PATIENT REPORTED-OUTCOME MEASURES OF QUALITY OF LIFE AS A COMMUNICATION TOOL FOR PRIMARY CARE PROVIDERS SERVING CAREGIVERS OF ADULTS WITH CANCER

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ABSTRACT

Caregivers are the family members, friends and sometimes neighbors who provide an intricate array of care to an adult with cancer. According to the literature, significant demands are placed on caregivers that can diminish their QOL. The aim of this project is to examine the communication of quality of life (QOL) between primary care providers (PCPs) such as a family nurse practitioner and patients who serve as caregivers to adults with cancer. As barriers common to the primary care setting can impede caregivers voicing their concerns, it is proposed that by improving patient-provider communication, PCPs will gain greater awareness of compromised QOL and thus will be better able to offer support. Patient-Reported Outcome Measures (PROMs) are standardized measures that report subjective experiences such as QOL. This capstone project seeks to answer the question: Can nurse practitioners, as primary care providers, use Patient-Reported Outcome Measures as a tool to improve patient-provider communication regarding health-related quality of life for caregivers to adults with cancer living in British Columbia? To answer the research question, an integrative literature review was conducted whereby evidence to support the use of PROMs as a tool to enhance patient-provider communication in the primary care setting was found.

Keywords: Patient-Reported Outcome Measures, PROM, quality of life, Primary Care

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DEDICATION

This capstone thesis is dedicated to those who are, who have, or will be caregivers. It is through their devotion, care, and self-sacrifice, those who need are comforted.

CHAPTER ONE

INTRODUCTION

"From caring comes courage"

- *Lao Tzu*

Cancer is a profound, life-altering disease that not only impacts the cancer patient but the quality of life (QOL) of informal caregivers (Minaya et al., 2011). Informal caregivers are the family members, friends and sometimes neighbors who provide an intricate array of supportive care to an individual living with cancer. Throughout this paper, the term 'caregiver' will be used to refer to an adult who is a patient who provides care to an adult living with cancer.

Caregiving for a person with cancer is often regarded as a moral and compassionate act (Lund, Lone, Aagaard, & Groenvold, 2014). The act of caregiving often brings many positive benefits such as a sense of giving or personal growth (Lund et al., 2014). Caregiving does, however, create challenges that ultimately can impact the caregiver's QOL (Minaya et al, 2011). While most caregivers manage the challenges of cancer care well, the demands placed on caregivers can compromise their psychological, physical and emotional well-being (Weitzner & McMillan, 1999). With recent health care delivery trends shifting care from the inpatient to the outpatient setting, there is an increase in the demands placed onto caregivers (Canadian Institute for Health Information [CIHI], 2011; Kitrungrote & Cohen, 2006). It is therefore not uncommon for individuals with cancer and their caregivers to experience anxiety and depression or have their QOL impacted (Weitzner & McMillan, 1999).

The aim of this capstone project is to examine the patient-provider dyad that exists between health care providers and their patients. The patient-provider relationship is a complex topic that has many considerations. Due to the scope and size of the capstone project, this paper focuses on the communication of QOL between patients who are caregivers and their primary care provider (PCP). While in British Columbia (BC), agencies such as the BC Cancer Agency (BCCA) support the needs of cancer patients and their families well, the longitudinal impact of the disease on cancer patients and their caregivers need to be acknowledged. This longitudinal impact is well represented by the term ‘cancer trajectory’. This term implies that the cancer journey is one that does not merely end once treatment is complete but rather extends past into remission and recovery. Therefore, as the needs of cancer patients and their caregivers often extends beyond the completion of treatment, caregivers, as patients themselves, will likely encounter PCPs, such as nurse practitioners (NPs), for their own regular care at various points throughout this trajectory. Regulated in British Columbia since 1995, NPs are health care providers who have achieved advanced nursing practice competencies at the graduate level of nursing education (College of Registered Nurses of BC [CRNBC], 2017). Inclusive of diagnosing disease, disorders and conditions, NPs are independent providers responsible for comprehensive patient care management. As part of their role, NPs order and interpret diagnostic tests, prescribe medications and therapeutic interventions, as well as collaborate and make referral to specialists, physicians, and other care providers as deemed appropriate (CRNBC, 2017). In BC, family NPs provide care for common acute and chronic conditions for all age groups, from newborns to older adults (CRNBC, 2017).

Both in my personal life and during my practice as a registered nurse in the emergency department, I have witnessed the burden caregiving for chronically ill family members have on the caregiver. My observation is that caregivers often delay seeking their own care needs and remain silent towards their own suffering. One experience, early in my career, has remained with me to this day – it is the case of an acutely ill elderly gentleman who as the caregiver to his wife, discharged himself from the emergency department in the middle of the night as he felt his own health needs were secondary to that of his wife's. Today, as I transition into the role of a family NP, the self-sacrifice and devotion caregivers display has become even more evident. Whether the impact of the caregiving role results in caregiver neglect of their own health concerns or eventual physical and psycho-emotional damage (Reinhard, Given, Petlick, & Bemis, 2008), health care provider awareness of the impact the caregiving role has on caregivers is necessary to ensure the support of the caregiver, and the cancer patient.

As health care providers, it is essential to recognize caregivers as valuable partners in care who as a result of their role, are inherently susceptible to poor health outcomes for two main reasons. Firstly, caregivers provide a vast array of intricate care to cancer patients, often with little support or preparation (Northouse, Katapodi, Schafenacker, & Weiss, 2012). When caregiving demands exceed caregiver's resources, distress and the feeling of being overwhelmed occurs (Northouse et al., 2012). In addition, unmet needs, limited support, and role burden can negatively impact caregiver well-being. The demands of caregiving can therefore easily overwhelm a caregivers' resources leading to deterioration of psychological, emotional, and physical QOL (Pauwels, De Bourdeaudhuij, Charlier, Lechner, & Van Hoof, 2012; Hasson-Ohayon, Goldzweig, Braun, Galinksy, 2010; Wallace & Coyne, 2013). Secondly, caregiver's needs are often forgotten as the primary focus of others is directed towards the cancer patient. Viewed as caregivers and not people in need of support, caregivers are also neglected by health care providers (Mitchell, Girgis, Jiwa, Sibbritt & Burridge, 2010) in addition to their own friends and families (Hasson-Ohayon et al., 2010; Pauwels et al., 2012). Ultimately, the impact to caregiver QOL risks impeding their capacity to fulfill their caregiving role thereby compromising their care of the cancer patient (Deeken, Taylor, Mangan, Yabroff, & Ingham, 2003; Weitzner & McMillan, 1999).

Within the primary care context, NPs and other PCPs can positively affect the caregiving experience by acknowledging the value caregivers bring and ensuring recognition of caregiver's physical, emotional, psychosocial and spiritual needs (Mitnick, Leffler, & Hood, 2010). According to the Doctors of BC, at the local level, family physicians are well-situated to support caregivers (2016). NPs, as PCPs are similarly well-positioned to engage with caregivers as partners in care while ensuring support by considering their needs.

While PCPs have a role in supporting caregivers, recognition of caregiver needs can however be challenging. Firstly, although health care professionals are increasingly more aware of the burden experienced by caregivers, they are often surprised to discover the widespread distress experienced by caregivers or to learn that for most; the caregiving role was not one of choice but of necessity (Guberman, Keefe, Fancey, Nahmiash, & Barylak, 2001; Reinhard et al., 2008). Secondly, it can be challenging to identify a caregiver in need of help as factors within the cancer caregiving setting make voicing caregiver concerns challenging. For example, many caregivers carry major responsibility to communicate the cancer patient's medical history to health care providers, discuss care with the patient, as well as relay the patient's status to respective family members (Wittenberg, Borneman, Koczywas, Del Farraro, & Ferrel, 2017). This responsibility can impact the way caregivers perceive communication leading to communication challenges and a sense of burden in speaking with other health care providers (Wittenberg et al., 2017).

A perceptual gap in care therefore exists as both caregivers and health care providers often focus on the cancer patient thereby neglecting the needs of the caregivers. Secondly, providers may not be fully aware of the extent to which the caregiving role impacts the QOL of the caregiver. Last, communication burden limits the willingness for caregivers to voice their needs. Left unaddressed, the demands of caregiving increasingly lead to poorer health outcomes for caregivers and the patients they care for (Doctors of BC, 2016). A feasible way then to bridge this potential perceptual gap between caregiver need and PCP awareness is to focus effort on improving the communication of caregiver QOL.

Within the clinical setting, best practices to foster communication include creating supportive relationships, exchanging information, responding to emotions, engaging in collaborative decision-making, and enabling patient self-management (King & Hoppe, 2013; Levinson, Lesser, & Epstein, 2010). The aforementioned practices, however, are difficult to achieve in the primary care settings as this is typically a busy environment that services a wide variety of patients with diverse needs, demographics, and resource availability (British Columbia College of Family Physicians, 2017). Tools to better facilitate communication could, therefore, be an asset in primary care.

Over the last 30 years, various instruments have been developed to measure aspects of caregiving, from caregiver burden to caregiver needs and health-related QOL. Patient-Reported Outcomes are an umbrella term covering a wide range of subjective outcomes relating to a patient's health, QOL, or functional status that is collected directly from the patient (Weldring & Smith, 2013). Patient Reported Outcome Measures (PROMs) are instruments commonly seen as questionnaires, scales, or indexes that measure patient experiences such as QOL (Yeo & Temple, 2012). While PROMs are commonly utilized in the research setting to determine the effect of an intervention, it is only more recently that they have been utilized in clinical practice to assess disease, evaluate treatment plans, and give health care providers insight into patient preferences, symptoms or health-related QOL (Yeo & Temple, 2012).

As caregivers and health care providers often do not recognize the impact of caregiving demands, and as communication barriers inherent to the clinical setting make it difficult for caregivers to voice their concern, the following question was developed to guide the research: Can nurse practitioners, as primary care providers, use Patient-Reported Outcome Measures as a tool to improve patient-provider communication regarding health-related quality of life for caregivers to adults with cancer living in British Columbia?

For the purpose of this project, the term ‘PCP’ and ‘provider’ will be used interchangeably to refer to an individual PCP, NP, physician, or physician assistant who delivers primary care. In addition, the term ‘clinical setting’ will be used to refer to a place where patients obtain medical care such as a primary care office or outpatient clinic. As, high-quality care requires patients to communicate their feelings, concerns, and symptoms to providers (Weldring & Smith, 2013), the hypothesis is that in the context of primary care in BC, the use of PROMs to measure and report health-related QOL will contribute to improving communication between providers and patients. By improving communication, providers will become more aware of caregivers needs that can facilitate provision of advice, supports, resources, and or referrals.

To answer the question chosen for this project, an integrative literature review was undertaken. Chapter two provides background information describing the phases of the cancer journey and the role of caregivers in the lives of a cancer patient. It will also address the concept of QOL and its relationship throughout the cancer trajectory, the role of communication in quality care, as well, the benefits and limitations of PROMs. To provide further context, the scope and role of PCPs in BC and the value of QOL measurement will also be explicated. Chapter three will describe the search methodology and appraisal approach used for the integrative literature review. Following this, Chapter four will analyze the literature gathered for review. Chapter five discusses the findings within the literature in relation to the research question and provides recommendations for practice and education. Chapter six concludes with the limitations of this paper and highlights research considerations.

CHAPTER TWO

BACKGROUND

"An individual doesn't get cancer… A family does."

- *Terry Tempest Williams*

For many years, it was assumed cancer only impacted those who were diagnosed, however over time, health care providers have become more aware of the impact on health-related QOL experienced by caregivers and family members of cancer patients (Northouse et al., 2016). Despite a shift towards greater awareness of the impact of caregiving, it is still common for caregivers and providers to focus primarily on the needs of the cancer patient (Mitchell et al, 2010). As discussed in chapter one, caregivers are often reluctant to mention their own needs (Aoun, Deas, Kowting, & Lee, 2015), and therefore can experience being unseen and neglected by others, including health care providers (Sherman, Austin, Jones, Stimmerman, & Tamayo, 2016).

This chapter begins by exploring the cancer journey and the related caregiving role. Next, the concept of QOL is presented, followed by a discussion of the challenges caregivers and their providers experience communicating and the role of PCPs in supporting caregivers in the primary care setting. The chapter ends by examining the purpose of measuring the impact to health-related QOL in caregivers of cancer patients.

The Cancer Journey

Cancer is a life-changing diagnosis that not only threatens one's life but also challenges one's "fundamental beliefs regarding personal vulnerability, safety and self-worth" (Brandao, Schultz, & Matos, p. 491, 2014). While each cancer patient's experience is unique, patients often undergo a sense of shock, the feeling of betrayal of their body, and are generally fearful of loss of previous function, independence, or death (Hall, Kunz, Davis, Dawson & Powers, 2015). During the onset of treatment, individual with cancer may feel overwhelmed, frightened, and anxious while making their way through the physical side effects of treatment pain, fatigue, and nausea (Hall et al., 2015). After treatment and into recovery, individuals with cancer work hard to adjust to a new life. This continued period of surveillance however is often associated with ongoing fear of cancer recurrence (Pauwels et al, 2012; Hasson-Ohayon, et al, 2010; Wallace & Coyne, 2013; Kim & Given, 2006). It is not uncommon for this fear of recurrence to evoke ongoing anxiety and depression known to persist throughout the post-treatment phase (Duggleby et al, 2015; Pauwels et al, 2012). This post-treatment phase represents completion of cancer therapy and a period where "[cancer] patients and caregivers expect life to go back to the way it was before the cancer diagnosis" (National Cancer Institute [NCI], 2015). Caregivers may struggle to adjust to the first year after treatment, however problems with adaptations in the relationship, poor communication between caregivers and cancer patients as well as a lack of social support can exist for much longer (NCI, 2015).

In BC, it is projected over 25,000 new cancer diagnoses will occur in the year 2017 alone (BCCA, 2017). Recent advancements in screening, diagnosis, and treatment have extended the survival of patients with cancer (NCI, 2015), however it takes a team approach to treat cancer. In addition, cancer patients typically do not cope in isolation, but rather within the context of an interpersonal relationship (Saita, Acquati, & Kayser, 2015). Both formal and informal caregivers therefore have a significant role within the cancer patient's journey. While not all cancer patients have family or a caregiver, for those that do, caregivers are central to patient support throughout the cancer journey (Kitrungrote & Cohen, 2006; Deeken et al., 2003).

The Caregiving Role

For both adults with cancer and their caregivers, cancer treatment and survivorship is nothing short of a journey. Caregivers provide uncompensated and extraordinary physical, emotional, and functional support to those they care for (Lund et al., 2014). As many caregivers experience caregiving as an honor and privilege, it is important to acknowledge that not all impacts of caregiving are negative, (Wong, Ussher, & Per, 2009). From improved self-worth to experiencing altered perspectives on life and relationship enhancement, caregiving can be rewarding and bring several positive benefits to those that undertake it (Lund et al., 2014; Wong et al., 2009). Through their advocacy and support, caregivers help cancer patients navigate the cancer trajectory; however, this does not come without a cost.

