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Exploring Healthcare Consumer Involvement in Clinical Practice Guideline Development

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Abstract

Involving healthcare consumers (HCCs) in clinical practice guideline (CPG) development can lead to identification of topics that guidelines should consider. To evaluate the strategies being used to involve HCCs in CPG development, a description of these strategies is needed. This study utilized qualitative description to analyze CPGs and related documents. Professionals involved in CPG development were also interviewed. Patients, family members, and informal caregivers have been involved in the formulation of recommendations, CPG reviewing and editing, and through use of patient resources. According to the results, involving HCCs is done to incorporate patient preferences and values into CPGs, and to improve their impact. By failing to provide opportunity for ongoing communication between stakeholders, some strategies may fail to ensure that input from HCCs is considered. Strategies being used will need to be evaluated in the future to ensure they are achieving the desired effects.

Keywords

patient and public involvement, healthcare consumers, clinical practice guideline, development, Canadian, qualitative description, mood disorders, anxiety disorders
Clinical practice guidelines (CPGs) are documents meant to advise healthcare providers on the most effective options for the management of illness. Involving patients, their family members, and members of the general public, collectively referred to as healthcare consumers (HCCs), in the process of developing CPGs may help in identifying important issues these documents should address. Involving HCCs in the development of CPGs can also help to make patients feel empowered, and help them work together with healthcare providers in decision making. In order to evaluate the effects of involving HCCs in CPG development, a description of current strategies is needed. This study therefore investigated how and why HCCs have been involved in the development of CPGs for the management of mood and anxiety disorders within Canada. Clinical practice guidelines and documents describing their development were analyzed to find answers to the research question. Professionals involved in CPG development, including authors and research advisors, also contributed information through participating in interviews or completing questionnaires. Results of this study indicate that patient resources were created to accompany the CPGs analyzed for this study. Patient resources are tools such as decision aids or CPG summaries meant to advise patients or their loved ones on their treatment options. Since these CPGs were released, additional strategies have been used to involve different types of HCCs throughout different stages of CPG development. Results of this study also indicate that currently, HCCs are involved in CPG development in order to identify information or treatment outcomes that are important to patients. A greater focus on facilitating the partnership between patients and healthcare providers could help to increase HCC involvement in CPG development in the future. In addition, future efforts to involve HCCs in CPG development must ensure that input from these stakeholders is gathered in a way that ensures it is acted upon.
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Chapter 1

1 Introduction

The benefits of involving healthcare consumers (HCCs) in clinical practice guideline (CPG) development include identifying information important to patients that should be incorporated into CPGs, helping to reduce the effects of professional biases, facilitating democratic decision making during CPG development, and empowering patients and other members of the public. How HCCs are involved is an important consideration for appraising what benefits can be achieved, or even how efficiently they are achieved. For example, involvement of HCCs in CPG development can be categorized by the direction of information flow between HCCs and professionals (Rowe & Frewer, 2005). Furthermore, the benefits and challenges encountered when involving HCCs in CPG development can depend on the type of HCC involved, the specific method used, and the stage of CPG development in which they are involved. Before we can evaluate the effectiveness of the strategies used to involve HCCs in CPG development, those strategies must first be documented and described (Armstrong & Bloom, 2017; Légaré et al., 2011). Such studies have been conducted outside of Canada with differing healthcare environments, and have not included Canadian CPGs or the practices used by Canadian CPG developers. This study seeks to address this gap by describing the strategies used to involve HCCs in CPG development within Canada.

Because of its potential benefits, involving HCCs in the development of CPGs has been recognized as important in recent years. The United States National Academy of Medicine (formerly the Institute of Medicine [IOM]; IOM, 2011), The Guidelines International Network (GIN; GIN, 2015), World Health Organization (WHO, 2014) and the United Kingdom National Institute for Health and Care Excellence (NICE, 2014), among others, have recommended that HCCs, or patients specifically, be involved in the development of CPGs. In addition, tools meant to advise on the development of high-quality CPGs, such as the Appraisal of Guidelines Research & Evaluation (AGREE) tool, recommend that HCCs be involved in CPG development. AGREE II, the latest iteration of the tool, asks guideline developers and evaluators to consider whether “the views and preferences of the target population (patients, public, etc.) have been sought” (Brouwers
et al., 2010). Despite the consensus that HCC involvement in CPG development can be beneficial, there is little agreement regarding best practices. A number of challenges exist that negatively impact the outcomes of HCC involvement in CPG development, and that may hinder its use (Légaré et al., 2011). The identification of the most effective strategies of HCC involvement in CPG development is needed to ensure the practice is used effectively.

This research examines the involvement of HCCs in CPG development in Canada, specifically in CPGs created for the management of mood and anxiety disorders. Mood and anxiety disorders were chosen as a focus because they represent a prevalent class of illnesses within Canada; high-quality CPGs can assist in the management of these illnesses; and there are enough CPGs developed in this area to support an analysis. Within this context, this study seeks to answer the questions of who is being involved in CPG development in Canada, how this is happening, including the specific methods used and the stages at which it is occurring, and why HCCs are being involved. Characterizing the strategies used to involve HCCs in CPG development will allow these strategies to be tested in future studies, in order to appraise their effectiveness in achieving the purported benefits of HCC involvement, and to identify challenges that must be overcome to do so efficiently.

This chapter provides important definitions utilized throughout this thesis, outlines the knowledge gap this study seeks to address, and provides a review of existing literature describing important concepts for this study. The relevance of this study to health information science, and the final research question are also provided.

1.1 Definitions

To provide context for this thesis, this section provides important definitions. Terms defined here include “healthcare consumer”, “professional”, and “clinical practice guideline”.

For the purpose of this research, the term “healthcare consumer” (HCC) is defined as any lay persons who do or could receive services from the healthcare system. Healthcare consumers include patients, family members, informal caregivers, the general
public, and patient representatives (Armstrong & Bloom, 2017; Qaseem et al., 2012). Patients are individuals with current or past lived experience with a disease or illness. Family members are those individuals with a close relative experiencing or who has experienced a disease or illness, who may take at least partial responsibility for caring for the individual living with a disease or illness. The general public refers to lay individuals without personal experience of a disease or illness of interest, and without relation or connections to others with a disease or illness of interest. Patient representatives are individuals with experience with a disease or illness of interest, tasked with representing a group of patients or patient organization at in health policy and services decision-making table. In addition, health care consumers include patient advocates. Patient advocates are professionals appointed to share knowledge regarding patient values within guideline development groups (Roth, 2011; Williamson, 1998).

For this thesis, the term “professional” is defined as any individual with formal training or education within healthcare and health services and policy design, excluding patient advocates. Previous reviews of CPG development procedures have outlined that these can include, but are not limited to, general practitioners, medical specialists, pharmacists, nurses, nurse practitioners, and other healthcare providers. Professionals can also include methodologists, topic experts, and researchers (IOM, 2011; Qaseem, 2012).

Finally, the definition of “clinical practice guideline” (CPG) used for this study is based on descriptions given by The American Academy of Family Physicians (2017), Davis and colleagues (2007) and the Institute of Medicine (2011). Clinical practice guidelines are defined as review documents that contain recommendations based on systematic review of available evidence and/or expert consensus, meant to inform primary care physicians, medical specialists, or allied health clinicians in the diagnosis, assessment, and treatment of illness.

1.2 Literature Review

This section provides an overview of current literature relevant to this study. First, an overview of the current use of HCC involvement in CPG development is provided. This section also outlines the potential benefits that make the practice important to
consider, evaluate, and improve to ensure these benefits are being achieved. A framework for categorizing how HCCs can be involved in the development of CPGs is also established. This includes explanations of consumer participation, consumer consultation, and consumer communication, as first described by Rowe & Frewer (2005). Strengths and weaknesses of each of these approaches are provided. This framework helps to guide data analysis in categorizing the strategies of HCC involvement encountered. Finally, additional factors likely to influence the effectiveness or outcomes of HCC involvement in CPG development are described. These factors include the type of HCC involved, the specific method used, and the stage of CPG development at which these methods are used.

1.2.1 Current Use of Healthcare Consumer Involvement in Clinical Practice Guideline Development

Internationally, HCCs have been involved in the development of CPGs in a wide variety of clinical areas. Légaré and colleagues (2011) characterized patient and public involvement programs within the United States, the United Kingdom, Germany, and Australia. These programs were used in the development of CPGs pertaining to the care of diabetes, stroke, cardiovascular diseases, kidney disease, and spinal cord injuries. Use of these programs was also found to be highly represented in CPGs developed for mental health and cancer (Légaré et al., 2011). Patients are the most common group of HCCs to be involved in CPG development. Results of the aforementioned study indicate that patients are involved in 63% of CPG development initiatives and family members or informal caregivers are involved in about 42% of these initiatives (Légaré et al., 2011). This same study demonstrated that patients, family members, and informal caregivers are most often involved during the formulation of recommendations, the process of knowledge synthesis, and during draft revision (Légaré et al., 2011).

There remains some room for improvement in the prevalence of patient and public involvement programs in CPG development. Between 1994 and 1999, only 19.6% of Canadian CPG developers included patients or other HCCs in their CPG development committees (Graham et al., 2003). A more recent study conducted in the United States indicated that only 8% of CPG development groups require input from patients in that
country (Armstrong & Bloom, 2017). A review of practices used by guideline developers from Africa, Asia, Oceania, Western Europe, Latin America, and North America revealed that 29% of these groups require patient or public involvement in CPG development, and 39% involve patients or the public only “when necessary” (Lavis, Paulsen, Oxman, & Moynihan, 2008). Results of these studies indicate that there remains some room for improvement in the use of patient and public involvement in CPG development, both within Canada and internationally. There is indication that use of the practice is increasing within Canada specifically, although this research does not describe recent trends. The aims of this study do not include providing a quantitative description of the prevalence of HCC involvement in CPG development. Instead, the aims of this study include providing a qualitative description of the strategies used to involve HCCs in CPG development in Canada.

1.2.2 Benefits of Healthcare Consumer Involvement in Clinical Practice Guideline Development

Involving HCCs in the development of CPGs has been described as beneficial for several distinct reasons. First, HCCs can bring additional perspectives and knowledge, in some cases gained through lived experience, to the CPG development process (van de Bovenkamp & Trappenburg, 2009). These perspectives can be important to consider because they may differ from those of healthcare professionals (Mühlbacher & Juhnke, 2013; Roberge et al., 2016). For example, meta-analyses have provided evidence that adult patients prefer psychotherapy over pharmacological treatment for unipolar depression; however, pharmacotherapy remains the standard choice of clinicians for the treatment of depressive disorders (McHugh, Whitton, Peckham, Welge, & Otto, 2013; Roberge et al., 2016). In cases where scientific evidence offers some degree of choice in treatment alternatives, input from HCCs can help ensure that information and recommendations contained within CPGs reflect the preferences of patients. This helps to ensure that CPGs remain accountable to both patients and the public (Légaré et al., 2009).

In addition, involving HCCs in CPG development can lead to the addition of valuable content, such as information regarding patient preferences and values, or to the identification of important topics CPGs should address (Armstrong et al., 2018).
Armstrong and colleagues (2018) conducted a parallel group study in which two groups were asked to create a CPG for the use of positron emission tomography in patients with dementia. In this study, the group that included patients identified the rate of progression of cognitive impairment as an important consideration for this guideline. This concern was not addressed by the group that excluded patients (Armstrong et al., 2018). In a similar study, Tong and colleagues (2012) conducted workshops with patients that led to the incorporation of a subtopic on “symptoms, natural history, and outcomes of chronic kidney disease” within a CPG pertaining to chronic kidney disease management. Input from HCCs during CPG development can also lead to the creation of additional resources, such as plain-language summaries meant to accompany guidelines (Tong et al., 2012). In a study by Tong and colleagues (2012), consultation with a group of HCCs during CPG development prompted the creation of a plain English version of the guideline for the reference of lay people. Research has demonstrated that including patients in CPG development can influence both content and format. CPGs developed with the involvement of HCCs are therefore more likely to include issues that patients consider to be relevant.

Some authors have suggested that knowledge and information contributed to CPG development by HCCs can lead to a greater focus on shared decision making and patient-centered care in individual clinical consultations (Légaré et al., 2009). A focus on patient-centered care in clinical consultations is associated with higher-quality decision making that results in improvements in health outcomes for patients (Ontario Medical Association, 2010). However, there remains little direct evidence to suggest that involving HCCs in CPG development will encourage the use of patient-centered care in individual clinical consultations. A Cochrane review assessed the effects of consumer involvement in developing healthcare policy and research, CPGs, and patient information material (Nilsen, Myrhaug, Johansen, Oliver, & Oxman, 2006). The authors concluded that there remains a “huge gap” in evidence about the desirable and undesirable effects of involving HCCs in healthcare decision making at the population level, including its effects on healthcare outcomes (Nilsen et al., 2006). A more recent study that included a review of CPGs and interviews with CPG developers, indicated that the focus on patient center care in these documents is unlikely to improve with patient input (van de
Bovenkamp & Zuiderent-Jerak, 2015). These researchers did not conclude that patient participation in CPG development was therefore undesirable, but rather that the design of patient participation matters significantly in the outcome.

Involving patients in the development of CPGs has been suggested as a method to help manage professional biases, potentially mitigating their effects on the final product. The National Academy of Medicine, in its comprehensive manual for the development of CPGs, recommends that patients and the public be involved in CPG development as a matter of transparency in order to “provide a window into the process and some assurance that guidelines were not developed ‘behind closed doors’ to suit special interests” (IOM, 2011, p. 89). In addition to improving transparency, patients may be able to resist recommendations that favor the self-interests of professionals (IOM, 2011). Professional endeavours, such as research, professional agency affiliations, or practice specialization, may influence professional input in CPG development (Ayanian, Landrum, Normand, Guadagnoli, & McNeil, 1998; Detsky, 2006; IOM, 2009). For example, physicians may be inclined to recommend a treatment that they have personally researched or developed, even if a wider body of evidence suggests the superiority of alternative treatments (Detsky, 2006). Physicians’ decision making during CPG development can also be influenced by their interactions with pharmaceutical companies, who may offer to provide training and funding to these physicians (Fickweiler, Fickweiler, & Urbach, 2017: IOM, 2011). Including patients at the guideline development table may allow them to bring their own interests back to the forefront of concern (Detsky, 2006).

Finally, justification for involving HCCs in CPG development has also included “principles-based” arguments of improving accountability and empowerment, called the democratic model and consumerist model, respectively (GIN, 2015, van de Bovenkamp & Trappenburg, 2009). The democratic model posits that including patients in CPG development allows for democratic decision making, which enhances the accountability of the process (Florin & Dixon, 2004). The democratic model states that patients and the public should be included in health policy development, including the development of CPGs, as it represents a chance for citizens to fulfill their duty to contribute to society,
and allows diverse interests to be represented in the process (Boivin, Green, van der Meulen, Légaré, & Nolte, 2009; Wait & Nolte, 2006). Furthermore, some authors have suggested that substantive democracy requires deliberation between stakeholders, with deliberation entailing discussions that involve careful and serious weighing of reasons for and against some proposition (Abelson et al., 2003; Dryzek, 2000; Fearon, 1998). The consumerist model stresses the importance of HCC empowerment through providing these stakeholders with information and the chance to become active decision makers within the healthcare system (Wait & Nolte, 2006). Empowering HCCs through providing information and the opportunity for free choice allows for well-informed decision making in CPG development and a chance to remedy information asymmetry in healthcare (GIN Public Working Group, 2015; Wait & Nolte, 2006). Furthermore, involving HCCs in CPG development could help to shift the balance of power between stakeholders in the healthcare sector, to make patients and professionals more like partners (van de Bovenkamp & Trappenburg, 2009).

Principles-based arguments have led advocates to describe HCC involvement in CPG development as a goal in itself (Rashid, Thomas, Shaw & Leng, 2017; van de Bovenkamp & Trappenburg, 2009). Authors advocating for HCC involvement in CPG development have suggested that principles-based arguments for HCC involvement in CPG development be brought to the forefront. However, these principles-based arguments, such as striving for a more representative democratic decision making process in the development of CPGs, have implications for the quality of CPGs being developed that can be described and potentially quantified. For example, empowering patients through involvement indicates that these individuals will become better educated on their healthcare and more likely to contribute to their design in the future (van de Bovenkamp & Trappenburg, 2009). Furthermore, making the process democratic should be done in order to stimulate debate, improve public understanding of complex healthcare issues, and produce consensus surrounding public and community values for health services priorities (Abelson et al., 2003).

In summary, several benefits to involving HCCs in CPG development have been described in the literature. These benefits include facilitating the incorporation of
knowledge coming from HCCs, that can help to navigate through unclear scientific evidence, or to identify topics that should be incorporated into CPGs. Healthcare consumers might also be able to manage professional biases. Finally, “principles-based” reasons include the potential to facilitate democratic decision making, and to achieve HCC empowerment. There is growing evidence that the purported benefits of HCC involvement in CPG development are attainable; however, there remains a lack of evidence to suggest that the practice will lead to a greater focus on patient-centered care and the associated higher-quality decision making in clinical consultations.

