the generation or development of theory or a framework. Our objective is to utilize an inductive qualitative methodology (grounded theory), to develop a framework for understanding the role of financial barriers in the health of patients with cardiovascular‑related chronic health conditions. Specific objectives include:

1. To explore and describe the circumstances which contribute to an individual experiencing financial barriers.
2. To explore what factors affect how impactful a financial barrier may be on a given patient.
3. To explore the coping strategies used by patients with chronic diseases to overcome financial barriers, and at what cost.

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4. To understand what patients feel may improve their access to care and help overcome their financial barrier.

Study Design:

This study will be informed by our previous research in the area of financial barriers. We previously conducted a survey of western Canadians with cardiovascular%related chronic diseases (n=1849) to understand the barriers that they face in self%managing their conditions [9]. We found that financial barriers were common among this population (12) and that there were significant associations between financial barriers and clinically meaningful outcomes (medication non%adherence, emergency department visits and hospitalizations). In the absence of a framework for understanding how financial barriers are experienced by individual patients, we have been unable to conceptualize the mechanisms by which financial barriers may translate into adverse clinical outcomes.

The aim of pursuing qualitative research is to gain in%depth understanding of experiences and processes such as people's behaviors, motivators, or perceptions. Qualitative methods are useful in studying topics which cannot be quantified, such as experiences and coping strategies [15]. We aim to undertake a thorough exploration of the experience of persons with cardiovascular%related chronic conditions who have financial barriers, and therefore our research question necessitates the use of qualitative methods to probe deep into this very personal process.

Grounded theory allows researchers to move beyond simple description to a more abstract theory or framework of a given human process. Grounded theory is used to describe processes of human behavior [16] through generation of frameworks and theories [17]. The principle of constant comparison is used to ensure that the theory generated is in fact grounded in the data, rather than preconceived notions. We chose to use grounded theory methodology with the goal

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of moving beyond a superficial description of the experiences of patients with financial barriers to care to a more theoretical and analytic description of the process of experiencing and coping with such a barrier.

Sampling and Data Collection:

Inclusion Criteria: The study population will consist of English speaking Albertan adults with at least one of the following self%reported chronic medical conditions: hypertension, diabetes, coronary artery disease, or stroke. To be eligible, participants must identify as having experienced a financial barrier within the previous year by answering affirmatively to the following question (used to define the exposure in the preceding quantitative study):

> "Some people have difficulty paying for services, equipment, and medications for chronic conditions. Other people may have difficulty paying for transportation or childcare to allow attendance at doctors' appointments… In the past 12 months did you have difficulty paying for services, equipment, medications for your chronic conditions?"

Exclusion Criteria: Individuals who are unable to converse in the English language (due to language barriers or physical impediments), those who do not have at least one of the pre% specified chronic conditions of interest and those with severe cognitive impairment will be excluded from participation in the study.

Recruitment: We will recruit study participants via signage in family physician offices and specialist clinics as well as via pre%existing research and clinical databases. We have planned a strategy of theoretical or purposeful sampling [18], by identifying a number of strata that were important to have represented in our pool of participants, based on the prior survey – as these variables were notable contributors to the presence of financial barriers:

- Age: ≥65 years and <65 years (as government sponsored health benefits for seniors are provided to those over the age of 65 years)

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- Gender
- Type of chronic disease
- Multimorbidity
- Aboriginal status
- Adequate and low health literacy [19]

Data Collection: We will collect data using semi%structured face%to%face or telephone interviews. An interview guide has been developed based on the findings of our preceding survey study, and learnings from the related frameworks previously reviewed (see Appendix A). Five domains will be explored in the interview: (1) patient experience of living with chronic disease; (2) experience of financial barriers; (3) perceived reasons for financial barriers; (4) health consequences of financial barriers; and (5) mechanisms for coping with financial barriers. All interviewers will be completed by investigators who are trained and experienced in qualitative interviewing techniques. Interviews will be digitally recorded and subsequently transcribed verbatim using standard linguistic conventions by a professional transcriptionist.

Sample Size: Data collection and analysis will occur simultaneously allowing us to continue sampling and data collection until theoretical saturation is achieved. Saturation will be deemed to have been met once three consecutive interviews do not yield any new substantive codes during initial analysis. Based on prior reports of grounded theory studies of this nature, [20] we anticipate needing to complete between 30 to 50 interviews to achieve saturation.

Data Analysis:

We will employ grounded theory coding using an inductive approach, as described by Charmaz [21] using techniques initially described by Strauss and Corbin [22]. Data collection and analysis will be done iteratively which will allow us "to explore and fill out these codes" [21], as

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necessary. Data analysis will begin after each interview, when the interviewer will reflect on the theoretical content in each interview and wrote memos to record analytic ideas. Finalized transcriptions will be analyzed using NVivo 10 software (QSR International: Doncaster, Australia).

Initial or open coding will proceed in a line%by%line fashion. During this process the data will be 'fractured' or broken down into granular codes [16]. Further analyses will be based on the principle of constant comparison [17]. Firstly, data from interview transcripts will be compared internally and subsequently, transcripts will be compared to one another using incident%to% incident coding. The process of initial coding will be done individually in triplicate, meaning that three experienced analysts will individually code the data. All coders will meet weekly to discuss their interpretations of the data to allow for consideration of various perspectives. Given that this research is informed by the interpretive paradigm, exact agreement is not the goal of these sessions, but rather to gather a multitude of viewpoints on the various incidents and themes derived from the data. However, consensus about how to code a given piece of data will be achieved after thorough discussion of each point. In cases where consensus is not reached allowances will be made such that a passage may retain multiple codes to enable future discussion.