Ultimately, caregivers take on a variety of roles that "extend across physical, psychological, spiritual, and emotional domains" (Honea et al., 2008). While caring for patients with cancer, the role places considerable demands that impact caregiver's well-being (Kitrungrote et al., 2005; Deeken et al., 2003). The burden associated with caregiving can therefore be viewed as originating from one of four associated domains: disruption related to the adjustment to the role, the physical demands of the role, the psychosocial consequences of caregiver roles, or the financial implications of caregiving (McMillan & Mahon, 1994).

Regarding the stress associated with adjustment to the caregiving role, for many people, the caregiver role implies an adjustment to new and unfamiliar tasks (Woźniak & Iżycki, 2014). From providing emotional support and personal care such as bathing to facilitating functional duties such as accompaniment to and from medical appointments, the tasks of caregiving vary widely. Ultimately, as stated previously, if caregiving tasks overwhelm caregiver's resources in which to cope, caregivers often are left feeling unprepared and overburdened. This continued sense of feeling overburdened eventually can take a toll on the physical and psychosocial domains of caregiver wellbeing (McMillan & Mohan, 1994). As such, it is not uncommon for caregivers to report fatigue, health problems, and deterioration in physical functioning (Lambert, Girgis, Descallar, Levesque & Jones, 2016; Woźniak & Iżycki, 2014; Kim & Given, 2006). In addition, many caregivers report feeling anxious, depressed, and fearful of a return of the cancer (Hasson et al, 2010).

Within the social domain, adjustment to the caregiver role can often lead to problems at work, home and within interpersonal relationships (Segrin, Badger, Sieger, Meek, & Lopez, 2006). Typically, the support provided by friends and family to both the caregiver and cancer patient dwindle over time and due to the focus on the cancer patient, caregivers often have less time to spend on themselves (NCI, 2015). Finally, if the cancer patient is unable to attend or return to work, caregivers are often faced with managing the financial needs of the family themselves. In some instances, caregivers may even have to work less or give up their jobs to stay home with the cancer patient. Added costs such as transportation, medical supplies, and accommodation for those who travel distances for treatment, only add to the financial strain caregivers and cancer patients face (NCI, 2015).

Under the circumstances, a caregiver’s ability to function is reflected by the degree to which the caregiver can adjust to the diagnosis and the demands of the caregiving role. Over time, the demands of caregiving can risk depleting the caregiver’s physical, psychological, and emotional reserves leading to compromised QOL (Kim & Given, 2008). Overall, when QOL is compromised, the caregiver’s ability to provide care can become compromised (Kim & Given, 2008; Northouse et al., 2012). As such, for PCPs, ensuring cancer patients are adequately supported implies awareness of their caregivers QOL.

Quality of Life

Quality of life is a complex and multifaceted construct for which no consistent definition exists (Moons, Budt, & De Geest, 2006). In addition to being highly contextualized according to the individual, QOL is a socially constructed sense of subjective well-being that is the result of differences between one's expectations and experiences (Schur et al., 2014). As such, no one definition can accurately represent what QOL is for any given person at any given time. The use of the term 'quality' denotes an evaluative measure of a person's reported satisfaction or well-being of a concept for which people themselves, are the best judge of the value or worth (Michalos, 2004).

The World Health Organization's broad definition considers QOL to represent a "state of complete physical, mental, and social well-being not merely the absence of disease" ([WHO], 2006). It can, therefore, be agreed, QOL encompasses many domains, from political and cultural values to more tangible constructs such as meaningful employment, adequate housing, or freedom from disease (Michalos, 2004). A high-level of well-being or QOL includes satisfaction with life; the presence of positive emotion and mood; the absence of negative emotions such as depression or anxiety; and positive functioning (Centre for Disease Control, 2016). To distinguish between QOL in the general sense from that of the health-related construct, the term health-related quality of life is commonly used. From this point forward, 'QOL' will be used to specifically refer to health-related QOL. As such, researchers generally agree that QOL is comprised of the following core domains: physical status, psychological functioning (well-being and emotional status), social and spiritual satisfaction, disease and treatment-related symptoms (Deeken et al., 2003; Schur et al., 2014).

In respect to caregiving, it is important to recognize that caregivers and cancer patients are a “unit of care” (Sherman et al., 2016) and that the caregiving experience is reciprocal, whereby distress experienced by one is experienced by the other and vice versa (Wittenberg, et al., 2017; Northouse et al., 2012). Cancer affects the QOL of caregivers in numerous ways (Northouse et al., 2012) and as such, it remains essential providers acknowledge caregivers are also in need of attention and support (Sherman et al., 2016). Given the substantial impact caregiving has on physical, emotional, psychological and financial health, caregiver QOL is a critical component of both caregiver and cancer patient well-being (Edwards & Ung, 2002).

Traditionally, issues involving QOL have been assigned a lower category of importance by providers and patients (Sadovosky, 2003). Over the last few decades, however, the concept of QOL has become increasingly significant in the appraisal of health care quality and outcomes of care (Moons et al., 2006; Kitrungrote & Cohen, 2006). As previously stated, cancer treatment has moved from the inpatient to the outpatient setting and caregivers are increasingly being relied upon to support cancer patients at home (Glajchen, 2012). As such, the health care system indirectly relies on the well-being of caregivers to support cancer patients throughout the cancer journey. Caregiver well-being is central to ensuring fulfillment of their caregiving role, and thereby the care of cancer patients at home (Deeken et al., 2003). As QOL is a central indicator of physical, mental and emotional well-being, for the purpose of this paper, QOL has been chosen as the indicator for caregiver’s health status and capacity.

In summary, throughout the cancer trajectory, both QOL of the cancer patient and caregiver are impacted. Ultimately for caregivers, a negative impact on their QOL reduces their capacity to provide continued care. As such, awareness of caregiver’s QOL is important to PCPs as available interventions and resources can be implemented to better support the caregiver, thus their ability to provide care.

The Role of Communication

Communication is essential to gathering the correct information in which to facilitate an accurate diagnosis and inform the appropriate therapeutic recommendations (Ha & Longnecker, 2010). Several challenges secondary to the demands associated with the caregiving role and factors innate to the clinical setting however exist, and each may limit the ability of caregivers to communicate their needs effectively to their health care providers.

With respect to the challenges related to the caregiving role, as discussed in the introduction, caregivers often find themselves burdened with the responsibility of relaying the patient's medical history, making decisions about care with patients, and having to communicate difficult content such as prognoses with other family members (Wittenberg et al., 2017). In addition, as previously stated, for some caregivers, the caregiving role was not one of choice but necessity, and as such, reluctance or a lack of confidence in one's ability to carry out this role may further impair communication (Wittenberg et al., 2017). Lastly, caregivers, afraid of upsetting the cancer patient, commonly suppress or disregard their own emotional, physical, or psychological needs (Kim & Given, 2006; Fried, Bradley, O'Leary & Byers, 2005).

These factors create difficult communication experiences and contribute to a condition known as 'communication burden' where caregivers avoid discussion of their own needs or feelings (Wittenberg et al., 2017). Communication burden is defined as the real or perceived exhaustion from continual difficult and challenging communication circumstances (Wittenberg et al., 2017). This type of burden, in addition to the role adjustment and caregiving demands, often causes caregivers to isolate themselves and avoid communicating resulting in a sense of feeling alone (Wittenberg et al., 2017). Social withdrawal is not uncommon and consistently reported by caregivers throughout the literature (Aoun et al., 2015; Zahlis & Lewis, 2010; Cochrane & Lewis, 2005; Lethborg, Kissane, Burns, 2003). Social withdrawal conceivably, only makes the access to supports more challenging.

In addition to these challenges, within the clinical setting, barriers such as provider discomfort in discussing psychosocial concerns, resistance by patients who are caregivers to disclose sensitive issues, and provider burden of work, limit the effectiveness of communication between patients and providers (Ha & Longnecker, 2010; Mira, Guilabert, Perez-Jover, & Lorenzo, 2014). In addition, as PCPs often work in fast-paced environments under considerable time constraints, due to resource and time limitations, the clinical setting by nature is not conducive to easily discussing such a sensitive topic as caregiver QOL.

In summary, communication burden, social isolation, and the inherent communication challenges within the busy clinical setting interfere with the ability for caregiver to effectively voice their concerns with their own PCP. Efforts to support and foster communication then become essential. As proposed by the research question, tools such as Patient-Reported Outcome Measures (PROMs) may be a way to facilitate communication related to QOL between patients that are caregivers to adults with cancer and their health care providers.

Measurement, Screening, and Assessment

Essentially, the objective of a PROM is to identify how a condition impacts a patient across specific domains. In the context of primary care, this information is important as it helps to establish how respondents are coping with a given situation or condition and identify issues to direct the appropriate solutions or resources as needed (Braga de Louredo, Salerno, Fernandes, & Blascovi-Assis, 2015). Inclusive of screening, measuring subjective experiences, monitoring treatment effect, and evaluating the quality of care, PROMs also have several clinical utilities when appropriately applied.

PROMs utilized for screening or measurements are disparate, as are tools used to conduct patient assessments. These terms are often commonly used interchangeably in error; therefore, it is important to establish the differences between them. As previously discussed, PROMs are standardized measurement tools used to assess various constructs, from health status and disease symptoms to QOL or satisfaction (Krabbe, 2017). In the clinical setting, PROMs are used to assess or screen for various conditions or states (Lohr, 2002; Higginson & Carr, 2001). An example of a commonly used PROM is the Brief Pain Inventory. This measurement tool consists of a questionnaire used to evaluate the severity of pain and its impact on daily function (Atkinson et al, 2011). PROMs as measurement tools do not screen for the condition or lead to a diagnosis, rather they represent a value attributed to an experience or state and can act as a point of reference.

Screening, on the other hand, is a method to quickly categorize respondents into mutually exclusive groups – for example, depressed or not depressed. With the assumption that early detection leads to more prompt intervention and therefore, lessens the likelihood of progression to dysfunction, the main purpose of screening is to detect disorders before clinical signs appear (Streiner, 2003). Screening is an objective, quick, and easily administered process that generally involves asking specifically designed questions to determine if a more throughout examination is required (Centre for Substance Abuse Treatment [CSAT], 2009). Typically screening categorizes a population into either a ‘positive’ or ‘negative’ group (Streiner, 2003). A commonly utilized PROM in the clinical setting is the Geriatric Depression Scale. This tool consists of a 15-item, self-report measure, designed to screen for depression amongst geriatric populations (Anderson, Michalak, & La, 2002). This tool demonstrates sensitivity and a positive predictive value for the diagnosis of major depression (Anderson et al., 2002). It is important to establish in addition that within the clinical setting, the term ‘screening’ often gets confused with the term ‘assessment’. Designed with the intention to gather more detailed information in which to establish a diagnosis and treatment plan, assessments are therefore a more elaborate and detailed process than the process of screening. Like screening tools, various standardized tools exist to help providers perform assessments of patients in care.

In summary, PROMs are standardized measures often labeled as questionnaires, scales or indexes by the respected developer. PROMs include standardized measures of QOL, health status or other subjective experiences. Such measurement tools often get confused with screening and assessment tools; however, they are developed differently and have distinct uses within the clinical setting. Measurement provides a ‘snapshot’ of a patient’s status whereas screening is an objective, quick way to categorize respondents into mutually exclusive groups.. Assessment, on the other hand, involves the gathering of detailed information in which to help establish a diagnosis and treatment plan. In the clinical setting, various PROMs are used to screen for a condition while others are designed to measure patient experiences within the specific domains of a PROM. Feedback of PROM results to a health care provider helps to communicate the patient’s perspective. While outside the scope of this paper, screening would be helpful in deciding to use a PROM with a patient who is a caregiver. As the goal of this capstone project is to seek tools that could support or improve patient-provider communication, the focus will be on PROMs that measure and report the QOL experiences of patients.

PROMs and the Role of the Provider

According to the British Columbia Ministry of Health "primary care is inclusive and designed to cover the spectrum of first-contact health care models from those whose focus is comprehensive, patient-centered care, sustained over time, to those that also incorporate health promotion and disease prevention" (British Columbia Ministry of Health [BC MOH], p. 21, 2015). As such, primary care is generally the principal location of continued medical care whereby patients access providers such as family physicians or NPs (BC MOH, 2015; Hutchinson, Levesque, Strumpf, & Coyle, 2011; Canadian Institute for Health Information [CIHI], 2016). As the aim of primary care is to treat, prevent and identify disease, PCPs can first, recognize patients with risk factors or health problems and secondly, intervene where appropriate (BC MOH, 2015).

PROMs therefore are a comprehensive way to capture an individual's personal health and psychosocial status. While merely inquiring into a caregiver's sense of their general QOL may be effective, due to the complex and abstract nature of the concept, it is more comprehensive to measure health-related QOL using an instrument which assesses various domains of well-being and function (Jacobsen, Davis, & Cella, 2002). Despite the history of use of PROMs in the clinical setting, many health care providers remain sceptical of tools measuring QOL (Lohr, 2002; Greenhalgh et al., 2017). Inevitably like any tool or instrument, there are constraints associated with the use of PROMs. As such, QOL PROMs suffer two main limitations. The first constraint relates to how effective a tool is at capturing information required to accurately measure a diverse population. In the instance of QOL measures, an inaccurate measurement could lead to the inappropriate allocation of resources or overlook those who require support (Alsaleh, 2013). Secondly, as PROMs are invasive in nature, such questioning may prompt additional and unnecessary distress in vulnerable patients who feel pressured to consent. It is therefore essential that the tool be not only reliable and valid, but also easily administered by those who are well informed regarding its use and risks. As PROMs inevitably require resources to implement and utilize, it is important their benefits are clearly understood to correctly justify their use. Within the context of this project, the degree to which PROMs improve communication and impact provider awareness of the QOL of caregivers is central to whether the tool is recommended in the primary care setting.

To summarize, cancer is a life-changing diagnosis that threatens the life of the cancer patient. Caregivers are essential in helping cancer patients navigate the cancer trajectory, however, such a rewarding and selfless act does not come without a cost to their physical, psychological and emotional QOL. While health care providers are more aware today of the burden of caregiving, many do not realize its impact on QOL. In addition, communication barriers within the clinical setting make it difficult for caregivers to voice their feelings and concerns. As such, there exists then a gap in care. This gap is the discrepancy between the QOL perceived by the caregiver and that assumed by their health care provider of the impact cancer and its treatment has on the caregiver's QOL. Effective communication regarding caregiver QOL could help bridge the gap and better ensure providers are aware of patients QOL and any unmet needs. As the nature of primary care implies servicing broad population needs and considerable time restrictions, the adoption of a standardized tool to enhance patient-provider communication seems logical, however, evidence regarding their impact in the clinical setting is not entirely clear. By using PROMs to measure caregiver QOL of various physical, mental, and social domains of health, it is proposed caregivers will have a way to express themselves and open space for communication. As such, it is the aim of the research question to clarify the utility of PROMs as communication tools within the primary care setting. Chapter three will describe the search methodology utilized to answer the research question.

