Patient-Centred Assessment of Symptoms and Activities (P-CASA)

by

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B.A, University of Victoria, 2005

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of the Requirements for the Degree of

MASTERS OF SCIENCE

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ABSTRACT

The Patient-Centred Assessment of Symptoms and Activities (P-CASA) is a new idiographic, open-ended assessment that examines each individual patient‘s symptoms within the context of his or her daily life. P-CASA asks patients for their most important activities, what interferes with these activities, and any coping strategies. This thesis presents the rationale and design of P-CASA and its first validation study. Sixty patients at the Pain and Symptom Management/Palliative Care Clinic of the BC Cancer Agency (Vancouver Island Centre) completed P-CASA and the Edmonton Symptom Assessment System (ESAS), which is the current nomothetic assessment at the Clinic. The results demonstrated that P-CASA was not redundant with ESAS because it assessed (a) information about patients‘ activities and coping strategies, which the ESAS does not; (b) all relevant cancer-related symptoms (not just pain or a fixed list); (c) co-occurring symptoms; (d) more specific details and different priorities about symptoms than in their ESAS.

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DEDICATION

I dedicate this thesis to all of the patients who were willing to participate in my study at this most difficult time in their lives.

CHAPTER ONE

INTRODUCTION

The purposes of this thesis are (a) to emphasize the importance of preserving the meaning of patients' experiences when using assessment tools, (b) to demonstrate the importance of assessing patients' symptoms within the context of their lives, (c) to introduce a new assessment tool called the Patient-Centred Assessment of Symptoms and Activities (P-CASA), and (d) to provide validation evidence for the use of this new tool with palliative cancer patients.

Background and Rationale for the P-CASA

This thesis developed in the context of the Pain and Symptom Management/Palliative Care (PSM/PC) Clinic of the BC Cancer Agency (BCCA), Vancouver Island Centre. In 2008-2009, I was a practicum student at the PSM/PC Clinic as part of my traineeship with a Canadian Institutes of Health Research New Emerging Team grant, "Overcoming barriers to communication in end-of-life and palliative care." Under the BCCA's confidentiality agreement, I was able, with the consent of the patients and the health care professionals, to attend PSM/PC consultations. The broad purpose of the traineeship was to introduce me, a research psychologist, to the workings of the Clinic.

Health care professionals who work in the PSM/PC Clinic specialize in treating palliative cancer patients for their cancer-related symptoms. These physicians, nurses, and pharmacists have clinical expertise and medical knowledge about cancer, symptoms of cancer, palliative care, cancer treatments, and medications. The diverse needs of their patients consistently challenge them to provide the most suitable treatment options to address each patient's needs. In order to do their job, they require information about which symptoms their patients are currently experiencing and how severe they are. However, gathering this information is often difficult because each patient's experience of symptoms is subjective and personal, so the patient is the only one who can provide it.

Symptoms according to Cleeland and Sloan (2010) and the Webster's Third New International Dictionary are "subjective evidence of disease or physical disturbance observed by a patient" (p.1079). Cleeland and Sloan (2010) expanded this definition:

> Implicit in this definition is the negative nature of symptoms and, most importantly, that symptoms are observations of the person directly experiencing the evidence of disease or physical disturbance. In contrast to 'signs' of disease (such as fever or high blood pressure), symptoms can only be known through patient report" (p. 1079).

Similarly, Turk and Melzack (2001) acknowledged that "we will probably never be able to evaluate pain without some reliance on patients' subjective reports" (p. 708). Patients are the experts on their subjective experiences and how their symptoms affect their daily functioning. Patients are also the experts on the activities they enjoy, their end-of-life goals, and their overall quality of life. Therefore, patients' experiences and preferences are just as essential to their treatment as the clinical expertise and medical knowledge of health care professionals (e.g., Haynes, Devereaux, & Guyatt, 2002a, 2002b). Together, these professionals and their patients must find a way to exchange their expertise with each other in order to provide the most suitable and effective treatment options for each patient.

The Edmonton Symptom Assessment System (ESAS)

At the PSM/PC Clinic, it is during the face-to-face consultation that the team of health care professionals and the patient have the opportunity to exchange most of this essential information. However, the process begins before they meet because PSM/PC procedures require patients to complete the Edmonton Symptom Assessment System (ESAS) before their consultation (Bruera, Kuehn, Miller, Selmser, & Macmillan, 1991).[1] The purpose of the ESAS is to gather information about the symptoms a patient is experiencing. Health care professionals use this information to determine the patient's current intensity levels for the symptoms. On the ESAS (which can be in paper or touch-screen form), patients rate nine cancer-related symptoms (i.e., pain, tiredness, nausea, depression, anxiousness, drowsiness, appetite, feeling of well-being, and shortness of breath) on a scale from zero to ten, where zero is the absence of the symptom and ten is the worst possible experience of the symptom.

At some point in the practicum, Dr. Peter Kirk, one of the palliative care specialists at the PSM/PC Clinic who routinely sees these ESAS ratings, expressed his curiosity about how his patients determined their rating. He was curious how a patient determined that he or she was a 7 on tiredness or a 4 on pain. During their consultations, patients often spontaneously assessed the severity of their symptoms by how much the symptoms disrupted their lives. Instead of providing numerical ratings, they talked about their ability or inability to participate in activities that were important to them. For example, one patient said, “I am unable to play with my grandchild because I am so

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[1] Patients also fill out the Patient Outcome Questionnaire, which includes some items about quality of life. However, in contrast to the ESAS, patients fill out this questionnaire once, during their first appointment; it is rarely revisited by physicians and does not influence treatment decisions.

exhausted. I just can't keep up!", and other patient said, "I like reading, but the methadone is drying my eyes out so they are becoming irritated after reading for only five minutes. I used to be able to read about an hour." It was also evident that the ability for patients to participate in their important activities at some level affected how they dealt with their symptoms; for example,

- Numerous patients reported doing an activity they enjoyed and then added that they had "paid for it."
- Other patients reported taking their breakthrough medication before they engaged in an activity they knew would cause pain, or they rested before they engaged in an activity that took a lot of energy (e.g., playing with their grandchildren).

My close examination of the ESAS revealed that it constrains the patients' ratings in four important ways:

1. The predetermined list of symptoms on the form constrains what the patient can report. On the ESAS paper form, patients can only report on the nine symptoms listed on the form and write in one other symptom, whereas on the computerized touch-screen format, patients are only able to report on the nine symptoms without the option to add any other symptom.
2. The standardized way that the ESAS assesses the severity of patients' symptoms requires patients to rate their symptoms numerically on a scale from zero to ten. There is no option to describe symptoms verbally or in the context of their lives.

3. The format of the ESAS assesses each symptom separately; therefore, patients are unable to indicate that two symptoms occur together or have a relationship with each other.
4. The ESAS does not specify the time to which the ratings apply—is it in the waiting room, while filling out the ESAS? Or during a particular daily activity?

The discrepancies between the information that the ESAS gathers and the way patients talked about their symptoms in their consultations led me to review and discuss the literature on the available symptom assessment tools during research meetings with my supervisor. As described below, it quickly became clear that all of these standardized tools required the patient to fit into the options they offered rather than fitting the assessment to the patient. Clearly, this was inconsistent with the Latimer model of end-of-life patient care (Latimer, 1991) which was the guiding model for the CIHR-NET grant supporting my traineeship. The literature also raised issues about the validity of the ESAS in particular, which led to a graduate course in Psychometrics in which I reviewed the questionable status of the ESAS in the light of contemporary validity standards (Tomori, 2009).

Altogether, it seemed that something was missing, not only in the ESAS, but in the current approach to symptom assessment, which led me to design the Patient-Centred Assessment of Symptoms and Activities (P-CASA). The P-CASA starts with the activities that are important to the individual patient, then asks about what (if anything) interferes with these activities, and finally asks about what (if anything) helps them participate in their important activities. The purpose of the P-CASA was to capture the concerns that patients have about their symptoms, to incorporate the way patients spontaneously assess the severity of their symptoms, and to view each patient's symptoms in the context of his or her life and how they affect it.

The rest of this chapter addresses the key issues in the literature. Chapter Two describes the P-CASA in detail and the standards it is designed to meet, then lays out the validation strategy that determined the research questions for this thesis. Chapter Three describes data collection at the PSM/PC Clinic. Four and Five, respectively, describe the results for the P-CASA itself and for its comparison with the ESAS. Chapter Six matches these results with the main goals of the research.

Previous Literature

Models of Care

Modern medicine has become increasingly disease focused and specialized. However, health care professionals may waste this scientific progress if they do not understand patients' concerns and needs in the context of the patient's life (Heath, 2005; Mezzich, Snaedal, van Weel, & Heath, 2010). There are several models of care that recognize the importance of the patient's perspective: Patient-centred medicine, patient-centred care, and the Latimer model for end-of-life care (Latimer, 1991). Each of these models provides a theoretical framework that emphasizes health care professionals should involve a patient in his or her own care, they should incorporate each patient's concerns and needs into this care, and they should provide individualized care to a patient in order to respect each patient's unique experiences.

According to Sackett, Rosenberg, Gray, Haynes, and Richardson (1996):

> Evidence–based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research... [Clinical] expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the *more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care* [all emphasis added]" (p. 71).

In short, evidence-based medicine "...cannot result in slavish, cookbook approaches to individual patient care" (Sackett, et. al; p. 72).

Similarly, patient-centred medicine emphasizes the importance of understanding the patient's unique experiences of their illness in order to make mutual patient-physician decisions (Stewart et al., 2003). According to the first component of the patient-centred clinical method, "the *physician actively seeks to enter into the patient's world to understand his or her unique experience of the illness* [all emphasis added]." (Stewart et al., 2003, p. 6). This component also includes *how the illness impacts the patient's functioning* (Stewart et al., 2003). The first two components of patient-centred care that Stewart (2001) identified were to "(a) explore *the patients' main reason for the visit, concerns, and need for information*; and (b) seek *an integrated understanding of the patients' world – that is, their whole person, emotional needs, and life issues* [all emphasis added]" (p. 445). Latimer (1991), focused on ethical decisions about goals of care or treatment with palliative patients and stated that it is important (a) *to consider the patient's experience of the illness (symptoms and suffering),* (b) to consider the illness itself (nature and status, likely course, medical options, nearness of death), and (c) *to consider the patient as a person with wishes, goals, plans, and hopes*.

It is clear that in order for health care professionals to practice patient-centred medicine or to provide care in a way that is consistent with patient-centred care or the Latimer model, they need to gather patients' individual preferences and circumstances and to tailor treatment plans according to the unique experience of each patient. They also must achieve this in a way they don't lose the individual patients' preferences by using "cookbook approaches." However, none of the frameworks provide the details about *how* health care professionals could accomplish this.

Patient-Reported Outcomes (PRO) and Patient's Perspective

Within clinical settings such as the PSM/PC Clinic, health care professionals use different kinds of assessments (e.g., symptom, functional, or quality of life assessments) in an attempt to gather information about the patient's subjective experience. Bottomley, Jones, & Classens (2009) refer to these types of assessments as *patient-reported outcomes* (PRO). Health care professionals use PROS as clinical assessments and researchers use PROs to measure outcomes in clinical trials (RCTs).

Both within clinical settings and clinical trials, the primary reason that professionals use these PRO assessments is to gain an understanding about how patients experience their disease or treatments, including how they feel or function. The United States Food and Drug Administration (USFDA), the European Medicines Agency (EMEA) and the interdisciplinary workgroup, Assessing the Symptoms of Cancer using Patient-Reported Outcomes (ASCPRO) emphasized patients' perspectives in their definitions of PROs. According to the USFDA, a PRO is "a measurement based on a report that *comes directly from the patient* (i.e., study subject) about the status of a patient's health condition *without amendment or interpretation of the patient's response by a clinician or anyone else* [all emphasis added]..." (U.S. Department of Health and Human Services [USDHHS], 2009, p.32). The EMEA defined PROS as "Any outcome *evaluated directly by the patient himself based on patients' perception* of a disease and its treatment(s) [all emphasis added]" (EMEA, 2005, p.3). The ASCPRO group further explained that "the effect of a treatment on how a *person feels or functions* is best known through patient self-report. Self-report of disease and/or treatment effects in clinical research is becoming known as a patient reported outcome (PRO)" (Cleeland & Sloan, 2010, p.1078).

The USFDA and ASCPRO group also used the patient's perspective to differentiate between *symptoms* and *signs*. According to the USFDA, *symptoms* are "any subjective evidence of a disease, health condition, or treatment-related effect that can be noticed and known only by the patient" (USDHHS, 2009, p.33) and *signs* are "Any objective evidence of a disease, health condition, or treatment-related effect. Signs are usually observed and interpreted by the clinician but may be noticed and reported by the patient" (USDHHS, 2009, p.33). Similarly, as pointed out above, the ASCPRO group used the following definition for *symptoms*:

> "...the subjective evidence of a disease or physical disturbance observed by a patient. Implicit in this definition is the negative nature of symptoms and, most importantly, that symptoms are observations of the person directly experiencing the evidence of disease or physical disturbance. In contrast to 'signs' of a disease

> (such as a fever or high blood pressure), symptoms can only be known through patient report." (Cleeland & Sloan, 2010, p.1079).

The EMEA also emphasized the patient's perspective when they defined Health-Related Quality of Life (HRQL): "HRQL is a broad concept which can be defined as the patient's subjective perception of the impact of his disease and its treatments(s) on his daily life, physical, psychological and social functioning and well-being" (EMEA, 2005, p. 3).

The USFDA and EMEA acknowledged the importance of gathering information from the patient's perspective and attempted to standardize their use and interpretation in RCTs in their recently released PRO guidelines (USDHHS, 2009; EMEA, 2005; Bottomley et al., 2009). However, there are limitations to the standardized assessments they outlined in these guidelines. One important limitation is that when professionals or researchers use these standardized "cookbook assessments", they may lose the meaning of the patient's information. This may result in data that does not reflect each patient's individualized preferences and circumstances. Because the utility of each tool for each clinical setting varies according to the purpose of its design, health care professionals must be careful to choose the appropriate assessment (Starkweather, 2010).

Nomothetic versus Idiographic Measurements

There is a long standing debate about nomothetic and idiographic measurements in the field of psychology. In 1894, a German philosopher, Wilhelm Windelband, coined the terms *nomothetic* and *idiographic* and in 1931 Gordon Allport introduced these terms into 20th century personality psychology (Lamiell, 1998). According to Lamiell (1998), since Allport introduced these terms to the field of psychology, the original meanings of these terms deviated over time. The modern definition of *nomothetic* is “relating to, involving, or dealing with abstract, general, or universal statements or laws,” and the modern definition of *idiographic* is “relating to or dealing with something concrete, individual, or unique” (Merriam-Webster dictionary, 2011). Currently, the nomothetic approach to the study of personality psychology refers to traditional mainstream trait psychology that focuses on the assessment and study of individual differences; it studies groups of individuals and compares one person with another using the same concepts (traits) (Colinger, 1996; Lamiell, 1998). The idiographic approach in the same field refers to the in-depth investigation of the individual person; it does not focus on individual differences and, therefore, does not compare individuals (Colinger, 1996; Lamiell, 1998).

Nomothetic symptom assessments. Most health-related assessments are nomothetic. These include traditional pain and symptom assessments (e.g., Brief Pain Inventory (BFI); Pain Research Group, 1991; ESAS; Bruera et al.,1991), functional assessments (e.g., Karnofsky Performance Scale (KPS); Karnofsky, Abelman, Craner, & Burcheneal, 1948; Palliative Performance Scale (PPS); Victoria Hospice Society, 2003; 36-Item Short-Form Health Survey (SF-36); McHorney, Ware, & Raczek,1993), and quality of life assessments (e.g., EORTC QLQ-C30; Aaronson et al., 1993; EORTC QLQ-PAL-C15; FACT-G; Cella et al., 1993). That is, they are standardized scales that aim (a) to measure abstracted concepts objectively (e.g., one or more symptoms, types of functioning, aspects of quality of life); (b) to compare individual scores against others within the same population in order; and (c) to make judgements about an individual.