1.2.3 Types of Healthcare Consumer Involvement Strategies and Their Relevance

Frameworks for involving patients and members of the public in healthcare service, policy, and research design have been described by Arnstein (1969) and by Rowe and Frewer (2005). These patient and public involvement frameworks can be applied to describe HCC involvement in the development of CPGs as a specific instance of health service design. Healthcare consumer involvement in health services design, including in the development of CPGs, has commonly been described in relation to a “ladder” of citizen involvement, as first described by Arnstein (1969). This ladder is divided into eight rungs of participation, according to the level of decision-making power that HCCs are afforded. These rungs are collected into broader groups of involvement that include “non-participation”, “tokenism”, and “citizen power”. Involvement at the non-participation level includes initiatives meant to enable education of patients or the public (Arnstein, 1969). Tokenism includes initiatives in which patients and the public have the opportunity to receive education from professional stakeholders, but also have opportunity to provide their own input into the task at hand. However, at this level, there are no safeguards to ensure that input from patients or the public is incorporated into final decision making. Finally, initiatives at the level of citizen power allow patients and the public to obtain at least some decision-making power. This can be achieved through engaging in trade-offs with professionals, or through taking over managerial positions within these initiatives (Arnstein, 1969). Previous literature has argued that in order for patients or the public to affect decision making within health services design, research
and policy-development, the involvement of these stakeholders must reach the level of citizen power (Arnstein, 1969; Caron-Flinterman, Broerse, & Bunders, 2007; Elberse, Caron-Flinterman & Broerse, 2011).

In a model related to Arnstein’s ladder of involvement, Rowe and Frewer (2005) described three categories of HCC involvement based on the flow of information between these stakeholders and professionals, called consumer participation, consumer consultation, and consumer communication (Armstrong & Bloom, 2017; GIN, 2015; Légaré et al., 2011). Consumer participation involves transfer of information between HCCs and professionals, while consumer consultation allows for the transfer of information from HCCs to professionals only. Finally, consumer communication allows only for the transfer of information from professionals to HCCs (Rowe & Frewer, 2005). Each of these approaches to HCC involvement offers unique benefits, but also come with their own challenges and shortcomings.

In consumer participation, HCCs act as active members in CPG development groups, allowing for active and ongoing dialogue between researchers, policy makers, and HCCs throughout the process of guideline development (Armstrong & Bloom, 2017; Rowe & Frewer, 2005). The correspondence between professionals and HCCs that consumer participation allows for has been theorized to contribute to the formation of meaningful agreements (Rowe & Frewer, 2005). In practice however, consumer participation poses some challenges. Professionals often perceive direct engagement with HCCs as counterproductive because differences in opinion between HCCs and professionals can lead to conflicts that are difficult to resolve (van de Bovenkamp & Zuiderent-Jerak, 2015). Healthcare consumers also experience problems when engaging in guideline development through consumer participation methods. Previous studies have shown that consumers contribute to dialogue within guideline development groups infrequently, often owing to perceived power imbalances between themselves and professionals (van Wersch & Eccles, 2001). Engaging directly as members of guideline development groups may also exacerbate issues regarding time commitments and the need for training (van de Bovenkamp & Trappenburg, 2009; van Wersch & Eccles, 2001).
Consumer consultation involves collecting information on opinions, values, and perspectives from HCCs at key points in the guideline development process, without iterative or formal dialogue directly between HCCs and professional members of the guideline development group (Rowe & Frewer, 2005). Consumer consultation often involves gathering the perspectives of HCCs through use of focus groups or surveys. These methods offer cost effectiveness as a benefit. These methods also encourage contribution from HCCs through allowing a large number of consumers to be reached and through removing the effects of perceived power imbalances, since HCCs do not need to directly interact with professionals (Légaré et al., 2011; Tong et al., 2012). The decreased interaction between professionals and HCCs in consumer consultation methods also aids in minimizing conflict between these two groups (van de Bovenkamp & Zuiderent-Jerak, 2015). However, the absence of ongoing dialogue between consumers and professionals may hinder the ability of professionals involved in CPG development to utilize information gathered from consumers and make guidelines that are acceptable to both groups (Rowe & Frewer, 2005). Even with this drawback, consumer consultation methods have been demonstrated to have a perceivable impact on developed guidelines, contributing to the creation of guidelines that are understandable to both clinicians and patients (Elwyn et al., 2017; Tong et al., 2012).

In contrast to consumer consultation and consumer participation, consumer communication methods do not offer opportunity for transfer of information from HCCs to professionals; however, they offer the opportunity to educate HCCs (Guidelines International Network Public, 2015; Rowe & Frewer, 2005). These methods attempt to provide HCCs with information deemed beneficial for their awareness and comprehension of CPGs to improve outcomes of their use. Patient education, a main focus of consumer communication, has been recognized as an important aspect of patient empowerment and patient-centered care (Grol, 2001). In addition, consumer communication helps to establish the trustworthiness and accessibility of guidelines by making the development process transparent (Armstrong et al., 2018). Consumer communication methods typically involve HCCs at the stages of guideline dissemination and evaluation (Armstrong & Bloom, 2017). Methods of consumer communication such as use of educational tools and decision aids meant to accompany CPGs, have been
demonstrated to improve consumer knowledge of guidelines, improve control of the targeted illness, and improve use of under-utilized treatment options (Gagné, Légaré, Moisan, & Boulet, 2017; Taddio et al., 2013). These methods are also beneficial because they are cost effective and do not require large time commitments from consumers (Armstrong, Mullins, Gronseth, & Gagliardi, 2017). Because consumer communication involves providing patients with information only, these strategies, such as the use of patient resources, do not allow HCCs to provide input during CPG development that may influence the content of these tools. These strategies involve a one-way flow of information from professionals to consumers, with no channel to provide feedback and no power for negotiation.

1.2.4 Important Aspects of Healthcare Consumer Involvement in Clinical Practice Guideline Development

As evidence continues to accumulate pointing to its benefits, involvement of HCCs in the development of CPGs has been increasingly recognized as important by international authoritative organizations. While there is a general consensus that the practice can have meaningful impact on guideline development and content, there are many challenges that need to be overcome to ensure these efforts are successful. Studies at a multinational level have identified challenges that limit the use and usefulness of patient involvement in guideline development (Légaré et al., 2011). From the perspective of health care professionals, these challenges include eliciting and incorporating another set of views. Challenges are also faced by HCCs, such as managing time constraints, or experiencing resistance from professionals (Légaré et al., 2011).

Authors have indicated that some of these challenges may be overcome simply by increasing efforts to include patients in CPG development on both national and international scales (Armstrong, Rueda, Gronseth, & Mullins, 2017; Légaré et al., 2011; van de Bovenkamp & Trappenburg, 2009). For example, resistance from professionals to incorporating input from HCCs might be overcome simply by allowing HCCs to be involved throughout CPG development to increase their influence on decision making (Armstrong et al., 2017). However, some authors have pointed out that focusing on increasing involvement of HCCs in CPG development is not the most efficient way to
maximize benefits, and may actually exacerbate the challenges faced (van de Bovenkamp & Zuiderent-Jerak, 2015). A better way to address challenges associated with the practice may be to involve HCCs in CPG development selectively, incorporating the best type of HCC at the right stage of CPG development, using proven methods (van de Bovenkamp & Zuiderent-Jerak, 2015). Doing so requires an understanding of the available methods that can be used to involve HCCs in CPG development. Important details can affect the strengths and weakness of approaches used and the outcomes of HCC involvement, including which stakeholders are involved, what specific methods are used, and at what stage of CPG development they are employed (Légaré et al., 2011; van de Bovenkamp & Trappenburg, 2009; van de Bovenkamp & Zuiderent-Jerak, 2015).

Individual patients have been most widely discussed as important knowledge contributors in health care research and policy development, including in the development of CPGs. However, engaging patients in CPG development comes with its own specific challenges. For example, the unique experience of individual patients and constraints around how many can be practically involved in CPG development raises concerns about the representativeness of involved patients (Earl-Slater, 2004, p. 25; Légaré et al., 2011). In addition, as lay persons, patients may require training to effectively contribute to the CPG development process. Training of patients has been criticized however, as it may devalue the experiential knowledge patients are asked to contribute to the development of CPGs (van de Bovenkamp & Trappenburg, 2009).

Other types of HCCs, such as family members or members of the general public, can also contribute to CPG development, and each group offers unique abilities to overcome certain challenges (Entwistle, Calnan, & Dieppe, 2008; Entwistle, Renfrew, Yearley, Forrester, & Lamont, 1998; Forsythe et al., 2016). In order to overcome concerns regarding the representativeness of patients engaged in CPG development, CPG development could engage patient representatives from larger patient organizations. Patient organizations can have separate discussions between their members on preferences and values for the management of specific illnesses, the results of which can be brought forward to guideline development groups by appointed patient representatives (Williamson, 1998). Patient advocates are professionals appointed to share knowledge
regarding patient values within guideline development groups. Patient advocates do not need to be members of patient organizations and may be appointed by the guideline development group itself. As professionals, patient advocates offer the unique ability to overcome certain challenges, such as the effects of perceived power imbalances between patients and professionals (Mallik, 1997; Roth, 2011; Williamson, 1998). Patient family members and informal caregivers may also be involved in CPG development and should be considered as separate groups, as family members and informal caregivers may have priorities or concerns that are different from those of patients themselves (Ahlström, Skärsäter, & Danielson, 2011; IOM, 2011; Roberts & Kim, 2016). Finally, members of the general public may wish to contribute as potential patients or as funders in publicly financed health care systems (Alonso-Coello et al., 2016).

Within the categories of consumer participation, consultation, and communication (section 1.2.3), there is a wide variety of specific methods that can be used. Specific methods used for consumer consultation, for example, include focus group discussions among HCCs. Results of focus group discussions can be relayed back to professional guideline developers through a professional mediator (Tong et al., 2012). Alternatively, consumer consultation can involve use of surveys to gather input from HCCs (Elwyn et al., 2017). Consumer communication could include use of lay versions of guidelines, or decision aids to help patients understand their options (Gagné et al., 2017; Taddio et al., 2013). Healthcare consumer participation is more limited in its potential varieties, as it requires ongoing dialogue between professionals and HCCs. Consumer participation might therefore be limited to involving HCCs as ongoing members of CPG development committees. Beyond these examples, other specific methods within each category exist, but these specific methods are poorly characterized.

The creation of patient resources meant to accompany CPGs is a commonly used method of consumer communication. Patient resources include documents that accompany CPGs, meant for patient use. These can include plain-English guidelines or summaries, or decision aids designed to help patients weigh benefits and harms of potential treatments (Stacey et al., 2014; Tong et al., 2012). Although they do not offer opportunity for HCCs to directly influence CPG development, the utility of patient
resources in patient education has been verified in past studies. A review of randomized control trials detailing the effectiveness of patient decision aids revealed that these resources improved patients’ understanding of their illness (Stacey et al., 2014). Use of these resources also led to more accurate perceptions of risk associated with treatments, as indicated by scores achieved on knowledge indexes (Stacey et al., 2014). Furthermore, decision aids helped to reduce decisional conflict relating to feeling uninformed or unclear about personal values (Stacey et al., 2014). Two studies included in this review also demonstrated a statistically-significant difference in adherence to a chosen treatment option, favoring the group that was provided with a decision aid (Stacey et al., 2014).

The process through which CPGs are created can be divided up into broad stages. These stages typically include formation of a guideline development group; formulation of key questions and outcomes for the guideline; retrieval, appraisal, and synthesis of research evidence; formulation of recommendations; publication and implementation; and finally, review and updating (Davis et al., 2007; GRADE Working Group, 2004; WHO, 2010; WHO, 2014). The impact of HCC involvement can vary with the stage of CPG development in which they are involved. For example, involving HCCs during formation of the guideline development group or during management of conflicts of interest serves to establish transparency for the development process (IOM, 2011). Involving HCCs during the stage of retrieval, appraisal, and synthesizing of research evidence may allow HCCs to have an impact on the final CPG product (Boivin et al., 2010). However, involving HCCs specifically during evidence retrieval and appraisal requires greater time commitments and the need for training to understand specialized terminology (van de Bovenkamp & Zuiderent-Jerak, 2015). In comparison, involving HCCs at the stage of formulating key questions and outcomes for the guideline allows HCCs to contribute without need for training (van de Bovenkamp & Zuiderent-Jerak, 2015). Overall, the challenges faced and the usefulness of HCC involvement may vary depending on the stages of development during which HCCs are asked to be involved.

1.3 Relevance to Health Information Science

A health information system should facilitate decision making that is based on sound and reliable information, through its four key functions of the generation,
compilation, analysis and synthesis, and communication and use of data (WHO, 2008). In relation, Health Information Science is concerned with knowledge translation, defined by the Canadian Institutes for Health Research as a dynamic and iterative process that includes the synthesis, dissemination, exchange, and ethically sound application of knowledge to improve health, provide more effective health services and products, and strengthen the healthcare system (Straus, Tetroe, & Graham, 2009; Western University, 2019).

In their overview of the process of knowledge translation, Graham and colleagues (2006) describe CPGs as knowledge tools, with the purpose of presenting knowledge in a clear, concise, and user-friendly format, influencing stakeholder decision making through providing explicit recommendations, and facilitating the uptake and application of knowledge through meeting stakeholders’ needs for information. The development of CPGs falls into the “knowledge synthesis” process of knowledge translation. This process involves utilizing explicit and reproducible methods to identify, appraise, and synthesize information relevant to specific questions (Graham et al., 2006). The purpose of this study is to characterize the methods used to involve HCCs in the development of CPGs. As unique knowledge holders within the healthcare system, engaging patients and other HCCs in the development of CPGs presents opportunity to ensure that their knowledge is utilized in practice and has the potential to improve the usability and outcomes of these tools (Armstrong et al., 2017; van de Bovenkamp & Trappenburg, 2009). Because the purpose of this study is to characterize a specific facet of the process of knowledge synthesis used to create an important knowledge tool, its area of focus is within knowledge translation and Health Information Science more broadly.

1.4 Formulation of the Research Question

This study seeks to describe how HCCs have been involved in CPG development in Canada. In order to limit the primary data sample to a size that would be manageable over the timeframe for the Master of Health Information Science program, the CPGs included in this study were limited to those pertaining to the management of mood and anxiety disorders. To provide explanation for this limitation placed on the research question, this section gives an outline of the relevance of mood and anxiety disorders in
Canada, including the role CPGs play in their management. This section also provides the research question for this study.

1.4.1 Relevance of Mood and Anxiety Disorders

Across Canada, mood and anxiety disorders are among the most common mental illnesses, with a combined prevalence of 11.6% in those 18 and over; even so, these illnesses are largely regarded as underdiagnosed (Public Health Agency of Canada [PHAC], 2016; McRae, O’Donnell, Loukine, Rancourt, & Pelletier, 2016; Swinson et al., 2006). Both mood and anxiety disorders have negative impacts on overall quality of life, limiting a person’s ability to engage in hobbies and recreation, and interfering with their social and professional lives, especially when left untreated (PHAC, 2016). It is therefore important for those suffering from mood or anxiety disorders to be properly diagnosed and treated, and for the current problem of underdiagnoses to be reconciled. In addition, mood disorders and anxiety disorders both represent categories consisting of multiple illnesses with similar symptoms, but with important differences in effective treatments (American Psychiatric Association [APA], 2000; Scott et al., 2013). Adding to the complexity of their management, mood and anxiety disorders often occur together, and often come with other comorbid conditions, such as substance use disorders, schizophrenia, and attention deficit hyperactivity disorder (Bystritsky, Khalsa, Cameron, & Schiffman, 2013; Kessler et al., 2010).

Clinical practice guidelines may help rectify the underdiagnoses of mood and anxiety disorders, by standardizing care practices used to identify and treat these illnesses (PHAC, 2016; Swinson et al., 2006; Woolf, Grol, Hutchinson, Eccles, & Grimshaw, 1999). As tools meant to help healthcare providers navigate through care plans and provide high-quality care, CPGs are also important for aiding healthcare providers in the management of complex illnesses such as mood and anxiety disorders (Davis et al., 2007). This study therefore focuses on characterizing how HCCs are involved in the development of CPGs for mood and anxiety disorders specifically.
1.4.2 Research Question

Canadian organizations have advocated for the inclusion of HCCs in the process of CPG development in order to take advantage of the purported benefits (Health Council of Canada, 2012; Lindsay et al., 2014). However, the practice remains poorly studied in Canada. Characterizing the strategies used to involve HCCs in CPG development is an important first step in demonstrating and appraising the benefits. Given the relevance of mood and anxiety disorders within Canada, and the potential for CPGs to aid in their management, this study focuses on the strategies used to involve HCCs in the development of guidelines for these illnesses. The question this study seeks to answer is What methods are used to engage HCCs in the development of CPGs for mood and anxiety disorders in Canada? Specifically:

- **How are HCCs involved in CPG development?**
  
  - At what stages of guideline development are HCCs involved?
  
  - What tools or strategies are used to involve HCCs in CPG development?
  
  - What groups of HCCs are involved?