CHAPTER THREE

METHODS

The Integrative Literature Review

To answer the research question, a rigorous and systematic approach outlined by Whittemore & Knafl (2005) was applied to inform an integrative literature review. Integrative literature reviews are commonly used to uncover evidence-based knowledge that informs nursing practice (Whittemore & Knafl, 2005). The integrative literature review methodology provides an opportunity for literature from mixed methodologies, both experimental and non-experimental, to be explored (Whittemore & Knafl, 2005). While reducing the risk of research bias and error, this methodology provides a more accurate view of the evidence than the original findings available from individual studies (Whittemore & Knafl, 2005). As integrative literature review present perspectives of various phenomenon, they require systematic methods in which to identify relevant literature (Whittemore & Knafl, 2005).

The approach utilized encompasses four methodological stages informed by the integrative literature review methodology. These stages consist of: 1) problem identification; 2) the search criteria and strategy; 3) a comprehensive search of the literature; and 4) data analysis (Grove, Burns & Gray, 2013; Whittemore & Knafl, 2005).

Literature Search

Stage One: Problem Identification

This capstone project is informed by the need for better awareness of the impact to QOL caregivers to adults with cancer experience. The topic of is both relevant and timely as NPs work with various patients, some of who are caregivers to adults with cancer.

To start the search, it was first important to clearly identify the central problem to the area of research regarding the gap in communication between caregivers and PCPs. As such, the research question posed was formed using the PICOS research question structure.

P (population) – adult caregivers to adults with cancer (all stages and cancer types)

I (intervention) –Patient-Reported Outcome Measures which measure health related QOL

C (comparison) – regular practice without the use of PROMs

O (outcome) – improve patient-provider communication of health related QOL

S (setting) – primary care setting

Stage Two: Search Criteria and Strategy

In attempt to become familiar with the literature and relevant search terms, a preliminary search of the literature was first conducted using the Google Scholar database. This initial search used the following search terms: Patient-Reported Outcome, impact, and clinical practice. This search resulted in 27,800 results of which the initial 200 were reviewed for relevance. The review did not extend beyond 200 as relevance to the question posed declined after the first 100 results. Based on the preliminary search, the keywords listed in each article were retrieved for use in the comprehensive search. Following this, a comprehensive search of the peer-reviewed literature was conducted using four major electronic databases available through the University of Northern British Columbia library: Cumulative Index to Nursing and Allied Health Literature (EBSCOhost), MEDLINE (Ovid), PubMed and Cochrane database. These electronic databases were searched as they integrate an array of literature regarding health sciences. Using the appropriate truncation symbols, the search was conducted first by searching each of the keywords. In aim of keeping the search relevant to the primary care setting, combination of key search terms and MeSH terms, when available, were incorporated into the searches. In effort to cast a wide net on the relevant literature, all MeSH terms were exploded where available. See Table 1 for search non-MeSH keywords and MeSH headings.

Table 1

Non-MeSH Keywords and MeSH Headings

Non-MeSH Terms	MeSH Terms Retrieved			
* = Truncation	CINAHL (ESBCOhost)	MEDLINE (Ovid)	PubMed	Cochrane Database
“Patient reported outcome*” or “PROM” OR “PRO”	Patient-reported outcomes; outcome assessment; outcomes (health care)	Patient reported outcome measures; treatment outcome; outcome assessment (health care); patient satisfaction; health status indicator; surveys and questionnaires	Patient reported outcome measures; patient outcome assessment	MeSH and subject terms not available through this database. Keywords used
“Quality of life”	Quality of life; health and life quality	Quality of life	Quality of life/psychology	
“well being” OR “well-being”	Psychological well-being	No MeSH	No MeSH	
“communication”	communication	communication	communication	
“Nurse practitioner*”	Nurse practitioners; family nurse practitioners	Nurse Practitioners; family nurse practitioner	Nurse Practitioners; family nurse practitioner	
“caregiver*”	Caregivers; caregiver burden	caregivers	caregivers	
“primary care” or “clinical practice”	Primary health care	Primary health care	Primary health care; practice patterns, physicians	
“impact” or “effect” or “influence”	No MeSH term	No MeSH term	No MeSH term	
“cancer” or “neoplasm*”	neoplasms	neoplasms	neoplasms	

From these search terms, Boolean search combinations were formulated (see Appendix VIII) with the aim at locating research relevant to:

- How PROMs measuring QOL support patients to raise QOL issues with providers
- How PROMs measuring QOL help providers gain an awareness to previously unrecognized QOL concerns
- How PROMs support patient-provider communication within the primary care setting

After minor limiters including language (English) and publication (peer-reviewed literature) were applied, the comprehensive search of the literature revealed 958 related articles. Next, citations located during the search were then uploaded to a web-based citation management program (EndNote), after which duplicates were removed. To refine the search and ensure the most relevant literature was retrieved, specific inclusionary and exclusionary eligibility criteria was then applied. The Oxford Centre for Evidence Based Medicine (CEBM) Levels of Evidence hierarchy scale to find the likely best evidence (Howick et al., 2011). Titles and abstracts were screened for relevance according to these criteria. Table 2 depicts the eligibility criteria and rationale utilized in the search.

Table 2

Inclusion and Exclusion Criteria

Inclusion	Exclusion	Rationale
Published between 2000 and 2017	Published prior to 2000	To reflect recent, current practices
May include systematic reviews, randomized controlled trials, cohort studies, case series in order of Centre for Evidence Based Medicine (CEBM) Levels of Evidence	Non-peer reviewed articles, opinion pieces, or articles from obscure journals	Seeking credible, peer reviewed references to ensure quality of evidence as per CEBM
May be any level of research (original studies, systematic reviews or meta-analyses)	Original studies if discussed in systematic review or meta-analyses unless original study specific to research question.	In aim of avoiding duplication of content
Abstract available, or title appears relevant if no abstract available	Title does not appear relevant and no abstract available	To focus the search to literature relevant to the research question
Adult patients	Mental health and pediatric patient settings	Distinctly different population needs.
Providers include nurse practitioners, physicians, and physician assistants	Nurses and other multidisciplinary team members	To accurately reflect the research question
Articles pertaining to the impact on communication in the clinical setting	Literature focused on dentistry, public reporting, quality evaluation, post-treatment/therapy PROM assessment.	To focus the search to literature relevant to the research question
Data addressing PROM impact on: 1) patient raising QOL issues with provider 2) patient-provider communication 3) provider awareness	Articles pertaining to psychometric properties, impact of PROMs on outcomes of care (i.e. patient QOL, symptom reduction, satisfaction with care), PROMs within the research setting, or PROMs used for quality improvement	To locate literature relevant to the aims and setting of the research question

Stage Three: Comprehensive Search of the Literature

Studies deemed eligible were retrieved and subjected to full-text assessment. Eligible studies were subject to a hand search for relevant citations. Articles retrieved from the hand search articles were reviewed using the same inclusion and exclusionary criteria. The process of the search involved a full review of each article. After full review, a total of 11 articles were deemed eligible for inclusion in this integrative review. The literature search is presented utilizing Moher, Liberati, Teztlaff, & Altman's PRISMA flow diagram (2009). See diagram 1 PRISMA literature search.

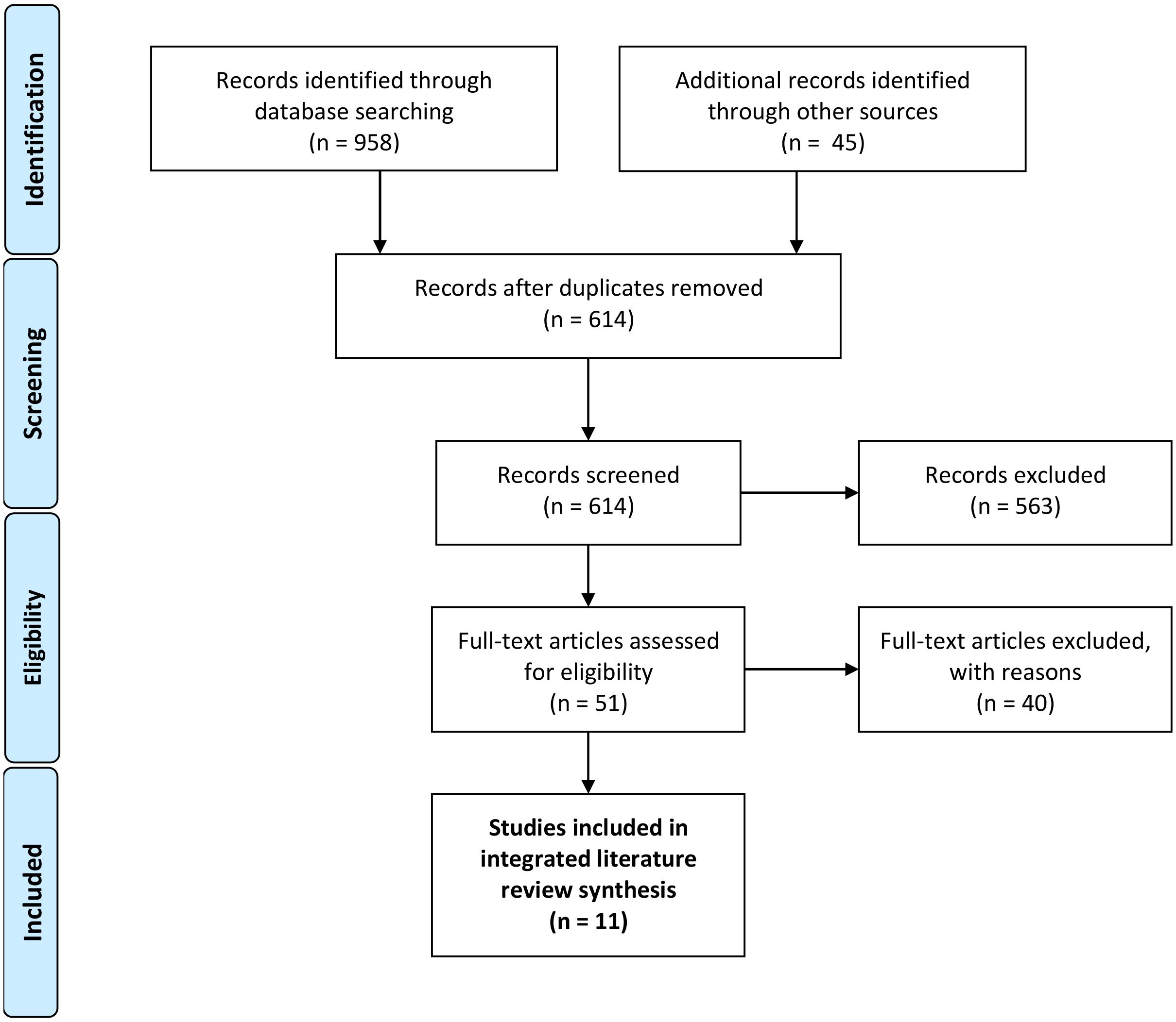

Figure 1. PRISMA flow diagram

Stage Four: Data Analysis

The final stage of the integrative review process was directed at critically appraising the 11 eligible articles. These 11 articles consisted of four systematic reviews, five randomized controlled trials (RCT), one sequential randomized pre-post cohort study and one pilot study. The Critical Appraisal Skills Programme ([CASP], 2013) checklist was used as a guideline to address the rigour and strength of the four SRs and remaining primary studies. To further guide the appraisal of the pilot study, a review by Leon, Davis, and Kraemer (2011) was also incorporated. Using column headings from the literature appraisal guidelines, a matrix was created to facilitate cross-analysis of the literature. During this analysis, four central themes emerged that help to answer the research question posed in this integrative review:

1. The positive impact PROMs have on patient(caregiver)-provider communication
2. The role and limitations of PROMs as ‘icebreakers’ for sensitive issues
3. The positive influence PROMs on increasing provider awareness of QOL issues experienced by their patients
4. The barriers to PROM implementation within the clinical setting.

The following section will provide detail of the findings of this review.

CHAPTER FOUR

FINDINGS

"The single biggest problem in communication is the illusion that it has taken place"

- *George Bernard Shaw*

The principal goal of the literature review is to assemble and integrate relevant evidence to answer the research question. This analysis aims to examine the impact of PROMs measuring QOL on patient-provider communication within the context of the primary care setting. To answer the research question, as outlined in the previous chapter, a systematic search process was undertaken for which the selected articles were then examined for their content and scientific rigor using the CASP appraisal system. A final cohort of 11 articles were selected as each discuss either the specific intervention, setting, or population posed in the research question.

Of the six primary studies included in this integrative literature review, three (50%) were conducted each in the UK while one was conducted each in Canada, the US, and the Netherlands. The four systematic reviews used in this paper used research predominantly from the US and UK in addition to Canada, the Netherlands, Australia, Germany, Sweden, and Norway. Overall, CASP ratings for the primary studies and four systematic reviews were moderate to high with exception to the single qualitative pilot study. Despite this study's low rating it was incorporated into this paper as it contained the only source of PROM feedback measured by caregivers of cancer patients. Details regarding the aim, research methodology, strength, limitations and major conclusions of each article are discussed within the chapter and summarized in a literature matrix (see Appendix VI).

As mentioned in the previous chapter, four central themes emerged within the gathered literature: (1) the positive impact PROMs have on patient-provider communication, (2) the role and limitations of PROMs as ‘icebreakers’ for sensitive issues, (3) the positive influence PROMs have on increasing provider awareness, and (4) the factors which impose implementation challenges within the clinical setting. The focus of this chapter is to expand on these themes as they are presented within the individual articles.

Impact of PROMs Measuring QOL on Communication

QOL PROMs in the Oncology Setting

PROMs measuring QOL and the impact on patient-provider communication is central to this capstone project. Of the selected articles, three systematic reviews, five randomized controlled trials (RCT) and one cohort study, specifically examined PROMs measuring QOL within the oncology settings. Although none of the selected articles specifically examine caregivers within the primary care setting, the impact PROMs measuring QOL have on patient-provider communication is captured within each article. The logic for the use of these selected articles rests on the fact that the patient, regardless if they are a caregiver or an oncology patient, and the provider, regardless if they are an oncologist or primary care provider, exist within a patient-provider relationship. Within this relationship, communication allows information to be exchanged between both parties which helps inform care. As such, evidence respective to the impact PROMs have on patient-provider communication is essential to understanding the utility PROMs have as tools to improve communication. The following section will now elaborate on these findings.

The first study examined, was the prospective RCT by Berry et al. (2011) which involved n = 660 patients with various stages and cancer types from two US cancer centers and n = 262 clinicians. In this study, patients completed an electronic version of a PROM measuring symptoms and QOL concerns prior to their medical visit. Data from the PROM was then provided to a clinical team consisting of physicians, NPs, and physician assistants. The control group completed the same PROM, however, results were not provided to the clinical team. It was determined that while the likelihood of QOL issue and symptom being discussed depended on how problematic the issues was ($p = 0.32$), the intervention group demonstrated a 29% higher chance that these issues would be discussed. In addition, it was noted 25.4% of the providers made direct reference to the PROM data during the patient visit. Clear strengths of this study include the adequately powered sample size and study design which included randomization and use of audio recordings to analyze clinic visit communication. The restrained generalizability of the findings was however a limitation of the study as was the presence of an audio recorder as this may have influenced the verbal behavior of patients and provider. Neither of these limitations however, greatly impair the robustness of the Berry et al. study.