Nomothetic measurement strategies are necessary to make inferences about a population (e.g., cancer patients) and to determine which treatment with a particular illness is most likely to be successful (Haynes, Mumma & Pinson, 2009). According to Bilsbury and Richman (2002), standardized assessments that use nomothetic measures are "less likely to be client-centred, but instead focus on the purpose for which they are intended – abstract constructs" (p.5). They also pointed out that measuring constructs of symptoms that are abstracted from patients' lives makes it difficult to determine the meaning of the symptom for each patient so that changes (both positive and negative) can be measured. Haynes et al. (2009) stated that "nomothetic assessment strategies are less useful for evaluating treatment outcomes for a particular client or sample of clients, describing the time-course of a client's behaviour problem, or identifying the functional relations relevant to a client's behaviour problem" (p.182). In 2001, Caraceni called for further research to look at the diversity of the cancer pain conditions and characteristics, and to have measurement techniques that are tailored case by case to patient characteristics.

Idiographic measures. In contrast to nomothetic measures, idiographic measures are at least partially individually tailored rather than administered in a standardized form and manner (Haynes et al., 2009). Idiographic measures maximize their relevance for individuals whereas nomothetic measures are not relevant for a particular person (Haynes et al., 2009). Idiographic measurements elicit content that is unique to individual patients, whereas nomothetic measures focus on targeted constructs (e.g., pain, depression, or quality of life; Haynes et al., 2009). Therefore, using idiographic measurements is one strategy that health care professionals can use to elicit relevant individual patient information within the context of his or her life. For example, they can gather information about how patients' symptoms disrupt their daily functioning, including the activities they enjoy, their end-of-life goals, and overall quality of life. Idiographic measurements can complement nomothetic measurements to assist physicians to provide treatment options that are most likely to be successful for each individual patient.

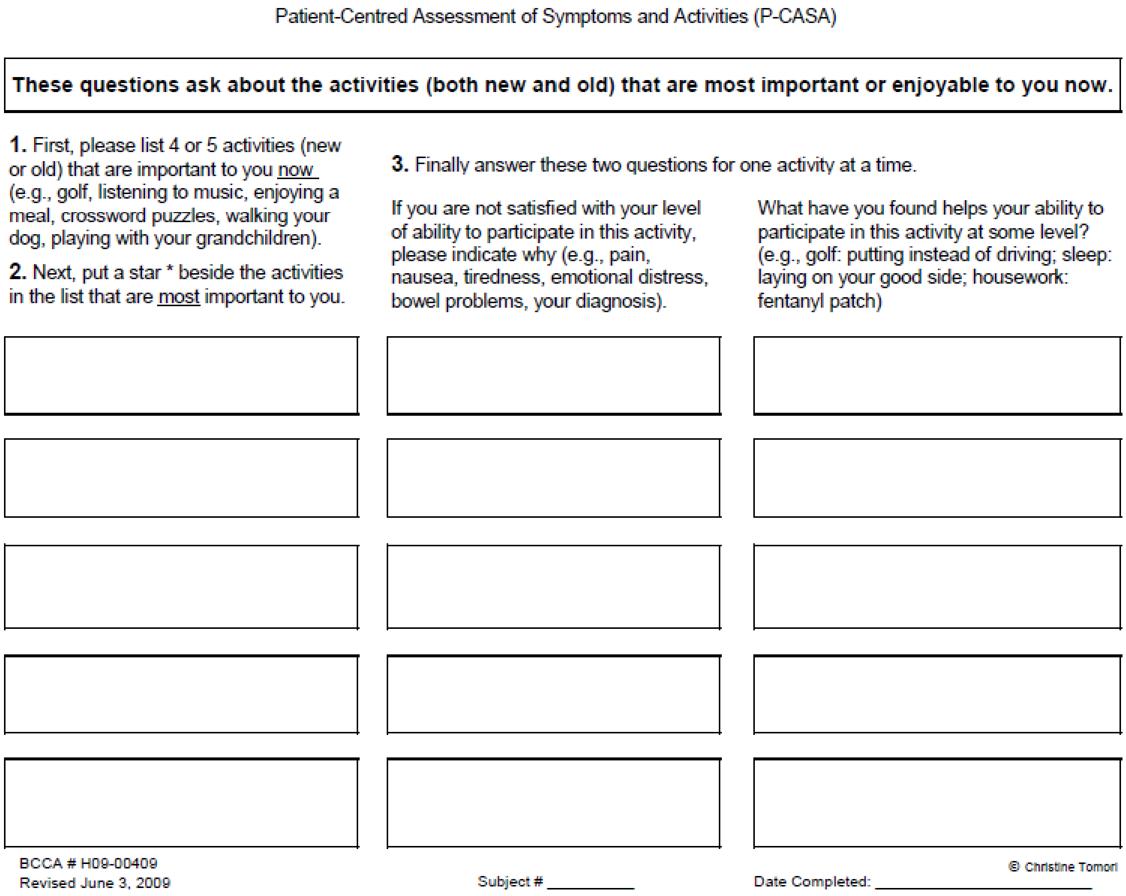
Clinimetrics. Feinstein (1982) introduced the term *clinimetrics* for a field concerned with distinctly clinical phenomena in medicine, such as indexes, rating scales, and other expressions that describe or measure symptoms or physical signs. Examples of these types of assessments are the functional status assessments mentioned earlier (e.g., KPS; Karnofsky et al., 1948), PPS; Victoria Hospice Society, 2003; SF-36; McHorney et al., 1993). Although the information these assessments collect from patients is clinically-relevant and can assist with making decisions about individual patients, the overall purpose is to classify each individual on the scale or staging system in order to make clinical predictions based upon their individual report. For example, the KPS and the PPS predict life expectancy and the SF-36 determines overall health. The Edmonton Classification System for Cancer Pain (ECS-CP; Fainsinger, Nekolaichuk, Lawlor, & Neumann, 2008) is a similar system, but it is a prognostic indicator for health pain management.

There is an important difference between the use of idiographic data that the P-CASA collects and the use of idiographic data within clinimetrics. The purpose of clinimetrics is classification and prediction. The P-CASA is an idiographic measure designed to gather information relevant to each individual patient with the overall purpose of assisting in more meaningful individualized care, not to classify and make predictions about patients. Individual patient information can help health care professionals capture a more meaningful snapshot of the patient’s experience and provide individualized care. Specifically, the information that the P-CASA gathers can assist health care professionals in understanding how patients experience their illness and the impact it has on activities that are important to them. This information can also help health care professionals formulate goals of care and evaluate the burdens and benefits of the possible treatments in a way that is consistent with patients’ wishes and goals.

CHAPTER TWO

THE PATIENT-CENTRED ASSESSMENT OF SYMPTOMS AND ACTIVITIES (P-CASA)

The purpose of the P-CASA is to involve patients in their own care by incorporating patients' perspectives into the assessment their symptoms. The P-CASA captures each patient's experience of his or her symptoms within the context of the important activities in his or her life. Health care professionals can use the P-CASA as a snapshot of each patient's life and how each symptom interferes with that patient's functioning. Below is an image of the P-CASA and the type of the information each column gathers.



Patient-Centred Assessment of Symptoms and Activities (P-CASA)

These questions ask about the activities (both new and old) that are most important or enjoyable to you now.

1. First, please list 4 or 5 activities (new or old) that are important to you now (e.g., golf, listening to music, enjoying a meal, crossword puzzles, walking your dog, playing with your grandchildren).

2. Next, put a star * beside the activities in the list that are most important to you.

3. Finally answer these two questions for one activity at a time.

If you are not satisfied with your level of ability to participate in this activity, please indicate why (e.g., pain, nausea, tiredness, emotional distress, bowel problems, your diagnosis).

What have you found helps your ability to participate in this activity at some level? (e.g., golf: putting instead of driving; sleep: laying on your good side; housework: fentanyl patch)

BCCA # H09-00409
Revised June 3, 2009

Subject # __________

© Christine Tomori

Date Completed: ________________________

Patients start with the first column of the P-CASA, listing the activities that are most important to them. Notice that they can list *any* activity that is important to them. These activities often ranged from activities that are associated with daily functioning (e.g., walking, cooking, shopping, driving) to ones that are more for enjoyment such as

- highly physical activities (e.g., walking for exercise, various sports)
- socializing (e.g., playing with grandchildren, meeting friends)
- hobbies/entertainment (e.g., reading, playing games on the computer, sewing, watching television).

Each patient then indicates the activities that are most important to him or her by starring them.

When patients fill out the second column of the P-CASA, they list what (if anything) interferes with the important activities they listed in the first column. Notice that patients can list anything that interferes with an activity; patients often listed symptoms in this column. The symptoms they list are directly connected to the activities they listed in the first column. Because of the idiographic format of the P-CASA, patients are able to list one or more symptoms (or non-symptoms) that interfere with one or more activity because of the idiographic format of the P-CASA. The format also allows patients to define their symptom(s) in a way that has meaning for them. The list of symptoms and non-symptoms in the second column determines the level that the patient can or cannot function and provides a list of symptoms that may need to be addressed by a health care professional.

In the third column, each patient lists some coping strategies that he or she may have in order to continue to participate in his or her important activities at some level.

That is, patients list how they modify their important activities in order to continue to participate in them. For example, a patient can list (in the third column) that she goes for short walks now instead of going hiking. Or, a patient can list (in the third column) that she take breaks when she is cooking a large meal.

In short, the P-CASA incorporates each patient's perspective into the assessment of his or her symptoms; each column of the P-CASA gathers information about each patient's experience of his or her activities and symptoms in a way that retains the meaning for each individual. Because the P-CASA is an idiographic assessment, patients are free to list any activity that is important to them and anything that interferes with their ability to participate in these activities. Because of the highly individualized information that the P-CASA gathers, health care professionals would be able to use this information to provide care in a way that the individual patient is not lost within a "cookbook" approach.

ASCPRO Recommendations and the P-CASA

Although the P-CASA was already in development before the ASCPRO recommendations, many criteria of the P-CASA are in alignment with their recommendations for assessing patient-reported cancer-related symptoms (Cleeland & Sloan, 2010). These recommendations emphasized the importance of (a) assessing all cancer-related symptoms (not just pain), (b) measuring symptoms in a way that combines symptom severity and the patient's perception of how these symptoms impact daily living, and (c) assessing multiple symptoms that patients experience because of their disease or treatment.

Assessing All Cancer-related Symptoms

Although the USFDA provides a set of recommended approaches for assessing patients' pain, similar recommendations for other symptoms do not exist (Cleeland & Sloan, 2010). There is a large literature that demonstrates the severity and pervasiveness of cancer pain and how physicians can help to manage it (Sykes, Fallon, & Patt, 2003; Tollison, Satterthwaite, & Tollison, 2002). However, patients experience other symptoms that are just as debilitating as pain. One recent article showed that fatigue was a more prevalent symptom than pain for patients with incurable cancer but that physicians paid more attention to the treatment of pain (Collins, de Vogel-Voogt, Visser, & van der Heide, 2008). Cheung, Barmala, Zarinehbaf, Rodin, Le, & Zimmermann (2009) showed that other symptoms, such as decreased appetite, drowsiness, and dyspnea intensified for palliative cancer outpatients. Elmqvist, Jordhøy, Bjordal, Kaasa, & Jannert (2009) also showed that anorexia, fatigue, and dyspnea (not just pain) impeded the quality of life for patients with advanced cancer. Therefore, it is important for health care professionals to assess each symptom equally, instead of assuming that one symptom is more important than the others.

The P-CASA assesses all cancer-related symptoms (not just pain). In the second column of the P-CASA, patients can list any symptom that is interfering with their important activities. Therefore, patients can list symptoms such as tiredness, bowel problems, mobility issues, and so forth. Although the ESAS lists symptoms other than pain, it still constrains patients to rating only the symptoms listed. That is, patients can only report their status on the nine symptoms listed on the form. The only freedom a patient has to introduce a symptom that is not listed on the ESAS is to list it as an "other" symptom, if they are filling out the ESAS paper form (see Appendix A.1). However, if they use the computerised ESAS kiosk, they have no ability to add a tenth symptom (see Appendix A.2 and A.3). The format of the P-CASA does not constrain the patient to list only certain cancer-related symptoms; it allows patients to list *any* symptom that interferes with their activities.

Connecting Symptoms and Functioning

Patients who have cancer often experience multiple symptoms at the same time which creates even more burden. *Symptom burden* is the "sum of the severity and impact of symptoms reported by a significant proportion of patients with a given disease or treatment" (Cleeland, 2007, p.17). According to Cleeland and Sloan (2010), "A measure of symptom burden might be the combination of the severity of the symptoms most associated with a disease or treatment and the patient's perception of the impact of these same symptoms on daily life." The figure below is *a measurement model for symptoms and overall HRQL*. It emphasizes the connection between the patient's *symptoms* and *functional status*. According to Cleeland, "Given that symptoms have an adverse impact on function and activity, symptom scales should also assess the interference with different activities caused by symptoms, as viewed from the patient's perspective" (Cleeland, 2007,p.17).

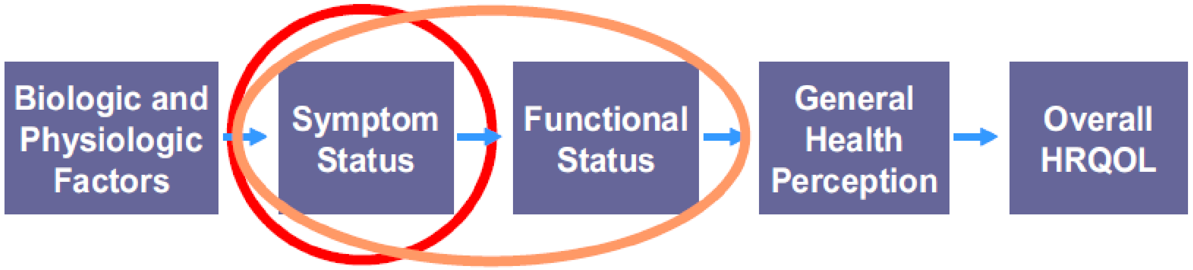


Fig. 1. A measurement model for symptoms and overall HRQOL. Symptoms are not synonymous with HRQOL. HRQOL is an inclusive concept comprising many domains outside of those that are most likely to be affected by disease and treatment. Symptoms are patients' perceptions of what is closest to the disease and treatment process. Symptoms and symptom interference are a subset of overall HRQOL domains, and knowing their status may be sufficient for making judgments about therapy effectiveness. © 2006 Charles S. Cleeland. Used by permission.

A central feature of the P-CASA is that it connects patients' perceptions of their symptoms with their daily functioning (i.e., activities that are important to them). When a health care professional views the first column of the P-CASA, he or she can use this information to determine the level and intensity of activities that are important to the patient. When the health care professional then views the second column of the P-CASA, he or she learns which symptoms are interfering with the majority of the patient's activities and how satisfied the patient is with their level of overall activity. Therefore, just as the *measurement model for symptoms and overall HRQL* suggests, the P-CASA connects patients' symptoms directly to their functional status. Health care professionals can use this information to determine how much patients' daily lives are interrupted by the symptoms that they experience. This information can be extremely informative for health care professionals, especially when patients indicate on the P-CASA that nothing helps their ability to participate in any of their activities. If a patient is unable to participate in any of his or her important activities, the health care professional can then provide some assistance with coping strategies or further investigate his or her health-related quality of life (HRQL).

Assessing Multiple Symptoms

Because patients who have cancer often experience multiple symptoms together, it is important to be able to measure more than one symptom at a time.

> "Disease-related and treatment-related symptoms rarely occur in isolation, and the combined effect of multiple symptoms imposes a 'symptom burden' and might be thought of as the subjective patient-reported counterpart of more objective constructs such as disease or tumor burden. This construct can only be

> made meaningful when the measurement of single and multiple symptoms is accepted and used" (Cleeland & Sloan, 2010).

The ability for health care professionals and researchers to assess multiple symptoms can contribute to research on s*ymptom clusters.* *Symptom clusters* are "two or more symptoms that follow the same time course in response to disease or treatment" (Cleeland, 2007, p.17). According to Cleeland, the meaning of symptom clusters is currently evolving as researchers create more multiple-symptom scales; these scales should include symptoms that are most distressing to patients and that occur most often.

The P-CASA assesses multiple symptoms that patients experience, and it addresses the challenges of measuring many symptoms they experience at one time. As demonstrated earlier, the format of the P-CASA allows for patients to list one or more symptoms that interferes with one or more of their activities. This allows health care professionals to determine which symptoms seem to occur together and which symptoms occur for certain types of activities. This additional information can help them provide individualized care for each patient. For example, a patient might experience both pain and tiredness when he or she participates in physically demanding activities. Or, a patient might experience irritability and depression when he or she participates in social activities. The information about co-occurring symptoms that the P-CASA gathers may be able to contribute to the growing research about symptom clusters in the future.