- **What are the objectives or desired outcomes for engaging HCCs in CPG development?**

To summarize, this study’s research question is how are HCCs involved in the development of Canadian CPGs for mood and anxiety disorders, who is being involved, and why HCCs should or should not be involved in the development of these CPGs. Understanding the methods of HCC involvement utilized in Canada will contribute to indicating the quality of CPGs being produced. This study will also allow for subsequent analysis of the effectiveness of methods currently in use in Canada.

1.5 Thesis Outline

Chapter 1 has outlined a rationale for this study, important factors that should be included in descriptions of HCC involvement in CPG development, as well as the
research question this study aims to answer. Following this, Chapter 2 provides a description of the methodology used for this study, including a description of the paradigm utilized in this study. A description of the methods used for sampling and data analysis is provided, along with descriptions of quality considerations made for this study.

Chapter 3 provides detailed descriptions of important results gathered throughout this study, including descriptions of strategies for involving HCCs in CPG development, organized by the stage of CPG development in which they are employed. A description of the use of patient resources, as well as themes from interviews are also provided. Finally, Chapter 4 provides a summary of important findings and discusses their relation to existing literature. Recommendations for future research and the limitations of this study are also considered.
Chapter 2

2 Methodology and Methods

This chapter provides a description of the design of this study, starting with outlining the paradigmatic view and methodology utilized. A description of the methods used is also provided, including the sampling method used to gather a dataset, as well as the process of qualitative content analysis used. Data collection was conducted in three parts: collection and review of CPGs, collection and review of related material, and completion of interviews or questionnaires by CPG authors or methodologists. Qualitative content analysis was utilized to code and synthesize results into detailed descriptions of how HCCs have been involved in CPG development in Canada. This chapter also provides a description of the measures taken to ensure the quality of this study. Finally, a description of the ethics approval for this study is provided.

2.1 Paradigmatic View

This study is rooted in a constructivist paradigmatic lens, focused on uncovering the subjective descriptions of involving HCCs in CPG development. In order to describe the strategies used within Canada to involve HCCs in CPG development, this research involved interactions between the researcher and a dataset made up of CPGs, related material, and professionals involved in CPG development. The researcher recognizes that his own interpretations, as well as the interpretations of participants, have influenced the processes of data collection and analysis. This research therefore utilized a relativist view of ontology and a subjectivist view of epistemology, in accordance with a constructivist paradigm (Guba & Lincoln, 1994; Ponterotto, 2005; UK Essays, 2013). Phenomena described through this study have been treated as mental constructions dependent on the individuals who describe them (Guba & Lincoln, 1994). Information collected during this study is considered to have been created through the investigative process, including through interactions between the researcher, participants, and the dataset (Guba & Lincoln, 1994). While interpretation has influenced data collection, analysis and reporting, the researcher has strived to minimize its role, and prioritize the descriptions provided through dataset and research participants, versus interpretations. The researcher
has striven to maintain close agreement between how information is presented within the dataset and how it is reported.

2.2 Methodology

2.2.1 Qualitative Description

Qualitative description was used in this study because it is a methodology that fits closely with the researcher’s views of epistemology and ontology. Use of qualitative description fits within a constructivist paradigm and allows the researcher to acknowledge the effects of subjectivity on data collection and analysis (Neergaard, Olesen, Andersen, & Sondergaard, 2009; Sandelowski, 2000). Use of qualitative description allows for minimizing the effects of this subjectivity in the form of interpretation. The aim of qualitative description is to provide detailed descriptions of phenomena in terms that are as similar as possible to those used by participants or data sources from which descriptions originate (Neergaard et al., 2009). Even so, proponents of qualitative description do not assert that “pure description”, in line with a positivist view of ontology and epistemology, is possible (Neergaard et al., 2009; Sandelowski, 2000). In contrast, according to Sandelowski (2000), researchers utilizing qualitative description should recognize that descriptions of a target phenomenon will always entail some level of interpretation. Sandelowski (2000) recognizes that “there is no pure looking with a naked, innocent eye”, and that descriptions will always depend on the perceptions and sensibilities of the describer. Therefore, Sandelowski’s (2000) description of qualitative description falls within a constructivist view of epistemology (Guba & Lincoln, 1994; Pearce, 1971). In this study, choices have been made regarding what data to present from large datasets, demonstrating the impact of researcher subjectivity on what is presented as findings.

Qualitative description borrows tenets from naturalistic inquiry to study phenomena in their natural state (Neergaard et al., 2009; Sandelowski, 2000). In alignment with naturalistic inquiry, variables are not manipulated, and there is no commitment to pre-existing theories, in order to allow data to be analyzed in a form it would be likely to appear if it were not under study (Lincoln & Guba, 1985;
Sandelowski, 2000). However, researchers are still allowed to create linkages between presentation of a current dataset and previous research (Neergaard et al., 2009). For this research project, this allows descriptions resulting from the current dataset to be guided by previously completed work. A literature review was therefore completed for this study to determine the factors that are likely to affect the outcomes of HCC involvement in CPG development. This literature review has been used to guide the aspects of this practice that are presented as findings for the current study.

2.2.2 Role of the Researcher

While I have sought to minimize the influence of interpretation on findings presented in this study, in line with both the constructivist paradigmatic view and qualitative description methodology utilized, I acknowledge that my own experiences and decisions influence this study.

I grew up in a small town in Northern Ontario, with parents who both work in the healthcare sector. As clinicians, my parents would often have stories of conflict with patients, who would request unnecessary or potentially harmful treatments, or who would become non-compliant with treatments likely to be effective. I became aware of the role of patients in their own healthcare through these discussions with my parents. I developed an understanding of the need for patients’ involvement in their own healthcare, such that it meets their needs for education, and the integration of their own personal values. My interest in exploring and developing strategies for including patients in their healthcare for their own benefit has been a result of my childhood experiences with my parents’ own careers.

From my experience arises a potential bias in this research. I believe that patient involvement in healthcare research, development, design, and delivery is a practice that should be utilized in order to facilitate agreement between patients, their care providers, and their care plans. This has affected my decision to focus on the benefits of HCC involvement in CPG development throughout this study. It may have also influenced the framing of questions used in interviews, as well as my own interpretation of data gathered throughout this study. Finally, it may have influenced how this information was framed in its reporting and discussion within this thesis.
My interpretations of the dataset utilized in this study, and the resulting findings that are presented, are influenced by my own review of the existing research literature. Through review of existing research, I have formulated my research question based on what others have previously described to be important factors in involving patients and other lay members of the public in the development of CPGs. Information from previous research has also influenced the processes of extracting important information from my data sources and coding this information. Review of previous research has allowed me to determine that important factors to consider are the specific groups involved, such as patients or family members, the stage of CPG development these stakeholders are involved in, and the specific methods used. I have striven to allow answers to my research question to arise directly from my data sources in the form of codes, but my decisions regarding how to code collected information have been influenced by descriptions of similar information provided in previous studies.

2.3 Methods

2.3.1 Design

This study has been conducted in three parts, consisting of collection and review of CPG documents, collection and review of related material, and correspondence with CPG authors or methodologists through interviews or questionnaires. Similar methods have been used in previous studies in order to describe involvement of patients in CPG development outside of Canada (Armstrong & Bloom, 2017; Légaré et al., 2011). Armstrong & Bloom (2017) identified information contained within webpages and CPG development manuals to identify organizations that involve patients in their CPG development processes. For organizations where information could not be gathered from these sources, these authors utilized information contained within the most recently published CPG from these organizations to identify information regarding their methodology (Armstrong & Bloom, 2017). Légaré and colleagues (2011) sought to describe key components of existing patient and public involvement programs in CPG development. To achieve this, Légaré and colleagues collected descriptions of patient and public involvement programs from qualitative and quantitative research articles, as well
as from documents describing these programs that were produced by national- or
government-supported or non-profit organizations that produce CPGs.

In this study, a sample of CPGs pertaining to the management of mood and
anxiety disorders was collected using searches of PubMed and the CMA CPG InfoBase.
Secondly, organizations involved in the development of each guideline were identified
using information contained within each CPG. Google searches were used to locate
websites corresponding to each organization. Relevant websites were searched for
sections, passages, or documents that describe the CPG development process adhered to
by the respective organization. Finally, authors or organizations listed as a
correspondence contact for each CPG were contacted for the purpose of conducting an
interview or alternatively completing a questionnaire. Four interviews and two
questionnaires were completed for this study. A full description of the sampling method
used in this study is provided through section 2.3.2 and section 2.3.3.

Inductive qualitative content analysis was used to code information contained
within the data sample for this study and create final categories to be presented as results.
Information contained within CPG documents and web-based material was used to
identify how HCCs have been involved in CPG development, including what groups of
HCCs have been involved, what strategies have been used, when they are involved, and
for what purpose. Interviews and questionnaires were used to gather information
pertaining to the strategies used to involve HCCs in CPG development. Interviews and
questionnaires were also used to gather information pertaining to professional
perspectives regarding the value of HCC involvement in CPG development and why this
practice is used or avoided. A full description of the analytic approach used in this study
is available in section 2.3.4 and section 2.3.5.

2.3.2 Criterion Sampling and Total Population Sampling

Purposeful sampling is a sampling method that is used commonly within
qualitative descriptive studies and that is likely to compile a dataset containing high-
quality information (Neergaard et al., 2009). Purposeful sampling involves utilizing
existing information in the field of study to help identify information-rich cases (Suri,
As specific types of purposeful sampling, this study utilized both criterion sampling and total population sampling (Lund Research, 2012; Suri, 2011).

Criterion sampling involves seeking a sample that meets a pre-determined set of inclusion criteria (Coyne, 1997; Suri, 2011). In line with the method of criterion sampling, this study based its sampling criteria on previously completed studies (Armstrong & Bloom, 2017; Légaré et al., 2011; Suri, 2011). This study utilized characteristics of CPGs outlined by the IOM (2011) and by other previous publications to define its sampling population (Alonso-Coello et al., 2011; Shekelle et al., 2001). Further inclusion criteria resulting from the research aim provided strict limitations on the CPGs considered in this study. Criterion sampling was used to define the population of CPGs that this study used as the basis of analysis.

Use of criterion sampling also allowed the researcher to seek out further information directly related to CPG documents that fit inclusion criteria from related documents, web-based material, and from interviews and questionnaires conducted with professionals involved in CPG development. Using CPGs and related material to define a dataset has been used successfully in similar studies (Armstrong & Bloom, 2017). In her description of purposeful sampling, Coyne (1997) outlines that this type of sampling can be planned at the beginning of a study based on existing knowledge of where high-quality information is likely to be found. In line with this, documents that describe CPG development procedures included in this study were sought out only before data analysis began. Professionals from organizations that developed CPGs included in this study were also invited to participate in interviews or questionnaires. Interviews and questionnaires were completed before data analysis began. Sampling was not done simultaneously with data analysis and was not done to contribute to the creation of a theory emerging from data, as in theoretical sampling (Coyne, 1997). To summarize, criterion sampling, a specific type of purposeful sampling, was utilized in this study because it allowed for the collection of data sources likely to provide important information, but did not require sampling to continue throughout data analysis in order to contribute to any emerging theories (Coyne, 1997; Suri, 2011).
Total population sampling involves gathering information from the entire population of units with particular characteristics (Etikan, Musa, & Alkassim, 2016; Lund Research, 2012). This study utilized CPGs that fell into a predetermined set of criteria as its sampling population and used each of these as starting points to gather a broader dataset that related directly to these documents. Because every CPG that adhered to inclusion criteria were analyzed in this study, total population sampling was also used, in addition to criterion sampling (Etikan et al., 2016; Lund Research, 2012). The number of CPGs that met inclusion criteria was relatively small, making total population sampling a reasonable choice for this study (Etikan et al., 2016). Total population sampling was also used in gathering related data sources for CPGs that met inclusion criteria. Web-based material describing the development of CPGs was collected for each CPG. In addition, recruitment materials were sent to one professional or one organization involved in the development of each CPG included in this study. Further details on the sampling method used in this study are provided in section 2.3.3.

### 2.3.3 Sampling and Recruitment Method

For this study, clinical practice guidelines were defined as review documents that contain recommendations based on systematic review of available evidence and/or expert consensus, meant to inform primary care physicians, medical specialists, or allied health clinicians in the diagnosis, assessment, and treatment of illness (American Academy of Family Physicians, 2017; Davis et al., 2007; IOM, 2011). The primary data sample for this study consisted of CPGs written in Canada to aid in the management of mood and anxiety disorders. Limiting the data sample to CPGs pertaining to the management of mood and anxiety disorders was done primarily as a means to ensure that the data sample remained small enough to analyze and describe within the timeframe of the Master of Health Information Science program for which this study has been completed. Section 1.4.1 provides a rationale for limiting the primary data sample to CPGs pertaining to the management of mood and anxiety disorders. Previous studies have demonstrated that many CPGs require updating within six years of publication, and most organizations that develop CPGs review and update these publications at least every five years (Alonso-Coello et al., 2011; Canadian Medical Association [CMA], 2018; Shekelle et al., 2001).
Consistent with this, to be included in this study, CPGs must have been published or most recently updated after January of 2013, five years prior to the initiation of this study.

Inclusion criteria for the primary data sample for this study were: 1) documents must meet the definition of CPG previously given, 2) CPGs and included recommendations must pertain primarily to the management of mood or anxiety disorders, as they are defined by the DSM-IV or DSM-V, 3) CPGs must be commissioned or developed by, or done so in conjunction with, a Canadian organization, 4) CPGs must be available and free for public use and 5) CPGs must be the most recent version of the respective guideline. Clinical practice guidelines published as a series or as multiple documents were considered as one guideline, but all relevant parts were analyzed for data extraction.

Collection of a primary data sample was completed using searches of databases likely to contain CPGs. As a known index for up-to-date CPGs, the Canadian Medical Association (CMA) CPG Infobase was first searched for relevant guidelines. Each result from the CMA CPG InfoBase were subject to a review of titles, abstracts, and author information to identify results that met inclusion criteria for this study. The CMA CPG InfoBase revealed 23 results relevant for use in this study. PubMed was also searched for relevant guidelines. Search terms used within PubMed were not designed to identify an exhaustive list of CPGs fitting the aforementioned criteria, but rather were limited to a short list of terms in order to ensure CPGs analyzed in this study remained clinically relevant (Appendix A). Results were limited to those published between January 2013 and July 2018 consistent with the inclusion criteria. Search results from PubMed were also subject to a brief review of titles, abstracts, and author information to isolate results that were relevant for this study. Results from the CMA CPG Infobase and PubMed were combined using Zotero, a resource management program, and duplicate results were identified and removed. Remaining results deemed to be relevant were subject to a full-text review to ensure adherence to inclusion criteria for this study. Finally, results belonging to CPGs published as a series were combined to be considered as complete CPGs. A total of twelve complete CPGs were found to be relevant for inclusion.
following full review (Appendix B). The process of collecting the primary data sample for this study was completed in July of 2018.

Following identification of the initial data sample, descriptions of how these documents were developed were sought. First, any documents referenced by each CPG that contained descriptions of development procedures were identified and collected. Organizations credited with or claiming responsibility for the development of or production of each guideline were also identified through review of author and publishing information contained within each CPG. Organizations that were credited only with funding or endorsement of the CPG, or the organizations affiliated with individual authors were not considered. Additionally, organizations credited only for creating a literature review protocol, participating in the review and comment, or publishing the CPG in question were also not considered.

Following identification of relevant organizations, Google was used to search for information corresponding to each of these organizations. The title of each organization that develops CPGs identified as relevant for this study was used as a search term. These searches were meant to identify the most up-to-date webpage corresponding to each organization responsible for the development of a CPG analyzed in this study. For each search term used, the first two pages of results were searched through to identify websites or documents belonging to these organizations. Relevant websites were those directly corresponding to the organizations that produced a CPG being considered, or a website for a parent organization. Each website was searched for descriptions of how the respective organization develops CPGs. Webpages were reviewed in full for descriptions of HCC involvement in their programs. Only the webpages directly related to the organizations being considered were reviewed in cases where, for example, these organizations were subsidiaries of larger organizations. Passages describing CPG development procedures were copied and saved into a word document, along with the corresponding URL. Documents made available with each website deemed likely to contain descriptions of CPG development procedures were identified and collected. These included, but were not limited to, annual reports, procedure manuals, policy documents, and program overviews. Financial reports were not collected for review.
Webpages and documents were not excluded from review or analysis based on their publication date. Collection of information from web-based material was completed from October of 2018 through to April of 2019.

Professionals involved in the development of CPGs analyzed in this study were also interviewed or invited to complete a questionnaire. Ethics approval for this study was granted by the Western University Non-Medical Research Ethics Board (ID# 112558). For this study, professionals were considered to be individuals with formal training or education within healthcare and health services and policy design, excluding patient advocates. Previous research has used interviews with professionals involved in CPG development to gather information on their experiences with HCC involvement in CPG development, and the perceived value of this involvement, although it focused on CPGs developed in the Netherlands (van de Bovenkamp & Zuiderent-Jerak, 2015). In this study, interviews and questionnaires were primarily used to gain a deeper understanding of professionals’ views regarding the involvement of HCCs in CPG development, and why HCCs are or are not involved in CPG development. This decision was made a priori, after considering that professionals would have expertise in CPG development and insight into the potential value of involving HCCs in this process. Interviews and questionnaires were also used to verify and add to data collected through an initial review of CPGs and related web-based materials.