In the RCT by Detmar, Muller, Schornagel, Wever, and Aaronson (2002), $n = 214$ patients and $n = 10$ doctors in a palliative chemotherapy outpatient clinic demonstrated that QOL PROMs improved communication of QOL issues compared to regular care. Although this study is from 2002 and originates from the Netherlands, it was included due to the relevance to the research question and strong research design. According to the researchers, the mean (SD) composite communication was 4.5 [2.3] in the intervention group versus 3.7 [1.9] in the control group ($p = 0.01$; effect size [ES] 0.38). In addition to discussing QOL issues more frequently, over time, physicians recognized at least 10% more health problems in several QOL domains in the intervention group compared to control. Limitations within the study include a small physician sample and risk of contamination of the control group due to the cross-over design. In addition, when utilizing the Hommel procedure to correct for multiple testing, group differences between specific QOL items discussed did not reach conventional levels of statistical significance. Statistically significant group differences were however observed and mean composite communication scores indicated a greater frequency of discussion within the intervention group. This helps in confirming the positive effect of the intervention on patient-provider communication.

Moreover, these findings were supported in the Velikova et al. (2004) RCT. Set in a medical oncology clinic in the UK involving $n = 28$ oncologists and $n = 286$ oncology patients, recorded clinic visits demonstrated QOL symptoms were discussed more in the intervention group than control ($p = 0.006$ and $p = 0.01$ respectively). No significant difference however was noted between intervention and attention-control group ($p = 0.80$). Based on these findings, researchers suggest PROMs alone may have validated caregiver's awareness and need to bring up QOL issues with their provider. Strengths of this study include the prospective study design which incorporated a three-arm trial as well as a large sample size. Due to the study design however, oncologists were susceptible to sensitization of the QOL content. While the failure to control for possible contamination is a limitation of the study, the effect would have likely have only dampened the statistical significance observed. An attrition rate of over 30% was observed, nevertheless, researchers claimed this rate was not too dissimilar to other longitudinal studies. The reason for subject loss was however unclear. While this study has certain limitations as pointed out, the CASP score was moderately high.

Furthermore, with the aim to assess secondary trial outcomes Velikova et al. (2010) examined results of their previous 3-arm RCT involving $n = 28$ oncologist and $n = 286$ cancer patients with repeated measures. From this study, researchers observed that estimate effect communication with doctors was significantly better than control (4.51, SE 2.04, 0.47 - 8.856 [95% CI], $p = 0.03$) however trivial difference between the attention-control arm and intervention arm were again appreciated (3.14, SE 2.24, -1.29 – 7.57 [95% CI], *p* = 0.16). However, despite this effect, compared to 29% (34) of the attention-control group, 86% (85) of patients in the intervention arm reported the PROM helped inform doctors how they were feeling. Patients in the intervention group also reported physicians considered their daily activities (65% vs 53%), emotions (87% vs 71%) and QOL (90% vs 74%) more than compared to the attention-control group. In addition, by helping providers focus consultation on topics important to the patient, researchers suggest the QOL PROM may have improved the patient-provider relationship and had a positive impact on some clinicians' communication practices. Limitations of this study include a high ceiling effect as well as possible contamination due to provider sensitization. A non-participation rate of 30% may also have suggested the QOL PROM was not suitable for all participants. The clear strengths of this trial include the study design and large sample population.

In contrast to the previous studies, the Takeuchi et al. (2011) article used exploratory analysis to examine a data set from a previous RCT involving *n* = 198 cancer patients randomly assigned to a QOL PROM. Researchers in this article analyzed the content of four consecutive recorded consultations (792 consultations in total) to determine the longitudinal impact of the PROM intervention on patient-provider communication. Through their analysis, researchers determined patients assigned to a QOL PROM discussed more QOL topics compared to both attention-control (3.32 vs 2.77, EE -0.55, SE 0.207, -0.96 to -0.14 [95% CI], *p* = 0.008) and control (3.32 vs 2.91, EE -0.41, SE 0.197, 0.79 to -0.02 [95% CI], *p* = 0.04). In addition, researchers theorized the PROM may have acted as a prompt for patients/family to raise issues with providers, as regardless of study arm, patients and their family, not providers, predominantly raised discussion concerning patient issues. In addition, while an association between symptom severity and clinic discussion was appreciated, no clear relationship was observed between psychosocial functional problem severity and clinical discussion. These findings contrast both the Detmar et al. and Taenzer et al. studies where oncologists exposed to PROM data were prompted to explore functional problems. Lastly, while this study was limited due to its lack of generalizability and potential contamination secondary to oncologists encountering patients in all three-study arms, it is recognized such contamination likely only diminished the room for any further significant improvement in communication to be appreciated. Researchers suggest PROMs while effective at initiating discussion of common symptoms such as fatigue, pain and insomnia, lack the capacity to influence provider discussion of psychosocial function secondary to numerous barriers. Barriers such as provider skepticism and lack of familiarity with the tool will be discussed in a later section of this chapter.

Alternatively, a sequential randomized pre-post two-arm cohort study conducted in Calgary, Alberta by Taenzer et al. (2000) examined $n = 53$ oncology patients in which usual care was followed by a group of patients who completed a validated QOL PROM prior to their clinic appointment. A randomized audit of the chart revealed that significantly more QOL items were discussed in the intervention group than compared to control ($t = -3.95$, $p < 0.01$). In effort to validate the perspective of patients regarding the impact the PROM had on discussion of QOL concerns during the clinical appointment, researchers employed both a validated evaluation patient questionnaire and structured exit interviews. From this evaluation, a statistically significant difference of QOL issues discussed during the medical appointment was noted ($t = -2.35$, $p < 0.05$) between patients in the experimental group (48.9%) and those in the control group (23.6%). While the lack of disclosure of sample size calculation do undermine the power of the study, researchers selected a sequential study design as a method to establish ‘usual care’ and avoid the possibility of sensitization of providers, a limitation common to previously reviewed studies. In addition, it should also be acknowledged that the reliance on medical charts to reveal the entirety of communication between a provider and their patient is limited, as often content discussed is missed in the documentation efforts - this limitation would however likely again diminished the room for further improvement in communication to be appreciated. Strengths of this study include the focus of the study being in the outpatient setting, a research design which controls for contamination, as well the application of a validated questionnaire and exit interviews to establish patient feedback on the PROMs usefulness. Lastly, while this trial is dated and contains certain methodological limitations such as internal bias due to a lack of randomization, this article was included in this review as it provides a valuable Canadian context.

Likewise, an association between QOL PROMs and improved patient-provider communication was further noted in two systematic reviews both set in the context of oncology. With the aim of locating evidence related to the impact of routine PROMs measuring QOL and symptoms on patients, providers, and health organizations, the Chen et al. (2013) systematic review located a total of 16 RCTs, nine observational studies and two cohort studies between the years 2000 and 2011. While most the studies originated in either the US (8) or UK (5), two Canadian trials (one representing the Taezner et al. study) were included. Researchers in this article applied the GRADE system in which to establish the quality and importance of the gathered articles. 74% (20) of the identified studies were rated moderate to high strength of evidence. Of the 23 studies examining patient-provider communication, over 91.3% (21) of these studies provided robust evidence to support that a well-implemented PROM can improve patient-provider communication. Of the two studies which failed to identify a positive impact with

PROMs, study limitations such as a low degree of cancer related complications and high ceiling effect limited the room for any significant improvement in communication to be appreciated. In addition, reasonably compelling evidence was located to support the impact PROMs have on detection of underreported or unrecognized problems in both the in-patient and out-patient settings.

Closely supporting the above noted findings, the well-designed systematic review by Kotronoulas et al. (2014) examined 22 RCTs, three cohort studies, and one pilot RCT ranging from 1994 to 2010 with the aim of determining the impact PROMs have on routine clinical practice. Except for five trials conducted in the general practice/home setting, all studies used in this review examined patients with cancer in the outpatient setting. While the type of PROMs examined, number of patients (median 194, range 48 to 1134), and number and type health providers sampled (median 22, range 4 to 262 physicians and nurses) varied considerably, irrespective of the specific PROM utilized, nine out of 11 (82%) of the studies to examine patient satisfaction with care and communication identified a positive result. However, the majority (78%) demonstrated a statistically insignificant impact ($p \geq 0.05$). With respect to these findings, researchers suspect a high ceiling effect may be responsible for the insignificant intervention effect. Of the trials examining patient satisfaction with the PROM intervention, the majority (83%) of patients regarded the PROM content important for them, and almost all (93%) reported to appreciate being asked about their emotional well being. In addition, of the studies with significant post intervention gains, compared to standard care, greater satisfaction with emotional support and enhanced communication was noted. As observed in the previously discussed trials, a direct correlation between the severity of a problem identified by the PROM influenced the content discussed during the clinical appointment was noted. Strengths of this article include the systematic review study design and extensive search methodology and the use of the Cochrane Collaboration Risk of Bias Tool to evaluate the robustness and quality of the gathered controlled trials.

In contrast to the above aforementioned reviews, with the aim to examine the scientific evidence behind the routine use of QOL scales in the outpatient setting, Alsaleh (2013) conducted a systematic review of randomized trials from 1990 to 2012. Due to various methodological limitations such as small sample sizes and weak disclosure of randomization, the Alsaleh systematic review was limited to six trials for which the Detmar et al., Taenzer et al., and Velikova et al. trials were included. In his analysis, Alsaleh found that while evidence exists to support QOL PROMs positively impact patient-provider communication, some of the trials contain methodological limitations which limit the certainty of the impact. Of the six trials examined, four, including the Taenzer et al. trial were identified as containing various methodological limitations. Apart from the Taenzer et al study, the remaining three studies were of no relevance to patient-provider communication, thus the findings of this article do not have much bearing on the overall conclusion of this integrative literature review. Moreover, while the Alsaleh review failed to disclose any limitations within his own study, a small sample size of six RCTs does draw inquiry into the stringency of the employed search methodology. Despite the limitation of this study, it was included as it does identify important barriers regarding the implementation of QOL PROMs in the clinical setting. These barriers will be explored further in the following sections of this chapter.

Generic PROMs in the Primary Care Setting

The articles previously discussed examined research specific to QOL PROMs within the context of oncology. In attempt to cast awareness of the impact PROMs have in the primary care setting, the systematic review by Valderas et al. (2008) was selected. Although the PROMs implemented in this article predominantly measured generic constructs such as pain or health status, the majority (67.9%) of RCTs examined were PROMs implemented within the primary care setting. With the aim of identifying the impact of PROMs in daily practice, while capturing data from mostly US settings (21), this review included one Canadian study and analyzed 34 RCTs from 1978 to 2007. The PROMs examined in this review measured constructs from mental status (10), general health status (7), and QOL (2). Researchers in this review analyzed $n = 7$ specific trials involving processes of care such as advice, education, and counseling. While not examining communication specifically, the researchers inferred such processes of care closely reflect the level of patient-provider communication occurring within the clinical encounter. While only three (43%) of the seven studies examining advice, education, and counselling demonstrated studies with statistically significant outcomes, of the 14 studies examining target diagnoses and notations, seven (50%) demonstrated a result of statistical significance. Through their analysis, researchers concluded PROMs impact on patient-provider communication is generally positive. While the Valderas et al. review provides important insight regarding the impact of PROMs in the primary care setting, due to a considerable degree of heterogenicity and different units of randomization, the review is not without its limitations. Strengths of this article however include the comprehensive search methodology guided by the Cochrane and use of the Jadad Scoring System to assess the selected RCTs for their quality of evidence. The Jadad scale examines study characteristics such as randomization, blinding, and subjects lost to follow-up and rates studies on a scale of 0 to 5, with higher scores indicating better quality of evidence (Jadad et al., 1996). Most studies (85%) utilized in the Valderas et al. review were graded between 3.0 to 4.5 on this scale, five (15%) of the studies were however of low quality (less than

3). Because of considerable heterogenicity within the trial, the researchers noted certain methodological study limitations exist which impact the clarity of evidence regarding PROMs, therefore the overall impact on outcomes of care such as mortality and morbidity is not clearly defined. As outcomes of care are however outside the scope of this review and, this limitation does not impact the value of the research findings in relation to patient-provider communication.

PROMs and Caregivers of Cancer Patients

Lastly, in attempt to locate literature respective to QOL PROMs and caregivers of cancer patients, a pilot study examining the impact of a computerized PROM questionnaire in a palliative/hospice setting was located. Using interviews and a validated usability scale, the Kallen, Yang, and Haas (2011) study evaluated patient, caregiver, and provider feedback of two well-validated, although generic PROMs. All (100%) patients and caregivers (n = 18) reported the prototype PROM facilitated patient-provider communication and shared decision-making. In addition, the majority (77.7%) of providers (n = 9) felt that the prototype PROM improved patient-provider communication and all (100%) indicated the prototype PROM improved multi-disciplinary team communication. The limitations of this pilot study included the constrained sample size (n = 27, 9 patients, 9 caregivers and 9 physicians) and limited generalizability as only a single site was analyzed. In addition, the lack of detail regarding subject recruitment arguably could have contributed to bias. While recognizing the primary role of a pilot study is to examine the feasibility of future research endeavors, the inclusion of a control or comparator group would have allowed for a more realistic comparison of the impact of the intervention. Nonetheless, this study sheds light on the impact PROMs have in supporting communication between cancer patients, providers and caregivers.

To summarize, except for the systematic review by Alsaleh (2013), studies examining the impact of PROMs on patient-provider communication established a positive influence in both the oncology and primary care setting. The RCT by Berry et al. (2011) was seminal to establishing the impact PROMs have on communicating QOL issues. In this trial, providers made specific reference to PROM data thereby suggesting that data significantly influenced the medical appointment discussion. Similar associations were drawn in the Detmar et al. (2002), Velikova et al. (2002, 2010), Takeuchi et al. (2011), and Chen et al. (2013) articles involving providers and patients. From the primary care context, while patient-provider communication was not measured directly, the analysis by Valderas et al (2008) of outcomes related to communication such as diagnosis, counselling, and offering advice were generally positively impacted using generic PROMs. Lastly, as previously discussed, the pilot study by Kallen et al. (2011) involving cancer patients, their caregivers and providers, demonstrated that the use of a PROM and sharing of patient information not only improved communication but was viewed as a valuable process.

The Role and Limitations of PROMs as 'Icebreakers'

The second major theme found within the literature review emphasized the role and limitations PROMs played in facilitating discussion of sensitive topics. While PROMs function well as facilitators of patient-provider communication, discussion of sensitive topics such as sexual or social functioning are limited due to factors within the clinical setting.

In two of the articles, researchers found that providers focused on those areas of care they perceived they have knowledge of or experience in. In the RCT by Berry et al. (2011), while the QOL PROM intervention resulted in a greater likelihood of discussion of issues related to social and sexual function more than compared to regular care, compared to medical concerns (discussed 41% of the time reported), discussion of sensitive issues only occurred 16% of the times it was reported. Researchers concluded that while the PROM acted as an 'icebreaker' in which to give patients and providers permission to discuss sensitive issues, clinicians likely choose to focus on issues they feel they have influence over. Berry et al. suggest the tendency for providers to avoid sensitive topics closely relates to the lack of awareness of available resources or specific knowledge of a particular issue. This concept too will be further explored in the next chapter.