Validation Strategy

The newest edition of the Standards for Educational and Psychological Testing (Standards; American Educational Research Association [AERA], American

Psychological Association [APA], & National Council on Measurement in Education [NCME], 1999) provides the following definition of validity and the validation process:

> Validity refers to the degree to which evidence and theory support the interpretations of the test scores entailed by proposed uses of the tests. Validity is, therefore, the most fundamental consideration in developing and evaluation tests. The process of validation involves accumulating evidence to provide a sound scientific basis for the proposed score interpretations. It is the *interpretations* of test scores required by proposed users that are evaluated, *not the test itself*. When test scores are used or interpreted in more than one way, *each intended interpretation must be validated* (AERA, APA, & NCME, 1999, p. 9 [emphasis added]).

Thus, this new definition no longer allows a test itself to be labelled as valid or not. Instead, validity refers to the demonstrated *utility* of a proposed interpretation of its scores in a particular setting and for a particular purpose. In short, validity is not transferable; demonstrated validity for one purpose in one setting may not be relevant to a new use in the same or a different setting.

A related change is the elimination of familiar terms for different kinds of validity. Test developers and users should now view validity as a “unitary concept.” That is, the utility of the test for its intended purpose will determine how valid it is, instead of the test itself “having” distinct types of validity (e.g., construct validity, criterion-related validity, construct validity; see AERA, APA, & NCME, 1999, p. 11). In short, according to *Standards:*

> A sound validity argument integrates various strands of evidence into a coherent account of the degree to which existing evidence and theory support the intended interpretation of test scores for specific uses (AERA, APA, & NCME, 1999, p. 17).

The design of the present study follows the principles of the 1999 *Standards* by focusing on the utility of the P-CASA for a specific use in a particular setting.

Setting and use of P-CASA. The P-CASA is for use by health care professionals who work with advanced cancer outpatients at a clinic that focuses on symptom assessment and management, such as the PSM/PC Clinic of the BC Cancer Agency (BCCA), Vancouver Island Centre. Both the development of the P-CASA and the present study took place at the PSM/PC Clinic, so the results would provide validity evidence for the use of the P-CASA in that particular clinic (Clinic A; see Appendix B). The patients who attend the PSM/PC Clinic have advanced cancer and are experiencing cancer-related symptoms (e.g., pain, nausea, and tiredness); therefore, the results provide validity evidence for the P-CASA to be used with that target population (i.e., advanced cancer outpatients).

In this study, participants completed the P-CASA *before* they went into their face-to-face consultation, and the patient information the P-CASA gathered was not given to their health care professionals. Ultimately, health care professionals might use the P-CASA during their symptom assessment consultations, but first it was necessary to determine whether the P-CASA does in fact gather unique and useful information. Therefore, this study focuses on the hypothesis that the P-CASA gathers information about patients’ symptoms and activities and that the P-CASA is not redundant with the ESAS (a symptom assessment that is routinely used at the PSM/PC Clinic). Therefore, the first step in the validation strategy was to determine (a) whether or not the P-CASA gathers information about patients' symptoms and activities and (b) whether or not the information that the P-CASA gathers is redundant with the information that the ESAS gathers.

The P-CASA and the ESAS. One of goals of this study is to compare the information that P-CASA gathers with the information that the ESAS gathers. There are inherent differences between the design of the ESAS and the P-CASA.

Research Questions. The differences between the ESAS and the P-CASA led to the following research questions:

1. What information does the P-CASA gather that the ESAS cannot gather because of its design?

1.1 *Activities.* What information does the P-CASA elicit about activities that are important to patients?

    1.1.1 How many participants listed important activities on the P-CASA?

    1.1.2 What types of important activities did participants list on the P-CASA?

1.2 *Activities and symptoms.* How does the P-CASA connect patients' symptoms with their functioning (i.e., important activities)?

    1.2.1 How many participants experienced symptoms that interfered with their important activities? What proportion of participants were satisfied versus dissatisfied with their important activities?

1.3 *Single versus multiple symptoms.* How does the P-CASA gather information about symptoms that co-occur?

    1.3.1 How many participants reported that a single symptom interfered with more than one of their important activities?

1.3.1.1 Which single symptoms interfered most often with more than one activity?

1.3.2 How many participants reported having two or more symptoms co-occurring?

1.3.2.1 Which symptoms occurred together most often?

1.4 *Coping Strategies.* How does the P-CASA elicit descriptions of what (if anything) works to enable patients to participate in their important activities?

1.4.1 How many participants reported that something works to enable them to participate in their important activities?

1.4.2 If participants reported that something worked to enable them to participate in their important activities, what proportion of these strategies were medication and what proportion were something else?

1.4.2.1 For strategies that used something other than medication, what types of things did participants' list?

2. *P-CASA and ESAS*. Does the P-CASA provide information about symptoms that is not available on the ESAS?

2.1 *Symptoms Unique to P-CASA.* Does the P-CASA elicit symptoms that are not on the ESAS (i.e., symptoms that interfere with activities important to the patient)?

2.1.1 How many participants listed symptoms that were not on the ESAS?

2.1.2 How many participants listed only symptoms that were not on the ESAS?

2.1.3 What proportion of symptoms did the P-CASA provide that were not on the ESAS?

2.1.3.1 What types of symptoms did participants list that were not on the ESAS?

2.2. *Overlap between ESAS and P-CASA Symptoms.* How much do the symptoms reported on the P-CASA duplicate the ESAS symptoms?

2.2.1 How many participants listed ESAS symptoms on their P-CASA?

2.2.2 How many participants listed only ESAS symptoms as interfering with their important activities?

2.2.3 What proportion of symptoms listed on the P-CASA were also listed on the ESAS?

2.2.4 What proportion of these ESAS symptoms did the P-CASA provide *additional information* for*?*

2.2.4.1 What types of additional information did participants add on their P-CASA?

2.3 *ESAS ratings.* For symptoms listed on the P-CASA and the ESAS, what is the ESAS rating?

2.3.1 For all P-CASA symptoms that are also on the ESAS, is the ESAS rating for the symptom the highest rating (or tied for the highest) of all the symptoms on the ESAS?

2.3.2 For all of the P-CASA symptoms that are also listed on the ESAS, does the ESAS rating correspond to how many important activities the symptom interferes with?

2.3.3 Do the highest ESAS rating for each participant correspond to how many important activities the symptom interferes with?

Confirming versus Disconfirming Evidence

Could this study fail to support the validity of the P-CASA in this setting? The overall validation strategy is to demonstrate that the P-CASA gathers the information it is designed to gather and that this information is not redundant with the ESAS. Several of the research questions above are particularly important for confirming or disconfirming the utility of the P-CASA in this setting:

1.1.1. Participants must be able to list *up to five activities* that are important to them now. The P-CASA would not be useful if they did not understand the question or did not, at this point in their lives, have any important activities.

1.2.1. Participants should usually list *symptoms* that interfere with some of their important activities. If they usually listed other kinds of interference (e.g., the weather, not enough money, appointment times), then P-CASA would not useful for symptom assessment.

1.3.2. Participants should sometimes list combinations of *two or more symptoms* that interfere with an important activity. If multiple symptoms were rarely listed, then the P-CASA would not be fulfilling this criterion.

1.4.1. Participants should ordinarily list some *coping strategy or strategies* for engaging in important activities. If they do not, the P-CASA would not be useful for identifying these strategies.

1.4.2. The P-CASA should elicit *other means of coping* in addition to medication. Otherwise, it would not be useful for obtaining such information.

2.1.1 to 2.1.3.. The *symptoms spontaneously reported* on the P-CASA should not be limited to those on the ESAS. A major goal of this open-ended, idiographic format is to gather information about the widest possible variety of symptoms in this population. If virtually all of the symptoms listed were already on the ESAS, the P-CASA would be redundant in this respect.

2.2.4. When participants list a symptom on the P-CASA that is already on the ESAS, they should often provide *additional, more specific information* as well. If not, the P-CASA would be redundant with the ESAS for these symptoms.

2.3.1 to 2.3.3. The symptoms listed on the P-CASA as interfering with one or more important activity should not correspond to those with the *highest ESAS rating*. If the ESAS ratings for symptoms are consonant with their interference with important activities, then the P-CASA is redundant in this respect.

CHAPTER THREE

METHOD

Participants

Sixty outpatients participated in this study. Each had advanced cancer and was attending the Pain and Symptom Management/Palliative Care (PSM/PC) Clinic of the BC Cancer Agency (Vancouver Island Centre). The recruitment of these patients followed the procedures set out by the two appropriate review boards. These were the University of Victoria's Human Research Ethics Board and the University of British Columbia Research Information Services System, which serves the BCCA. The approved recruitment script and consent form are in Appendix D.

Patients at the PSM/PC Clinic experience intense levels of pain and other symptoms related to their cancer, and many of them are also in transition to either palliative or end-of life care. We required participants to be 19 years or older and fluent in English. We also required them to be sufficiently mentally and physically alert to give their consent and complete the P-CASA and ESAS forms. All of the participants in this study were returning to the Clinic for a follow-up consultation. We excluded new patients from this study because first visits to the Clinic are generally anxiety-provoking, especially for those who are experiencing acute symptoms; new patients might not have the level of alertness required to give consent and to complete the forms involved in this study. Even so, five patients who gave their consent did not meet criteria for participation. Two patients were not emotionally stable (i.e., one patient was visibly anxious and the other was irritated), one patient was unable to fill out the P-CASA accurately because her son dominated her responses, one patient was experiencing symptoms that were caused by a disease other than cancer, and we mistakenly recruited a new patient. Therefore, the final sample was 55 participants between the ages of 34 and 90; 19 were male and 36 were female. Primary cancer diagnoses for these patients were: breast (n=14), gynaecological (n=10), gastrointestinal (n=10), lung (n=5), genitourinary (n=5), leukemia (n=2), head and neck (n=1), other (n=8). Many participants had secondary cancers as well. Thirty-two participants died within 7 months of participating in the study.

Measures

Edmonton Symptom Assessment System (ESAS; see Appendix A).

The ESAS is a *symptom-focused* assessment form that requires patients to rate nine specific symptoms (i.e., pain, tiredness, nausea, depression, anxiousness, drowsiness, appetite, feeling of wellbeing, and shortness of breath) on a scale from 0 to 10, where 0 is the absence of the symptom and 10 is the worst possible experience of the symptom. All patients who attend the PSM/PC Clinic routinely complete the ESAS before their consultation with their physician. The PSM/PC Clinic uses two different formats for patients to fill out the ESAS.

One format is a touch-screen ESAS kiosk where patients select the rating of their nine symptoms by touching the computer screen; see Appendix A.2. The ESAS kiosk displays a spectrum of colors underneath the numerical ratings. On one extreme end of the spectrum (i.e., a rating of 0), the color is yellow. On the other extreme end of the spectrum (i.e., a rating of 10), the color is red. The touch-screen computer is located in the waiting room for the PSM/PC Clinic (See Appendix B). When new patients arrive at the Clinic, the clinic volunteer helps each patient enter their health care number and set up a password into the computerized system. The volunteer then guides the patient through each ESAS symptom, helping him or her to select the number and color that corresponds to how severe each ESAS symptom is for the patient *right now*. When patients finish rating their symptoms, the volunteer commands the ESAS kiosk to print a histogram of the ratings (See Appendix A.3). The histogram includes each patient's ESAS ratings from the current clinic visit as well as his or her ESAS ratings from previous visits.

The other format is the paper ESAS form; see Appendix A.1. The ESAS form lists the nine symptoms, along with an “other symptom” on a scale from 0 to 10. Patients rate each symptom on this list by circling the numerical rating that corresponds to the severity of their symptom.

Physicians use patients’ ESAS ratings as a way to determine, at a glance, which symptoms are most severe for a patient, and also as a way to start their consultation.

Patient-Centred Assessment of Symptoms and Activities (P-CASA; see Appendix C)**.**

The P-CASA is a *patient-centred* and *activity-focused* inventory. As we mentioned in the previous chapter, the P-CASA is a paper form that includes the following instructions: (1) Please list four or five activities (new or old) that are important to you *now*. (2) Put a star (*) beside the activities in the list that are the *most* important to you. (3) If you are not satisfied with your level of ability to participate in this activity, please indicate why. (4) What have you found helps your ability to participate in this activity at some level? (see Appendix C.1).

BC Cancer Agency's Cancer Agency Information (CAIS) System

The oncology nurse from the PSM/PC Clinic later consulted the CAIS system at the BCCA to ascertain whether a participant had died and, if so, when.

Physicians' Dictations

At the outset of this study we had planned to analyze physicians' dictations of the consultation they had with our participants. We planned to compare the information in the dictations with the information the P-CASA and ESAS gathered. Although we successfully gathered the dictations for each participant, we were unable to analyze the data in the way we had intended because the primary purpose of the dictation was to record treatments and tests the participants received.

Procedure

We conducted this research in the waiting room at the Pain and Symptom Management/Palliative Care Clinic (Clinic A; see Appendix B), Vancouver Island Centre, BC Cancer Agency. This clinic is equipped with the touch-screen ESAS, a computer for patients to use, and chairs. The volunteer and I also used the PSM/PC Clinic meeting room throughout the study (see Appendix B). The PSM/PC Clinic team worked out of this room throughout the day of the clinic and used it as a place to keep the medical charts for the patients who are attending the clinic that day. The room is equipped with a system for physicians to dictate their interactions with their patients, a large table, and chairs.

Data Collection Procedure

Before the clinic started, the volunteer printed the list of the patients who were scheduled for a consultation that day. I reviewed this list with the volunteer and put a star next to the patients who were eligible to participate in the study (i.e., follow-up patients who had symptoms primarily caused by cancer, had not participated in the study, and had not previously declined participation).

Administration procedure for the ESAS. When patients arrived at the clinic, the volunteer had them fill out the ESAS form using either the ESAS form or kiosk. The volunteer encouraged the patients who had already used the computerized ESAS system to use the system on their own. However, most patients still needed some assistance from the volunteer because they often forgot their passwords or they were uncomfortable on the computer. Some patients preferred to fill out the paper ESAS form or could not use the ESAS kiosk for logistical reasons (e.g., the patient forgot the password, the kiosk was occupied by another patient, or the computer system was not working). In these cases, the volunteer would give the patient the paper ESAS form on a clipboard. Without the help of the volunteer, patients would circle the number that corresponded to the severity of each of the symptoms listed on the form.

When a patient used the ESAS kiosk (see Appendix A.2) and had completed the ratings, the volunteer would print off the histogram and then guide the patient to the seated waiting area in the Clinic. When a patient used the paper ESAS form (see Appendix A.1) and had completed the form, the volunteer would take the clipboard and paper ESAS form.

After patients completed their ESAS, the volunteer would ask eligible patients whether a researcher could ask them a few questions regarding their symptoms. Whether or not the patients agreed to have a researcher speak to them, the volunteer would go to the clinic meeting room to notify me about each patient’s willingness to participate in the study as well as the patient's level of alertness. While the volunteer was in the clinic meeting room, he would place patients' ESAS ratings (in the form of the histogram or paper ESAS form (See Appendix A.1 and A.3) on their medical file so it was available for the consulting physician.

(In total, 28 participants in this study used the ESAS kiosk and the remaining 27 participants used the paper ESAS form. We did not assign participants to any particular format in any systematic way because, for the reasons listed above, it was difficult for the volunteer to determine which format participants would use before they arrived at the clinic).

If patients agreed to have me speak to them, I would approach the patients in the waiting room, and using a recruitment script (see Appendix D.1), ask them if they would like to participate in the study. If patients expressed interest in the study, I gave them the consent form to read (see Appendix D.2). After the patients read the consent form, they could either decline participation or sign the consent form. If the patient did not agree to participate in the study, I checked to see whether the physician was ready to see him or her. If the patient wanted more time to think about it, I left him or her with the consent form before I checked to see whether the physician was ready to see the patient. If the patient agreed to participate in the study, he or she completed the P-CASA form with me.

Administration procedure for the P-CASA. I asked participants if they wanted to fill out the form themselves or if they would prefer me to fill it out on their behalf. If the participant wanted to fill out the form, then I read the questions out loud to the participant, and the participant wrote his or her response on the P-CASA. If the participant preferred me to fill out the form, then I read aloud the questions on the P-

CASA, and the participant responded to me. Together we decided what I should write on the P-CASA. Some participants opted for me to fill out the P-CASA form because they could not write for physical reasons (e.g., pain, eyes blurring, loss of function of writing hand, tiredness). Other participants opted for me to fill out the P-CASA for other unknown reasons. Twenty-seven participants filled out their own P-CASA form and 28 opted for me to fill out their P-CASA form.