Total population sampling was utilized to recruit authors or other professionals involved in the development of CPGs. CPG authors were chosen as the target population for recruitment because 1) they represented a group of professionals whose involvement in the development of the respective CPG could be reliably verified and 2) contact information for the first author of the CPGs included in this study were often made available in the CPG itself. For those CPGs that provided it, contact information was collected for the corresponding author. For CPGs that provided an organizational email explicitly as a correspondence contact, this email was collected, in substitution of an author email.

If contact information for a corresponding author or for an overseeing organization was not made available within the CPG document itself, the first author’s
institutional affiliations were collected from the CPG. A Google search was used to identify the webpage corresponding to the first listed affiliate institution. Search terms used were composed of the author’s first and last name, in combination with the institution’s name. The author’s e-mail address and phone number were collected from the first webpage that provided this information, provided it was made publicly available. This information was preferentially collected from webpages belonging to the first identified affiliate institution.

The first author or organization for each CPG under review, for which contact information could be collected, was contacted by email in order to request they participate in an interview or complete a questionnaire for this study. In cases where no response was received within two weeks, a reminder email was sent. If, after one week from sending the reminder email, the first contacted author or organization had not responded, the author or organization was called. If these attempts to reach the first author or organization were unsuccessful, the next author or organization for which contact information was publicly available was contacted by email once. Contact information for the second author or organization was collected using the same procedure described previously. Recruitment emails and telephone calls followed a recruitment-style script and indicated how the author’s contact information was obtained, who was conducting the study, and what the study required from participants (Appendix C and Appendix D). Recruitment materials also presented opportunity for the contacted author or organization to forward the recruitment script to individuals who would be better able to answer questions regarding the involvement of HCCs in the development of the respective CPG. A letter of information and consent was provided as an attachment to recruitment emails (Appendix E). Recruitment materials were sent to potential participants from November of 2018 to January of 2019.

Although listed authors served as the initial point of contact for recruitment for this study, they were not the only professionals invited to participate in interviews. The email recruitment script did not indicate that CPG authors were the desired population, and these recruitment emails contained directions to forward them to the professional who would be the most capable of addressing the study’s subject matter (Appendix C).
Professionals involved in this study therefore varied in their area of expertise and in their level of involvement in the development of each CPG analyzed. The decision to allow for variance in the role in CPG development and area of expertise within professionals participating in interviews was made a priori, in order to increase the likelihood of response by potential participants. The roles of each professional who participated in this interview are described later in this section.

Through communication via email or phone calls, participants who had responded to recruitment materials were presented with the opportunity to schedule an interview at a time convenient for them. Interviews were conducted via telephone, to ensure geographic location did not hinder the researcher’s ability to reach participants. Interviews followed a semi-structured design and consisted of open-ended questions regarding why HCCs were or were not involved in the development of the respective CPG, and how this occurred (Appendix F). Participants were asked to comment on or clarify information collected through the review of CPGs or related material in cases where information was found describing the involvement of HCCs in CPG development from these sources. Participants were also asked to comment on the value of HCC involvement in CPG development, as well as any challenges or facilitators for the process, when appropriate. Interviews took twenty to thirty minutes to complete.

Interviews were audio-recorded using the Apple Voice Memos application, and audio recordings were transcribed verbatim by the researcher. To ensure accuracy of transcription, and to add to the rigour of this study, completed transcripts were reviewed at least twice while listening to the corresponding interview recording (Milne & Oberle, 2005). Completed transcripts were handed back to participants to allow them to check for accuracy and provide further comment, again to add to the rigour of this study (Milne & Oberle, 2005). The concept of rigour as it applies to this study is further discussed in section 2.4.1. The process of conducting interviews, transcribing audio-recordings, and reviewing the transcripts was completed from December of 2018 to March of 2019. Related data sources were reviewed, but not coded, prior to conducting the corresponding interview, to give the researcher the opportunity to ask for clarification on any relevant information if needed.
Through recruitment materials, participants were also provided the option to complete a questionnaire if they were unwilling or unable to schedule a telephone interview. Upon their request, participants were provided a secure link to a questionnaire created using the Qualtrics tool. Participants were also provided a unique six-digit code to be entered into the survey to identify their responses. A list of these codes and the corresponding participant names was kept by the researcher as a Microsoft Word file on a password protected and encrypted flash drive. Open-ended questions were used to gather relevant information equivalent to that gathered through interviews (Appendix G). These questions were also suited to collect data on how HCCs were involved in CPG development, and why HCCs were or were not involved in this process.

In total, six participants contributed information for this study through participation in interviews or questionnaires. Two individuals were the primary authors of the respective CPG analyzed for this study and both of these participants completed questionnaires. Four individuals participated in interviews, and each of these individuals held positions in either quality improvement or research coordination at their respective organizations.

Finally, in two cases, participants forwarded the researcher additional materials describing the development of the respective CPG, or material describing how HCCs were involved in this process. Materials received this way included a peer-reviewed journal article as well as a webpage corresponding to an additional organization that had created a patient resource for the respective CPG. The peer-reviewed journal article was collected for analysis, and the webpage was reviewed in an identical fashion to those webpages identified through Google searches, to collect information describing how HCCs were involved in the development of the respective CPG.

2.3.4 Qualitative Content Analysis

Qualitative content analysis is a method that is used to systematically describe or interpret information (Graneheim & Lundman, 2004). Qualitative content analysis involves combining codes into categories that are titled based on language used directly in the dataset (Elo & Kyngäs, 2008). Abstraction of data is allowed to stop at this point, and the researcher can report these categories as minimally theorized descriptions of the
dataset (Erlingsson & Brysiewicz, 2017; Vaismoradi et al., 2013). Use of qualitative content analysis therefore helps to minimize effects of the researcher’s interpretations and allow descriptions to remain in close agreement with the dataset. Qualitative content analysis still allows the researcher to view description and interpretation as existing on a continuum, with description always entailing some amount of interpretation (Sandelowski, 2000). Use of this method therefore allows the researcher to view data creation and analysis as a constructive act and encourages the researcher to recognize their biases and preconceptions during analysis (Sandelowski, 2010; Vaismoradi et al., 2013). Because the researcher viewed research data and results arising from its analysis as constructed through interactions between the researcher, the data, and participants, qualitative content analysis is a suitable choice for data analysis in this research.

For use in this study, a meaning unit was defined as a verbatim passage taken from the dataset that described a phenomenon of interest (Erlingsson & Brysiewicz, 2017). Furthermore, a meaning unit was any sentence or paragraph that described how HCCs are involved in CPG development. Codes were defined as labels that described what a particular meaning unit was about, and that were usually one or two words long (Erlingsson & Brysiewicz, 2017). To describe the dataset in detail, multiple codes may have been applied to any individual meaning unit. A category was formed by combining codes that were related in their content (Erlingsson & Brysiewicz, 2017). Categories were used to address the question of who is being involved in CPG development, how this is happening, and why. Creation of themes requires a higher level of abstraction. Themes express an underlying meaning, or a connection between categories that has been interpreted by the researcher (Erlingsson & Brysiewicz, 2017). This study used themes to express ideas that emerged from interviews only, that regard the motivations for involving HCCs in CPG development, and the increasing efforts to involve HCCs in CPG development. Themes have not been used to describe the actual strategies that have been used to involve HCCs in CPG development.

Inductive content analysis is an appropriate choice for data coding in research that aims to minimize use of existing theory while still providing detailed descriptions of a target phenomenon (Neergaard et al., 2009). In inductive qualitative content analysis,
existing theory should not guide creation of codes. Instead, codes should originate from data being analyzed, and summarize important concepts (Erlingsson & Brysiewicz, 2017). Codes should be combined into categories, to provide comprehensive descriptions of important information. In order to provide a detailed description that remains in close agreement with the dataset, each unique code should be integrated into final categories (Granheim & Lundman, 2003). In addition, codes should not be assigned a relative level of relevance based on their frequency of occurrence (Erlingsson & Brysiewicz, 2017).

2.3.5 Analytic Approach

Qualitative content analysis was used to analyze information from CPGs, related material, and interviews (Neergaard et al., 2009; Sandelowski, 2000). Individual CPGs were considered the primary unit of analysis for this study. Data pertaining to an individual CPG, including the CPG itself, related materials and interview transcripts, were coded and categorized together. As an important first step in data analysis, all information pertaining to an individual CPG was reviewed before coding was conducted for this CPG. This allowed the researcher to become familiar with the dataset before codes were applied (Erlingsson & Brysiewicz, 2017). Inductive content analysis was then applied to analyze individual CPGs, their related materials, and interview or questionnaire information if available, to provide descriptions of who was involved in this CPG’s development, as well as how and why they were involved. Inductive content analysis was utilized to code data because the researcher sought to minimize use of existing theory while still providing detailed descriptions of HCC involvement in CPG development.

Meaning units were pulled from each data source, and codes were subsequently applied to those meaning units. Important concepts pulled from the dataset included descriptions of what groups HCCs belonged to, what stage of development these individuals were involved in, the direction of information flow between professionals and HCCs, and why these individuals were being involved.

In accordance with use of inductive qualitative content analysis, existing theory did not dictate creation of predetermined codes. Instead, codes were generated from data being analyzed, and were used to summarize important concepts (Erlingsson &
Brysiewicz, 2017). For each individual CPG and its related materials, codes were combined into categories, to provide comprehensive descriptions of information deemed important for answering the research question. In order to provide detailed descriptions that remained in close agreement with the dataset, each code was integrated into final categories (Granheim & Lundman, 2003). Categories served as the final level of reporting for describing the strategies that have been used to involve HCCs in CPG development, to avoid further reliance on interpretation (Elo & Kyngäs, 2008; Erlingsson & Brysiewicz, 2017).

As analysis progressed for an individual CPG, codes and categories were compared with those applied in previously analyzed CPGs to ensure consistent application of similar descriptors (Erlingsson & Brysiewicz, 2017). However, codes from separate CPGs and their related materials were not combined to finalize codes and categories to be applied across the data set. This was done to allow for creation of descriptions that remained closely in line with information contained within the initial dataset (Neergaard et al., 2009).

In addition to analyzing materials related to individual CPGs as a unit, interviews were analyzed independently from other data sources. Interviews contained important information regarding the professionals’ perceptions of the value of HCC involvement, and the efforts that have been made to utilize the practice. This information did not pertain to individual strategies of HCC involvement in CPG development. To convey this information, the appropriate categories arising from interviews only were combined to form themes. The researcher strived to ensure that themes were used only to connect related categories and not to convey latent or underlying content, to minimize the effects of the researcher’s interpretation (Erlingsson & Brysiewicz, 2017).

Throughout data analysis, reflexive notes were taken to document decisions made regarding what information was incorporated into codes, categories, and themes (section 2.4.2). The research advisory committee was involved in confirming decisions regarding what information to include in codes, categories, themes, and the final presentation of results. The researcher has also utilized reflexivity to document how his knowledge of
existing theory may have influenced the descriptions of HCC involvement in CPG development that were produced throughout this study, as described in section 2.4.2.

2.4 Quality Considerations

In line with the use of a qualitative descriptive methodology and the constructivist paradigm underpinning this study, the researcher has considered data collected as co-constructed by himself, interview participants, the authors of analyzed documents, and the research advisory committee members. The researcher realizes that data labelled as important, and interpretations of this data, may vary between researchers. However, the researcher has striven to ensure that descriptions of HCC involvement in CPG development resulting from this study follow participant data directly, by following the description of qualitative description given by Sandelowski (2000; 2010). This effect is enhanced through using categories of information as the final level of abstraction of data to describe how HCCs have been involved in CPG development, rather than extending interpretation to create themes (Erlignsson & Brysiewicz, 2017). In considering how quality would be achieved throughout this study, Tracy’s (2010) “big tent” criteria were each considered. Because the research has aimed to minimize the effects of interpretation, important quality considerations for this study include rigour and credibility (section 2.4.1), and sincerity (section 2.4.2; Milne & Oberle, 2005; Neergaard et al., 2009; Tracy, 2010). Furthermore, Tracy’s (2010) criteria of rigour, credibility, and sincerity have each been described as important in the use of qualitative description, or in the use of a constructivist paradigm (Neergaard et al., 2009; Salkind, 2010).

2.4.1 Rigour and Credibility

For this study, rigour has been defined as the thoroughness, richness and care put into data collection, analysis, and reporting (Tracy, 2010). Within a constructivist paradigm, researchers reject the notion of objectivity, and therefore accept themselves, including their preconceptions and sensibilities, as part of the research process and its results (Salkind, 2010). Within a constructivist paradigm, interactions between researcher and participants, or even the researcher and the dataset, must be described as a crucial part of the research project (Salkind, 2010). Rigour in qualitative description therefore
involves detailed description not only of the dataset, but also of how the research process proceeded and how results were affected by interactions between the researcher, their existing ideas, the dataset, and research participants.

Credible research is that which “readers feel is trustworthy enough to act on and make decisions in line with” (Tracy, 2010). Achieving credibility involves providing thick description of methods and results and working towards crystallization. Thick description involves reporting data and conclusions in abundant detail (Tracy, 2010). Similar to rigour, thick description is necessary to provide an adequate description of HCC involvement in CPG development and to provide a solid basis for conclusions made by the researcher. Crystallization in qualitative research refers to the idea that if two or more sources or types of information can converge on the same conclusion, then the conclusion is more valid (Tracy, 2010). The term “crystallization” is used instead of “triangulation”, in order to acknowledge that results remain partial constructions of an issue, even if they are collected from multiple data sources or types of data, or using multiple theoretical frameworks (Tracy, 2010). The use of crystallization as a quality criterion therefore remains in close agreement with the constructivist paradigm utilized throughout this study. Achieving crystallization requires researchers to gather information from multiple data sources to provide an in-depth, but still subjective, understanding of an issue (Tracy, 2010). This concept has been applied in the current research through collection of information through CPGs, related documents, and interviews in order to gather detailed descriptions of HCC involvement in CPG development. The author realizes that data collected in this manner do not converge on a single “truth” of what strategies are used, but instead result in a more in-depth description constructed through interactions between the researcher, the dataset, and participants.

The rigour of this research project has been enhanced through the collection of information from multiple data sources. Specifically, information describing how HCCs were involved in the development of each CPG under review has been pulled from the CPG documents themselves, related materials found online originating from organizations responsible for their development, as well as from interviews or questionnaires completed with professionals from these organizations. Clinical practice
guidelines and related information taken from the related organizations have been used as data sources in similar studies (Armstrong & Bloom, 2017; Légaré, 2011). These studies were able to provide in-depth descriptions of strategies used to involve HCCs in CPG development outside of Canada. The use of multiple data sources in this study has contributed to the detail of the descriptions of strategies used to involve HCCs in CPG development. Use of participant interviews has added to the comprehensiveness of data sources when compared to those used in previous studies, contributing to the rigour of the current study.

The researcher has identified aspects of HCC involvement in CPG development likely to influence the usefulness of these strategies, and the challenges encountered. An awareness of existing theory and descriptions given in the literature has allowed the researcher to detect nuance in the dataset and make appropriate decisions regarding what is important for addressing the aims of this study (Tracy, 2010). While utilizing existing theory is useful for detecting nuance in the dataset, in studies utilizing qualitative description, it is important to allow codes applied to the data to originate from the data itself (Milne & Oberle, 2005). To reduce the influence of the use of existing theory on data analysis, and therefore keep the process of data analysis commensurate with a qualitative descriptive methodology, the researcher has documented his preconceptions and biases resulting from literature review within reflexive notes as appropriate. A summary of these is available in section 2.2.2. The researcher’s decisions regarding what was considered important information for coding, and how to code and categorize this information have also been documented (Tracy, 2010). These decisions have been focused on ensuring that codes originate from the data sources analyzed in this study. Decisions made throughout the completion of this research, as well as the corresponding reflexive notes, have been shared with the research advisory committee for this project.

In addition to adding to the rigour of this study, the use of multiple data sources for each guideline under review provides a useful tool for crystallization (Tracy, 2010). As previously mentioned, information from online sources has been reviewed, and interviews with professionals involved in CPG development have been conducted, in addition to the initial review of CPGs themselves. Throughout the analysis of individual
CPGs and their related data sources, codes emerging from the dataset were critically reviewed to ensure similar codes were consistently applied when appropriate, and new codes were created when required (Milne & Oberle, 2005). Furthermore, as data analysis progressed, the researcher returned to previously analyzed CPGs and their related data sources, in order to ensure consistent application of codes and categories between CPGs (Elo et al., 2014). Comparison of coding and categorization between individual CPGs was not done to influence the content of codes, but only to ensure that similar codes and categories were applied consistently. Analysis of different data sources has allowed the researcher to ensure that information analyzed in this study was understood more deeply and interpreted consistently, so that congruent and in-depth descriptions of perceptions of the dataset could be given (Tracy, 2010). Use of multiple sources of information has therefore ensured that this research achieved crystallization and credibility, while maintaining its agreement with a constructivist paradigm (Neergaard et al., 2009; Tracy, 2010).