The second article by Takeuchi et al. (2011) further supports the above findings. In their study, researchers observed PROMs function well as a ‘prompt’ for both oncologists and patients in which to discuss various issues and support a more comprehensive discussion. As discussed earlier, the discussion of patient psychosocial functioning, particularly social and role function, was not impacted by the PROM feedback. Researchers theorize that PROMs while helpful in prompting discussion of patient symptoms, can not overcome existing barriers such as limited clinical time, personal provider preferences, or patient’s general sense that the oncology setting is not an appropriate forum to raise such psychosocial issues. These specific clinical barriers will be discussed in a later section of this chapter.

In contrast to the findings of the Takeuchi et al. study, the RCT conducted by Detmar et al. (2002) reported increased discussion of functional domains with the use of PROMs. Here, the intervention increased the discussion of physical function social function ($p = 0.05$), fatigue ($p = 0.02$), and dyspnea ($p = 0.02$) compared to regular care respectively. The PROM intervention did not impact other areas of measure such as physical or cognitive function. Despite this, providers reported the PROM feedback was useful for providing an overall impression of their patient’s functional health and symptoms, especially with regard to psychosocial and unexpected symptoms such as sleep problems.

PROMs Impact on Provider Awareness

The third major theme important in this literature is the impact PROMs have on provider awareness. While the focus of this integrated review is patient-provider communication, it is important to recognize communication as a process whereby information is exchanged or shared. Communication can be in the form of verbal dialogue, non-verbal communication, or written word. The previous findings examined the verbal discussion that occurred between providers and their patients. To only examine communication as it pertains to the discussion that occurs in a clinical appointment risks neglecting the full benefit PROMs provide. As the PROMs utilized in the following studies each provided a written summary of the PROM data to the respective provider, data which captures provider's awareness of previously unrecognized patient concerns should be acknowledged as another way to validate the benefit of a PROM in the clinical setting.

Six of the articles to examine the impact of PROMs on provider awareness each noted a positive impact. First, in the 2004 Velikova et al. RCT, while 27% of providers found the PROM useful to identify problems for discussion and provide additional information, 69% reported the PROM provided an overall assessment of patients. Next, in the Kotronoulas et al. (2014) systematic review, patients reported that the PROM summary helped enhance their provider's knowledge of their health problem (79% to 89%) and that the PROM would be a useful standard as part their future consultations. Furthermore, with rates of usefulness ranging from less than 50% to 68%, health care providers indicated the PROM helped provide an overall assessment of the patient which enabled the provider to guide the discussion with the patient and uncover issues of concern. As a result, providers reported a willingness to use PROM data in every day practice. Likewise, overtime, the Detmar et al. (2002) RCT demonstrated that physicians recognized at least 10% more health problems in several QOL domains in the intervention group compared to control. In the same way, the systematic review by Chen et al. (2013) reported that of the 16 studies examining provider awareness, 94% (15) of the studies reported either a strong or moderate positive impact on provider's detection of previously unrecognized patient problems.

Within the articles examined thus far, all have represented QOL PROMs impact on communication, however within the context of the oncology setting. Although most are from the outpatient setting, there remains a lack of data specific to QOL PROMs within the primary care setting. As discussed previously, the systematic review by Valderas et al. (2008) observed generic PROMs implemented in the primary care setting positively impacted certain processes of care. To manage the considerable heterogeneity of the RCTs used in the review, the researchers carefully grouped study results to analyze each according to the impact on five distinct processes of care: (1) counselling, (2) diagnoses, (3) referrals, (4) impact to patient functional state, or (5) physician-related usefulness. Researchers reported 65% ($n = 23$) of the trials measuring the impact of PROMs reported a statistically significant difference in at least one of process of care. Lastly, researchers in the Canadian study by Taenzer et al. (2000) summarized that the intervention not only increased detection and awareness of QOL problems ($p < 0.1$) but a trend towards greater action ($p < 0.13$) was also appreciated. Here it was identified that action was taken by providers on 73% of the QOL items identified as problematic in the intervention group compared to 68.5% in the control group. Evidence of providers taking action on a patient problem could conceivably imply a greater awareness of the severity or existence of a patient concern.

In summary, PROMs are associated with improved provider awareness of previously unrecognized patient problems. As awareness and provider attention to QOL is an obstacle in care (Taenzer et al., 2000), evidence to suggest PROMs impact provider recognition is essential to narrowing the perceptual gap between patient concerns and provider knowledge of need.

Barriers hindering the impact of PROMs in the clinical setting

As the purpose of this literature review is to analyze if PROMs can be used as a tool to improve patient-provider communication within the primary care setting, acknowledgement of the logistical challenges to foresee the feasibility of PROM implementation is important. Thus, the final theme which emerged during analysis of the gathered literature focuses on barriers to the implementation. Although the predominance of literature gathered represents studies conducted in the oncology setting, these findings can be applied to the primary care setting as the barriers identified within the literature gathered for this integrative review are similar to barriers observed within the general literature (Higginson & Carr, 2001; Boyce, Browne, & Greenhalgh, 2014). These barriers can essentially be categorized into three types: 1) attitudinal, 2) administrative, and 3) structural. Each of the three barriers that surfaced as factors restricting the implementation of PROMs within the clinical setting will be described.

Attitudinal Barriers

The first barrier to surface in the literature was related to several attitudinal biases. Inclusive of general scepticism, a preference to conduct more informal ways of assessing patient issues, or the belief that PROMs may inflict unnecessary distress onto patients, these biases represent perceptions and beliefs held by providers that can be seen to limit their acceptance and willingness to utilize PROMs in the clinical setting.

The first article to clearly identify these attitudinal biases was the Takeuchi et al. (2011) RCT whereby researcher identified three main ‘existing barriers’: (1) the personal preference of some providers to not use tools such as PROMs in practice, (2) the inherent limited ability of some providers to discuss psychosocial issues, and (3) the perception of some providers that psychosocial concerns are an inevitable consequence of cancer for which they are unable to offer suitable advice or solutions. With respect to the first attitudinal barrier, the preference to not use tools such as PROMs and scepticism regarding the accuracy or relevance of QOL PROMs for all patients was noted by providers in both the Valderas et al. (2008) systematic review and Velikova et al. RCT (2004). It is logical to deduce that such scepticism might interfere with a provider's willingness to utilize a PROM in practice.

Furthermore, researchers found that a lack of familiarity is strongly linked to providers not being willing to utilize PROM data. Within the literature, many of the trials indicated limited formal training was given to providers on how to utilize the tool in practice (Alsaleh, 2013; Takeuchi et al., 2011; Taenzer et al., 2000; Chen et al., 2013). As familiarity and formal instruction regarding tool interpretation are factors that impact provider scepticism and willingness to utilize a tool, the researchers proposed PROM training as a crucial way to address some of these attitudes. It is important to also note that some of the attitudinal barriers exist in the form of professional concerns. In his systematic review, Alsaleh highlighted these concerns include issues such as the impact of PROMs on patient's privacy, the reallocation of clinical resources to support PROM application versus other key areas of care, or potential damage to patient-provider relationships (Alsaleh, 2013). In his systematic review, Alsaleh (2013) indicated that PROM questionnaires have the potential to instigate unnecessary anxiety, distress or burden onto patients. Of the studies that measured patient satisfaction, all reported similar or improved satisfaction with care (Velikova et al., 2010; Detmar et al., 2002; Taenzer et al., 2000; Chen et al., 2011; Valderas et al., 2008; Kotronoulas et al., 2014). And while in two of the studies, a high ceiling effect was noted (Taenzer et al., 2000; Kotronoulas et al., 2014), the consistency in patient satisfaction in the studies support the notion that if any distress was experience, it did not impact satisfaction ratings. With respect to the lack of personal comfort in discussing psychosocial issues, Takeuchi et al. (2011) propose that providers could be better supported through specific training respective to patient's psychosocial needs. Through increased knowledge and awareness of available resources to provide patients, providers may feel more capable to discussing psychosocial needs. In addition, attitudes may be shifted to be more open-minded towards the use of PROMs.

While barriers may exist in the clinical setting, many providers indicated PROMs had utility in the clinical setting. For example, the RCT by Velikova et al. (2004) found physicians reported the QOL information to be "very useful/quite useful" in 43% of oncology/medical outpatient visits, "somewhat useful" in 28% and a "little useful" in 21% of visits. In addition, although Velikova et al. (2010) study demonstrated that almost 20% of physicians cited the tool 'sometimes/often' interfered with their clinical work, most physicians (71%) in this study were willing to use to tool routinely in practice.

Administrative Barriers

As provider's concerns surfaced respective of the potential for PROMs to disrupt care and consume valuable clinical time, the next barrier to emerged within the literature was deemed administrative in nature. For example, researchers in the Velikova et al. (2004) RCT reported providers' main reasons for not using PROM data included: forgetting (55%), lack of time (36%), or finding the data irrelevant to patient problems (23%). While some of these reasons represent attitudinal barriers, providers remain considerate of the impact PROM may impose to their limited clinical time with patients. In addition, while electronic versions of PROMs make data collection and distribution more efficient (Kotronoulas et al., 2014; Alsaleh, 2013), the implementation of PROMs in the clinical setting also may impact the workload of office and nursing staff. With respect to total clinical time, of the studies gathered which analyzed clinical time, all (3) reported the use of PROM data did not negatively impact the length of clinic visits (Detmar et al., 2002; Takeuchi et al., 2011; Berry et al., 2011). Researchers in the Detmar et al. (2002) RCT reported no statistically significant difference was observed between intervention group visit duration (9.8 [6.2] minutes) and control (20.4 [6.2]). Similarly, researchers in both the Takeuchi et al. (2011) and Berry et al. (2011) RCT reported no significant difference in time in either control or study arm. Finally, after comparing clinical appointment times of studies utilizing QOL PROMs, researchers in the Taenzer et al. study established the PROM intervention to be a "simple, time effective protocol [that] is easy to use, efficient and acceptable to both patients and medical staff" (p. 212, 2000).

Structural Barriers

The last obstacle to implementing PROMs within the clinical setting is related to structural barriers inherent to PROMs. Firstly, within the literature gathered, several providers experienced challenges either interpreting and applying PROM data in practice. In this case, both the Kotronoulas et al. (2014) and Alsaleh (2013) systematic reviews noted several of the PROMs analyzed were challenging for providers to interpret or integrate into care. In addition, links to clinical recommendations were either absent or not clear. PROMs difficult to interpret or utilize in practice are at risk of becoming redundant or dismissed. As such, efforts to support provider's understanding of PROMs are recommended (Kotronoulas et al., 2004). Specifically, treatment recommendations designed to help link a recommended intervention with a respective problem could better support provider's confidence in using PROMs in the clinical setting.

In addition, as it is not uncommon for respondents to experience respondent burden when completing surveys and questionnaires, the potential for patients to not complete a PROM does exists. Although patient burden was not directly measured in any of the articles obtain, a non-participation rate of 30% noted in the Velikova et al. (2010) RCT could suggest a degree of respondent burden and or a lack of acceptance of the PROM utilized in this study.

Chapter Summary

To summarize, this review has provided a critical analysis of common themes within the literature gathered on both QOL and generic PROMs within the primary care and oncology setting. The value of QOL PROMs as a communication tool to aid patient-provider discussion of QOL issues is strong. In addition, within the primary care setting, generic PROMs have a positive effect with regards to patient-provider communication. Furthermore, PROMs have a role as facilitators for sensitive issues; however, barriers within the clinical setting can limit their effect. Last, PROMs have demonstrated effectiveness in aiding providers detect previously unrecognized conditions. While several methodological limitations exist within the literature, none limit the robustness of the research such that a conclusion regarding PROM impact is compromised.

Within the literature, potential factors that may limit the ease to which providers are willing to incorporate PROMs into the clinical setting were observed. These factors consist of three main barriers: attitudinal, administrative and structural barriers. From scepticism to beliefs that PROMs are burdensome in terms of time or are difficult to utilize due to poor interpretability, PROMs face several barriers towards acceptance and clinical application that need to be navigated to support full acceptance in the clinical setting. In consideration of the research question, these findings present evidence supporting the role PROMs can play in the clinical setting to improve communication. The next chapter of this paper will discuss these findings in context to the research question in addition to providing recommendations, limitations and areas for future research.

CHAPTER FIVE

DISCUSSION

“The quieter you become, the more you can hear”

- *Ram Dass*

Guided by the research question, the integrated literature review explored the available and relevant literature with the aim to ascertain the impact PROMs have on patient-provider communication. In this process, a combination of qualitative and quantitative studies examining both QOL and PROMs in both the oncology and primary care setting were examined. The objective of this chapter is to synthesize the research findings and discuss their relevance within the context of the primary care setting. It begins with a summary of the key research findings and practice recommendations, and concludes with a discussion of related study limitations and areas for future research.

Key Findings

Chapter four presented the four themes central to the research question that emerged during the analysis of the literature:

- The positive impact of PROMs on patient-provider communication of QOL
- The role and limitations of PROMs as ‘ice-breakers’ for sensitive issues
- The positive influence PROMs have on provider awareness of QOL issues experienced by patients
- The presence of attitudinal, administrative and structural barriers in the clinical setting which limit the utilization and implementation of PROMs.

These themes will now be discussed within the context of caregivers of adults with cancer in the primary care setting.

Recommendations for Practice

Although it might seem effective to informally ask a caregiver how they feel about their QOL, due to the complex and abstract nature of QOL, it is best to measure this construct using an instrument that assesses various domains of well-being and function (Jacobsen et al., 2002). Except for the systematic review by Alsaleh (2013), the remainder of studies gathered demonstrated evidence that PROMs positively impact patient-provider communication (Velikova et al., 2010; Takeuchi et al., 2011; Detmar et al., 2002; Taenzer et al., 2000; Berry et al., 2011, Chen et al., 2013, Kallen et al., 2011). Within the context of the primary care setting, several generic PROMs measuring constructs from pain to general function improved patient-provider communication as well (Valderas et al., 2008). In addition, the implementation of QOL PROMs in the oncology setting not only improved communication but also improved interpersonal relationships between patients and providers enabling emotional and personal issues to be discussed more openly (Velikova et al., 2010; Takeuchi et al., 2011; Kotronoulas et al., 2014). Lastly, findings suggest that PROMs positively impact certain processes of care such as increased provider awareness of previously unrecognized patient concerns, and/or the facilitation of diagnosis and referrals (Velikova et al., 2004; Detmar et al., 2002; Taenzer et al., 2000; Valderas et al., 2008; Chen et al. 2013).

Based on the findings obtained from the literature reviewed, it is recommended that QOL PROMs be implemented as a tool with at risk patients to improve the communication between caregivers and their primary care providers. Implementing PROMs into primary care does, as identified in the literature, imply certain challenges. First it needs to be appreciated that patient-provider communication is the result of a series of unfolding intricate causal links inclusive of: a) the willingness of respondents to talk about their concerns, b) the inclination of the provider to see QOL concerns as clinically relevant, and c) to PROM to support provider's accurate interpretation of data. For PROMs to effectively impact patient-provider communication, it is logical to argue that these causal links must be each met.