After the participant completed the P-CASA, I escorted him or her to the appropriate clinic room for their consultation (if the physician was ready). For participants who wanted their own copy of these documents, I made photocopies of the consent form and P-CASA form while the participant was in the consultation with their physician. Once they finished, I delivered these photocopies to the participant. If I had access to the participant's ESAS ratings, I recorded them on the back of the original P-CASA form and assigned the participant a subject number. The oncology nurse at the PSM/PC Clinic later used the BCCA CAIS system to gather information about the participant (e.g., demographic information, treatments, date of death).

CHAPTER 4

ANALYSIS OF THE P-CASA

This chapter summarizes the data that the P-CASA obtained from the participants in the sample as a whole, including any analyses required to answer research questions unique to the P-CASA. This chapter focuses on information in the P-CASA that the ESAS cannot gather because of its design. The next chapter focuses on where they overlap, that is, comparisons between the information about symptoms in particpants' P-CASAs and their nine ESAS symptoms.

Because the P-CASA is an idiographic and open-ended instrument, participants were free to supply their own best words to describe their important activities, their experience of their symptoms, and their coping strategies. It was important to preserve each participant's exact words rather than assigning them to nomothetic categories. However, in order to answer the research questions, it was also necessary to summarize the answers in a way that would extract information about the activities, symptoms, and coping strategies of the sample as a whole. We aggregated the data to varying degrees in order to extract sample information and, in some cases, to conduct a formal analysis. These operations permitted us to answer increasingly focused research questions about the unique information the P-CASA elicits.

The first step was to create an electronic version of the data that P-CASA elicited. Each participant's P-CASA responses went into an Excel spreadsheet exactly as they appeared on the P-CASA, including any symbols the participant had used such as a star, ampersand (&), forward slash (/), plus sign (+), or dash (-). The Excel spreadsheet for each participant organized his or her responses into the three columns of the P-CASA:

- The first column contained the participant's responses to the question, "Please list 4 or 5 activities (new or old) that are important to you now.
- The second column contained the responses to the question, "If you are not satisfied with your level of ability to participate in this activity, please indicate why."
- The third column contained the responses to the question, "What (if anything) helps your ability to participate in this activity at some level?"; see Appendix C.2.

All further analysis preceded on the data in the Excel versions of the P-CASAs. Each step generated a new spreadsheet that extracted the variables of interest. Below is a description of these analyses.

Activities

The first column on the P-CASA yielded a list of participants' important activities. Because of the open-ended nature of the P-CASA, participants were free to list any type of activity that was important to them, so it was the participants who spontaneously defined what *activities* meant. In order to determine how participants had interpreted and defined activities, we grouped their responses into broad categories. As shown in Table 1, these responses ranged from highly physical activities to passive mental stimulation:

- *highly physical activities* that involved movement of their entire bodies; e.g., walking for exercise, gardening, camping, running, golfing, tennis

- *socializing;* e.g., volunteering, playing with grandchildren, meeting friends
- *daily functioning and responsibilities*; e.g., walking, cooking, shopping, driving
- *active mental stimulation or hobbies*; e.g., reading, playing games on the computer, teaching, sewing, baking
- *passive mental stimulation with no physical movement*; e.g., watching television, listening to music.

All participants listed four to six important activities on their P-CASA. Sometimes participants had starred the activities that were most important to them (in response to the instruction “Next, put a star * beside the activities in the list that are <u>most</u> important to you”). However, only 39 participants had done so, and five of them had starred all of the activities they listed. It was unclear why the remaining 16 had not starred any activity. It may be that they had not been able identify an activity that was most important to them, that all activities they had listed were most important to them, or that they may have simply forgotten to star any activity. Therefore, we did not conduct a separate analysis on participants’ activities that were starred versus not starred.

Symptoms

The second column on the P-CASA (“If you are not satisfied with your level of ability to participate in this activity, please indicate why”) yielded three kinds of responses from participants: (a) that they were satisfied with a particular activity; (b) that they were not satisfied because of a symptom or symptoms (e.g., pain and tiredness); (c) that they were not satisfied for a reason other than a symptom (e.g., too many appointments). In order to focus on symptoms that interfered with participants’ important activities, it was necessary to re-organize the data to separate these three different responses.

This analysis required a new Excel spreadsheet for each participant that included only his or her responses in the second column of the P-CASA. This sheet did not contain any participants' responses that indicated they were satisfied with their level of ability to participate in one or more of their activities (e.g., statements such as "satisfied," "yes," "okay," "absolutely," or "satisfied with meds."). Fifty-four of the 55 participants said that they were not satisfied with their ability to participate in at least one important activity. (See Figure 1 and 2 to see the proportions of activities participants were satisfied with versus not satisfied with.) Therefore, the *N* for the following analyses was 54.

Removing the responses that indicated the participant was satisfied from the second spreadsheet left only the reasons the participant was not satisfied with his or her ability to engage in an important activity. Note that when the participant had included additional information with the reason, e.g., not just "pain," but "pain when walking," we kept these together. For example, one participant had listed "pain and seasonal" as two reasons she wasn't satisfied with gardening. The new spreadsheet listed these two reasons separately. When the participant had listed two reasons they were unsatisfied and also included additional information (e.g., "equilibrium poor because of drugs and pain"), then we separated these reasons and included the additional information in both entries: "equilibrium poor because of drugs; equilibrium poor because of pain".

As noted above, the participants' written responses often included symbols or abbreviations, and I converted these into words in the second spreadsheet. Because I had worked with every participant who had filled out the P-CASA, I was very familiar with the information that the participant had provided as well as its meaning. When a participant (or I) had used a symbol on the P-CASA, I interpreted it in a way that was consistent with the conversation I had had with the participant and changed it in the second spreadsheet accordingly. For example, I interpreted an ampersand, forward slash, or a plus sign to mean *and*. (E.g., one participant had listed "pain/irritability" as the reason he was not satisfied with his ability to socialize, so I entered "pain" and "irritability" as separate reasons.) Also, when the participant (or I) had used a dash (--), I interpreted this to mean *because of,* and replaced the dash with these words in the second spreadsheet. For example, I would input "pain [because of] posture" instead of "pain – posture." The second spreadsheet now contained a list of reasons why each participant was unsatisfied with the ability to participate in his or her most important activities, with each reason listed separately and in words.

Operational Definitions of Symptoms and Non-Symptoms

Notice that the instructions for this column (i.e., "If you are not satisfied with your level of ability to participate in this activity, please indicate why") did not use the word *symptoms*. Therefore, participants could (and did) list any reasons at all. For example, one participant had said that he was not satisfied with his ability to travel because of his "frequent appointments" at the BCCA, whereas another participant had indicated that she wasn't satisfied with her level of ability to garden because of the "season."

Because we were interested in symptoms that interfered with the participants' most important activities, the next step was to conduct a formal analysis to determine which reasons were symptoms and which reasons were not. Two analysts created and applied a procedure for separating symptoms from non-symptoms in a reliable way (see Appendix E). The analysis used the definition of *symptom* that Cleeland and Sloan (2010) took from *Webster's Third New International Dictionary*: "The subjective evidence of disease or physical disturbance observed by a participant" (p.1079). The analysis also included Cleeland and Sloan's (2010) addition to that definition (given earlier):

> Implicit in this definition is the negative nature of symptoms and, most importantly, that symptoms are observations of the person directly experiencing the evidence of disease or physical disturbance. In contrast to "signs" of disease (such as fever or high blood pressure), symptoms can only be known through participant report. (p.1079).

The nine ESAS symptoms (i.e., pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, wellbeing, shortness of breath) and other physical disturbances (e.g., bowels problems, mobility problems, mental functioning) were examples of symptoms for this analysis; see Appendix E.1).

Although one might argue that mobility problems are simply consequences of other symptoms such as pain or tiredness, this is often not the case. Many participants discussed their inability to move because of treatments they had received or the disease itself. For example, one participant used a walker because of surgery, and another participant was unable to lift his arm because of a tumour that was physically impeding this movement. Therefore, mobility problems fit the definition of a symptom; they are "subjective evidence of disease or physical disturbance observed by a patient" (Cleeland & Sloan, 2010, p. 1079; Webster's Third New International Dictionary).

Non-symptoms were reasons that participants were not satisfied with their level of ability to participate in important activities but that were neither subjective nor physical in nature. For example, one participant had listed “medical appointments” as the reason why he could not travel out of town. Although he had observed this “disturbance” in his life, it was neither a subjective experience nor a physical disturbance.

The two analysts (CT and JB), using the P-CASA symptom analysis sheets (see Appendix E.2) for 10 participants, independently examined the responses and identified each reason as a symptom or non-symptom. Then for every symptom, they independently determined whether the symptom

- was on the ESAS
- was on the ESAS but included additional information
- was equivalent to an ESAS symptom (e.g., a synonym)
- was equivalent to an ESAS symptom with additional information
- was not on the ESAS.

They agreed on 50/53 decisions (94.33%). After assessing reliability, one analyst (CT) examined all 361 symptoms elicited from the 54 participants, including any symptoms that participants repeated. In this Chapter we will cover the distinctions of symptoms and non symptoms and in Chapter 5 we will discuss the relation of P-CASA symptoms to ESAS symptoms.

Results for Symptoms versus Non-symptoms

Eleven of the 54 participants listed one or more non-symptoms as the reason they were unable to participate in their important activities, yielding 20 non-symptom reasons in the sample. The remaining 361 reasons listed were symptoms. However, participants often listed the same symptom more than once because it interfered with more than one activity. Eliminating these repetitions by each individual participant still left 247 symptoms. Thus, symptoms were the primary reason that these participants were not satisfied with their ability to participate in an important activity. In the next chapter, a further analysis will reveal how many of these symptoms corresponded to the nine symptoms on the ESAS versus how many were unique to the P-CASA.

Coping Strategies

The third column ("What helps your ability to participate in this activity at some level?") yielded a list of coping strategies that helped participants to participate in their activities at some level. Forty-six of 54 participants had found at least one coping strategy to help them participate in their important activities; the remaining eight had nothing that would help.

Because of the open-ended nature of the P-CASA, participants were free to list anything that they considered helped them. For example,

- taking medication
- modifying the activity (e.g., "going for walks instead of hiking")
- resting frequently
- determination to do the activity (e.g., "just push myself to do it"); see Table 2.

Participants gave 204 responses to the question about what enabled them to participate in their important activities. Grouping the participants' responses into broad categories revealed whether medication was the main coping strategy in this sample. Surprisingly, only 9.3% of these coping responses were a medication, 54.4% were something other than medication, 5.9% combined medication and something else, and 30.4% were that nothing helped. (See Figure 3).

One reason that participants may not have credited the medication they take is that they have been on various medications for a long time, and it is working. That is, participants' alleviated symptoms become normal, and they do not realize how much pain (or other symptoms) they must otherwise be experiencing.

Relationship between Activities and Symptoms within the P-CASA

We designed the P-CASA so that patients could report their symptoms within the context of their lives. Therefore, they listed their most important activities first and only then describe what (if anything) is interfering with these activities. Each participant was also free to link symptoms and activities in any way (e.g., to list one symptom that interfered with all of their activities or two symptoms that together interfered with most of their activities. These relationships between activities and symptoms directly connected the individual participant's symptoms with their functioning.

The particular activity-symptom connections were unique for each participant, but it is possible to find some overall patterns. For a symptom to have appeared in the middle column ("If you are not satisfied with your level of ability to participate in the [corresponding] activity, please indicate why"), it must have interfered with at least one activity important to the participant; however, some symptoms could interfere with more than one activity. Forty-four of 54 participants reported one symptom that interfered with more than one important activity. As shown in Table 3, pain, tiredness, and mobility problems were the symptoms that most often interfered with more than one activity. Participants could also report two symptoms that together interfered with one activity.

Forty-two of 54 participants had symptoms occurring together, with pain and tiredness the most frequent pairing (see Table 4).

Summary of Results of Research Questions

The results presented in this chapter answered the first set of research questions posed in Chapter 2. What information does the P-CASA gather that the ESAS cannot gather because of its design?

1.1 *Activities.* What information does the P-CASA elicit about activities that are important to patients?

1.1.1 All of the participants (i.e., 55 out 55 participants) listed 4 to 6 important activities on the P-CASA.

1.1.2 As shown in Table 1, these activities included highly physical activities, socializing, active mental stimulation/hobbies, and passive mental stimulation.

1.2 *Activities and symptoms.* How does the P-CASA connect patients' symptoms with their functioning (i.e., important activities)?

1.2.1 Fifty-four of 55 participants said they were not satisfied with their ability to participate in at least one important activity. The majority of participants were not satisfied with their level of ability to participate in their important activities. Figure 1 shows the proportion of participants who were not satisfied with their activities, and Figure 2 shows the proportion of participants who were satisfied with their activities.

1.3 *Single versus multiple symptoms.* How does the P-CASA gather information about symptoms that co-occur?

1.3.1 Forty-four of 54 participants had a single symptom that interfered with more than one important activity.

1.3.1.1 Pain, tiredness, and mobility problems were symptoms that interfered with more than one activity. See Table 3.

shows all of the symptoms that most often interfered with more than one important activity

1.3.2 Forty-two of 54 participants had symptoms that occurred together.

1.3.2.1 Pain and tiredness occurred together most often (See Table 4)

1.4 *Coping strategies.* How does the P-CASA elicit descriptions of what (if anything) works to enable patients to participate in their important activities?

1.4.1 Forty-six of 54 participants found at least one thing to help them to participate in their important activities.

1.4.2 Participants gave 204 responses to the question about what enabled them to participate in their important activities: 9.3% of these coping responses were a medication, 54.4% were something other than medication, 5.9% combined medication and something else, and 30.4% were that nothing helped (see Figure 3).

1.4.2.1 Participants mentioned numerous coping strategies other than medication that helped them continue to participate in activities that were important to them. For example, they would modify the activity (e.g., "going for walks instead of hiking") or rest frequently; see Table 2 for a complete list of coping strategies).

CHAPTER 5

SYMPTOM ANALYSIS: COMPARING ESAS AND P-CASA SYMPTOMS

A main component of the validation strategy was to determine whether the P-CASA gathered information about symptoms that the ESAS did not gather. Because the PSM/PC Clinic currently uses the ESAS to screen patients' symptoms, it was important to show that the P-CASA is not redundant with the ESAS. This chapter presents both the analysis and the results of this comparison.

Analysis

Procedure

As described in Chapter 4, the two analysts used formal operational definitions (Appendix E.1) and a corresponding decision tree (Appendix E.3) to analyze participants' responses from the middle column of the P-CASA, that is, participants' responses to the question: "If you are not satisfied with your level of ability to participate in this activity, please indicate why." The reliability reported in Chapter 4 included decisions using the operational definitions about the relationship between the symptom the participant described and the ESAS list of symptoms. The sections below go into detail about these operational definitions. After assessing reliability, one analyst (CT) examined all 361 symptoms elicited from the 54 participants, including any symptoms that participants repeated.

Operational Definition of an ESAS Symptom. The nine cancer-related symptoms listed on the touch screen ESAS kiosk and the paper ESAS form are *pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, wellbeing,* and *shortness of* *breath*. On the paper ESAS form, the addition of "other symptom" on the list gave participants the opportunity to name and numerically rate a symptom not listed on the ESAS. However, because only six participants used this option, the "other symptom" responses were not usable in this analysis.

Operational Definition of Words Equivalent to ESAS Symptoms. The words that participants used often matched an exact term on the ESAS list. However, participants also listed symptoms on the P-CASA that were synonyms for an ESAS symptom or were closely related to an ESAS symptom. For example, some participants listed "tired," "fatigue," or "energy" on their P-CASA, which are all closely related to the symptom "tiredness" on the ESAS. These synonyms all went in the category of *words equivalent to ESAS symptoms.*

Operational Definition of Symptoms not on the ESAS. Participants often listed symptoms that were not on the ESAS list or equivalent to any ESAS symptom, which meant that the P-CASA elicited symptoms from participants that the ESAS did not assess. As shown in Table 5, these unique P-CASA symptoms included

- *physical mobility* (e.g., "not enough control over motor movement")
- *stamina* (e.g., "can't walk for long [because] stamina isn't there")
- *strength* (e.g., too weak," "lack of strength")
- *emotional/psychosocial issues* (e.g., "too frustrated to go out," "lack of motivation")
- *gastrointestinal issues* (e.g., "bowel problems," "bloating")
- *mental functioning* (e.g., "lack of concentration"),
- *physical comfort* (e.g., "no comfortable position")

- *eye symptoms* (e.g., "eyes blur")
- *other symptoms* (e.g., "prednisone increases restlessness").