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Once all transcripts are initially coded, we will proceed with focused coding where we will group initial fractured codes into coherent subsuming categories. The final analytic stage will be axial coding. This process will be done through a process where the research team will meet to discuss the relationships between the various codes and categories, while reviewing pertinent excerpts from the data.

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A number of procedures are planned to maximize the rigor and enhance the trustworthiness of this qualitative study. Member checking, the process of presenting research findings to participants to obtain their feedback, will be accomplished by holding two focus groups of prior interview participants. The use of multiple analysts will enrich our ability to interpret and understand incidents described by respondents. Negative case sampling, selecting individuals who stated that they had experienced financial difficulties associated with their chronic condition but that they would not describe these as "barriers", will help to illuminate why financial issues may be more or less pertinent for some than for others. Extreme case sampling will involve including those who experienced a hospitalization or adverse event that was directly attributed their financial barriers. Finally, throughout the process of data collection and analysis, we will actively employ the principle of reflexivity – or thinking about how our own personal experiences and characteristics may shape participants' responses or our interpretations [23].

Ethics approval:

Ethics approval has been obtained from our institution's Conjoint Health Research Ethics Board and study procedures will be in accordance with Canada's Tri%Council Policy Statement guidelines. Informed consent will be received verbally over the telephone for interviews and written consent obtained for focus group participation.

Interpretation

Despite the fact that a significant proportion of Canadians with chronic diseases experience financial barriers to accessing care, there are currently no frameworks or theories that adequately represent the patient experience or can be used to guide interventions to minimize the

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impact of these barriers. We propose a rigorous qualitative (grounded theory) study using data derived from semi%structured patient interviews to develop a novel framework to enhance our ability to understand the role of financial barriers on patients' lives and health outcomes.

In previously published literature, there are two salient approaches for understanding how financial%related concerns influence healthcare decision making: The Grossman Theory of Health Production and the Brown Framework of Socioeconomic Position in Health. While both of these frameworks have been helpful for understanding access to care, they both have significant limitations for understanding the role of financial barriers, summarized in Table 1.

While there are strengths of this study, there are also important limitations. As a qualitative study, we acknowledge that the small sample may not be fully representative of the Canadian population. As such, some groups will not be represented in the sample (ie. non% English speakers and those with communicative limitations). Thus, the study findings may not necessarily be transferable to these groups of patients. However, employing a purposive sampling strategy will minimize the problems caused by non%representativeness.

We are optimistic that the development of a comprehensive framework to understand the experience of financial barriers for patients with chronic diseases will be educational and highly relevant for policymakers, clinicians and health services researchers. Through our framework, we hope to generate an understanding of how and why some patients come to experience financial barriers which may be useful for informing future health policy around healthcare accessibility. Furthermore, the development of a framework to understand this particularly vexing problem would also be of great value to individual clinicians who care for these patients and may not fully understand the barriers that prevent their patients from being fully adherent to their recommended medical and lifestyle therapies. Finally, we plan to utilize the findings from

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this study in our future research on financial barriers to help design and test interventions to minimize the impact of these barriers on patient-relevant outcomes.

Table 1: Comparison of Grossman Model and Brown Framework for Understanding Financial Barriers to Care

	Grossman Model of Health Production		Brown Framework of Socioeconomic Position (SEP) in Health	
	Strengths	Limitations	Strengths	Limitations
Generalizability	Applicable to a variety of conditions	May be overly simplified to apply in all circumstances	Is thought to be applicable to other chronic health conditions	Derived only from participants with diabetes
Endogeneity	By separating the investment and consumption demand for health, it is able to account for endogeneity			Unable to tease apart reverse causation between SEP and health
Definition of socioeconomic status/position		Narrow – only considers income	Broad – considers a multitude of factors	Does not consider psychosocial variables
Evidence/empiric support	Many studies support model	Some studies also refute certain aspects of the model	One recent study by Walker et al validates several components of the framework	No other studies to support this framework
Ability to use for prediction	Simplified model allows one to assess how changes in one variable will affect demand for health	Overemphasises individuals' agency without consideration of their circumstances		Model too complex to be used to predict health-seeking behaviors
Possible result of using	Victim blaming: Does not acknowledge the social		Fatalism: Has such a complex view of how	

framework/ model to understand financial barriers	determinants of one’s willingness to pay for services.	SEP contributes to healthcare access that it is difficult to create interventions to address these barriers.

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Appendix A: Interview Guide

Topic	Question	Follow-up/Probe
Illness experience	Tell me about your experience living with _________ (heart disease, diabetes, stroke, hypertension)?	When were you diagnosed? What impact has it had on your life? What are the challenges you've faced? How did you cope with these?
Financial barrier experience	1. You previously stated that you have had difficulty accessing care due to cost. Please tell me about that…	Tell me about the financial repercussions of your chronic disease. How has your financial situation changed since diagnosis? What exactly did you have difficulty accessing? Did you ever not get what you needed due to cost? What are your out of pocket costs for your chronic diseases each month?
	2. Did you experience any health-related consequences due to your financial barrier?	Have you ever had to stop taking medications due to cost? Has this barrier ever led to you having to go to the hospital?
	3. What are the personal, emotional and psychological impact of having financial barriers?	Family? Work-life balance? Stress? How would things in your life be different if you didn't have financial barriers?
Reasons for financial barriers	What things led you to have financial difficulties?	Employment status? Personal debts? Do you have health insurance? If no, why do you not have health insurance? If yes, why do you still have financial barriers? Do you have copayments?
Coping	How do you deal with your chronic disease and financial difficulties?	What kinds of things do you do ensure you are able to get the care you require? Have you tried to access financial supports for assistance? How aware are your family members and friends of your financial situation? How aware are your healthcare providers of your financial situation?
Suggestions	What might be done to improve the situation for people like yourself?	Government programs? Other programs or initiatives?

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