Secondly, although PROMs were identified as effective at evoking greater discussion between providers and patients, they are not without their limitations when dealing with topics of a sensitive nature. Lastly, with respect to the implementation of PROMs, several barriers exist which make employing PROMs in the clinical setting challenging. Both the limitations and challenges as well as relevant practice recommendations will be discussed within the context of the primary care setting in the following sections.

The role and limitations of PROMs as 'icebreakers'

In the primary care setting, it is not uncommon for health care professionals and patients alike to find it difficult to speak freely about topics deemed sensitive. Despite wanting to discuss sensitive issues, patients report experiencing barriers in raising issues with providers. For instance, patients may cite feeling more comfortable discussing sexual wellbeing only with certain providers such as gynecologists or PCP, or do not identify the issue as being serious enough to discuss with providers, or feel discussing the issue would be uncomfortable for the provider (Mellor, Greenfield, Dowswell, Sheppard, Quinn, McManus, 2013).

In addition, it can be particularly difficult for providers to discuss sensitive psychosocial concerns such as sexual well-being or social function (Reinke et al., 2011; Reinhard et al., 2008). Health care professionals often cite several barriers to discussing sensitive issues such as: a general lack of time; feeling inadequately trained or insufficiently skilled; the presence of another third party being present during consultations; or concern regarding uncovering an issue for which no solution exists (Mellor et al. 2013; Bober & Varela, 2012; Gott, Galena, Hinchliff & Elford, 2004; Sadovosky, 2003). Given the wide variety of health concerns dealt within the primary care setting, is it easy to appreciate providers may share lack of experience, or strong working knowledge of all areas of care.

Within the literature, evidence supports the fact that PROMs are beneficial in facilitating communication as well the discussion of sensitive topics, at least up to a certain point. In one of the primary studies, the term ‘icebreaker’ was used to refer to PROMs. The term 'icebreaker' represents a tool or phrase used to relieve tension between people or to initiate a difficult conversation. As icebreakers, PROMs can be used by providers to enter into challenging clinical conversations. PROMs however, have inherent limitations in that despite the level of significance a PROM attributed to an issue, if the concern is sensitive in nature, PROMs are often not strong enough to override preceding provider hesitancies to discuss sensitive issues (Berry et al, 2011).

As a lack of knowledge, sense of skill limitations, or lack of awareness of available resources is most commonly behind the hesitancy for providers to avoid discussion of certain sensitive topics, efforts to increase provider’s knowledge can help support communication, recognition, and a meaningful response to patient needs (Sadovsky, 2003). As the capacity for PROMs to act as icebreakers function up to the point that providers perceive to have knowledge or capacity to influence, for PROMs to be used to their maximum benefit, providers require access to resources and information to support various patient problems. With respect to caregivers of cancer patients within the primary care setting, the NCI’s (2015) Family Caregiver in Canada (PDQ): Supportive care – Patient Information resource would be recommended as a first line information for PCPs. This resource contains valuable information regarding interacting with family caregivers, the impacts to QOL, and recommended interventions for caregivers.

Barriers and Facilitators of PROMs in Primary Care

In addition, while "quality of life measures will never capture all aspects of life that are important to an individual", systems where patients can specify qualities, come close (Higginson & Carr, p.1297, 2001). While PROMs were originally utilized in the research setting, they are by no means a novel instrument in the clinical setting. However, as discussed in the findings, there are both attitudinal, administrative, and structural barriers that potentially limit the integration of PROMs within primary care and other clinical settings (Boyce et al., 2014).

In terms of attitudinal barriers, given that QOL is a complex and multifaceted construct influenced by personal, cultural and societal values, its measurement imposes several conceptual issues for which some of the scepticism shared by providers in the clinical context is justifiable (Boyce et al., 2014). Unlike measures of specific patient outcomes such as anxiety or depression, QOL measures are more expansive, and therefore may be less accurate and responsive (Higginson & Carr, 2001). While some providers prefer "watchful waiting" or to simply rely on clinical judgment rather than data from a PROM (Greenhalgh, 2009), it is well recognized that to be of clinical value and direct appropriate care, PROMs must accurately measure and report patient experiences in a format accessible to health care providers. PROMs that are recommended for use in the research and clinical setting should, therefore, have extensive psychometric analysis to ensure validity and reliability of measurement.

In aim of locating a standard in which to identify validated PROMs, a rigorous criterion to appraise and standardize instruments measuring health status and QOL was selected. The criteria selected represents a standard developed by the Scientific Advisory Committee (SAC) within The Medical Outcomes Trust (MOT), an American organization dedicated to the development of standardized, high-quality instruments to measure health outcomes (Lohr et al., 2002). Based on existing standards and principles of both classic and modern test theory, the MOT SAC developed eight main attributes and review criteria by which QOL instruments should be examined against (Lohr et al., 2002). To ensure selected PROMs have psychometric properties that are valid, reliable and easily integrated into the primary care setting, application of the MOT SAC criteria is recommended. PROMs evaluated using criteria established by the MOT SAC may more easily engage providers and influence provider attitudes to accept the relevance and validity of PROMs measuring QOL within the clinical setting.

In the same way attitudinal barriers are common, so are the related administrative barriers. In a busy primary care setting, as the administering and collection of PROM data will likely incur time and administrative resources, it is suggested clerical and nursing staff are closely involved in decision-making process regarding PROM implementation (Lohr, 2002). For example, supporting administrative staff to dictate the administrative processes involved with handing out and collecting PROMs may help facilitate success during the implementation of the tool. As clinical administrative and nursing staff are keenly aware of the steps involved in workflow processes, involvement of these key members also helps to ensure their awareness of the importance of the role of data collectors and value of PROM to overall patient care. Other efforts to support the ease of administration include offering questionnaires in alternative modes such as electronical platforms (tablets or smart phones) and utilizing appropriate cultural and or language adaptations if available (Lohr, 2002). Electronic versions of PROMs can make data collection and distribution more efficient thereby cutting down on administrative workloads (Kotronoulas et al., 2014; Alsaleh, 2013). Lastly, as demonstrated in the gathered literature, PROMs did not negatively impact the duration of clinical visits (Detmar et al., 2002; Velikova et al., 2002; Berry et al., 2011). However, as time is a limited resource in the primary care setting, it would be advised to utilize PROMs are a tool to increase QOL communication for caregiver patients who are deemed at risk of low QOL.

In terms of structural barriers, it is not uncommon for providers to have trouble interpreting PROM data, or for patients to feel burdened in having to complete additional forms (Boyce et al., 2014). PROMs can be challenging for providers to either interpret or integrate into care (Boyce, Browne, & Greenhalgh, 2013; Greenhalgh, 2009). Clear cut-off thresholds that allow health care providers to easily identify a QOL domain of concern and, as suggested by Kotronoulas et al. (2004), links to appropriate recommendations and resources may support PCPs in addressing areas identified as concerns for caregivers.

In summary, attitudinal, administrative, and structural barriers exist within the clinical setting which make implementation of PROMs into primary care challenging. Through careful selection of validated QOL PROMs, involvement of key staff, linking PROM scores to recommended interventions or resources, and use of electronic devices to upload PROMs onto, QOL PROMs can more easily be incorporated into the primary care setting.

Recommended QOL in Primary Care

During the literature research, several PROMs specific to caregivers of adult cancer patients were located. Of the PROMs identified, three were selected as tools that could be applied in the primary care setting as each is practical, applicable to caregivers, and lastly are reliable and valid as per the MOT SAC criteria. Specifically, the three PROMs selected include the Caregiver QOL Index-Cancer questionnaire (CQOLC) (Weitzner & McMillan, 1999), the Quality of Life in Life-Threatening Illness-Family Caregiver questionnaire (QOLLTI-F)

(Cohen, Kuhl, & Ritvo, 2006), and the Caregiver Oncology Quality of Life questionnaire (CarGOQoL) (Minaya et al., 2012). See Appendix I for PROMs description. While transferring PROMs used in research to the clinical setting can be a challenge, it can be attained if certain properties such as validity, reliability, responsiveness, acceptability, and interpretability are met (Higginson & Carr, 2001). See Appendix II for operational definitions and standard psychometric criteria for PROMs.

The first PROM recommended in the primary care setting is the Caregiver Oncology Quality of Life questionnaire (CarGOQoL). This PROM demonstrated the most extensive psychometric support and displayed good internal consistency, test-retest reliability, responsiveness, content validity, and construct validity. See Appendix III for PROMs content validity and Appendix IV for selected PROMs psychometric properties. Similarly, the Canadian instrument Quality of Life for Life-Threatening Illness – Family Caregiver version (QOLLTI-F), and the Caregiver Quality of Life Index-Cancer (CQOLC) each demonstrated strong psychometric measures. All three instruments can be completed on average in 10-20 minutes, are available for use at no cost, and have been well received by respondents. See Appendix V for burden and administrative qualities of PROMs. The CarGOQoL is validated for use in several different languages, including French, Farsi, Mandarin, Korean, and Turkish, while the QOLLTI-F is validated in both French, English, and German. The CQOLC is validated for use in both English and French. As each of the PROMs located were designed for the research setting, clinically relevant links to interventions or referrals are missing. Such links would require further development however would benefit their value clinically as health care providers would have accessible recommendations in which to focus their care or attention. In addition, while noting the QOLLTI-F has a specific focus on palliative care, each of these three PROMs would be recommended for use in the primary care setting to provide greater awareness of QOL concerns and increase communication between PCPs are their patients.

Recommendations for Education

From the increased need of awareness of the impact cancer has on caregivers QOL to the scrutiny respective to the role of PROMs in the clinical setting, throughout this project there exists a role for continued provider awareness and knowledge. As this project focuses on NPs as PCPs in BC, there exists recognition that nursing practice informs an awareness of the needs of caregivers. As such, this awareness can be built upon to ensure the specific needs of caregivers of cancer patients, and numerous ways of improving communication are fully supported in practice. It is recommended then, that the impact to caregiver QOL, challenges in communicating, discussion of common sensitive issues and local resources, as well as suitable PROMs to support communication be adopted in all BC NP university curricula.

For NPs currently in practice, there exist opportunities through jurisdictional associations such as the BC Nurse Practitioner Association to introduce practice related content. With ongoing education, NPs can be better equipped to communicate with caregivers to recognize distress and offer viable solutions. Lastly, with respect to the lack of familiarity with PROMs as clinical tools, many of the trials indicated a failure to formally train providers on how to implement the tool in practice. Ensuring providers are familiar with the measures prior to implementation has been shown to help facilitate the uptake and utilization of PROMs (Boyce et al., 2014). Appropriate training to ensure familiarity of a PROM therefore recommended to facilitate use within the primary care setting.

Limitations and Future Areas of Research

This integration of relevant studies is not without its limitations and as such, this capstone project is constrained by three main limitations. The first limitation is related to the narrow scope and the size of the literature review. In effort to speak to such a multifaceted and complex topic as QOL, communication between the patient (caregiver) and provider (PCP) dyad was focused on. In efforts to focus on the primary care setting, it was determined that due to contrasting dynamics of the mental health and pediatric settings, both settings would be excluded from the literature review. During the synthesis of the review, as barriers towards implementation of PROMs emerged from the literature, it was recognized that in the mental health setting, PROMs are well embedded into routine practice where professional attitudes towards the use of these tools are often more positive (Boyce et al., 2014). While the differences unique to each setting need to be acknowledged, valuable precedence within literature set in mental health may have been missed which better informs the understanding of how to negotiate barriers involving PROM implementation. An expanded search inquiry inclusive of mental health settings is therefore recommended if future research respective to barriers faced in the implementation of PROMs should be considered.

With respect to the size of this review, while it can be acknowledged the search strategy incorporated four relevant electronic databases and a hand-search of citations, the search was limited to one individual and due to concerns of credibility of non-peer reviewed sources, grey literature was excluded. Although a systematic process was followed and a matrix was utilized to find common ideas and concepts from the gathered material, as there was only one researcher, inherent bias could exist. Additionally, by excluding grey literature, valuable studies could have been missed due to reasons such as limited dissemination or publication bias (Schmucker et al., 2017). As there sometimes is a tendency for journal articles to publish articles with positive rather than weak or neutral findings, the inclusion of grey literature can help counterbalance this bias (Schmicker et al., 2017; Adams, Smart & Sigismund Huff, 2016). In addition, if data within the grey literature were to exist that differed significantly from the published data, a review excluding unpublished literature may be at risk for overestimating the treatment effect (Schmucker et al., 2017; Polanin, Tanner-Smith, & Hennessy, 2016). When making recommendations for clinical practice, trials that result in a lack of effect can be just as important as trails demonstrating an effect occurred. It is therefore recommended unpublished data available in the gray literature be considered in the future.

The second limitation is in respect to the external validity of its findings in relation to primary care in BC. As many studies were conducted in the oncology setting, only one systematic review contained studies that were predominantly within the primary care setting. While two Canadian studies were included in the integrated literature review, as one was a RCT set in a Calgary outpatient setting and the other set in a Montreal emergency department, neither were set in primary care. While the findings from these studies can be discussed within the context of primary care in BC, a generalization to how caregivers and providers interact in BC can not be inferred solely based on this research.

Lastly, while it is not within the scope of this project to make specific practice intervention and resources recommendations, future examination regarding specific links to practice recommendations could better support PCPs when area of need are identified. These links may represent suggestions to respond to QOL issues or provide appropriate resources and referral considerations. In addition, as it is well established, the caregiver role changes according to the cancer phase and needs of the patient (Woźniak & Iżycki, 2014), there exists a lack of evidence to suggest the time frame best to measure caregiver QOL. As several factors, inclusive of stage and cancer type, coping style, available resources, and concomitant health conditions of the caregiver may impact well-being differently at various stages along the cancer journey (Woźniak & Iżycki, 2014), further research that examines the frequency and clinical situations for which primary care providers are best recommended to utilize the PROM would be beneficial.

Conclusion

The caregiver role imparts major challenges to those who care for patients with chronic life-threatening conditions such as cancer. The literature selected and presented in the background and introduction provided evidence that caregivers commonly experience symptoms of depression, anxiety, decreased physical health as well as financial and emotional strain. Moreover, it showed that caregiver's needs are often neglected by friends and family who center their attention on the needs on the patient. As pointed out by Mitchel et al. (2011), even health care providers often fail to recognize caregiver's distress and compromised QOL. In addition, because of experiencing repeatedly stressful dialogue, it is not uncommon for caregivers to feel the burden of continual communication. As a result, a communication burden may result leading to caregivers failing to express their own needs or concerns. Given this scenario, and with the final intention of better supporting caregiver needs, QOL, and capacity to continue care, this capstone project proposed to use QOL PROMs as a potential tool to bridge the perceptual communication gap regarding QOL between caregivers and providers.