Operational Definition of Additional Information to the ESAS Symptoms.

The next and final step of the analysis was to determine whether or not each symptom classified as an ESAS symptom or as equivalent to an ESAS symptom also included additional information about the symptom.

The P-CASA permitted participants to provide additional information about their symptoms. For participants who listed ESAS symptoms, over 50% of them included additional information about these symptoms (see Table 7). Participants included information about

- *when the symptom occurred* (e.g., "*cannot continue activities beyond mid-afternoon due to* tiredness")
- *where the symptom was located* (e.g., "*Chest* pain," "*leg* knots")
- *the physical disturbances the symptom caused* (e.g., "*light-headed* [because of] breath")
- *the duration or intensity of the symptom* (e.g., *constant* nausea)
- *how the symptom disrupted their activities* (e.g., "too tired *to clean up*")
- *other symptoms it caused* (pain *keeps me awake*")
- *treatments that caused the symptom* (e.g., "drowsiness *from pain medication*").

For every ESAS symptom (or equivalent), the analyst noted whether the participant included additional information or not.

Results

Symptoms on the P-CASA versus the ESAS

Figure 4 shows the relative distribution of all of the 247 (non-redundant) symptoms that participants reported on the P-CASA. Sixty-four were ESAS symptoms or equivalents, 73 of these symptoms were ESAS symptoms that also included additional information, and 110 symptoms were symptoms that were not on the ESAS.

In terms of the number of participants, 74.07% of participants listed at least one ESAS symptom on their P-CASA, 59.25% included additional information about at least one ESAS symptom, and 81.48% of participants listed at least one symptom that was not on the ESAS. Only 16.66% of participants listed only ESAS symptoms as interfering with their important activities. Conversely, 7.4% of participants listed only symptoms that were not on the ESAS.

Comparisons of ESAS Ratings with Information on the P-CASA

This analysis focused on the ratings that participants gave to ESAS symptoms that also appeared on the same participant's P-CASA. For example, if a participant listed "tiredness" on the P-CASA, it was possible to look for the rating he or she gave for "tiredness" on the ESAS form and then to determine how the ESAS rating corresponded with the important activities on the P-CASA.

Mean ESAS ratings for symptoms on the P-CASA. When a symptom appeared on the P-CASA, it is because it interfered with something important in the participant's life. Does this importance correspond to the severity rating on the ESAS? For all participants' symptoms listed on the P-CASA that were also ESAS symptoms, the mean ESAS rating on their ESAS form was 5.62 out of a possible 10 (SD= 2.34). Thus, participants did not rate the ESAS symptoms that interfered with their important activities as very severe. In fact, one standard deviation above and below the mean yields a range of 3.26 to 7.96. Thus, a symptom did not have to have a high ESAS rating to interfere with one of the participant's most important activities.

ESAS ratings and number of important activities on the P-CASA. The next question was whether symptom severity, as rated on the ESAS, affected the number of activities the symptom interfered with on the P-CASA. A comparison of participants' ESAS symptom ratings with the number of important activities those symptoms interfered with on their P-CASA showed there was virtually no relationship. Some ESAS symptoms with low ratings interfered with many of their activities, and some ESAS symptoms with high ratings interfered with none of their activities. Figure 5 shows the relationship of ESAS ratings to the number of important activities the symptom interfered with.

Participants' highest ESAS ratings and the P-CASA. The highest rating that participants gave on their ESAS varied considerably from participant to participant; the range was from 2 to 10. One might expect that symptoms with the highest ESAS ratings for that individual would interfere with more of that individual's important activities. However, the symptoms with the highest ESAS ratings for that individual ranged from interfering with no activities to all of their important activities. Figure 6 shows the relationship of participants' highest ESAS ratings to the number of important activities the symptom interfered with.

Summary of Results for Research Questions

Below is a summary of how the results presented in this chapter answer the research questions listed in Chapter 2 about whether the P-CASA is redundant with the ESAS.

2. *P-CASA and ESAS*. Does the P-CASA provide information about symptoms that is not available on the ESAS?

2.1 *Symptoms Unique to P-CASA.* Does the P-CASA elicit symptoms that are not on the ESAS (i.e., symptoms that interfere with activities important to the patient)?

  2.1.1 44 of 54 participants listed symptoms that were not on the ESAS

  2.1.2 4 of the 54 participants listed only symptoms that were not on the ESAS

  2.1.3 Of the 247 symptoms listed on the P-CASA, 110 of the symptoms were not on the ESAS.

    2.1.3.1 As shown in Table 5, these symptoms involved

      - *physical mobility* (e.g., “not enough control over motor movement”)
      - *stamina* (e.g., “can’t walk for long [because] stamina isn’t there”)
      - *strength* (e.g., “too weak,” “lack of strength”),
      - *emotional/psychosocial issues* (e.g., “too frustrated to go out,” “lack of motivation”)
      - *gastrointestinal issues* (e.g., “bowel problems,” “bloating”)
      - *mental functioning* (e.g., “lack of concentration”)

- *physical comfort* (e.g., “no comfortable position”)
- *eye symptoms* (e.g., “eyes blur”)
- *other symptoms* (e.g., “prednisone increases restlessness”).

2.2 *Overlap between ESAS and P-CASA Symptoms.* How much do the symptoms reported on the P-CASA duplicate the ESAS symptoms?

2.2.1 40 out of the 54 participants listed ESAS symptoms on their P-CASA.

2.2.2 9 out of 54 participants listed only ESAS symptoms as interfering with their important activities.

2.2.3 Of the 247 symptoms listed on the P-CASA, 64 were also on the ESAS (without additional information).

2.2.4 Of the 247 symptoms listed on the P-CASA, 73 were also on the ESAS but included additional information.

2.2.4.1 For a complete list of ESAS symptoms with additional information see Table 6 and 7.

2.3 *ESAS ratings.* For symptoms listed on both the P-CASA and the ESAS, does the ESAS rating reflect information on the P-CASA?

2.3.1 For all symptoms listed on the P-CASA that were also ESAS symptoms, the mean ESAS rating was 5.62 (SD= 2.34). This means that the rating of ESAS symptoms that interfered with participants’ important activities were, on average, slightly above the midpoint.

2.3.2 There was no relationship between ESAS symptom ratings and the number of important activities those symptoms interfered with on their P-CASA. Some ESAS symptoms with low ESAS ratings interfered with many activities, and some ESAS symptoms with high ratings interfered with none of participants' activities (see Figure 5).

2.3.3 There was no relationship between symptoms with the highest ESAS ratings and how many of participants' important activities the symptom interfered with; it could be either no activities or all of participants' important activities (see Figure 6).

CHAPTER 6

DISCUSSION

Goals of the Thesis

The purposes of this thesis were (a) to emphasize the importance of preserving the meaning of patients' experiences when using assessment tools, (b) to demonstrate the importance of assessing patients' symptoms within the context of their lives, (c) specifically, to introduce a new assessment tool, P-CASA, and (d) to provide initial validation evidence for the use of this new tool with palliative cancer patients.

Importance of the Patient's Perspective

The literature review documented the importance of incorporating the patient's perspective within the design and use of symptom assessments. Large organizational bodies such as the USFDA and EMEA have acknowledged and emphasized the importance of using information from the patient's perspective for clinical trials. Most of patient-reported outcomes (PROs) on pain assessment management are nomothetic, but one can argue that both idiographic and nomothetic assessments are essential. This is especially true when determining the difference that a treatment provides for each patient. Idiographic assessments best preserve the individual patient's perspective and can complement the abstract constructs that nomothetic assessments aim to measure.

Assessing Patients' Symptoms within the Context of their Lives

Another section of the literature emphasized that symptom assessments should connect patients' symptom status and their functional status. One response to the USFDA and EMEA guidelines for using PROs in clinical trials was the creation of an interdisciplinary workgroup, on "Assessing the Symptoms of Cancer using Patient-

Reported Outcomes" (ASCPRO). ASCPRO formed to generate recommendations for assessing *all* patient-reported cancer-related symptoms (not just pain), as well as co-occurring symptoms, in order to facilitate clinical research and decision making. In addition, the ASCPRO group distinguished between abstract constructs such as health related quality of life and measures of patients' experience, such as their symptom status and functional status. They concluded that connecting patients' symptom status and functional status is a superior measure of PROs.

The Design of the P-CASA

The P-CASA starts by incorporating the patient's perspective. It is an idiographic tool that assesses each patient's symptoms within the context of his or her life. It is in alignment with the ASCPRO recommendations because it assesses all cancer-related symptoms; it directly connects patients' symptoms and functioning (i.e., important activities); it assesses multiple symptoms that patients' experience; and it can identify co-occurring symptoms.

Validation Evidence

Information obtained by the P-CASA. The participants in the study reported many and varied important activities that they wanted to continue to participate in. Although they could list anything that interfered with these activities, the majority of participants listed symptoms, especially pain, tiredness, or mobility problems (e.g., standing, sitting, not enough control over motor movements). The majority of the participants had co-occurring symptoms, especially pain plus tiredness, that interfered with most of their activities.

Finally, although participants had symptoms that interfered with their activities, the majority had found ways to cope with them. Most reported something they could do (e.g., modify the activity or rest frequently) to continue to participate in their important activities. Surprisingly, the most frequent coping strategies were other than medication. Unfortunately, some participants no longer participated in some of their important activities because no coping strategy helped them. The latter information could be extremely helpful to their health care professionals, who might use it to identify symptoms that are not being addressed and to suggest possible treatments and coping strategies.

The P-CASA and the ESAS. As predicted, the P-CASA was not redundant with the ESAS, a nomothetic tool that health care professionals currently use to screen cancer-related symptoms. First, because of the design of the P-CASA, it gathers information about patients' activities, it directly connects patients' activities and symptoms, and it also gathers information about patients' coping strategies. The ESAS does not gather any of this information.

The P-CASA was also not redundant with the ESAS in the area they overlapped, namely, symptom assessment. First, the majority of participants listed symptoms on their P-CASA that are not on the ESAS (e.g., physical mobility, stamina, strength, emotional/psychosocial issues, gastrointestinal issues, mental functioning). Second, the P-CASA was not redundant with the ESAS because, even when participants listed ESAS symptoms on their P-CASA, they often included additional information about the symptom (e.g., when the symptom occurs, where the symptom is located, the duration or intensity of the symptom). Third, the participant's ESAS ratings did not indicate how a symptom interfered with their functioning as reported on the P-CASA. That is, some low ESAS ratings interfered with many activities and, conversely, some high ratings interfered with none of participants' activities.

In summary, the validation evidence from 55 participants showed that the P-CASA obtains information about patients' symptoms, activities, and coping strategies from the patient's perspective and that the P-CASA is not redundant with the ESAS. Because the design and validation of the P-CASA took place in the Pain and Symptom Management/Palliative Care clinic of the BC Cancer Agency, Vancouver Island Centre, the results provide evidence supporting the use of the P-CASA with the population that attends that particular clinic, that is, outpatients with advanced cancer who are attending a pain and symptom management clinic.

Future Studies and Validation of the P-CASA

As mentioned earlier, our ultimate goal is to have health care professionals use the P-CASA in their symptom assessment consultations. This study successfully demonstrated that the P-CASA does gather information about activities, symptoms, and coping strategies and that it is not redundant with the ESAS. Further validation studies should include health care professionals using the information that P-CASA collects. The Centre for Palliative Care & St. Vincent's Hospital in Melbourne, Australia, is currently beginning a validation study with physicians using the P-CASA and the ESAS in their consultation with their patients and then comparing the utility of the two tools.

With further validation, the P-CASA might be useful for determining the efficacy of new treatments. According to Cleeland and Sloan (2010), "the sensitivity of changes in symptoms [is] a good indicator of disease and response to treatment" (p.1079). One possible future study is to have health care professionals use the P-CASA repeatedly with the same patients as a way of tracking how symptoms and activities change over time. This type of study would indicate how patients' symptoms and ability to function change in response to treatments. It would also be useful to conduct studies that test the utility of the P-CASA in different clinical settings, such as medical or radiation oncology consultations. One medical oncologist who has reviewed the P-CASA said that it would be useful for helping him to be clear what the patient's goals are and therefore which kind of chemotherapy to prescribe. He used the example of a patient who was a cellist and therefore opted for a chemotherapy treatment that did not cause neuropathy of the fingertips. If the oncologist had not asked this patient what was important in her life, he may have inadvertently risked her ability to play the cello again.

The validation of the P-CASA will undoubtedly be an ongoing process. We encourage researchers and health care professionals to join us in further validation studies on the P-CASA. If successful, the P-CASA will provide a clear snapshot of patients' lives while they are coping with a disease that interferes with what is important in their life. When life is short, as for most palliative patients, the important activities matter even more.

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Table 1.
Activities Categorized by Frequency

Physical activity and sports	Socializing and social events	Daily functioning and responsibilities	Active mental stimulation/hobbies	Passive mental stimulation
Walking/hiking (14)	Socializing (7)	Cooking (10)	Reading (16)	Watching TV (12)
Biking/Cycling (5)	Playing/being with grandchildren (7)	Walking (10)	Travelling (6)	Listening to music (8)
Gardening (5)	Walking dog (5)	Driving (6)	Crossword puzzles (3)	Sporting Live events
Golfing (5)	Socializing with friends/family (5)	Enjoying a meal (5)	Writing (3)	Music
Swimming (2)	Going out for dinner (3)	Cleaning the house (3)	Sewing (2)	Music & keeping up with news
Running (2)	Grandkids (2)	Sleep (3)	Teaching (2)	Jazz music
Fishing	Being with family (2)	Getting out of the house (2)	Playing music (2)	Distractions- TV
Renovations	Telephone conversations with friends	Shopping for household needs	Doing physics	Listening to CBC radio
Camping	Going places with my kids	Small chores around the house	Playing computer games	
Cross country skiing	Being with my kids	Anything requiring strength	Sudoko	
Hockey	Volunteering	Keeping my life in order	Painting	
Yoga	Family riding bikes	Working on quality of life	Writing poetry & songs	
Boating	Playing with our dog	Happy hour	Baking	
Doing exercises with weight and legs	Entertaining	Getting out and driving	Painting portraits & landscapes	
Curling	Outings with grandsons	Getting enough rest	Making glass fusing work	
Tennis	Meeting friends	Meals	Reading with magnifying glass	
Going to beach	Hanging with cats	Getting ready for Christmas	Puddle around garage (polishing car)	
Ping pong	Visiting grandchildren	Eating and cooking a good meal	Spider solitaire on computer	
Dancing	Seeing friends	Working	Writing letters	
	Going to the theatre	Sleeping though the night		
		Participating in activities in house		
		Activities for a full 8-hour		

Table 1. *Important Activities Categorized by Frequency* (Continued)

Physical activity and sports	Socializing and social events	Daily functioning and responsibilities	Active mental stimulation/hobbies	Passive mental stimulation
	Getting out to people’s houses, malls, lunches, etc. Car → driving Walking/playing with my dog Craft sales & Bazaars Shopping/price Comparing Watching grandson play football Visit friends and social interaction Visiting friends and being with friends Family Out for coffee Going out with friends Going to bookshops Meeting family – going for tea Going out at night – movie, play, dinner, opera Going to son’s hockey games Talking with friends going to their houses	day is now shorter Working with my inner world thru this crisis Eating	Playing on computer Playing the piano Riding motorcycles RRC. On computers Design sound systems Reading newspaper Cribbage on internet Going to school Rug hooking Learning Bridge Puzzles - sudoko Doing crossword puzzles and games Play on computer – games Online – website updating Driving to Saskatchewan Long distance driving Bus travelling ex: tours Social justice and environmental issues– signing petitions, writing letters, etc	

Table 1. *Important Activities Categorized by Frequency* (Continued)

Physical activity and sports	Socializing and social events	Daily functioning and responsibilities	Active mental stimulation/hobbies	Passive mental stimulation
	Dinner with friends			
	Catching up on emails			
	Spending time with dog			
	Seeing kids and grandson			
	Bingo with my neighbour			

Table 2.