2.4.2 Sincerity and the Reflexive Process

Sincerity involves transparency, or honesty about the research process (Tracy, 2010). Achieving transparency involves providing clear documentation of decisions made and activities conducted throughout the research process (Tracy, 2010). The transparency of this study has been achieved through providing details on the proceedings of this study and the methods used, including how information was coded, and the level of detail included in transcriptions, for example (provided in section 2.3.3 and section 2.3.5; Tracy, 2010). The limitations of this study and a personal reflection are also given in section 4.2 and section 4.4 respectively, to outline the challenges encountered in this study (Tracy, 2010).

Sincerity also involves self-reflexivity, or the process of promoting honesty and authenticity with one’s self, one’s research and one’s audience through self-assessment of biases and motivations (Tracy, 2010). Use of reflexivity allows the personal experiences of researchers to be documented and analyzed for their potential effects on data analysis (Salkind, 2010). Because the experiences and interpretations of the researcher are considered an essential component of the data within a constructivist paradigm, the use of
reflexivity is required within studies that utilize this paradigm (Salkind, 2010). Within qualitative description, reflexivity can also help the researcher to reduce the effects of their perceptions, inclinations, and sensibilities on data analysis (Neergard et al., 2009). The use of reflexivity to document potential sources of bias or influence, what measures were taken to reduce the effects of these influences, as well as how decisions were made, are therefore important in this study.

As outlined previously, the researcher has documented his preconceptions and potential sources of bias and has used self-reflexivity to describe how his knowledge of existing theory surrounding HCC involvement in CPG development may have influenced this study and its results. A summary of these is provided in section 2.2.2. Reflexive notes have also been taken throughout the research process in order to document details of interactions between the researcher, the dataset, and interview participants, and their possible influence on data analysis. The researcher has kept detailed notes regarding what was considered important to be included in the coding and categorization of analyzed data. Decisions regarding how to code information that was considered important were also rationalized, and these rationalizations were recorded. The researcher’s reflexive notes regarding his preconceptions and biases, and regarding the decision making done during data analysis have been shared with the research committee members involved to ensure the credibility of this study (Tracy, 2010). A summary of reflexive notes taken throughout the research process is provided in Appendix H.

The role of the research participants in this study has also been considered through reflexivity. Participants recruited for involvement in this research have played a significant role in the development of the CPGs analyzed in this study or have been identified as the individual best suited to provide valuable information for this study by their respective organization, following review of recruitment materials. Although the population of potential participants has been limited by the inclusion criteria applied to the initial sample of CPGs gathered for this study, the role each participant has played in the development of the respective guideline has varied. To compensate for this, the role of each participant in the development of the respective guideline has been documented and considered during data analysis and communicated in this thesis (section 2.3.3).
2.5 Ethics

The Western University Non-Medical Research Ethics Board approved this study (ID# 112558; Appendix I). A letter of information and consent was provided to participants through recruitment emails (Appendix E; Western University, 2017b). In cases where interviews were conducted, participants were asked to confirm that they had reviewed the letter of consent and provide verbal consent for participation after having reviewed the letter of information. The researcher made note of having asked the participant these questions and of the participant’s answers. For each interview conducted, verbal consent to participate was audio-recorded. Interview audio-recordings were transferred to an encrypted and password protected flash drive (Western University, 2017a). Participants were presented with the opportunity to forgo audio recording of responses to interview questions. In cases where questionnaires were completed, return of a completed questionnaire was assumed to signify consent to participate in this study and this was made clear in the letter of information provided to participants. Participants who completed a questionnaire for this study were provided with a random six-digit code to be attached to their completed questionnaire. A list of these codes and the names of the corresponding participant was kept by the researcher on a Microsoft Word file on a password protected and encrypted flash drive.

Names of participants were replaced by a pseudonym for the purpose of data analysis and reporting. Any other identifiable information included in the data collected during correspondence with participants, such as titles of CPG documents or professional organizations, was removed from the data set. All information collected throughout this study was kept on an encrypted and password protected flash drive. This flash drive will be kept for a period of seven years following the researcher’s completion of the Master of Health Information Science program for which this study was conducted. After this period, the flash drive used to store this information will be sanitized (Western University, 2017a).
Chapter 3

3 Results

The results for this study primarily focus on the strategies that have been or that are used to involve HCCs in CPG development in Canada. These results are divided into four different parts, corresponding to the four parts of this study’s research question:

1) what stages of clinical practice guideline (CPG) development are healthcare consumers (HCCs) involved in;
2) what tools or strategies are used to involve HCCs in CPG development;
3) what groups of HCCs are involved;
4) and what are the objectives or desired outcomes for involving these groups in CPG development.

This study was designed to gather this information from published CPGs, documents describing how they were developed, and interviews with professionals involved in CPG development.

The creation of patient resources served as one of the only strategies of HCC involvement used for CPGs included in this study. HCCs were also involved in the dissemination of one of the CPGs included in this study. Even though very little had been done to involve HCCs in the development of CPGs included in this study, within the data sources analyzed, including web-based materials and information collected through interviews or questionnaires, there was discussion of new (implemented since the release of CPGs included in this study) or planned strategies for the involvement of HCCs in CPG development. These strategies have been implemented since the publication of the CPGs included in this study and are still being used currently, but they were not used in the development of the CPGs included in this study. For five of the CPGs included in this study, evidence of strategies to involve HCCs in CPG development could not be found, including strategies developed after their publication.
This chapter summarizes key results gathered for this study. A description of the data sample, and interview and questionnaire participants are provided. Descriptions of the few strategies used to involve HCCs in the development of the CPGs included in this study are also provided. Strategies implemented after the release of CPGs included in this study are also described. Individual strategies used to involve HCCs in CPG development, as well as new and planned strategies, are organized based on the stage of CPG development in which they have been or are employed. Finally, themes regarding the value of HCC involvement are presented. Important themes emerged regarding the perceived value and increased use of HCC involvement that could not be attached to any individual strategies of HCC involvement, but that described the practice in general.

3.1 Data Sample and Participants

Searches completed through PubMed and the CMA CPG Infobase revealed a total of twelve complete CPGs that were eligible for review in this study (Appendix B). Review of webpages corresponding to the CPGs included in this study revealed thirty-six documents relevant for analysis. These included guideline development protocols, patient engagement protocols, annual reports, author information summaries, initiative or program overviews, strategic frameworks, and newsletters.

Five first authors and seven organizations were contacted to request participation in this study. An additional two CPG authors were contacted when responses were not received, in cases where this contact information was available. Two first authors agreed to participate through completing questionnaires, each representing a separate CPG included in this study. Four other professionals agreed to participate in interviews, representing four separate CPGs included in this study. Interview participants included a health research methodologist, a research coordinator, a research officer, and a quality improvement coach. One additional document relevant for analysis was collected from a research participant.
3.2 Strategies Used to Involve Healthcare Consumers, Organized by Stage of Clinical Practice Guideline Development

This section describes individual strategies of HCC involvement in CPG development encountered through this study, including strategies used in the development of CPGs included in this study, new strategies, and planned strategies. Strategies encountered are organized by the stage of CPG development in which they are used. These stages include project planning, review of scientific literature, formulation of recommendations, reviewing and editing, and dissemination. HCCs were also involved throughout guideline development, and finally through the use of patient resources. Results are presented as individual strategies for involving HCCs in CPG development. Data sources utilized for this study did not contain enough detail to fully answer the research questions for each strategy encountered. The research questions are therefore answered for each strategy to the extent that this information was available.

3.2.1 Project Planning

Data analysis for this study revealed a two-part strategy implemented three years after the release of the corresponding CPG included in this study. This strategy was not used in the development of the guideline included in this study but is used currently in the development of new CPGs. In the first part of this strategy, patients are involved in project planning as part of a consultation group, separate from the main CPG development working group. Project planning is one of the first stages of guideline development, and involves defining a topic, determining research questions, deciding on the scope of the guideline development project, and drafting a project plan to describe this scope. A definition of the term “patient” could not be identified; however, this term was used to refer to the stakeholders involved through this strategy. Through data analysis it was noted that the consultation group is asked to review the project plan at the beginning of CPG development. Feedback is gathered through focus groups called “consultation group meetings”. Interviews replace focus groups when consultation group meetings involve only one participant. This strategy is utilized in order to increase the
likelihood that appropriate questions are asked and that the appropriate outcomes are examined, and to ensure that patient preferences and values are considered in the interpretation of evidence and the formulation of recommendations. The second part of this strategy, used in combination with this first part, is described in section 3.2.2.

Results indicate that at the time one CPG included in this study was published, input from the general public was solicited during the process of topic selection for the development of new CPGs or the updating of existing CPGs. Topic selection involves determining topics that the overseeing organization will consider over the upcoming year. While this strategy was in place at the time the CPG included in this study was published, the general public did not contribute to the topic selection for this guideline. Information reviewed for this study indicated that this strategy remains in use. Further information regarding this strategy could not be found.

3.2.2 Review of Scientific Literature

Data analysis revealed one strategy for involving HCCs in CPG development that is the first part of a three-phase process and takes place during the review of scientific literature. The review of scientific literature informs the content of the guideline being developed, including its recommendations. This strategy is used currently in the development of CPGs but was implemented four years after the release of the corresponding CPG included in this study. Patients, family members, and informal caregivers are involved in CPG development through this strategy. In this context, patients are defined as the “intended targets of the guideline”, while family members and informal caregivers are defined as the “partners or caregivers of the intended targets”. Individuals belonging to these groups can participate in CPG development if they are “not practicing health care professionals”. Through data analysis, it was noted that the first phase of this strategy involves collecting information on patient preferences regarding screening outcomes, using a survey to rank pre-determined outcomes in terms of their importance for a particular screening procedure. In this strategy, participants are provided with information on outcome rankings by all other participants and then take part in a focus group to discuss their preferences. Data reviewed for this study indicated that within a week of having participated in this focus group, participants fill out a
survey, identical to the one used previously, to confirm their outcome rankings. Results gathered during this phase are used to inform the evidence review completed by members of the CPG development working group. Patients, family members, and informal caregivers are involved in this phase to facilitate the incorporation of patient preferences in the ranking of outcomes of interest for a guideline. These results also partially inform the content of knowledge translation tools meant for patient use (described in section 3.2.7).

### 3.2.3 Formulation of Recommendations

The second part of a three-part process that has been implemented since the release of the corresponding CPG included in this study involves patients, family members, and informal caregivers in the formulation of recommendations. The first phase of this strategy is described in section 3.2.2. Patients are defined as the “intended targets of the guideline”, while family members and informal caregivers are defined as the “partners or caregivers of the intended targets”. Participants are provided with information from the previously completed systematic review in order to inform them of the relative likelihood of achieving each listed screening outcome. With this information, participants are again asked to rank pre-determined outcomes in terms of their importance for a particular screening procedure. Participants are again provided with information on outcome rankings by all other participants and take part in a focus group to discuss their preferences. Again, within a week of having participated in this focus group, participants fill out a survey identical to the one used previously, to confirm their outcome rankings. Results gathered through this phase are used to inform the final recommendations within CPGs being developed. Results gathered through this phase also inform the content of knowledge translation tools accompanying the CPG being developed. These patient resources are described in section 3.2.7. Patients, family members, and informal caregivers are involved in this phase to facilitate the incorporation of patient preferences in the ranking of outcomes of interest for a guideline.

In another strategy found through this study, patients are allowed to be involved in CPG development as part of a consultation group. This strategy is the second part of a two-phase process. The first phase of this strategy is described in section 3.2.1. This
strategy was implemented three years after the publication of the CPG included in this study and is used currently in the development of new CPGs. The consultation group from the first phase is asked to review draft recommendations to be included in the published CPG and provide feedback throughout a focus group meeting. Interviews replace focus groups when focus group meetings involve only one participant. This strategy is utilized in order to increase the likelihood that appropriate questions are asked, that the appropriate outcomes are examined, and to ensure that patient preferences and values are considered in the interpretation of evidence and formulation of recommendations. The organization that developed this strategy assessed it for usability and concluded that when both parts of this strategy are used together, the strategy is feasible and effective for involving patients in CPG development.

3.2.4 Reviewing and Editing

Data analysis revealed one new strategy that allows for the potential to involve HCCs in CPG reviewing and editing, through a public review process. This strategy was implemented four years after the release of the CPG included in this study, and so was not utilized through its development. However, this strategy is in use currently. Through this strategy, HCCs can take part in an external review process that facilitates peer review and the finalization of CPGs, before they are published. Clinical practice guidelines are placed online, and can be accessed and reviewed by anyone. Individuals can access CPG materials made available for external review and fill out a questionnaire to comment on how a particular guideline could be improved. Alternatively, draft versions of CPGs under review are mailed to a random sample of physicians, nurse practitioners, and “key stakeholders”. As part of this process, HCCs can provide feedback through stakeholders asked to participate in this review. Theoretically, any group of HCCs can contribute to this review process, although this strategy does not actively seek input from any one group of HCCs. Because CPG materials are placed online or mailed to key stakeholders primarily to facilitate review by professionals such as clinicians, this strategy of HCC involvement is unintentional. Healthcare consumers can participate in this process only as a result of draft material being made publicly available. The stated purpose of seeking
feedback in this manner, including allowing HCCs to provide feedback, is to ensure that guidelines are clear, usable, and error-free.

Data analysis revealed another strategy for HCC involvement that is being considered, but has not been put into practice at the time that data collection was completed for this study. When this strategy is put into use, the general public will be involved in the process of CPG reviewing and editing. Clinical practice guidelines will be posted to the organization’s webpage to allow members of the general public to post comments. Alternatively, members of the general public will be able to submit information regarding their personal areas of interest. This will allow these individuals to receive draft CPGs related to their areas of interest so that they may review them and provide feedback. The organization will involve HCCs in this way with the intention of ensuring that patient preferences and values are considered in the formulation of final recommendations.

Finally, one strategy was implemented four years after the release of the respective CPG included in this study but has since been used in the development of only one CPG. In this strategy, both patients and informal caregivers were involved in CPG development as part of the “target audience” for these guidelines. Detailed definitions for the target audience involved in this process were not provided. These stakeholders were provided with outlines of four draft CPGs, each pertaining to different substance use disorders, and asked to provide feedback on these CPGs. The rationale for involving patients and informal caregivers was not provided. It is not clear if this strategy will be used in the future by the respective CPG developer.

3.2.5 Dissemination

Data analysis for this study revealed that HCCs are involved in the dissemination of CPGs. Dissemination is the final stage of CPG development and involves publishing and distributing the finalized CPG. As part of the process of dissemination for one CPG included in this study, HCCs were involved in a “quality improvement” initiative related to the corresponding CPG included in this study. In this case, quality improvement initiatives are used to provide support for applying CPGs within clinical practice. A redesign of this process led to the involvement of patients. Patients were involved in
order to gather their perspectives on how research evidence and information contained within the CPG should be applied in practice. Involving patients in this initiative was done to gather perspectives and strategies for improving care for patients. This strategy was not meant to inform only the development of the specific CPG included in this study, but instead to inform all knowledge translation efforts made by the overseeing organization. Furthermore, involvement of patients in similar dissemination initiatives has not been made a standard part of guideline development, and it is unclear whether this strategy has been used in the development of other guidelines.

One strategy involved the use of “community-based dialogue workshops” during CPG dissemination. This strategy was not used in the dissemination of the CPG included in this study. Instead, it was only used in the dissemination of one separate CPG that was published four years after the release of the CPG included in this study. For this strategy, patients participated in focus groups, in order to educate these stakeholders on draft recommendations. Patients were defined as “older adults” in this context. Feedback was also gathered on the potential for further dissemination activities, including where community members may have wanted to learn about these guidelines. As indicated previously, this strategy has only been used in the dissemination of one CPG at the time that data collection was completed for this study, and it is not clear if this strategy will be used in the development of future guidelines.

3.2.6 Throughout Clinical Practice Guideline Development

Analysis of related materials for one CPG included in this study revealed an “iterative” process for engaging key stakeholders throughout the CPG development process. This process was not used in the development of the corresponding CPG included in this study but is currently used in the development of CPGs. The general public is involved through this strategy, in order to gather unique and important perspectives on the organization’s activities. Healthcare consumer involvement is utilized at various stages of CPG development, including selection of guideline topics and outcomes, and while gathering information on patient preferences. Feedback is collected from members of the general public through use of questionnaires, interviews, focus
groups, and online surveys. Further information regarding the details of these procedures were not found.

A separate strategy to involve HCCs throughout CPG development was implemented three years after the publication of the respective CPG included in the primary dataset for this study. This strategy was therefore not used in the development of this CPG but is used currently. This strategy is designed to involve patients as active members of CPG working groups. This strategy involves patients in every aspect of CPG development. The organization that utilizes this strategy does so in order to increase the likelihood that appropriate questions are asked, that the appropriate outcomes are examined, and to ensure that patient preferences and values are considered in the interpretation of evidence and formulation of recommendations. A definition of the term patient could not be identified; however, this term is used to refer to the stakeholders involved through this strategy. The organization that developed this strategy assessed it for usability and concluded that this newly proposed model was both feasible and effective for involving HCCs in CPG development.