Key findings in the research revealed that PROMs positively impact patient-provider communication, support processes of care such as provider awareness, and that if providers have the necessary information and resources available, PROMs may help providers discuss topics sensitive in nature. Of importance, however, various attitudinal, administrative and structural barriers related to the implementation of PROMs exist within the clinical setting. In effort to better support NPs, as PCPs, communicate with patients who may experiencing compromised QOL, the findings of this review informed practice recommendations inclusive of incorporating PROMs into the primary care setting to improve communication between patients and providers. In addition, three QOL PROMs, the CarGOQoL, QOLLTI-F, and the CQOLC were recommended for use in the primary care setting as each are specific to caregivers of cancer patients and each meet the criteria for assessment of QOL measures established by the MOT SAC. In addition, within the primary care setting, the NCI's (2015) Family Caregiver in Canada (PDQ): Supportive care – Patient Information resource was recommended as this resource contains valuable information respective to treating family caregivers, the impacts to QOL, and recommended interventions for caregivers. In addition, in order to navigate administrative barriers in the primary care setting, close involvement of nursing and clerical staff is recommended as their recommendation and cooperation in terms of facilitating collection of the tool is imperative. Lastly, while dissemination of the practice recommendations provided in this capstone at both the academic and professional level can be achieved at, more specific research is needed to link recommended responses, interventions and referrals to identified QOL problems. Direct links to clinical recommendations would help PROMs guide PCPs to more easily ensure caregivers are supported so they can continue to provide care for those who need.

GLOSSARY

attrition: number of participants who drop out of a study before completion creating a threat to internal validity of the study (Grove, Burns, & Gray, 2013).

cluster randomization: a research method employed to prevent "contamination" between intervention and control groups.

cross-over design: the administration of more than one treatment to each subject in a sequential order to compare effect of different treatment on the same subject (Grove, Burns, & Gray, 2013).

contamination: a type of bias which occurs when member of the control group are inadvertently exposed to the intervention (Krishna, Maithreyi, & Surapeneni, 2010)

ceiling effect: a statistical point where the upper limit of a test is attained.

GRADE: a systematic approach developed by the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) Working Group to evaluate quality of evidence (Schunemann et al., 2008).

gray literature: studies with limited distribution such as dissertations, theses, unpublished literature or articles in obscure journals (Grove, Burns, & Gray, 2013)

Hommel procedure: a form of multiple hypothesis testing which implements a stage wise multiple test procedure based on a modified Bonferroni test to determine whether each hypothesis is accepted. (Hommel, 1998).

psychosocial: the influence of psychological and social environment on physical and mental wellness and function.

survivorship: the process of living with, through, and beyond cancer whereby cancer survivorship begins at diagnosis and continues past treatment over the long term.

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APPENDIX I

QOL PROM Descriptions

Caregiver Oncology Quality of Life (CarGOQoL)

The CarGOQoL is a 29-item questionnaire to assess QOL of caregivers to cancer patients using 10 dimensions of QOL: psychological and physical well-being; burden; relationships with health care; finances; self-esteem; leisure time; social support; and private life (Minaya et al., 2011). Using a 5-point response scale of terms “never/not at all”, “rarely/a little”, “sometimes/moderately”, “often/a lot”, and “always/enormously”, each response has a value for which the COQOL is scored by adding up the total value of each item. Scores can range from 29 to 145, with a higher number reflecting higher QOL.

Quality of Life in Life-Threatening Illness – Family Carer Version (QOLLTI-F)

Based on a qualitative study on caregiver QOL, the questionnaire is a 16 item self-report instrument developed by Cohen, Kuhl, & Ritvo (2006). The QOLLTI-F contains an assessment of seven domains specific to carer QOL in the palliative stages of cancer care. Using a Likert scale ranging from 0-10, with higher values indicating a higher QOL, the QOLLTI-F is the only Canadian instrument and is unique amongst other instruments as it accounts in the measurement for the carer’s perception of the palliative cancer patient condition.

Caregiver Quality of Life-Cancer Index (CQOLC)

The CQOLC is a brief self-report measure comprised of four dimensions each measuring caregiver QOL: emotional, social, psychological, and financial (McMillan & Mahon, 1994). Using a 100-mm visual anchored analogue line, responses to the left side represent “lowest quality” of life while answers appearing on the right side representing “highest quality” of life. Scores are summed and averaged to obtain a total score of 0-100.

APPENDIX II

Operational Definitions and Psychometric Criteria

Psychometric property	Operational definition	Standard criteria
Internal consistency reliability	Cronbach's alpha coefficient	< 0.70 questionable 0.70 – 0.80 acceptable > 0.8 good
Test-retest reliability	Pearson's correlation coefficient	> 0.70
Convergent validity	Strong Pearson's correlation with similar construct	< 0.20 Low 0.20 – 0.35 slight 0.36 – 0.65 moderate 0.66 – 0.85 high > 0.86 very high
Discriminant validity	Weak Pearson's correlation with different construct	< 0.30
Concurrent validity	Scores are highly correlated at a statistically significant level on measure of interest	$P < 0.05$

(Edwards & Ung, 2002, p. 345; Grove et al., 2013; Nunnally & Bernstein, 1994; Cohen, Morrison & Manion, 2000)

APPENDIX III

Content Validity of Selected PROMs

Instrument	Participants	Content validity
CarGOQoL	Cancer caregivers (phase 1 *n* = 22; phase 2 *n* = 96; phase 3 *n* = 263)	Phase 1: content analysis conducted by expert reviewers of semi-structured interview with cancer caregivers to identify themes regarding QOL. Phase 2: item importance ranking completed through administration of items to new sample of caregivers. Phase 3: developed instrument administered to new set of cancer caregivers to examine validity, test-retest reliability and internal consistency.
QOLLTI-F	Cancer caregivers (phase 1 *n* = 30, phase 2 *n* = 60, phase 3 *n* = 245)	Phase 1: researchers develop preliminary items based on their qualitative study of cancer caregiver QOL. Items reviewed by team for final questionnaire tested by caregivers to enable item reduction. Phase 2: questionnaire retested on new caregivers, feedback regarding clarity and response of items obtained. Distribution of each item was determined, with focus on skewness, range of 0-10 scale used. Missing content and redundancy using Pearson correlation coefficient was analyzed in revision of questionnaire. Phase 3: acceptability was determined by asking respondents to comment on questionnaire clarity and applicability of terms.
COQOL	Cancer caregivers (*n* = 77)	Content analysis of interviews with cancer caregivers. Items reviewed for missing data and inter-item correlation. Items with floor and ceiling effect >70%, missing data >15%, absolute value of skewness > 4.0, or correlation coefficient > 0.80 were removed

APPENDIX IV

Psychometric Properties of Selected PROMs

Instrument & study	N	Internal consistency α ($p < 0.001$)	Test-retest r	Convergent validity	Divergent validity	Responsiveness R
CarGOQoL-C						
Weitzner & McMillan, 1999	239	0.87	omitted	> 0.45	0.01	Not significant
Weitzner et al., 1999	263	0.91	0.95	> +/- 0.45	< 0.3	- 0.046 ($p<0.0001$)
Rhee et al., 2005	270	0.90	omitted	> +/- 0.45	0.07	omitted
Mahendran et al., 2015	183	0.89	0.79	omitted	omitted	omitted
Khanjari et al., 2011	166	0.72-0.90	omitted	> 0.45	0.18-0.25	omitted
Yakar et al., 2013	120	0.88	0.96	> 0.30	0.26	omitted
QOLLTI-F						
Cohen et al, 2006	245	0.857	0.77-0.80	Omitted	Omitted	0.50-0.79
Schur et al, 2014	308	0.85	0.92	0.40	-0.41 to -0.55	omitted
CQOLC						
Minaya et al., 2012	837	0.72-0.89 (PL = 0.55)	0.52-0.80	> +/- 0.45	< 0.3	ES 0.31 and δ 3.65
Kaveney et al., 2016	87	0.71-0.87 (PL,C, LT & RH = <0.70) INFIT 0.78 all but RH 0.62-1.38	0.53-0.94 (RH 0.46) (PL 0.48)			Not significant except L 8.13 (day 30) and PWB -11.46, RH 6.60, SS 9.89, F -7.03 (day 90)

PL = private life
C = coping
L = leisure
RH = relationship with health care
F = finance
SS = social support
δ = delta change
ES = effect size minimum 0.2 to detect sensitivity to change (Minaya et al., 2012).
INFIT = Rasch analyses item goodness of fit range 0.7-1.2 (Kaveney et al., 2016)

APPENDIX V

Burden and Administrative Qualities of Selected PROMs

Instrument	Administrative considerations	Completion	Language	Language adaption
CarGOQoL	10-20 min. Scoring instructions: Highlighted items on questionnaire should be reversed scored.	90% completed, low refusal rate. Absence of missing data implies user friendly and easy to complete	English Korean Mandarin Farsi Turkish	Translation and blind back-translation with bilingual experts, expert cultural panel, committee review, and pilot test
QOLLTI-F	Mean of 13.4 min (mode 12min).	Missing 3% of items (item identified and subsequently removed). Ease of completion 0=10 (easy – difficult) 1.3.	German English French	Translated, back translated as per World Health Organization
CQOLC	Average 6 min (range of 4-11min).	Low missing data <5%	English French	Forward/backward translation, acceptability testing, and cognitive reviews

APPENDIX VI

Research Matrix

Author, Year & Study Aim	Sample size, setting, intervention & outcome	Strengths	Limitations	Major conclusions
Velikova et al., 2010 Prospective RCT using repeat measures investigating the effects of regular use of QOL in oncology practice in terms of patient satisfaction and patient's perspectives on continuity and coordination of their care **CASP Rating = High**	*n* = 28 oncologists and *n* = 286 cancer patients at medical oncology clinic in Leeds, UK Intervention: completion of EORTC QLQ-C30 and HADS with feedback to physicians; attention control arm: same PROM completion without feedback; control: regular care no PROM assessment Patient's experience of continuity of care including communication, coordination, satisfaction, and patient & physician evaluation of intervention.	Mixed-effects modelling, multiple regression and descriptive statistics employed to analyze data. Original 3-arm trial used decent sample size, well-validated QOL PROM. Population represented varied demographics (gender, cancer type, extent of disease, and treatment). 87% patients remained to MCQ, 91% completed end of study questionnaire	Can not rule out possible bias as sample size does not allow for modeling of more complex data. Possible contamination as clinicians exposed to intervention patients as well as attention control arm which showed improvement in well-being despite no further issues being discussed by providers. Medical Care Questionnaire Instrument to measure patients' perception of continuity/coordination of care was new and made comparison with other studies difficult. Attrition rate >30% (58% due to death)	Patients reported improved communication with doctors, especially in area of building rapport, better interpersonal relationship, and easier to discuss emotional/personal issues. PROM helped focus consultation on topics important for patient to discuss including non-medical issues. 86% of intervention vs 29% of attention control arm rated HRQOL as useful and reported their doctors considered daily activities, emotions and QOL. Authors concluded PRO feedback increases patient wellbeing because of focusing appointments on 'topics important to patient and facilitated discussion of non-medical issues'

Takeuchi et al., 2011 Exploratory analysis of data set of longitudinal RCT with to determine how PRO feedback impacts patient-physician communication and patient care over time **CASP Rating = High**	*n* = 198 cancer patients and *n* = 28 oncologists at a medical clinic in a UK hospital over four consecutive visits intervention: regular completion of EORTC QLQ-C30 and HADS with feedback to oncologists; attention-control: completion of same questionnaire without feedback; control: standard care Outcome: consultations recorded over four consecutive visits to examine impact of PRO on communication and severity of symptoms	Detailed statistical analysis which employed mixed-effect models, multivariate and univariate logistic regression models to examine longitudinal impact of intervention on communication, interaction dynamics, and clinical content discussed. 3-arm longitudinal study design with large sample size. Validated and recognized QOL PROMs.	Impact of patients' HRQOL may be underestimated as study population predominately female recruited from a single centre. EORTC QLQ-C30 refer to 'past week' and therefore not fully capture effect of patients' treatment. Study may have been limited by consultation analysis method which failed to provide information on how PRO feedback may have influenced quality of patient-provider communication or how oncologists used PRO data.	Intervention arm discussed more symptoms over time compared to attention control ($p = .008$) and control ($p = .04$). between control and attention-control arms. Although discussion increased, largely due to patient-initiation in PRO intervention, PRO feedback did not substantially change clinicians' communication practices. Symptoms more commonly discussed than functional problems, the authors interpret these findings as indicating patients did not feel visits were an appropriate forum to raise these issues. PRO feedback alone does not overcome existing barriers that prevent discussing functional issues. Communication and guideline driven training recommended.
Velikova et al., 2004 Prospective RCT with repeated measures to examine the effects of process of care	*n* = 286 cancer patients and *n* = 28 doctors at UK medical oncology clinic in intervention: EORTC QOQ-C30 and HADS with feedback to physicians; Attention-control arm: same questionnaire no	Analysis employed mixed-effect modeling and multiple regression. 3-arm prospective study design. Large sample size. Validated and recognized QOL PROM. Outcomes	Possible contamination effect as clinicians in the attention control arm were also exposed to intervention patients therefore could have been. Differences of item discussion not statistically relevant however can not	More QOL symptoms discussed in intervention than control (p = .03). More frequent discussion of chronic nonspecific symptoms without prolonging appointment. Physicians explicitly referred to PROM data 66/103 interventions (64%) and focused on physical and functional issues. Data were most useful for providing an overall assessment of

and patient wellbeing of regular collection and use of QOL in oncology practice **CASP Rating = High**	feedback; control: standard care. Outcome: FACT-G for QOL MCQ to analyze communication, coordination, patient preferences, satisfaction with care, patient and physician evolution of intervention (K-index)	measured over time of 6 months. >30% attrition checked using logistic regression where drop-out as outcome and study arm not found to influence attrition (*P* = .31). No significant “doctor” effect noted.	exclude possible sensitization to HRQOL issues. Non-respondent rate of 30% may indicate PRO not suitable for all patients. Possible ‘Hawthorn effect’ may have occurred however different reporting of outcome questionnaire used. Attrition rate >30% observed.	the patient (69%) but less useful for providing additional information (33%) or identifying problems for discussion (27%). PRO data feedback led to an increased number of symptoms discussed and improvement in patient wellbeing.
Detmar et al., 2002 Prospective, cross-over RCT to examine whether or not the regular feedback of HRQOL data to doctors would increase the discussion and awareness of HRQOL issues during visits **CASP Rating = High**	*n* = 214 patients with cancer and *n* = 10 doctors in outpatient clinic in the Netherlands Intervention: EORTC QOQ-C30 completed during successive outpatient visits and physician and patient received copy before visit. Control: regular care. Outcome: audiotapes of consultation to evaluate patient-provider communication.	Double blind prospective RCT design. Washout period of 7 weeks. Well validated and recognized QOL PROM. Good sample size. Content analysis utilized 3 blinded and trained raters to code with high level of agreement. Strong statistical analysis using stepwise linear regression	Small physician sample of however no reason to suspect results atypical of larger group of providers. Risk of contamination due to cross-over design as providers may have been sensitized. Single hospital setting only. Providers were the unit of analysis and patients seen by same clinician would have been more familiar with provider.	Authors found statistically significant differences in the total number of HRQOL issues discussed between intervention (mean 4.5) and control (mean 3.7) arms. Both providers indicated PROM data was useful as an overall impression of patients’ symptoms and functional health and helped to facilitate communication, particularly psychosocial topics