Coping Strategies

Participant Number	Coping Strategies
1	Nothing at the moment
	Nothing at the moment
	Nothing at the moment
	Nothing at the moment
	Nothing at the moment
2	Using a stool to sit at
	Saving energy and only doing 1 activity per day
	Saving energy and limiting daily activity
	Doing a little at a time/ resting
3	Partner
	Meds Dialudid
	Good diet
	Coaching along
4	Nothing
	Nothing
	Nothing
	Nothing
	Nothing
6	Gabapentin
7	Fentanyl Patch (2) , but not enough
8	Go for walks with a friend who can't walk fast
	Prune, deadhead, pay for a gardener
	Don't go out or go to restaurants where I can get small meals
10	Meds
11	Limit the distance
	Take turns with wife driving
	Enjoy local area
	Take a nap in afternoon
12	Because we only see her occasionally, I tend to do all the things I want to - and then suffer
	Try to schedule
	Sheep skin to go over the seat belt
	Try to walk when I feel Best
13	Rest through the day
	Wait for pain to ease off
14	Using a walking aid
15	I can take morphine cause after I have pain
	A rest helps greatly
	My husband & I babysit together

Table 2. *Coping Strategies* (Continued).

17	Morphine
	Rest/ to nothing
18	Dog begs - push myself
	Nap between reading
	Pills for nausea
19	Using cane
	Husband to help cook + standing
20	Pain & nausea management. Have an attitude of gratefulness for my home
	Having more people over to my place, having the energy to stay in touch
	Help and input from professionals and friends. Seeing a therapist
	Getting stabilized in my physical work
	Being picked up. Flexibility of others
21	Wife and dog encourages him
	Look with corner of eye. Sit close.
	Wife
22	Pain medication. Help from family
23	Ok. For now, Just stop reading if too tired.
	Walker, cane.
	Husband helps me in car
	Walker
	Travel with someone.
25	Medication
	Medication
	Extra sleep & rest
	Sleep & rest & medication
	Medication & rest
26	Do it slower
	Medication. Do it earlier in the day
	Shorter visits. Visit their homes so I can leave when I get tired.
	Earlier in the day, not at midnight. Get more help.
27	Nothing
	Going out for dinner
	Laying on the couch, relaxing
	Energy, relaxing, having Gin on hand. Just don't do it if too much nausea.
	Energy. Just do it - no choice. Ready made, or ordering in, going out.
28	Nothing
	Grin and do it.
	Friends help me work around it
	Own motivation to get out & buy a few things
29	Do other things with her
30	Social/ competitive. Just do it.
	Feel that I will need a cart to start again hopefully in new year

Table 2. *Coping Strategies* (Continued).

31	Nothing so far
	Nothing so far
	Nothing so far
	Nothing so far
	Knowing where bathroom is
32	Helpful family and friends
	Play - music - deep breathing
33	Nothing - maybe supervise
	Rest and then read when I feel better
	Have someone cooking for me
34	Nothing
	Short segments
	Napping
35	Talk on phone or email
	Ask my daughter to help
	Ask others to drive her or she takes the bus
	Nothing
	Nothing
36	Having someone to walk with me
	Nothing
	Nothing. someone else do the cooking
37	Turn off tv and do something else
	Stop. Rest. Wait to remember
	Eating something cold. Yogurt, ice cream.
	Medication. Pain killers
	Rest. Come back. Put record on.
38	Nothing
	Patch, drugs
	Drugs - ativan. Exercise
	Drugs (anti-nausea)
39	(satisfied so no coping)
40	Meds. Rest
	Meds. Rest
	Meds. Go to bed. Rest
	Timing. 10am-2:30pm
41	Learning to write with left hand
	Get driven down to cloverpoint & ocean
	Transportation - family driving me
	Nothing
43	Nothing
	Nothing
	Nothing
44	Nothing
	Nothing

Table 2. *Coping Strategies* (Continued).

45	Nothing
46	Medication -pain. Sleeping pills don't work
	Nothing
	Medication - pain.
	Medication - pain. Finding the balance.
47	Good murder mystery
	Nothing
	Rest
	I want to. Weather is good. Satistfies restlessness
48	Enjoy it and dog pushes
	Someone driving. Holidays are easier. Coffee/latte/cappichino
	Coffee/latte/capp. Sleep in and go to later class
	Don't go long distances
	Close games
49	Nothing for long distances. walk shorther distances [until bounces back from chemotherapy]
50	Rest a bit and then continue
	Boredom - pick it up and do a row or 1/2 a row
	Frustrated and depressed to go out
	Nothing
51	Nothing - keep the beat with my upper body
	Nothing
52	Opportunity to come across one.
	Their willingness to spend time with me. Determination. Putting them first.
	Nothing
	Determination.
53	Stay on flat ground and walk slow and shorter distances.
	Pain pills (not that helpful). Limiting reading.
	Sit in chair and be in the garden.
	Someone else deals and shuffles. Increase pain killers.
	Take pain killers
	Pain killers and meditate
54	Alertness to be able to drive to the pool
	Nothing
	Push myself. Determination.
	Answer a few messages and get back to it.
	Suggestion for cooking from partner. Encouragement.
	Pureed food.
55	Family comes to see me.
	Nothing

Table 2. *Coping Strategies* (Continued).

56	If it's a good book - interesting read. If feeling comfortable -decreased anxiety.
	Knowing that I can control how long I'm out for. ride home arranged.
	Someone else there to work it or Watch with her.
	If feeling comfortable
57	Nothing. Not participating
	Nothing.
	Watch for short periods of time
	Short periods of time
58	Neighbour phones & drives. Don't go if pain & tired
	Nothing
	Feeling good. Nothing if feeling pain & tired
59	Walker to walk. No hiking.
	Sit up. Don't read in bed.
	Nothing
	Nothing
	Nothing
60	Just do it.
	Work through the pain
	Put your mind to it and do it

Table 3.

Symptoms that Interfered (most often) with More than One Activity

Symptoms interfering with 5 activities (5 patients)	Symptoms interfering with 4 activities (11 patients)	Symptoms interfering with 3 activities (15 patients)	Symptoms interfering with 2 activities (32 patients)	Symptoms interfering with 1 activity (44 patients)
Pain (4)	Pain (5)	Pain (5)	Pain (14)	Mobility issues (12)
Tiredness (2)	Tiredness (5)	Tiredness (14)	Tiredness (14)	Psychosocial/emotional issues (11)
Gastrointestinal functioning (1)	Stamina (1)	Discomfort (2)	Mobility issues (6)	Pain (11)
	Mobility issues (1)	Mobility issues (3)	Psychosocial/ emotional issues (4)	Tiredness (10)
		Gastrointestinal functioning (2)	Mental functioning (3)	Gastrointestinal functioning (9)
		Drowsiness (1)	Stamina (3)	Strength (7)
		Strength (1)	Strength (2)	Mental functioning (7)
		Problem with part of body (1)	Drowsiness (2)	Nausea (5)
			Nausea (1)	Eye symptoms (4)
			Eye symptoms (1)	Stamina (4)
			Problem with part of body (2)	Drowsiness (4)
				Shortness of breath (3)
				Comfort (2)
				Other symptoms (5)

Table 4.

Two or More Symptoms that Interfered with One Activity

Two symptoms interfering with one activity	Three symptoms interfering with one activity	Four symptoms interfering with one activity
Pain, tiredness (25)	Pain, tiredness, mental functioning (2)	Tiredness, nausea, mental functioning, psychosocial/emotional issues
Pain, gastrointestinal functioning (9)	Pain, tiredness, stamina	Pain, tiredness, nausea, mobility issues
Pain, mobility issues (5)	Pain, tiredness, gastrointestinal functioning	
Tiredness, drowsiness (4)	Pain, tiredness, psychosocial/emotional issues	
Pain, stamina (3)	Pain, tiredness, S.O.B.	
Eye symptoms, tiredness (3)	Pain, tiredness, nausea	
Pain, strength (2)	Pain, nausea, mental functioning	
Pain, comfort (2)	Pain, strength, stamina	
Tiredness, mobility issues (2)	Pain, stamina, gastrointestinal issues	
Tiredness, psychosocial/emotional issues (2)	Pain, strength, mobility issues	
Tiredness, mental functioning (2)	Tiredness, strength, stamina	
Pain, mental functioning	Tiredness, stamina, psychosocial/emotional issues	
Pain, psychosocial/emotional issues	Tiredness, discomfort, strength	
Pain, other (tendency to Stay awake)	Tiredness, stamina, gastrointestinal issues	
Tiredness, discomfort	Drowsiness, mental functioning, psychosocial/emotional issues	
Drowsiness, mental functioning	Drowsiness, strength, stamina	
S.O.B, mobility issues	Strength, stamina, gastrointestinal issues	
S.O.B, strength		
Stamina, psychosocial/emotional issues		
Stamina, psychosocial/emotional issues		
Eye symptoms, other (hearing)		

Table 5.

Symptoms Unique to the P-CASA categorized

Physical mobility**:** (28 entries; 18 patients experienced this symptom)

Getting around with walker
Not enough control over motor movements
Can't get down for periods of time to do weeding. Can do pruning, etc.
Restricted mobility of leg where I had surgery
Leg bending limit
Posture
Mobility issues
Can't lift grandchild. Instructed not to lift more than 8lbs because will throw back out
Shoulder but hope to be back soon
I can't stand up for any period of time
The thought of walking up and down stairs makes me opt out sometimes
Sitting
Loss of function of right hand. [Using] left hand
Wheelchair
Wheelchair limits where I go
Not possible [because of] hand
Sitting
Standing
Moving
No balance
Too slow physically [because of] health issues
Hard to get a hold of one grandchild
Can't sit at computer. Stiffness to sit a long time at the computer.
Bending neck is uncomfortable
Equilibrium poor because drugs
Hard time sitting for that length of time
Getting in and out of the car is difficult

Stamina: (11entries; 8 patients experienced this symptom)

Can't keep up with friends
Not enough stamina to go far
Can't walk 9 holes
Not as able to walk any great distances
Stamina
2 hours is my limit. They [Grandchildren] are very active
Can't walk for long [because] stamina isn't there
Endurance
Not as much endurance
Can't walk as long

Table 5. *Symptoms Unique to the P-CASA categorized* (continued)

Strength: (11 entries; 10 patients experienced this symptom)

Weakness
No strength
Strength
Can't walk very far because of strength in legs
Lack of strength
Too weak
Strength
Can't walk for long [because] strength isn't there
Can't stand long enough [because of] weakness
Weakness in the legs
Light-headed [because] weak
Not walking as far

Physical comfort: (5 entries; 4 patients experienced these symptoms)

Physical discomfort sitting there
Discomfort
The seat belt is really bothering my chest
Feel too physically overwhelmed
Can't get into a comfortable position
No comfortable position

Emotional/psychosocial issues: (18 entries, 13 patients experienced these symptoms)

Distress
Not feeling well enough to see others
Not feeling up to it
Not feeling as confident
Lack of ambition
Motivation
Mind busy with what normally would do now
Lack of motivation
Bored
Lack of motivation
Not interested
Lost interest
Not interested
Not interested
Haven't done one for a long time. Preoccupied with health issues.
Irritability
Too frustrated to go out
Get nervous going out, but getting better

Table 5. *Symptoms Unique to the P-CASA categorized* (continued)

Gastrointestinal functioning (15 entries, 10 patients experienced these symptoms)

Bowel problems
Very restricted diet
Bowel problems
Bowel distress
Bowel problems
Bowel symptoms
Don't feel I can keep appointments [because of] bowel problems
Tastes different
Bloating
[Can’t] leave house [because of] bowel troubles
[Can’t] socialize when eating [because of] bowel
Tummy troubles
Bowel
Doesn’t taste good
Catheterized because of urinary retention possibly from the drugs

Mental functioning (15 entries; 8 patients experienced these symptoms)

Concentration
Unable to concentrate
Inability to concentrate
Takes organization
Lack of concentration
Concentration
Lack of concentration
Hard to focus
Cannot concentrate
Cannot concentrate
Takes a long time to write. forget things
Mind wandering
Lack of concentration
Tv is hard to figure out
Lack of concentration

Eye symptoms (6 entries; 5 patients experienced these symptoms)

Eye sight
Vision going downhill
Eyes blur
Hard to see
Eye strain
Glaucoma in one eye

Table 5. *Symptoms Unique to the P-CASA categorized* (continued)

Other symptoms (5 entries; 5 patients experienced other symptoms)

- Hearing going downhill
- Unable to drive for 6 months [because of] seizures
- Prednisone increases restlessness
- Tendency to stay awake
- Old injuries

Table 6.

ESAS symptoms with Additional Information

Participant	ESAS Symptoms with Additional Information
1	Sore back
3	{Energy} The amount of prep
7	Discomfort in stomach/back area [because of] pain
11	Can't travel very far due to pain
	Can't travel very far due to tiredness
	Cannot continue activities beyond the mid-afternoon due to tiredness
	Leg knots
	Leg cramps
12	Can only actively play for short time [because] "tired out"
	Cannot pick her up. chest pain.
	Need to have "set time" so not to be too tired
	Need to have "set time" so not to be Dozee
14	Pain [because of] posture
15	1.5 hours then I should stop. Tiredness
	1.5 hours then I should stop. Backache.
	Too tired to clean up
18	Glasses hurt stitches on head
19	Pain when standing
	Eyes become tired
23	Tiredness sometimes interferes but mostly ok
	Unable to walk even small distances without pain
25	Constantly nausea
	Sore muscles
26	Tired. I want to last longer.
	Not as much energy
30	Light-headed [because of] breath
32	Too tired to enjoy talking
35	Don't feel I can keep appointments. Pain.
36	Back too sore
	Tired. Like to walk further.
37	Pain keeps me awake
	Takes too long to write. hand hurts
38	[Can’t] leave house [because of] pain
	[Can’t] socialize when eating [because of] pain
43	Sitting up pain
47	Not too long [because of] tired.
	Fatigued quickly

Table 6. *Additional information that patients' provided about their ESAS symptoms* (Continued)

48	Not walking as far and as long [because of] pain.
	It [walking] causes pain. Not long enough to get heart rate up.
	It [walking] causes pain. Not hard enough to get heart rate up.
	Can attend close [hockey games], not far ones [because of] Tired and long day and drive
49	Fatigue [caused by] chemotherapy
50	Too depressed to go out
	Doesn't sit on bike [because] pelvis too sore
52	Mostly satisfied. Sometimes fall asleep
	Can't sit at computer. Pain to sit a long time at the computer.
	Pain returns easily
53	Pain. more I walk, the worse it gets
	Spasm up back. More I walk the worse it gets.
	More I sit, the worse the spasm gets
	More I use arm, the worse the spasm gets
	Comfortable level decreased [because of] pain
	Disrupted [sleep because of] pain
54	Equilibrium poor because pain
	Drowsiness from pain medication
	[Cooking]1 big meal. Needs more planning. Drowsiness
	[Cooking]1 big meal. Needs more planning. Tired.
	No sharp objects. Drowsiness.
	No sharp objects. Tired.
	Can't swallow it [because] burns esophagus
55	Can't sit because of pain
56	Uncomfortable [because of] anxiety
58	Not able to drive if feeling pain
	Not able to drive if feeling tiredness
59	Can't stand long enough because pain from surgery
	Amount of time it takes to get ready to swim tires me out
	Can't walk for long. Too sleepy from the drugs.
	Start reading and fall asleep
	No energy to swim
60	Can't go on roof or climb trees. pain in feet and hands.
	Can only work for 4 hrs max. Causes me anxiety.
	Energy level goes down too quickly.

Table 7:

ESAS Symptoms with Additional Information Categorized

When it happens

- Cannot continue activities beyond the mid-afternoon due to tiredness
- 1.5 hours then I should stop [painting portraits and landscapes] Tiredness
- 1.5 hours then I should stop [painting portraits and landscapes] Backache
- Pain. more I walk, the worse it gets
- Spasm up back. More I walk the worse it gets.
- More I sit, the worse the spasm gets
- More I use arm, the worse the spasm gets

Where it is located

- Leg knots
- Leg cramps
- Sore back
- Chest pain
- Backache
- Glasses hurt stitches on head
- Back too sore
- Hand hurts
- Pain in feet and hands

Physical disturbances it causes

- Pain [because of] posture
- Pain when standing
- Eyes become tired
- Unable to walk even small distances without pain
- Cannot pick her up. Chest pain.
- Pain keeps me awake
- Sitting up pain
- Doesn't sit on bike [because] pelvis too sore
- Can't sit at computer. Pain to sit a long time at the computer.
- Comfortable level decreased [because of] pain
- Can't sit because of pain
- Can't swallow [food because] burns/cuts/scratches esophegus
- Takes too long to write. Hand hurts.