3.2.7 Use of Patient Resources

This section provides descriptions of patient resources developed to accompany CPGs. Patient resources are an important strategy of consumer communication as described by Rowe & Frewer (2005). Three CPGs included in this study are accompanied by a patient resource meant to educate patients on their choices for treatment or other resources at their disposal. For one of these CPGs, the creation of patient resources is a typical part of CPG development. For two CPGs included in this study, a patient resource was not created even though this was a normal part of the CPG development process for the overseeing organizations at the time of their release.

One strategy uncovered through data analysis involves HCCs through the use of knowledge translation tools meant to accompany CPGs. The organization that creates these tools described their use in a procedures manual published one year after the release of the CPG included in this study. These tools include CPG summaries, frequently asked question sheets, and patient decision aids. These tools can be developed for use by patients and the general public. In documents describing this strategy, the term “patient”
is used to refer to users of the healthcare system. Each of these resources is created in order to improve the use and impact of published CPGs as well as educate patients on their content. However, knowledge translation tools meant for patient use were not created for the CPG included in this study. Although not considered a strategy for involving HCCs in CPG development, patients, family members, and informal caregivers are involved in the development of knowledge translation tools when they are meant for patient use. Content of these resources is informed by the first two phases of a three-phase process for involving HCCs, as described in sections 3.2.2 and 3.2.3. These stakeholders also contribute to reviewing and editing these resources.

Analysis of one CPG included in this study revealed a patient resource that was created in collaboration with a separate national research program. This patient resource was created two years after the release of this CPG but is meant to accompany this guideline. This patient resource contains “practical information” and was developed in order to provide educational material to patients and informal caregivers regarding options available for treating depression. Patients and informal caregivers are defined as “people with lived experience” with depression, the target illness of the corresponding CPG. Informal caregivers were additionally referenced to as “caregivers”, who are distinct from professional “healthcare providers”. Providing information on treatment options is done to empower patients and facilitate shared-decision making between patients and healthcare providers in clinical settings. As a resource that was developed after the initial publication of the corresponding CPG, this resource was developed as part of the dissemination and updating of the guideline.

Another organization has indicated that patient resources are developed “when relevant”. These patient resources are developed for use by patients, during the dissemination of certain guidelines, although no details describing when these materials are considered relevant were found. Furthermore, a patient resource had not been made available for the CPG analyzed for this study at the time data analysis was completed.

A brochure was developed to accompany a separate CPG included in this study, two years after its most recent update. This brochure is a patient resource created for use by patients and family members in order to help improve the lives of patients living in
long term care, as well as improve the lives of their family members. As a patient resource developed from the updated guideline after the time of its publication, this patient resource was developed as part of the dissemination and updating process for this guideline. It is not clear if the overseeing CPG developer creates these patient resources for each CPG it publishes. However, similar patient resources have been created for the topic areas of delirium, depression, and the prevention of suicide since the release of the CPG included in this study. Each of these patient resources was developed based on material from previously published CPGs focused on the same topic areas. These patient resources contain frequently asked questions and a resource guide. Each of these patient resources were developed to inform patients and family members on the diagnosis and treatment of a specific mental illness, and additional resources through which patients and their families can seek help or provide help to the individual suffering from the illness in question.

For another CPG included in this study, a patient resource, called a “resource guide”, was made available as part of the CPG document itself. This resource contains information on resources for support services, self-care, and suicide prevention for individuals suffering from depression. Similar resources have been created for other CPGs produced by the same CPG developer. The organization that created these patient resources indicated that they are meant for use by patients, in order to outline health system services and resources available in the province in which these resources are meant to be used. This organization also published an annual report, four years after the publication of the CPG included in this study. This report indicated that work has been done to standardize the approach used by this organization to create patient resources. This report included recommendations to create patient resources on a limited basis. Further details of this strategy could not be found.

3.3 Summary of Strategies Used to Involve Healthcare Consumers in Clinical Practice Guideline Development

To summarize, three CPGs analyzed in this study were accompanied by patient resources. The organizations responsible for the development of three CPGs included in
this study develop patient resources as a normal part of their CPG development process, but two of these failed to do so for the CPG included in this study. Patients, family members, and informal caregivers have been the intended targets of these resources, and they have included such tools as decision aids, frequently asked question sheets, resource guides, and guideline summaries. These tools are created to educate patients on treatment options and available resources. These tools are also seen as helpful in facilitating shared decision making in clinical consultations, and in improving the use and impact of the accompanying CPG. Healthcare consumers were also involved in the dissemination of one CPG included in this study, in order to identify patient perspectives on how the CPG should be applied to practice. In total, only four CPGs analyzed in this study involved HCCs in their involvement. One additional strategy was in place at the time the corresponding CPG included in this study was published, but was not used in the development of this guideline. This strategy is still used, and involves the general public in CPG topic selection.

Furthermore, several strategies for HCC involvement have been implemented since the release of the CPGs analyzed in this study. These strategies are being used currently but were not used in the development of the CPGs that made up the primary data sample for this study. Patients, family members, and informal caregivers are now involved in the design and review of literature searches conducted to inform guideline content and in the formulation of their recommendations. In addition, patients are involved as active members of development groups, throughout all stages of their development. Patients might also have been involved in the process of CPG reviewing and editing. In one strategy, involving HCCs during the process of reviewing and editing is not intentional, and is only a possibility for CPGs produced by the respective organization, given that they post their draft CPGs publicly as part of their call for expert feedback. Involving HCCs in the process of CPG development in these ways is done in order to ensure that patient preferences are incorporated into CPG content. HCCs are also involved in CPG development in order to gather unique perspectives from these stakeholders, identify appropriate outcomes for treatment, and to educate these stakeholders on recommendations for treatment.
3.4 The Use and Value of Healthcare Consumer Involvement in Clinical Practice Guideline Development

Key themes emerged regarding the increasing use of HCC involvement in CPG development and the perceived value of this practice. Information contributing to these themes was collected from interviews only and does not correspond to specific strategies used to involve HCCs in CPG development. Information collected through interviews has therefore been considered independently from other data sources used in this study. This section presents results gathered that described the increasing use of HCC involvement in CPG development, and the value of the practice in general.

3.4.1 Theme One: Efforts to Involve Patients in Clinical Practice Guideline Development are Increasing, but Best Approaches are Unclear

Information collected through interviews confirmed that HCCs were not involved in the development of the CPGs corresponding to these interviews, indicating that at the time of their release, HCC involvement was poorly utilized. One participant indicated that their organization usually involves patients in their initiatives, including in CPG development, but this practice was not utilized for the CPG analyzed in this study. Why HCCs were not involved in the development of this guideline was unclear to the research participant. Furthermore, another organization had performed literature searches to collect information on patient preferences and values within a particular CPG’s topic area. However, in the majority of these cases, HCC involvement was not part of the normal development process used to develop CPGs.

Since the release of the CPGs analyzed in this study, CPG developers have begun to implement strategies for involving HCCs in their CPG development procedures or have looked to improve upon their existing strategies. One participant had indicated that patients or other groups of HCCs were never intentionally involved in their respective organization’s CPG development process. However, this participant described an ongoing "pilot project" meant to involve patients in CPG updating, as well as in the development of “patient-facing” materials to accompany that CPG. Another organization
has since developed a strategy for involving patients in their CPG development processes in response to emerging evidence regarding its benefit, as well as calls for its integration into CPG development:

“So they were basically taking steps to align themselves with the patient engagement standards, the ones established by, I think its AGREE… the Appraisal of Guidelines for Research and Evaluation. So they had called for patient involvement in the guideline development process… basically, they were taking steps to align themselves with the best available evidence at the time”

These efforts to incorporate recommendations and evidence for the benefits of HCC involvement have only been made since the release of the CPG analyzed for this study.

In other organizations, changes in system design lead to alterations to strategies used to involve HCCs in CPG development:

“And then [the organization] changed and there were no disease site groups, so the way that we developed guidelines and how guidelines were produced weren’t coming from the disease site groups. Usually the disease site groups decided that there was a topic that was of interest and very important, and that was how we decided what guidelines we were going to do. And now there is a different process from [the organization] where a group of people decide what guidelines are very important and need to get developed. So that was one difference, so then we didn’t have a patient on each disease site group. So then, the director of [the clinical practice guideline development program], she decided to do a study on different models of how to engage patients since they weren’t on the disease site groups, how were we going to get patients involved in guidelines.”

As the systems put in place to develop CPGs have changed, there have been continued and increasing efforts to involve HCCs in these systems. One organization has also implemented their first strategy for involving HCCs in the development of CPGs as part of a quality improvement approach in recent years. This quality improvement approach involved patients in a discussion to identify what measures could be taken to improve the use of an individual CPG. Involving patients in this quality improvement approach has
not been made a standard practice, but the organization that utilized this strategy is considering further opportunities for involving these stakeholders.

Although each CPG developer represented by an interview participant has developed strategies for involving HCCs in their CPG development procedures, professionals who participated in interviews expressed concern that the optimal strategies for doing so remain unclear. Participants indicated that neither they nor their respective organizations were informed on best-practices for involving HCCs in CPG development and indicated that examples of what has worked in the past could help them set up their own strategies. In cases where organizations have developed strategies for involving HCCs in CPG development, challenges have been encountered in the recruitment process. Patients or family members are reluctant to contribute to the development of CPGs for illnesses with which they have no experience. Ensuring minority groups or people living outside of urban areas have adequate representation is also a challenge. Finally, patients and family members struggle to meet time commitments needed to participate in CPG development while dealing with work, family lives, and contending with their illness.

3.4.2 Theme Two: Patient Involvement in Clinical Practice Guideline Development Leads to Identification of Important Issues

For those professionals who participated in interviews, the perceived value of involving HCCs in CPG development centers around incorporating patient preferences and values into information contained within the CPG. One participant pointed out that incorporating HCCs in the CPG development process ensures that “patient preferences and opinions are considered”. Another participant indicated that patients can “identify additional outcomes that are important to them, that the working group hadn’t thought of, or didn’t realize were as important as patients actually declare them to be”. Incorporation of patient preferences and values is perceived to improve the applicability and quality of CPGs.
Although participants agreed that involving HCCs in CPG development should help to identify additional information that should be incorporated into CPGs, perspectives regarding how this should be utilized differed between participants. One participant indicated that information taken from patients could be integrated directly into recommendations included within CPGs:

“…their perspective was very important in terms of keeping us focused, what was important on the recommendations, like what was the end point of the recommendations to ensure that things are clear and concise and really helpful for the patient. And that’s the purpose of the guidelines right, is to help patients so, patients always need to be considered and remembered, not just the data.”

The participant indicated that HCC involvement facilitates the consideration of patient preferences and values during review of evidence and formulation of recommendations and is therefore helpful for identifying the appropriate treatment outcomes that a CPG should focus on. Another indicated that information collected from patients should be utilized to guide literature reviews done before recommendations are formulated.

Finally, another participant indicated that patient involvement in CPG development should be done in order to identify gaps in the information being incorporated into CPGs. This participant stated that HCC involvement was not done as a “check and balance”, indicating that involvement isn’t focused on patient empowerment. In this case, the exact value of HCC involvement was instead identifying assumptions made by professionals during the CPG development process, rather than identifying issues important to patients. Having patients to identify, question, and address these assumptions was perceived to help create more detailed and clear CPGs. This participant was therefore focused on the identification of information that can make CPGs more usable both for patients and professionals. Furthermore, this participant did not indicate that patient input was useful within any individual stage of CPG development, but instead could be utilized throughout development to identify gaps in the information put into the CPG.
Chapter 4

4 Discussion

This chapter provides a summary of results of this study and discusses their implications for the practice of involving healthcare consumers (HCCs) in clinical practice guideline (CPG) development. A summary of important reflexive notes gathered throughout this research project is also presented. The study limitations and directions for future research are provided, and finally, the author’s conclusions are discussed.

4.1 Implications

To the best of the researcher’s knowledge, this is the first study to describe the strategies used to involve HCCs in CPG development within Canada. Results of this study add to our understanding of how HCCs are involved in the development of CPGs for mood and anxiety disorders within Canada, what groups are involved, and why they are involved.

Healthcare consumers were involved in the development of only four CPGs included in this study. Healthcare consumers were involved in the development of three CPGs included in this study through the use of patient resources. These resources were created in order to educate patients, family members, and informal caregivers regarding what resources are at their disposal for helping them manage their illnesses. Patient resources were also used to improve the use of the corresponding CPGs, and facilitate shared decision making. Healthcare consumers were also involved in the dissemination of one guideline included in this study in order to identify how the guideline could be applied in practice.

Additional strategies to involve HCCs in CPG development were found, but the majority of these were developed only after the release of the CPGs included in this study. Strategies currently used to involve HCCs in CPG development vary. Patients, informal caregivers, family members, and the general public are involved in the review of scientific literature, the formulation of recommendations, the review of draft guidelines, and throughout CPG development. These stakeholders are involved in these stages in
order to facilitate the consideration of patient preferences and to identify appropriate outcomes for treatment or screening. An examination of documented CPG development procedures revealed that HCCs are not involved in the normal development procedures for five of the twelve CPGs analyzed in this study. Overall, HCC involvement is used primarily to identify issues that are important to patients, and utilization of the practice is increasing.

Results of this study suggest that currently, HCCs are inconsistently involved in CPG development. For example, five CPGs included in this study did not involve HCCs in their development, and their analysis did not reveal any strategies that have been implemented since their publication. Furthermore, there was little overlap in the strategies that were identified through this study. The inconsistent involvement of HCCs in CPG development outlined in this study mirrors results found through similar studies completed outside of Canada. Failing to involve HCCs in CPG development has been described as a missed opportunity (Armstrong & Bloom, 2017). Involving HCCs in CPG development can help to increase the quality of guidelines being produced. For example, research has been done to prove that involving patients leads to the incorporation of important topics within these tools (Armstrong et al., 2017; Armstrong et al., 2018; Tong et al., 2012). Avoiding HCC involvement in CPG development can mean that guideline developers miss the opportunity to take advantage of these benefits. As a result, CPGs being developed may be of lower quality.

There was little opportunity for HCCs to contribute information directly to the CPGs included in the primary data sample of this study. However, the use of patient resources was a common strategy of HCC involvement for these CPGs. These resources have been shown to be useful for patient education and should continue to be created to accompany CPGs (Stacey et al., 2014). Creating patient resources to accompany CPGs does help to disseminate information to patients, their family members and informal caregivers, which agrees with the desired benefits of patient resources encountered through this study. However, when these resources are the only form of HCC involvement utilized, many of the purported benefits of HCC involvement are still missed. As tools for patient education, these resources only allow for the transfer of
information from professionals to HCCs, falling into the category of consumer communication (Rowe & Frewer, 2005). These resources therefore do not allow for an ongoing dialogue between HCCs and professionals. Patients and other groups are not given opportunity to raise their concerns while the corresponding CPG is being developed. Their knowledge of patient preferences and values may therefore remain missing from the content of CPGs. Furthermore, involving patients in the dissemination of CPGs in order to identify how the guideline should be implemented into practice might not lead to the incorporation of information from these stakeholders into the guideline. Although this strategy would allow for the flow of information from HCCs to professionals, this transfer would take place only after the guideline had been completed. It is therefore unlikely that this would have had an effect on the content of the CPG, and that many of the purported benefits of HCC involvement in CPG development were missed.

Although there was little opportunity for HCCs to contribute information to the CPGs included in this study, many strategies have been implemented since the publication of these CPGs. However, some of these strategies still have shortcomings. Not all of these strategies involved a range of stakeholders, and others involved HCCs at single or isolated points throughout CPG development. Strategies that have involved only one type of HCC through one stage of CPG development miss the opportunity to gather perspectives from different groups with potentially different priorities. Furthermore, by failing to encourage an ongoing interaction between HCCs and professionals, these strategies allow for only the transfer of information from HCCs to professionals (Rowe and Frewer, 2005). These strategies may miss the opportunity for professionals to provide feedback to HCCs and for HCCs to subsequently continue to advocate for their own interests. As a result, information gathered from HCCs may not be fully considered and incorporated into final CPG materials. However, HCC involvement is likely to be less resource intensive when it is achieved through the use of individual focus groups or interviews at specific points of the CPG development process, as opposed to allowing for continued interactions between professional stakeholders and HCCs. The reduced demand for time and resources offered by these strategies may warrant their continued use, as long as input gathered through these strategies is adequately considered.
The increasing use of HCC involvement in CPG development could be a result of the increasing recognition of the potential value of the practice. Results of this study suggest that recommendations from authoritative organizations have motivated CPG developers to involve patients and the public in their CPG development procedures. As research continues to develop evidence for the usefulness of HCC involvement, and authoritative organizations continue to publish recommendations for its use, HCC involvement in CPG development is likely to continue to increase. Furthermore, results of this study suggest that greater clarity regarding how HCCs should be involved in CPG development would be beneficial for its use. Enlarging and clarifying the body of evidence regarding the usefulness of involving HCCs in CPG development may help to resolve skepticism surrounding the practice and allow CPG developers to feel confident in its utility. Providing further information on the most efficient methods for involving HCCs in CPG development may also contribute to the adoption of this practice by aiding CPG developers in designing their own strategies.