Taenzer et al., 2000 Sequential pre-post cohort study to determine if providing patient specific QOL information to clinic staff before appointment improved care **CASP Rating = Moderate**	*n* = 57 patients with lung cancer in Alberta outpatient clinic. intervention: EORTC QLQ-C30 completed prior to visit and results provided to physician; control: standard care and same PROM provided after visit outcome: PDIS and exit interview to measure issues addressed in appointment. Randomized chart audit to measure QOL issues and actions taken by provider.	Strength of study design to control for sensitization. Randomized chart audit. Canadian study. Use of well validated PROM. ANOVA analysis completed, no significant group differences. Highly structured exit interview to evaluate if concerns addressed in the PROM were discussed in appointment.	Lack of dissatisfaction between groups may be attributed to ceiling effect. Lack of variability with PDIS implies may need further psychometric work and not be best outcome to measure. Intervention limited to one clinic and small sample size so difficult to generalize results. Sequential design of study may have introduced bias	Medical audit revealed charting on a greater number of QOL categories in intervention group compared to control ($t = -3.95$, $p < 0.01$). Patients in intervention group reported average of 48.9% of QOL items they identified were addressed during clinic appointment compared to 23.6% for control ($t = -2.35$, $p < 0.05$). Intervention group reported on average 48.9% of the QOL items identified were addressed during the clinic appointment, compared with 23.6% for patients in the Control Group ($t = −2.35$, $p<0.05$).
Berry et al., 2011 RCT to determine the effect of PROM on the likelihood of patient reported cancer symptoms and QOL discussed between	*n* = 660 patients with various cancer diagnoses and stages and *n* = 262 clinicians (physicians, NPs, physician assistants) at two ambulatory care cancer centre in USA. Intervention: QOL PROM graphical summary provided to clinical team before visit; control: no summary provided.	Large sample size which included sample size calculation. Validated QOL PROM utilized. Statistical analysis employed ANCOVA approach and logistic regression modeling. Brief tutorial provided to patients on PROM.	Presence of audio recorder may have influenced behaviour. Sample not generalizable. Because only one recording of visit, data retained is only a 'snap shot' of patient provider communication. Unclear exactly how many clinicians actually came into	29% higher chance of symptoms and quality of life issues being discussed in the intervention group than the control group. In 75 out of the 295 recorded consultations in the intervention arm (25.4%) clinicians made direct reference to the PROM. Sexual and social functioning were more likely to be discussed in the intervention arm. No differences in visit duration ($p = .35$). Clinicians agreed intervention was useful in identifying QOL

clinicians and patients **CASP Rating = High**	Outcome: audio recorded clinic visit scored for discussion of QOL. Investigator-developed post study questionnaire to measure usefulness in identifying QOL and promoting communication.	Participants lost to attrition were excluded from analysis.	contact with patient as only 112 returned post interview questionnaires for which 57 reported receiving at least one report.	issues and symptoms (67.8%), guiding interview (64.3%), promoting communication (50%), and identifying need of referrals (53.6%)
Kotronoulas et al., 2014. Systematic review to examine whether or inclusion of PRO in routine clinical practice is associated with improvement in patient outcomes, processes of care, and heath service outcomes during active anticancer treatment	*N* = 26 studies majority RCT PROMs, patient population and health providers varied considerably. Most frequent PRO was the EORTC QLQ-C30. Other PROs focused on symptoms, supportive care needs, and sources of distress. PROs completed in variety of form from take-home log books to electronic questionnaires. Patients study samples varied in size (median 194, range 48 to 1134). Health providers varied similarly (median 22, range 4 to 262).	Systematic review of five electronic databases. Located 26 studies with focus on cancer care. Majority of studies (22) were RCTs and all but 6 were longitudinal. Strict systematic methods during identification and risk-of-bias appraisal. Calculated size of effect where possible synthesis of result, consideration of bias, and determination of effect size.	Search limited to English only. Gray literature not searched. Unable to complete a meta-analysis due to vast heterogeneity of studies. Possibility of measurement bias interfering with effect of PRO intervention. Limited psychometric robustness in many of the PROs may have interfered with ability to capture actual intervention may have limited ability to capture magnitude of effect. Possible sources of bias, limited randomization, and uncertainty of whether	Communication generally positive however 77% trials failed to show significant effect. In the studies in which postintervention gains were reported, the positive effects referred to greater satisfaction with emotional support and enhanced communication with physicians. Odds of discussing patient concern depended of level indicating a problem. PROM easy to use and a useful way for patients to describe their situation and communicate. <83% patients regarded the PROM content important for them. Almost all patients (93%) appreciated having been asked about their emotional well-being during treatment. Use of PROMs most effective increasing patient satisfaction with communication around emotional concerns. Patient

CASP Rating = High			clinicians used the information generated by PROs during consultation may have impacted trial’s internal and external validity.	and providers are willing to use PROMs however algorithms to better support concerns and electronic systems would better support incorporation of PROM feedback during encounters.
Valderas et al., 2008 Systematic review to summarize the best evidence regarding the impact of providing PRO feedback to health care providers in daily practice **CASP Score = Moderate**	*N* = 34 (28 original studies) Majority of trials conducted in primary care setting (19) in the USA (21) with adult patients (25). PROs collected information regarding generic health status (10), mental health (14), and other (6). Trials organized by conceptual framework: processes of care (i.e. communication, behaviour) outcomes of care, and satisfaction.	Systematic search with broad time span guided by Cochrane Review Search. Search also included comparison of all previously available systematic reviews on the subject and use of 6 teams of two reviewers in all stages of the study selection process. Jadad scale used to assess validity of the studies. Most PROMs used well-validated.	Search limited to 2 databases. No qualitative data and no evidence to suggest adverse effect on patients was examined. Analysis of some trials did not match unit of allocation. Heterogenicity of trials limits ability to easily compared and some studies were of limited methodological quality.	Majority of studies (65%) reported positive impact to process of care such as patient-provider communication. While results are generally positive with respect to improving diagnosis, recognition of patient problems and patient-provider communication, methodological limitations restrict a clear direction for the use of PROMs to improve patient outcomes. Further research is required to validate the impact to care PROMs have.
Chen et al,. 2013 Systematic review to synthesize the	*N* = 27 16 of articles were RCTs, 2 before-after studies, 9 observational. Improved quality of studies for those	Studies were located using a systematic review covering PRO and QOL measures between 2000 and 2011. Strong search	No attempt to contact authors was made therefore may be missing some grey literature. No qualitative studies	Routine collection of well-implemented PROs enhances patient-provider communication and patient satisfaction. Growing evidence exists supporting PROs impact on detecting of

evidence regarding the impact of routinely collected PROs on patients, providers and health organizations in the oncologic setting **CASP Rating = High**	published after 2010 including 3 trials with sample size > 200 and 2 trials over 580. PROs utilized greatly varied most common utilized were EORTC QLQ-C30 then FACT-G. Outcomes measured varied considerably and grouped into 12 categories including communication, monitoring of treatment response, health outcomes, public reporting, patient satisfaction.	methodology included both quantitative observational studies and experimental trials. Generally large sample sizes >200. The quality and importance to the research population was rated using the GRADE system.	were included therefore may limit insight into research question. Lack of cluster randomized controlled design and limited generalizability as all trials due to limited setting thus restricting of findings. Researchers report possibility of subjectivity in assessment of study eligibility due to various endpoints and trials and that GRADE system was potentially simplistic.	unrecognized problems and monitoring of treatment. Evidence of impact to patient management or improved health outcomes is weak. Evidence regarding impact to patient health behaviour or health care system performance is non-existent.
Alsaleh, 2013 Systematic review regarding QOL scales routinely in outpatient evaluation. **CASP Rating = High**	*n* = 6 All studies RCT, adults, one cluster randomization and one cross-study. Patients all living with cancer. Unit of randomization varied. Outcomes assessed ranged from improved pain, satisfaction, improved QOL, communication, patient outcomes.	Strength in being a systematic review. Similar QOL scale contributed to ease comparison of overall findings. GRADE approach used to assess quality and limitation of trials.	Small sample. Limited to trials published in English only. Methodological problems in a number of the trials including the lack of clear description of randomization process, no clear rationale for use of other scales, and lack of sample size in 2 trials.	Some evidence suggests use may improve communication between patients and providers, but this is uncertain. Currently no good evidence that routine use improves patient’s QOL or changes management, therefore routine implementation is hard to justify before implementing on a large scale. Consideration of cluster randomization in future studies to confirm the usefulness in routine practice.

Kallen et al., 2012. Pilot study for electronic PROM in palliative / hospice setting to improve care **CASP Rating = Low**	*n* = 9 patients and their caregivers (total *n* = 18), 9 providers Patients and caregivers provided ESAS and CAGE and feedback available to providers	Validated PROMs utilized in cancer caregiver setting.	Pilot study design and small sample population. Risk of bias as no randomization or detail to methodology to sample population recruited.	All providers reported electronic system improved patient monitoring. Patients and caregivers generally felt at ease and satisfied with use of PROM.

APPENDIX VII

Boolean Search Combinations

CINAHL: June 10, 2017

1. (MH "Patient-Reported Outcomes") OR (MH "Outcomes (Health Care)+") OR (MH "Outcome Assessment") OR "patient reported outcomes"
2. PROM or PRO
3. (MH "Quality of Life+") OR "quality of life" OR (MH "Health and Life Quality (Iowa NOC)+")
4. (MH “Psychological Well-Being”) OR “well-being OR well being”
5. (MH "Communication+") OR "communication"
6. (MH "Nurse Practitioners+") OR (MH "Family Nurse Practitioners")
7. (MH "Caregivers") OR (MH "Caregiver Burden")
8. (MH "Primary Health Care") OR "primary health care"
9. clinical practice
10. impact or effect or influence
11. (MH "Neoplasms+") OR "neoplasms"
12. cancer
13. 1 OR 2
14. 3 OR 4 OR 5
15. 7 OR 11 OR 12
16. 6 OR 8 OR 9
17. 10 AND 13
18. 16 AND 17
19. 14 AND 18 Limiters - Full Text; Published Date: 19700101-; English Language; Peer Reviewed Search modes - Boolean/Phrase

MEDLINE: June 10, 2017

1. Patient reported outcome measures.mp or exp “Outcome Assessment (Health Care)”/ or exp patient reported measures.mp or exp “Outcome Assessment (Health status indicators/or exp “survets and questionnaires”/
2. limit 1 to (english language and full text and yr="1970 -Current")
3. (PROM or PRO).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, keyword heading word, protocol supplementary concept word, rare disease supplementary word, unique identifier, synonyms]
4. limit 3 to (english language and full text and yr="1970 -Current")
5. quality of life.mp. or exp “Quality of Life”/
6. limit 5 to (english language and full text and yr="1970 -Current")
7. (well being or well-being).mp. [mp=title, abstract, original title, name of substace word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementart concept word, unique identifier, synonyms]
8. limit 7 to (english language and full text and yr="1970 -Current")
9. exp Communication/ or communication.mp.
10. limit 9 to (english language and full text and yr="1970 -Current")
11. nurse practitioners.mp. or exp Nurse Practitioners/
12. limit 11 to (english language and full text and yr="1970 -Current")
13. (impact or influence or effect).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept words, rare disease supplementary concept word, unique identifier, synonyms]
14. limit 13 to (english language and full text and yr="1970 -Current")
15. (neoplasms or cancer).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
16. limit 15 to (english language and full text and yr="1970 -Current")
17. caregivers.mp or exp Caregivers/
18. limit 17 to (english language and full text and yr="1970 -Current")
19. primary health care.mp or exp Primary Health Care/
20. limit 19 to (english language and full text and yr="1970 -Current")

21. clinical practice.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
22. limit 21 to (english language and full text and yr="1970 -Current")
23. 2 OR 4
24. 6 OR 8 OR 10
25. 12 OR 20 OR 22
26. 16 OR 18
27. 13 AND 23 AND 24
28. 25 AND 27
29. 26 AND 28

Cochrane: June 10, 2017

1. patient reported outcome measures.mp. [mp=to, ot, ab, tx, kw, ct, sh, hw]
2. primary care.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]
3. nurse practitioner.mp. [mp=to, ot, ab, tx, kw, ct, sh, hw]
4. quality of life.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]
5. (well-being or well being).mp. [mp=to, ot, ab, tx, kw, ct, sh, hw]
6. (PROM or PRO).mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]
7. communication.mp. [mp=to, ot, ab, tx, kw, ct, sh, hw]
8. caregivers.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]
9. clinical practice.mp. [mp=to, ot, ab, tx, kw, ct, sh, hw]
10. (impact or effect or influence).mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]
11. (cancer or neoplasm).mp. [mp=to, ot, ab, tx, kw, ct, sh, hw]
12. 1 OR 6
13. 2 OR 3
14. 4 OR 5 OR 7 OR 9
15. 8 OR 11
16. 12 AND 13
17. 12 AND 14
18. 10 AND 13 AND 17

PubMed: June 10, 2017

1. (((patient reported outcome measure[MeSH Terms]) OR patient outcome assessment[MeSH Terms]) OR PROM) OR PRO
2. (((quality of life[MeSH Terms]) OR well being) OR well-being) OR communication
3. ((impact) OR effect) OR influence
4. ((nurse practitioners[MeSH Terms]) OR primary health care[MeSH Terms]) OR practice pattern, physicians[MeSH Terms]
5. ((neoplasm[MeSH Terms]) OR cancer) OR caregiver[MeSH Terms]
6. ((((((patient reported outcome measure[MeSH Terms]) OR patient outcome assessment[MeSH Terms]) OR PROM) OR PRO)) AND (((impact) OR effect) OR influence)) AND (((nurse practitioners[MeSH Terms]) OR primary health care[MeSH Terms]) OR practice pattern, physicians[MeSH Terms])
7. ((((((((patient reported outcome measure[MeSH Terms]) OR patient outcome assessment[MeSHTerms]) OR PROM) OR PRO)) AND (((impact) OR effect) OR influence)) AND (((nurse practitioners[MeSH Terms]) OR primary health care[MeSH Terms]) OR practice pattern, physicians[MeSH Terms]))) AND ((((quality of life[MeSH Terms]) OR well being) OR well-being) OR communication)
8. ((((((((((patient reported outcome measure[MeSH Terms]) OR patient outcome assessment[MeSH Terms]) OR PROM) OR PRO)) AND (((impact) OR effect) OR influence)) AND (((nurse practitioners[MeSH Terms]) OR primary health care[MeSH Terms]) OR practice pattern, physicians[MeSH Terms]))) AND ((((quality of life[MeSH Terms]) OR well being) OR well-being) OR communication))) AND (((neoplasm[MeSH Terms]) OR cancer) OR caregiver[MeSH Terms])

9. limit to full text; English; 1970/01/01 to 2017/12/31