Table 7: *ESAS Symptoms with Additional Information Categorized* (Continued)

Duration or intensity

Tiredness sometimes interferes but mostly ok
Constantly nausea
Not too long [because of] tired.
Fatigued quickly
Too depressed to go out
Mostly satisfied. Sometimes fall asleep
Pain returns easily
Amount of time it takes to get ready to swim tires me out
Not as much energy
Tired. I want to last longer.
Start reading and fall asleep
Energy level goes down too quickly.
Tired. Like to walk further.

How it disrupts their activities

The amount of prep [to go camping takes] energy
Too tired to clean up
Can't travel very far due to pain
Can't travel very far due to tiredness
Can only actively play for short time [because] "tired out"
Too tired to enjoy talking
[Can’t] leave house [because of] pain
[Can’t] socialize when eating [because of] pain
Not walking as far and as long [because of] pain.
It [walking] causes pain. Not long enough to get heart rate up.
It [walking] causes pain. Not hard enough to get heart rate up.
[Can’t use] sharp objects [used for cooking because of] Drowsiness.
[Can’t use] sharp objects [used for cooking because of] Tired.
Not able to drive if feeling pain
Not able to drive if feeling tiredness
Need to have "set time" [to interact with friends and family] so not to be too tired
Need to have "set time" [to interact with friends and family] so not to be Dozee
Don't feel I can keep appointments [to see friends and family because of] Pain.
Can attend close [hockey games] not far ones [because of] Tired and long day and drive
No energy to swim
Can't go on roof or climb trees [because of] pain in feet and hands.
Causes me anxiety [because] can only work for 4 hrs max.
[Cooking]1 big meal. Needs more planning. Drowsiness
[Cooking]1 big meal. Needs more planning. Tired.

Table 7: *ESAS Symptoms with Additional Information Categorized* (Continued)

Other symptoms it causes

Shortness of Breath causes light-headedness
Light-headed [because of] breath
Pain causes discomfort in stomach/back area
Discomfort in stomach/back area [because of] pain
Pain causes poor equilibrium
Equilibrium poor because pain
Anxiety cause her to be uncomfortable
Uncomfortable [because of] anxiety

Treatments that caused them

Fatigue [caused by] chemotherapy
Drowsiness from pain medication
Can't stand long enough because pain from surgery
Can't walk for long. Too sleepy from the drugs.

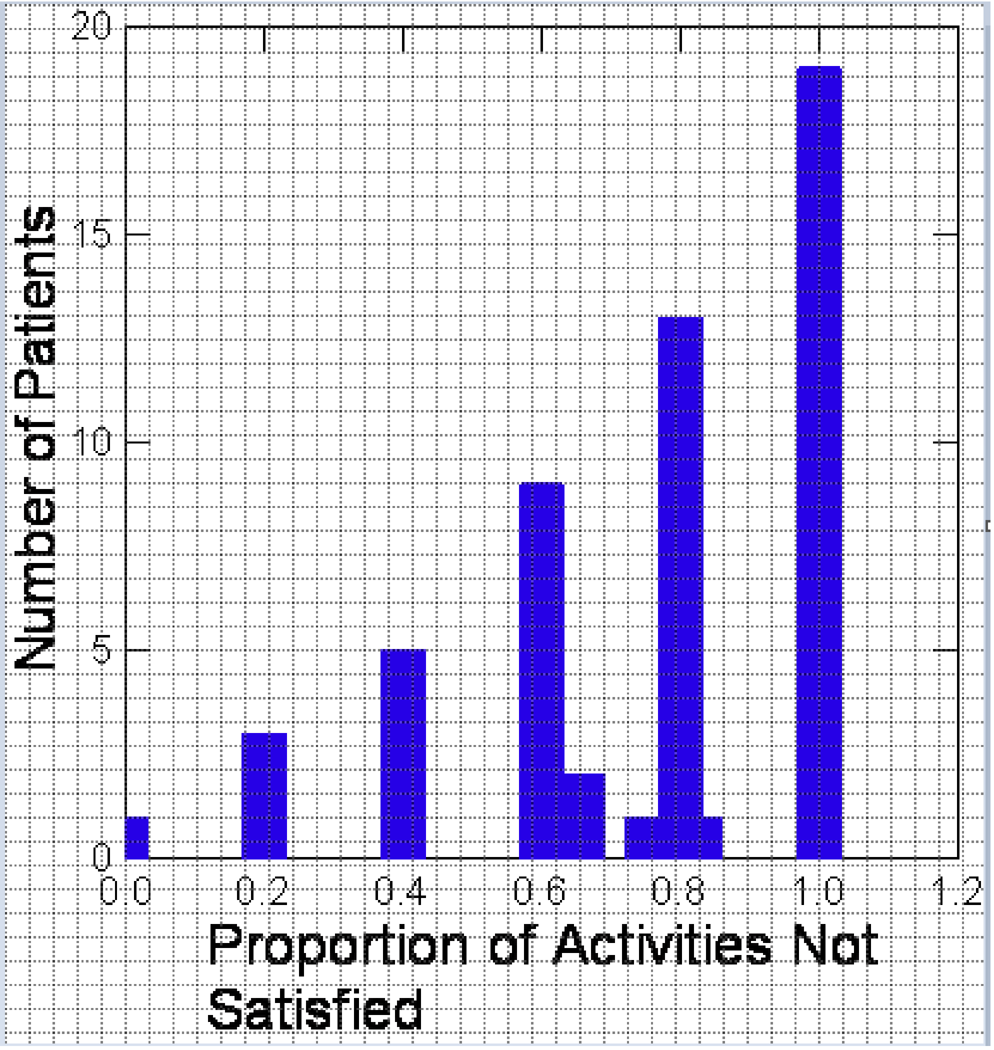


Figure 1. Proportion of activities participants are not satisfied with.

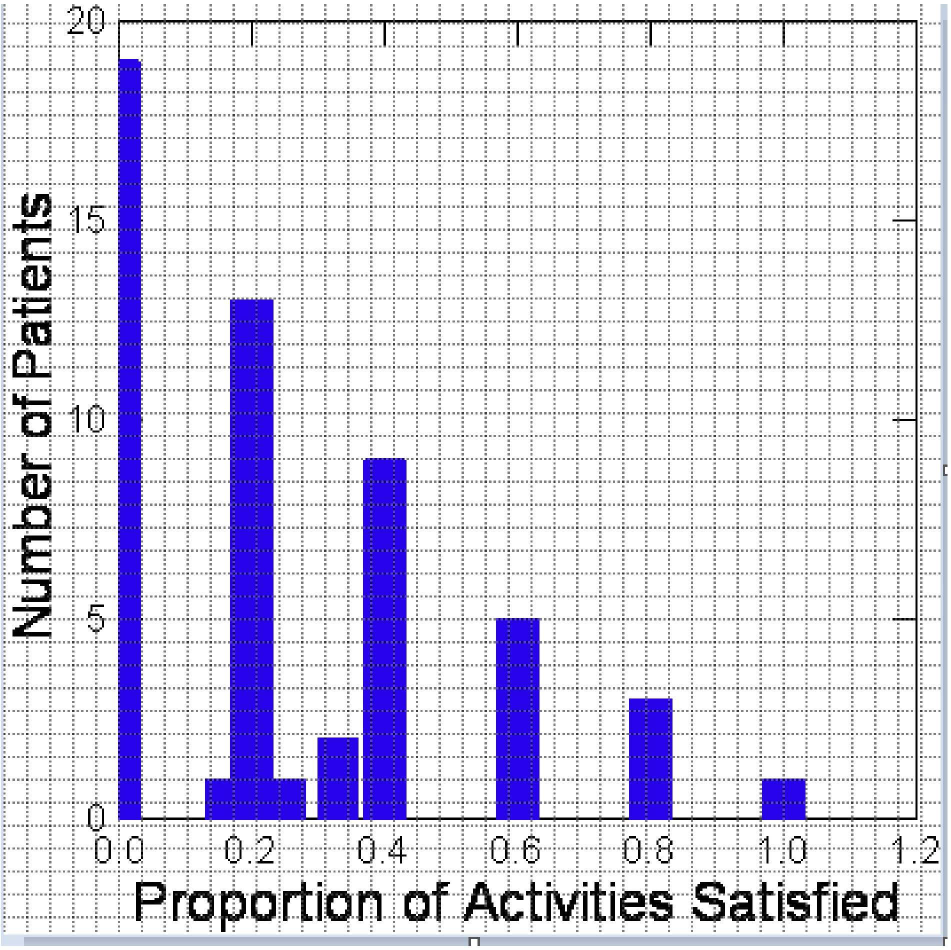


Figure 2. Proportion of activities participants are satisfied with.

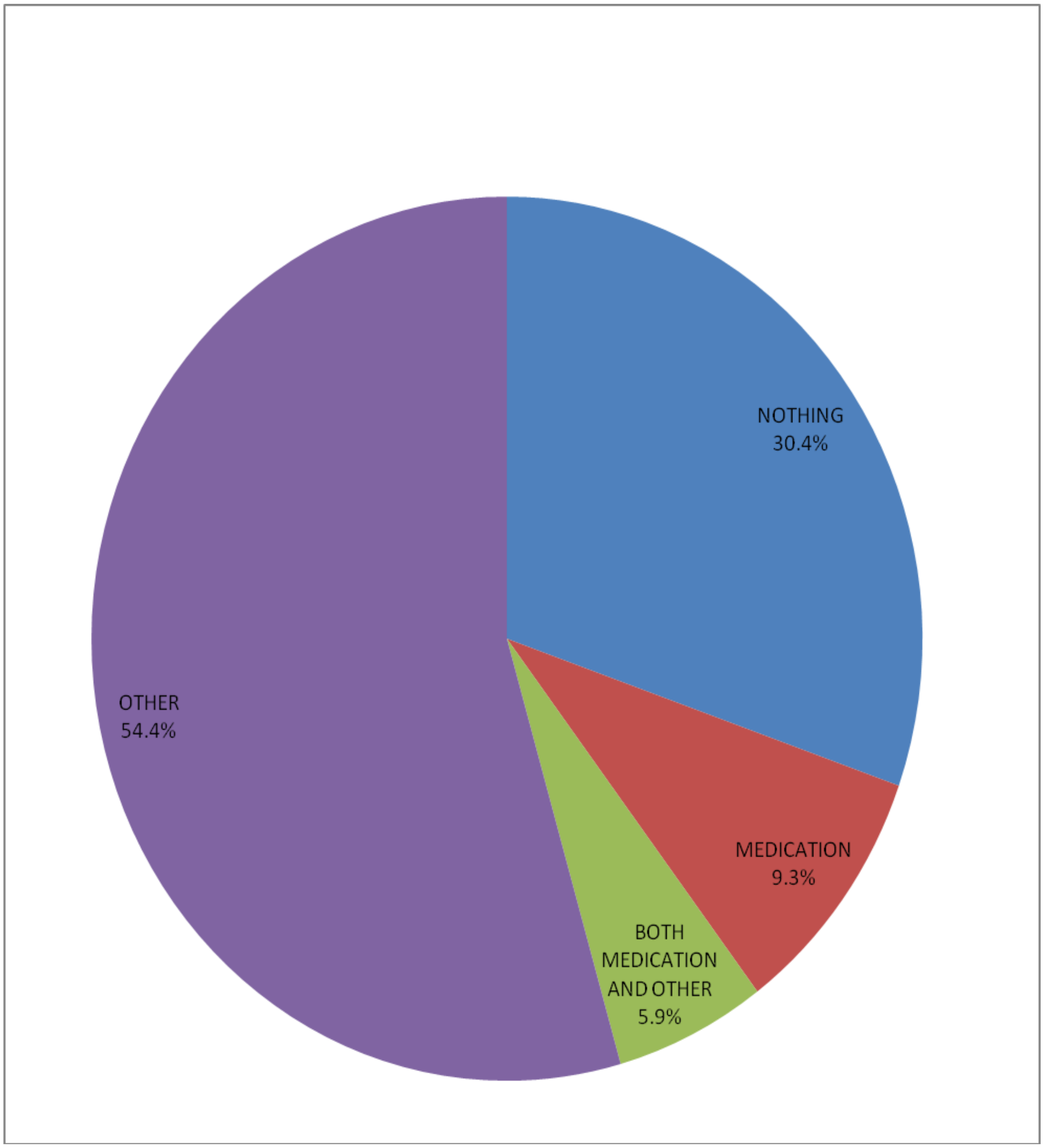


Figure 3. Proportion of participants' coping strategies.

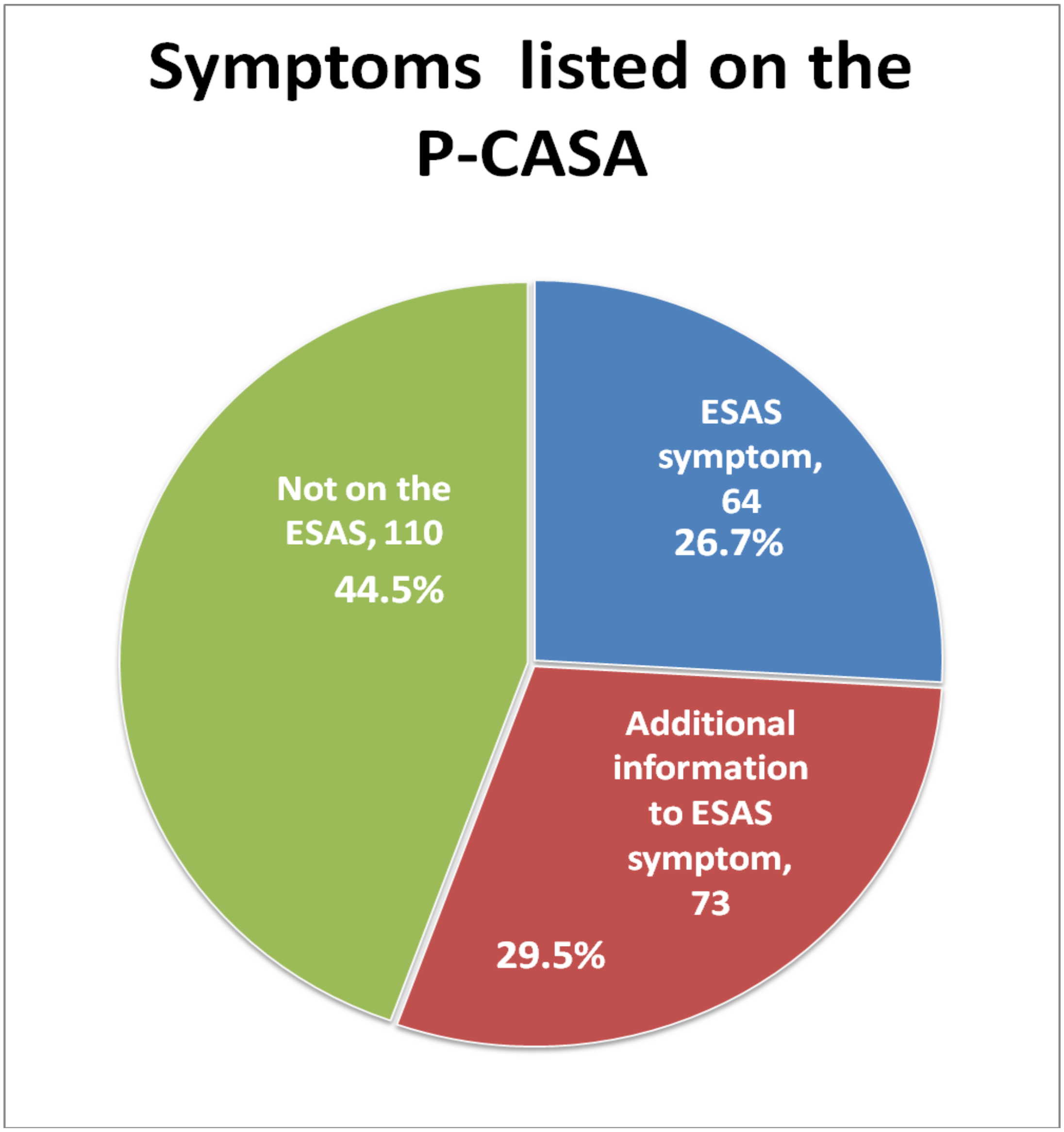


Figure 4. Symptoms listed on the P-CASA.