Even with the current uncertainty surrounding best practices for its use, there remain “principles-based” reasons for involving HCCs in CPG development that can rationalize the use of the practice. There are benefits to this practice that reflect the values of a democratic society, including emphasizing patient autonomy, and encouraging the democratic rights of patients and members of the public as taxpayers (GIN, 2015). Additionally, HCCs should be involved in the development of CPGs in order to empower these stakeholders and enable them to work as partners with healthcare providers in the design and delivery of health services (van de Bovenkamp & Trappenburg, 2009). Organizations that develop CPGs within Canada should strive to involve HCCs in CPG development in order to make the process of CPG development reflect these values. A greater focus on the value of these benefits could help to increase the use of HCC involvement in CPG development.

Descriptions of how HCCs have been involved in CPG development provided through this study can be used in the future to guide CPG developers in designing and implementing their own strategies. Evidence continues to build regarding the beneficial effects of HCC involvement on the content and scope of CPGs, and the subsequent
effects the practice can have on the impact and usability of these guidelines, including their ability to encourage patient-centered care. As stronger evidence for the benefit of HCC involvement emerges and according changes are made to advisories on how to develop high-quality CPGs, HCC involvement may continue to increase, both within Canada and in other nations. As this evidence builds, a stronger focus on the principles-based benefits of HCC involvement may help to improve use of this practice in the present.

4.2 Study Limitations

This study used a qualitative descriptive methodology in order to describe how HCCs are involved in CPG development within Canada. Qualitative description is commonly used to produce interpretations of data that are “data-near” or that produce pure descriptions of a given dataset (Neergaard, 2009). However, this methodology has been criticized for its avoidance of the use of theory (Neergaard et al., 2009; Sandelowski, 2010). Although this study utilized previous theory to inform the extraction of relevant information from the dataset, only general descriptions of HCC involvement in CPG development are given. Descriptions are left in general terms and are not integrated directly back to existing theories regarding patient and public involvement. Instead, only descriptive summaries are given.

There are some limitations to the methods used that may have impacted the level of detail in the descriptions of HCC involvement provided by this study. First, interviews and questionnaires were utilized to supplement information uncovered from CPGs and related web-based materials. Interviews were completed for four CPGs included in this study, and questionnaires for an additional two. For the remaining six CPGs, the only sources of data were the CPG documents themselves and the related web-based material. Publicly available material, including CPG documents and web-based documents, may not have referenced every strategy of HCC involvement utilized. In these cases, strategies used to involve HCCs in CPG development that were not described in publicly available websites or documents would not have been analyzed in this study. Furthermore, for many of the strategies described in this study, the sources of information that were accessed did not provide adequate detail to fully answer the research questions. As a
result, some details of how HCCs are involved in CPG development, including the type of HCC involved, the stage in which they are involved, or the reason for their involvement could not be identified for each strategy. Finally, several organizations provided descriptions of involving patients or other lay members of the public in their programming but did not explicitly describe how this related to involving these stakeholders in CPG development. These descriptions were not reported for this study, as it was not possible to link these strategies for patient and public involvement directly to the processes of CPG development.

In order to facilitate the collection of results directly from professionals involved in CPG development in Canada, interviews and questionnaires were completed with professionals of varying backgrounds. Authors of two of the CPGs included in this study completed questionnaires that were less flexible and potentially less detailed than interviews. Interviews were completed with professionals involved in research coordination or quality improvement at the respective organization that developed CPGs included in this study. Each of these professionals had different roles in the process of CPG development at their organization. This could have contributed to differences in their experiences with, and perspective on the value of HCC involvement in CPG development, or in their knowledge of how HCCs are involved in CPG development at their organization.

Theoretical saturation occurs when new information collected from a qualitative sample informs existing findings but does not add anything new to them (Milne & Oberle, 2005). Although difficult to achieve, theoretical saturation is an important factor contributing to the rigour of a qualitative descriptive study (Milne & Oberle, 2005; Tracy, 2010). Clinical practice guidelines were used as the primary data sample for this study in following with what had been done in previous, similar studies (Armstrong & Bloom, 2017). Utilizing CPGs as the primary data sample allowed for efficient identification of organizations that develop CPGs. However, this study was limited to analyzing CPGs pertaining to the management of mood and anxiety disorders in order to ensure the data sample could be analyzed within a Master’s thesis timeframe. As a result, only twelve CPGs were analyzed in this study. Because this study’s sample size is limited, it is likely
that other organizations excluded from review in this study utilize different strategies for involving HCCs in CPG development. Furthermore, the strategies used to involve HCCs in the development of the CPGs included in this study have been limited to those applied to the development of CPGs pertaining to mood and anxiety disorders. It is possible that different strategies are used for CPGs developed for other types of disease or illness. Finally, organizations that have developed CPGs for the management of mood and anxiety disorders may have also been left out of this study if, for example, they have not created a CPG that adhered to this study’s inclusion criteria. Organizations were left out of consideration if they had contributed only to the funding or endorsement of a CPG included in this study. Additional organizations credited in the development of CPGs included in this study were left out if they had only contributed to the creation of a literature review protocol, the process of CPG editing, or the publication of the CPG. Because of this, this study may not report some strategies used to involve HCCs in the development of CPGs specifically for mood and anxiety disorders. For these reasons, it is unlikely this study has achieved theoretical saturation in describing how HCCs have been involved in CPG development in Canada.

4.3 Directions for Future Research

Awareness of the value of the practice of involving HCCs in CPG development is increasing (Boivin et al., 2010). The results of this study, along with those of past research, indicate that there is room for improvement in utilizing this practice (Armstrong & Bloom, 2017). This study has provided insight into the strategies that are used to involve HCCs in CPG development. This information can be used by organizations that have not yet considered the practice or are in the process of developing their own strategies for doing this. It has also provided some insight into the perceived value of the practice. There remains a gap in research that evaluates the effectiveness of these strategies, or that outlines the facilitating factors that improve HCC involvement in CPG development, or the challenges that may inhibit its use. Future research should address each of these gaps.

There remains some criticism surrounding the idea of involving HCCs in CPG development, including the idea that involving these groups may be tokenistic given the
challenges involved in gathering meaningful input, such as concerns regarding the ability of lay persons to understand scientific terminology, or the effects of perceived power-imbalances on willingness to contribute (Légaré et al., 2011; van de Bovenkamp & Zuiderent-Jerak, 2015). Furthermore, alternative options exist for gathering information on patient preferences and values, such as through gathering this information from existing research (Fraenkel et al., 2016). Because bringing HCCs in to contribute to CPG development can be a time- and resource-intensive process, it may be more efficient to gather information on patient preferences and values as part of the literature review. A final concern is that incorporating evidence regarding patient preferences, directly from these stakeholders or otherwise, may hinder the consideration of patient preferences and values in individual clinical consultations (van de Bovenkamp & Trappenburg, 2009). Research should be conducted to establish the validity of these issues and how they may be overcome of present.

Even with these potential issues, previous studies have pointed out that involving patients in CPG development leads to identification of important material that should be included in CPGs (Armstrong et al., 2018; Tong et al., 2012). Similar studies will be needed to verify the generalizability of these results and to further demonstrate the effects that HCC involvement can have on CPG content. In addition, there remains a large gap in our knowledge of the potential benefits of HCC involvement in CPG development. Future research should aim to determine the connections between HCC involvement in CPG development, improved focus on patient-centered care in clinical consultations, and the resulting improvements in health outcomes. The impact of HCC involvement on the usability of CPGs, and their responsiveness to individual patient needs should also be addressed in future research. Further research will also be needed to determine whether HCC involvement can help reduce the effects of professional biases or conflicts of interest on CPG content.

As a separate concern from evaluating the effectiveness of involving HCCs in CPG development, future research should also add to previous work done in evaluating the effects of certain facilitating factors. Previous research has identified how patients may be more effectively involved in CPG development, including through providing
training to help them understand the overall process of CPG development and the specialized terminology that is used throughout the development process. Patients may also be asked to provide feedback at specific points in the development process, or to contribute at specific working group meetings, in order to avoid issues related to time-commitments for these stakeholders. Future research will have to identify the most efficient strategies for involving HCCs in CPG development. Providing this information to organizations that develop CPGs may encourage the use of the practice. This study provides insight into some of the details of HCC involvement that can be changed to help guide this research. In addition, further research should evaluate the value of involving specific patient populations in CPG development. For example, elderly patients may be involved as they demonstrate a greater variance in preferences and values compared to younger patients (Jansen et al., 2015).

Finally, future research should evaluate the effects of HCC involvement in CPGs for different types of illness and disease. Some authors have suggested that involving HCCs in CPG development may be more beneficial for those illnesses that have little perceived effects, but whose treatments come with perceived side effects, such as in various forms of cardiovascular diseases (Albarqouni, Doust, Glasziou, 2017; Yebyo, Aschmann, Yu & Puchan, 2018). Treatment of these illnesses may require a greater emphasis on patient preferences to achieve an effective treatment plan. More information is needed regarding the benefit of involving HCCs in development of CPGs meant for mood and anxiety disorders specifically. Future research should therefore work to identify whether involving HCCs has differing impacts on the usability and the outcomes of use for CPGs for different types of illness or disease.

4.4 Personal Reflection

I completed my undergraduate degree with a double major in Physiology and Pharmacology. I began my studies in the Master of Health Information Science program in the hopes that I could build my knowledge of public health and of the healthcare system, to better prepare myself for a career in medicine. Completing this thesis, and the Master of Health Information Science program, has been a wonderful learning experience that I believe will be essential in determining the direction of my future career. The
Interdisciplinary Issues in Health Information Science and Knowledge Translation classes confirmed my interests in evidence-based medicine and in patient and public involvement in research and in health services and policy development. I hope to be able to continue to advocate for patient and public participation in my future career and build upon existing evidence for its benefits through research.

The Canadian Health Policy course that I completed this past year has allowed me to explore my interests in public health and health policy, specifically surrounding access to healthcare amongst Indigenous populations in Canada. Furthermore, the opportunities I have had to present at conferences across Canada have ignited my passion for public health. Engaging with like-minded professionals who have accomplished so much in their careers and have contributed invaluable knowledge to the healthcare industry has been an inspiration. I look forward to my own career in healthcare in which I may build on these interests. I plan on expanding my research endeavours to include critical issues in public health, such as the growing opioid crisis, and the effects of climate change on public health. I especially look forward continuing to travel throughout Canada and the world, in order to talk about my own research, as well as learn from that of others. Overall, I am truly grateful for the opportunities I have had to explore issues across public health and healthcare services and policy development.

Completing this thesis has also provided invaluable experience in the process of designing and conducting a research project. This project has exposed me to the expansive world of qualitative research methods. Through Gail Teachman’s Qualitative Research Methods course, I have had the opportunity to study some of the more common methodologies such as grounded theory, ethnography, and phenomenology. I was able to explore the complex paradigms, epistemologies, and ontologies that underline commonly used methodologies, and the overlap between each that compounds their complexity. I was also able to develop my ability to clearly articulate the paradigmatic underpinnings of a particular research study and understand the importance of doing so. The complex theory and unique terminology were often overwhelming; however, the value of qualitative research in establishing theories and hypothesis within the health and social sciences remained clear. Qualitative description remained an ideal choice for this
research project. I was able put qualitative research into practice using a methodology that required only minimal use of this complex theory. This allowed me to gain experience in some of the methods utilized throughout qualitative research, such as coding and the use of reflexivity, without becoming overwhelmed. I look forward to building on my expertise in qualitative research and exploring the use of other methodologies in the future. I also look forward to expanding into the use of quantitative methods.

Finally, this research project has demonstrated to me just how difficult and time-consuming research can be. Each action required rationalization, consideration of the possible outcomes, and comparison with that of alternatives. I have learned that anticipating problems and preparing before they arise is absolutely crucial to the success of a research project. Collecting high-quality information from interviews posed an important challenge. I found that I was focused only on keeping my research participants on-topic, and on getting to my next pre-determined question. I hope to be better able to remain engaged in the present while conducting interviews in the future, so that I may respond to the information coming from participants. This would have been a much more effective strategy for ensuring that I collected the appropriate information. The process of coding and categorization was also somewhat difficult. I struggled with determining what was relevant for answering my research question, and what terms would be appropriate as codes or categories. I look forward to practicing these skills in the future and improving my ability to conduct high-quality research overall.

4.5 Conclusions

In conclusion, understanding the key characteristics of how HCCs are involved in CPG development will help in designing this practice so that its benefits are clearly articulated and realized. This study utilized qualitative description to provide insight into the strategies used in Canada to involve HCCs in the development of CPGs pertaining to the management of mood and anxiety disorders. Healthcare consumers have been involved throughout CPG development, using strategies that allow these stakeholders to provide input into CPG development. Some strategies also allow for ongoing communication between professionals and HCCs. Finally, patient resources have been
used to provide these stakeholders with information regarding their illnesses and additional resources that they may wish to access. Efforts to involve HCCs in CPG development are focused on identifying important information that should be incorporated into CPGs, but best practices for how this should be done are unclear to professionals involved in CPG development.

Results of this study can be used to design patient and public involvement programs for future CPG development initiatives. A better understanding of how HCC involvement can lead to the creation of higher-quality CPGs and can help to improve and increase efforts to utilize the practice. A greater focus on principles-based reasons for HCC involvement is warranted, including the potential to improve democratic decision making and achieve patient empowerment. A focus on these principles may help to improve the use of HCC involvement in CPG development. In the future, these strategies should be evaluated further to determine their effectiveness in incorporating information important to patients or even in improving the quality of guidelines being developed.
References


https://doi.org/10.1186/s12872-018-0838-9
Appendices

Appendix A: Terms Used to Search PubMed

Initial Search Term:

((canada OR canadian OR canad* OR nova scotia OR ontario OR pei OR prince edward island OR british columbia OR new brunswick OR quebec OR newfoundland OR labrador OR Manitoba OR Saskatchewan OR Alberta OR Yukon OR Nunavut OR Northwest))

Combined with One of:

((((((((((guideline[ti] OR guidelines[ti]))) AND (((anxiety disorders OR anxiety disorder)) OR (mood disorders OR mood disorder)))))

This combined search term displayed 73 results.

((((anxiety disorders OR anxiety disorder)) OR (mood disorders OR mood disorder)) AND ((Guideline[ptyp] OR Practice Guideline[ptyp])))

This combined search term displayed 10 results.

((((anxiety disorders OR anxiety disorder)) OR (mood disorders OR mood disorder))) AND guidelines as topic[mesh])

This combined search term displayed 58 results.
Appendix A: Clinical Practice Guidelines Relevant for Analysis

Antidepressants in Elderly Patients with Major and Minor Depression: A Review of Clinical Effectiveness and Guidelines
Affiliated Organization: Canadian Agency for Drugs and Technologies in Health
Date of Publication: August 17, 2015

Best Practice Guidelines for Mental Health Disorders in the Perinatal Period
Affiliated Organizations: Provincial Health Services Authority British Columbia (BC Mental Health and Substance Use Services, Perinatal Services BC), British Columbia Ministry of Health
Date of Publication: March, 2014

Canadian Clinical Practice Guidelines for the Management of Anxiety, Posttraumatic Stress and Obsessive-Compulsive Disorders
Affiliated Organizations: Anxiety Disorders Association of Canada, McGill University
Date of Publication: July 2, 2014

CANMAT 2016 Clinical Guidelines for the Management of Adults with Major Depressive Disorder (Series)
Affiliated Organizations: Canadian Network for Mood and Anxiety Treatments
Date of Publication: August 2, 2016

CANMAT and ISBD 2018 Guidelines for the Management of Patients with Bipolar Disorder
Affiliated Organizations: Canadian Network for Mood and Anxiety Treatments, International Society for Bipolar Disorders
Date of Publication: April 21, 2018

Depression in Multiple Sclerosis Clinical Practice Guideline
Affiliated Organizations: Towards Optimized Practice
Date of Publication: December, 2015

Major Depressive Disorder in Adults: Diagnosis and Management
Affiliated Organizations: Guidelines and Protocols Advisory Committee, British Columbia Ministry of Health, Doctors of British Columbia (formerly British Columbia Medical Association)
Date of Publication: December 15, 2013

Maternal Depression and Child Development
Affiliated Organizations: Canadian Paediatric Society (Mental Health and Developmental Disabilities Committee)
Date of Publication/Updating: January 30, 2015

Recommendations on Screening for Depression in Adults
Affiliated Organizations: Canadian Task Force for Preventive Health Care
Date of Publication: June 11, 2013
The Assessment and Treatment of Mental Health Issues in Long Term Care Homes: (Focus on Mood and Behaviors Symptoms)

Affiliated Organizations: Canadian Coalition for Seniors’ Mental Health

Date of Publication/Updating: 2014

The Management of Depression in Patients with Cancer

Affiliated Organizations: Cancer Care Ontario (Program in Evidence-Based Care)

Date of Publication: May 11, 2015

Use of Selective Serotonin Reuptake Inhibitor Medications for the Treatment of Child and Adolescent Mental Illness

Affiliated Organizations: Canadian Paediatric Society (Mental Health & Developmental Disabilities Committee)

Date of Publication/Updating: February 1, 2016
Appendix C: Email Script for Study Recruitment

Subject Line: Request for participation in research

Hello,

**An email was sent to you two weeks ago and I wanted to send you a quick reminder about my study.**

My name is Adam Jordan, and I am a Master of Health Information Science student at Western University in Ontario, Canada. I have collected your email address from the clinical practice guideline titled *respective CPG title* published by *organization name*. As a listed corresponding author for this publication, you are being invited to participate in a study that I, Adam Jordan, am conducting at Western University for the Master of Health Information Science program, under the supervision of Dr. Jaquelyn Burkell. Briefly, this study involves characterizing the involvement of health care consumers in the development of clinical practice guidelines for mood and anxiety disorders. As a corresponding author for a guideline being considered in my research, you will be asked to participate in an interview focusing on the involvement of patients or other members of the public in the development of the relevant guideline. Answering these questions should take twenty to thirty minutes. If you are unable or unwilling to commit to scheduling an interview, you may also request that a secure link to an online questionnaire be sent to you via email. This questionnaire will also contain questions surrounding the involvement of patients or other members of the public in the development of the relevant clinical practice guideline.

If you believe there is a different professional involved in the development of this guideline who would be better able to answer questions related to the material outlined above, please forward this email to them.

If you would like to schedule an interview, request a questionnaire, or would like more information on this study, please contact the researcher at the contact information given below.

*If the researcher does not receive a response to this email within 2 weeks of it being sent, a reminder email will be sent. One attempt to contact potential participants via telephone will be made if the researcher is unable to establish a connection through email.*

**If the researcher does not receive a response to this email within one week of it being sent, one attempt to contact the potential participant via telephone will be made.**

Kind regards,

Adam Jordan

*Email Redacted*

*Phone Number Redacted*
Master of Health Information Science student
Western University
*To be included in initial email only.*
**To be included in reminder email only.**
Appendix D: Telephone Recruitment Script

Hello, may I speak with respective participant’s name?

Hi, respective participant’s name, my name is Adam Jordan, and I am a master of Health Information Science student at Western University. I am calling today to see if you are interested in a research study I am conducting. This research is being conducted by myself under the supervision of Dr. Jacquelyn Burkell from Western University’s Faculty of Information and Media Studies. This study will look at how patients and other members of the public are involved in the development of clinical practice guidelines in Canada. Your participation would entail answering questions regarding how these stakeholders were involved in the development of respective title of clinical practice guideline, as you have been identified as a corresponding author for this publication. Answering these questions over the phone is estimated to take twenty to thirty minutes. Would you be interested in hearing more about this study at the present time?

*If no, present opportunity to schedule a call-back. If the participant is still not interested, ask if they are aware of another author who may be better suited to participate in the interview. If so, ask that they forward the recruitment email to them, thank them for their time and hang up*

*If yes, continue to explain study details to them based on the letter of information*

I am now going to read over our letter of information over the phone. This letter of information has also been provided to you through email. *read letter of information to participant*

Do you have any questions?

Do you agree to participate in this study by being interviewed at the present time?

*If no, present the opportunity to schedule the interview for a better time. If the participant is still not interested, present opportunity to complete questionnaire. If the participant is still not interested, thank them for their time and hang up.*

*Questions below will be asked and boxes will be checked off for each participant who agrees to be interviewed*

Do you confirm that you have read the Letter of Information [or the Letter of Information has been read to you] and have had all questions answered to your satisfaction?

☐ YES ☐ NO

Do you agree to participate in this research?

☐ YES ☐ NO

Do you agree to be audio-recorded?
☐ YES ☐ NO

Do you consent to the use of unidentified quotes obtained during the study in the dissemination of this research?

☐ YES ☐ NO

*If the participant prefers to complete the questionnaire, proceed with explaining how this process should work*

I can provide you with the letter of information and consent, and a link to the online questionnaire though email. I have collected your email from a public source, namely the corresponding author information given for the clinical practice guideline relevant clinical practice guideline title.

Do you have any other questions?

*If no, thank them for their time and end call*

*If yes, answer questions, thank participant for their time and end call*
Appendix E: Letter of Information and Consent

Principal Investigator

Dr. Jaquelyn Burkell, Assistant Dean, Research
Faculty of Information and Media Studies
Western University

Phone Number Redacted
Email Redacted

Co-Investigator

Adam Jordan, Master’s Student, Health Information Science
Western University

Phone Number Redacted
Email Redacted

Introduction

You are being invited to participate in a research study which seeks to characterize the methods used to involve patients and other members of the public in the development of clinical practice guidelines. You are being invited because you have been identified as a corresponding author for one of the clinical practice guidelines which was selected for analysis in this study. Your knowledge of the methods used to develop this clinical practice guideline will be important for this study.

Involving patients and other members of the public in the development of clinical practice guidelines has been shown to have positive effects on the scope of these documents. How these stakeholders are being involved in the development of Canadian clinical practice guidelines is poorly studied. The purpose of this study is to characterize the methods used to involve patients and other members of the public in the development of clinical practice guidelines in Canada. Specifically, guidelines pertaining to the management of mood and anxiety disorders will be analyzed. This will allow for current practices in Canada to be compared to national and international recommendations. Collecting this information will also allow for future analysis of the effectiveness of the methods being used.

If you agree to participate in this study, you will be interviewed. During this interview, you will be asked to comment on the methods or procedures used to involve patients or other members of the public throughout the development of the respective clinical practice guideline in which you took part. The interview will be completed over the telephone and is anticipated to take twenty to thirty minutes. With your permission, the telephone call will be recorded to allow for transcription.

If you are unable to commit to scheduling an interview, you may still participate in this study through filling out a questionnaire. The questionnaire will also ask you to comment
on the methods or procedures used to involve patients or other members of the public throughout the development of the respective clinical practice guideline in which you took part. This questionnaire will be provided through Qualtrics, and a secure link to this questionnaire will be provided to you via email at your request. You will also be provided with a unique study ID. This ID should be entered when prompted by the questionnaire, to allow collected information to remain identifiable to the researchers only. The questionnaire is anticipated to take twenty to thirty minutes to complete.

There are no known or anticipated risks associated with participating in this study. You may not directly benefit from the results of this study; however, the results may bring to light current practice in Canada regarding the development of clinical practice guidelines. This is a critical first step in analyzing the effectiveness of current practice so that it may be improved in the future in an attempt to make clinical practice guidelines more relevant to the patients whose care they affect.

If you wish to withdraw from this study in the future, you have the right to request the withdrawal of information collected from you. Please let the researcher know if you wish to have your information removed, using the contact information given below.

Your contact information has been collected from a public source, namely the corresponding author information given in a clinical practice guideline being analyzed in this study. Any information collected from you will not be connected back to the related clinical practice guideline. Your name will be replaced with a pseudonym for the purposes of data analysis and reporting (different from the aforementioned study ID), and any further identifying information will be removed from data collected during the interview or questionnaire process. Any publications resulting from this study will not use your name or other identifying information.

Representatives of The University of Western Ontario Non-Medical Research Ethics Board may require access to your study-related records to monitor the conduct of the research.

While the researcher for this study will do their best to protect your information there is no guarantee that they will be able to do so. If any information collected during this study is required to be reported by law, the researcher will have a duty to report.

The researcher will keep any personal information collected about you in a secure and confidential location for a minimum of seven years. Information collected for analysis will be stored electronically on an encrypted and password protected flash drive, in line with Western University’s Data Security Guidelines. A list linking your pseudonym with your name will be kept by the researcher in a secure place, separate from the study file.

You will not be compensated for your participation in this study.

Your participation in this study is voluntary. You may decide not to be in this study. Even if you consent to participate you have the right to not answer individual questions or to withdraw from the study at any time. If you choose not to participate or to leave the study at any time it will have no effect on your relationship with the researcher or professional endeavors. You will be updated with new information gathered throughout the study which may affect your decision to stay in the study.
You do not waive any legal right by agreeing to participate in this study.

If you have any questions about this study please contact:

Dr. Jaquelyn Burkell, Assistant Dean, Research
Faculty of Information and Media Studies
Western University
*Phone Number Redacted*
*Email Redacted*

Or

Adam Jordan, Master’s Student, Health Information Science
Western University
*Phone Number Redacted*
*Email Redacted*

If you have any questions about your rights as a research participant or the conduct of this study, you may contact:

The Office of Human Research Ethics
*Phone Number Redacted*
Toll free: *Phone Number Redacted*
email: *Email Redacted*

In the case that you prefer to complete the questionnaire, you indicate your voluntary agreement to participate by responding to the questionnaire which will be provided to you as an attachment through email.

This letter is yours to keep for future reference.
Appendix F: Interview Guide

1. Were patients involved in the development of respective guideline title?

   If yes, please describe how they were involved (eg the stage of guideline development during which they were involved, the methods used, and for what purposes they were involved).
   Can you describe the decision making process?
   If no, was involving patients in the development of this guideline ever considered?

2. Were other groups of lay persons or patient representatives involved in the development of this guideline?

   If yes, please describe how they were involved (eg the stage of guideline development during which they were involved, the methods used, and for what purposes they were involved).
   Can you describe the decision making process?
   If no, was involving other groups of lay persons in the development of this guideline ever considered? Why was it avoided?

3. What do you see as the value in involving patients or other members of the public in clinical practice guideline development?

4. What are some potential challenges, or challenges that you have already identified in involving patients or other members of the public in clinical practice guideline development?
Appendix G: Survey Questions

Patient Involvement in Clinical Practice Guideline Development

Start of Block: Question 1

Q1 Please provide your unique study ID (provided in the email through which you accessed this questionnaire).

________________________________________________________________

End of Block: Question 1

Start of Block: Question 2

Qa Were patients involved in the development of the clinical practice guideline in question?

________________________________________________________________

Qb If yes, please describe how they were involved (eg the stage of guideline development during which they were involved, the methods used, and for what purposes they were involved).

________________________________________________________________

Qc If no, was involving patients in the development of this guideline ever considered? Why was it avoided?

________________________________________________________________
Qa Were other groups of lay persons or patient representatives involved in the development of this guideline?

________________________________________________________________

Qb
If yes, please describe how they were involved (e.g. the stage of guideline development during which they were involved, the methods used, and for what purposes they were involved).

________________________________________________________________

Qc
If no, was involving other groups of lay persons in the development of this guideline ever considered? Why was it avoided?

________________________________________________________________

End of Block: Question 3
Appendix H: Summary of Reflexive Notes

This section of the appendices presents summaries of the reflexive notes taken while this study was being carried out. These notes include my reflections on challenges encountered, and how my interactions with the dataset could have impacted the results of this study. To begin, I tried to encourage participation in my study by indicating that information collected in this study would be used only to describe strategies being used to involve HCCs in CPG development, and not to evaluate these strategies. However, it was also indicated that the results from this study could be used to evaluate these strategies in the future, to either improve on them or identify what methods work most effectively for the purported benefits. I think my research participants were able to give well informed and genuine answers to my questions. However, it is possible that knowledge of future plans to evaluate strategies being used impacted the information provided by participants. Participants may have been eager to describe instances of HCC involvement even outside of CPG development, and used information from these cases to describe the value of HCC involvement in CPG development specifically. Furthermore, it is possible that participants chose not to focus on the challenges encountered, but to focus on the possible benefits instead, in order to cast efforts in a positive light. I do not believe this affected the honesty their answers, but only the level of detail provided for the benefits versus the challenges encountered. The challenges associated with HCC involvement were still reported on in some cases. Additionally, participants indicated that only patients were involved in CPG development, and were reluctant to comment on the value of involving other groups of HCCs. It is likely this was due only to a lack of experience with involving other groups of HCCs.

Conducting interviews was strenuous, and, in retrospect, I missed opportunities to delve into detail on certain topics with my research participants. I tried to stay on topic as much as possible, in order to adhere to the research outline I had submitted for ethics approval. I also wanted to respect the time my research participants had taken from their work to dedicate to this study. Resultantly, I followed my interview guide very strictly. I therefore missed opportunities to explore ideas brought up by my research participants, such as plans for future involvement strategies, or details regarding quality improvement.
strategies that involve CPG development. I also noticed that I was distracted by my note
taking and backreferencing to materials I had collected to prepare for my interviews. This
may have resulted in some confusion between my research participants and myself and
hindered their ability to fully answer my questions in some cases.

Additionally, my interactions with web-based data sources utilized in this study
are worth mentioning. The process of extracting meaning units and codes from the data
sources utilized in this study required some interpretation. In many cases, it was not clear
how to code certain pieces of information. For example, some terms used to describe
important factors of HCC involvement were ambiguous and required me to make a
decision in regard to how I would code the information. For example, the use of the term
“community member” could have implied that members of the general public were
involved in a particular strategy being described. However, this term referred to both
“older adults” and “service providers”. Because “older adults” were interpreted to be the
population who’s care this CPG pertained to, “older adults” was interpreted to refer to
patients. Furthermore, “service providers” was interpreted as referring to professional
healthcare providers, in the absence of a direct definition for this term within the data
source. The term “community member” was therefore interpreted to include
professional stakeholders, meaning that it could not be interpreted as meaning only
members of the general public.

Finally, many of the data sources analyzed for this study referenced patient and
public involvement strategies used outside of CPG development. Much of this
information contained insight into the value of patient and public involvement initiatives,
and descriptions of how these initiatives were utilized. However, none of these pertain
directly to the development of CPGs. This information has not been considered as
relevant for reporting in this study, unless it could be explicitly linked to the process of
CPG development. This information was still reviewed in full to ensure appropriate
decisions were made regarding its relevance. There was a focus on the promotion of
patient-centered care within descriptions of these patient and public involvement
initiatives. This focus on patient-centered care within the organizations that develop
CPGs may have influenced the discourse surrounding HCC involvement in CPG
development within these organizations, and likewise the information provided by professionals from these organizations during interviews. The focus on patient-centered care in these materials could have also influenced my own interpretations of data sources when deciphering what material was describing how CPGs are developed.
Appendix I: Ethics Approval Form

Dear Dr. Jacquelyn Barkell

The Western University Non-Medical Research Ethics Board (NMREB) has reviewed and approved the WREM application form for the above mentioned study, as of the date noted above. NMREB approval for this study remains valid until the expiry date noted above, conditional to timely submission and acceptance of NMREB Continuing Ethic Review.

This research study is to be conducted by the investigator noted above. All other required institutional approvals must also be obtained prior to the conduct of the study.

Documents Approved:

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Document Type</th>
<th>Document Date</th>
<th>Document Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email Script for Study Recruitment</td>
<td>Recruitment Materials</td>
<td>27/Sept/2018</td>
<td>2</td>
</tr>
<tr>
<td>Interview Guide</td>
<td>Interview Guide</td>
<td>06/Sept/2018</td>
<td>1</td>
</tr>
<tr>
<td>Letter of Information/Final</td>
<td>Implied Consent/Assent</td>
<td>05/Oct/2018</td>
<td>3</td>
</tr>
<tr>
<td>Letter of Information/Final</td>
<td>Verbal Consent/Assent</td>
<td>05/Oct/2018</td>
<td>3</td>
</tr>
<tr>
<td>Online Survey/Final</td>
<td>Online Survey</td>
<td>05/Oct/2018</td>
<td>1</td>
</tr>
<tr>
<td>Telephone Script for Study Recruitment</td>
<td>Recruitment Materials</td>
<td>27/Sept/2018</td>
<td>2</td>
</tr>
<tr>
<td>Telephone Script for Study Recruitment</td>
<td>Verbal Consent/Assent</td>
<td>27/Sept/2018</td>
<td>2</td>
</tr>
</tbody>
</table>

No deviations from, or changes to the protocol should be initiated without prior written approval from the NMREB, except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the trial.

The Western University NMREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the Ontario Personal Health Information Protection Act (PHIPA, 2004), and the applicable laws and regulations of Ontario. Members of the NMREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB. The NMREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 0000941.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Kathryn Harris, Research Ethics Officer on behalf of Dr. Randal Graham, NMREB Chair

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations).
Curriculum Vitae

Name: Adam Jordan

Post-secondary
Education and
Degrees:

Western University
London, Ontario, Canada
Master of Health Information Science
2017-2019

Western University
London, Ontario, Canada
BMSc., Major in Physiology, Major in Pharmacology
2013-2017

Conference Presentations:

2019 Canadian Association for Health Services and Policy Research
Exploring Health Care Consumer Involvement in Clinical Practice Guideline Development
Poster Presentation
May 29, 2019
Halifax, NS.

20th Canadian Collaborative Mental Health Care Conference
Exploring Health Care Consumer Involvement in Clinical Practice Guideline Development
Poster Presentation
May 10, 2019
Vancouver, BC
Public Health 2019
Exploring Health Care Consumer Involvement in Clinical Practice Guideline Development
Poster Presentation
April 30, 2019
Ottawa, ON

FIMULAW Graduate Interdisciplinary Research Day
Exploring Health Care Consumer Engagement in Clinical Practice Guideline Development
Lightning Talk
March 22, 2019
Western University, London, ON

**Related Work**
Teaching Assistant

**Experience**
The University of Western Ontario
2018-2019