Number of Activities listed on the P-CASA that the ESAS symptom interfered with (0-5)

5					1		1		1						2		1				
4					1						1		2		1	1	2				
3		1							2		3				2		2				
2			1		2	1	2		4		1		7		4		3		2		2
1	1		2		4		3		2		7		3		6		6		2		1
0																					
	0	**0.5**	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**5.5**	**6**	**6.5**	**7**	**7.5**	**8**	**8.5**	**9**	**9.5**	**10**

ESAS Symptom Ratings (0-10)

Figure 5. The ESAS Symptom Ratings and Number of Activities the ESAS symptoms interfered with. Note: The number in the scatter diagram indicates the number of instances that it occurred. For example, there were 4 instances that for an ESAS rating of 2, the ESAS symptom interfered with 1 important activity.

Number of Activities the highest ESAS ratings interfered with (0-5)

5															2		1				
4											1		1		1	1	3				
3															1		2				
2									1				2		3		2				2
1					1						2		1		3		4		3		1
0					2				6		7		4		5		11		2		1
	0	**0.5**	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**5.5**	**6**	**6.5**	**7**	**7.5**	**8**	**8.5**	**9**	**9.5**	**10**

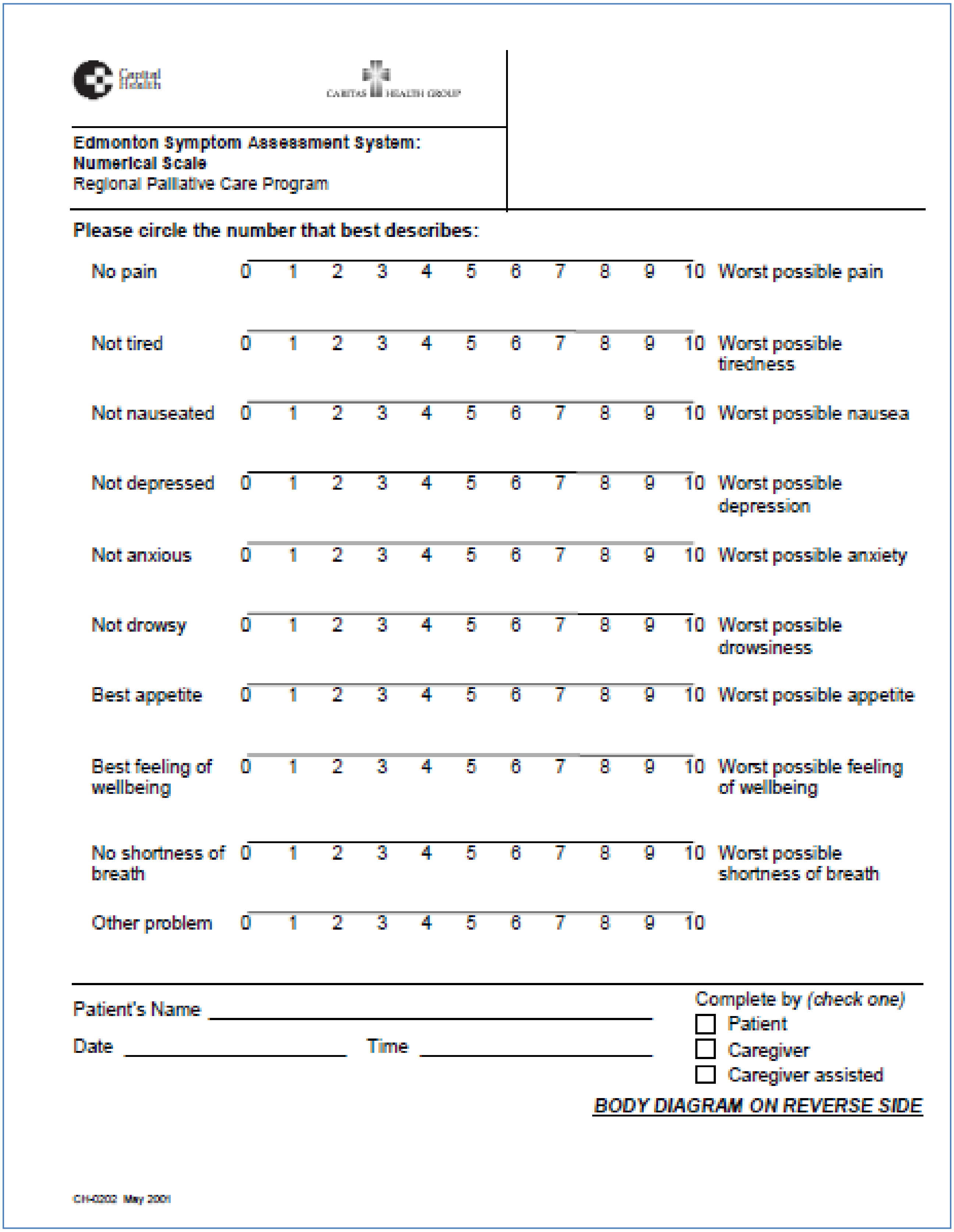
Participants’ Highest ESAS Symptom Ratings (0-10)

Figure 6. The highest ESAS Symptom Ratings that interfered with activities listed on P-CASA and not listed on the P-CASA. Note: The number in the scatter diagram indicates the number of instances that it occurred. For example, there were 11 instances that the highest ESAS rating of 8 did not interfere with any (0) important activities.

APPENDICES

Appendix A.1

Edmonton Symptom Assessment Symptom (ESAS) Form



Capital Health

CARITAS HEALTH GROUP

Edmonton Symptom Assessment System:
Numerical Scale
Regional Palliative Care Program

Please circle the number that best describes:

No pain	0	1	2	3	4	5	6	7	8	9	10	Worst possible pain
Not tired	0	1	2	3	4	5	6	7	8	9	10	Worst possible tiredness
Not nauseated	0	1	2	3	4	5	6	7	8	9	10	Worst possible nausea
Not depressed	0	1	2	3	4	5	6	7	8	9	10	Worst possible depression
Not anxious	0	1	2	3	4	5	6	7	8	9	10	Worst possible anxiety
Not drowsy	0	1	2	3	4	5	6	7	8	9	10	Worst possible drowsiness
Best appetite	0	1	2	3	4	5	6	7	8	9	10	Worst possible appetite
Best feeling of wellbeing	0	1	2	3	4	5	6	7	8	9	10	Worst possible feeling of wellbeing
No shortness of breath	0	1	2	3	4	5	6	7	8	9	10	Worst possible shortness of breath
Other problem	0	1	2	3	4	5	6	7	8	9	10	

Patient's Name ______________________________

Date ________________ Time ________________

Complete by *(check one)*
☐ Patient
☐ Caregiver
☐ Caregiver assisted

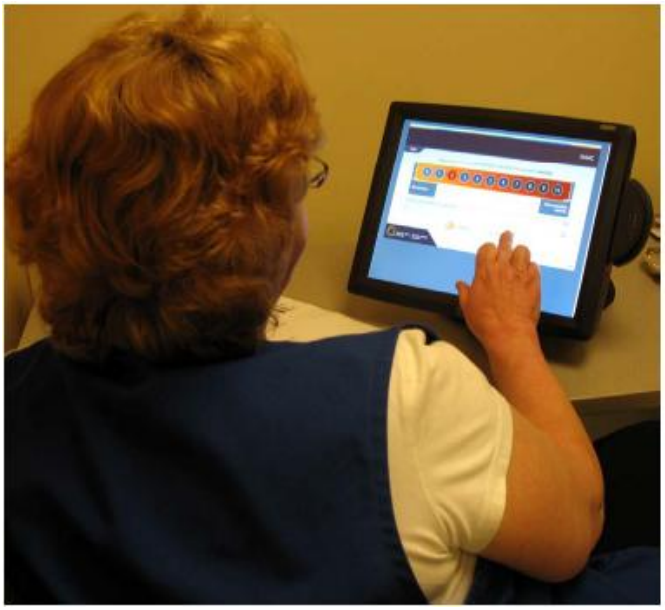
BODY DIAGRAM ON REVERSE SIDE

CH-0202 May 2001

Appendix A.2

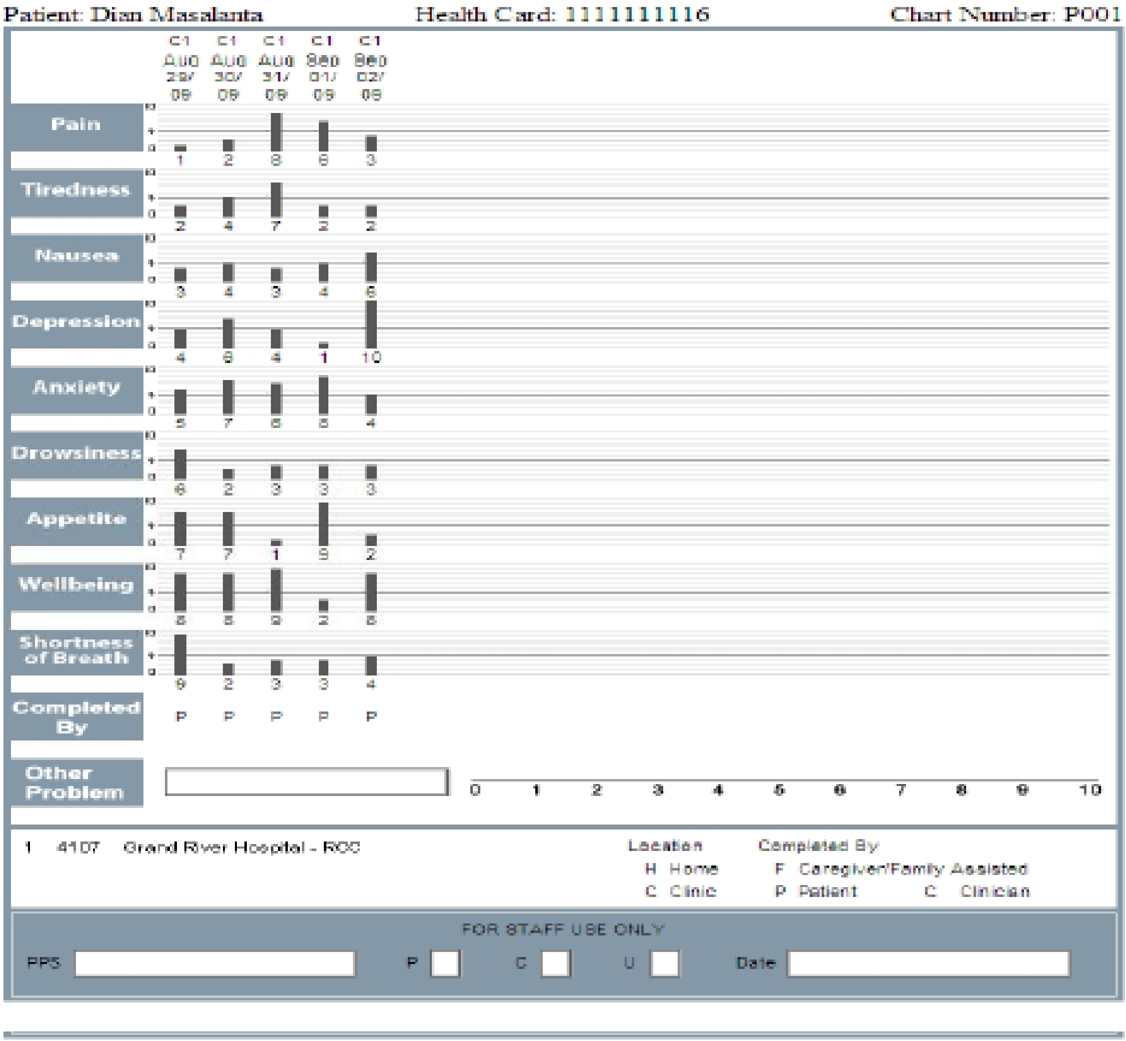
Interactive Symptom Assessment and Collection (ISAAC) ESAS Kiosk

Please select the number that best describes the symptom **pain**



Appendix A.3

ISAAC ESAS Kiosk Histogram



Patient: Dian Masalanta   Health Card: 1111111116   Chart Number: P001

	C1 Aug 29/ 09	C1 Aug 30/ 09	C1 Aug 31/ 09	C1 Sep 01/ 09	C1 Sep 02/ 09
Pain	1	2	8	6	3
Tiredness	2	4	7	2	2
Nausea	3	4	3	4	6
Depression	4	6	4	1	10
Anxiety	5	7	6	8	4
Drowsiness	6	2	3	3	3
Appetite	7	7	1	9	2
Wellbeing	8	8	9	2	8
Shortness of Breath	9	2	3	3	4
Completed By	P	P	P	P	P

Other Problem

1   4107   Grand River Hospital - ROC

Location
H Home
C Clinic

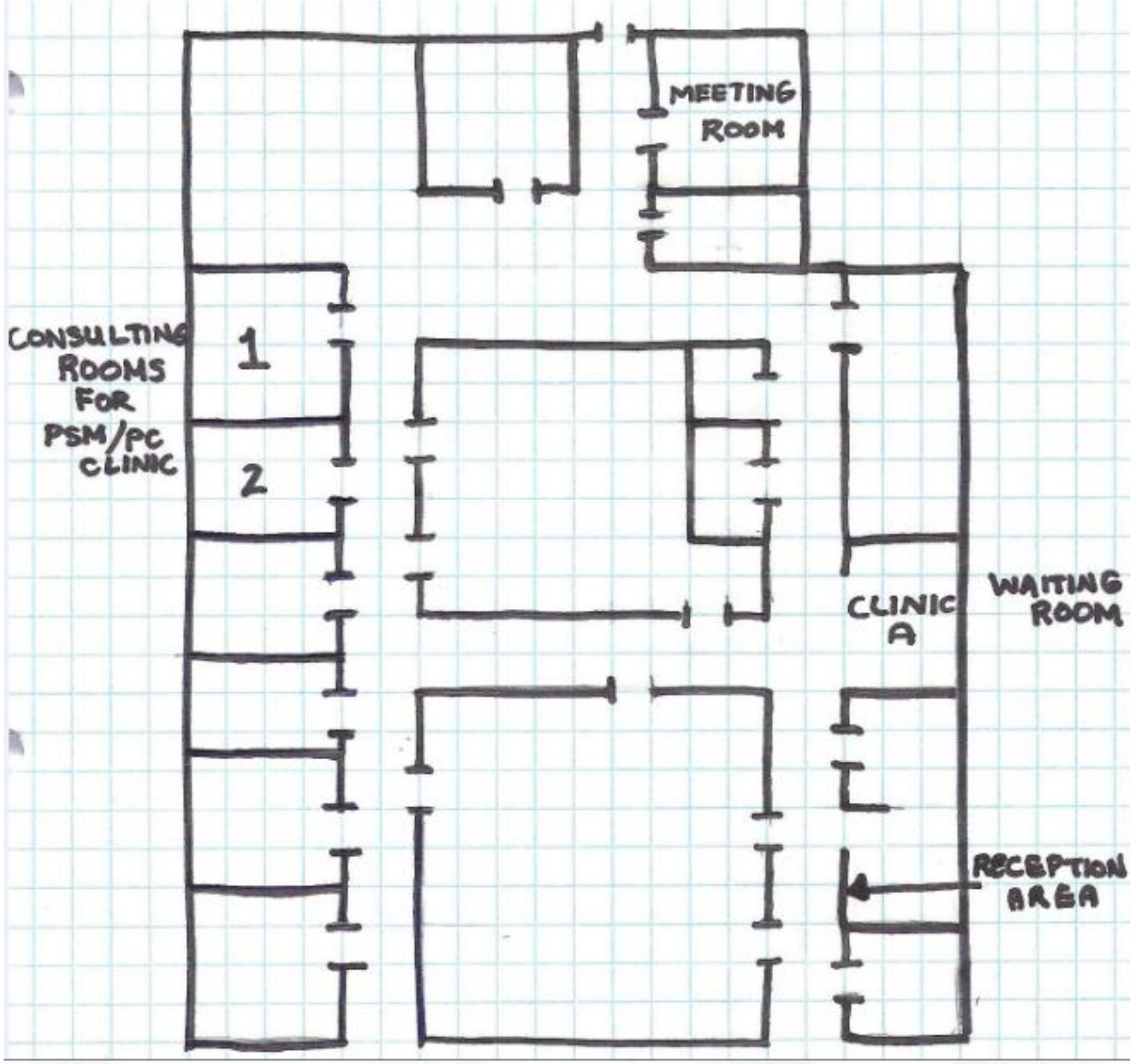
Completed By
F Caregiver/Family Assisted
P Patient   C Clinician

FOR STAFF USE ONLY

PPS   P   C   U   Date

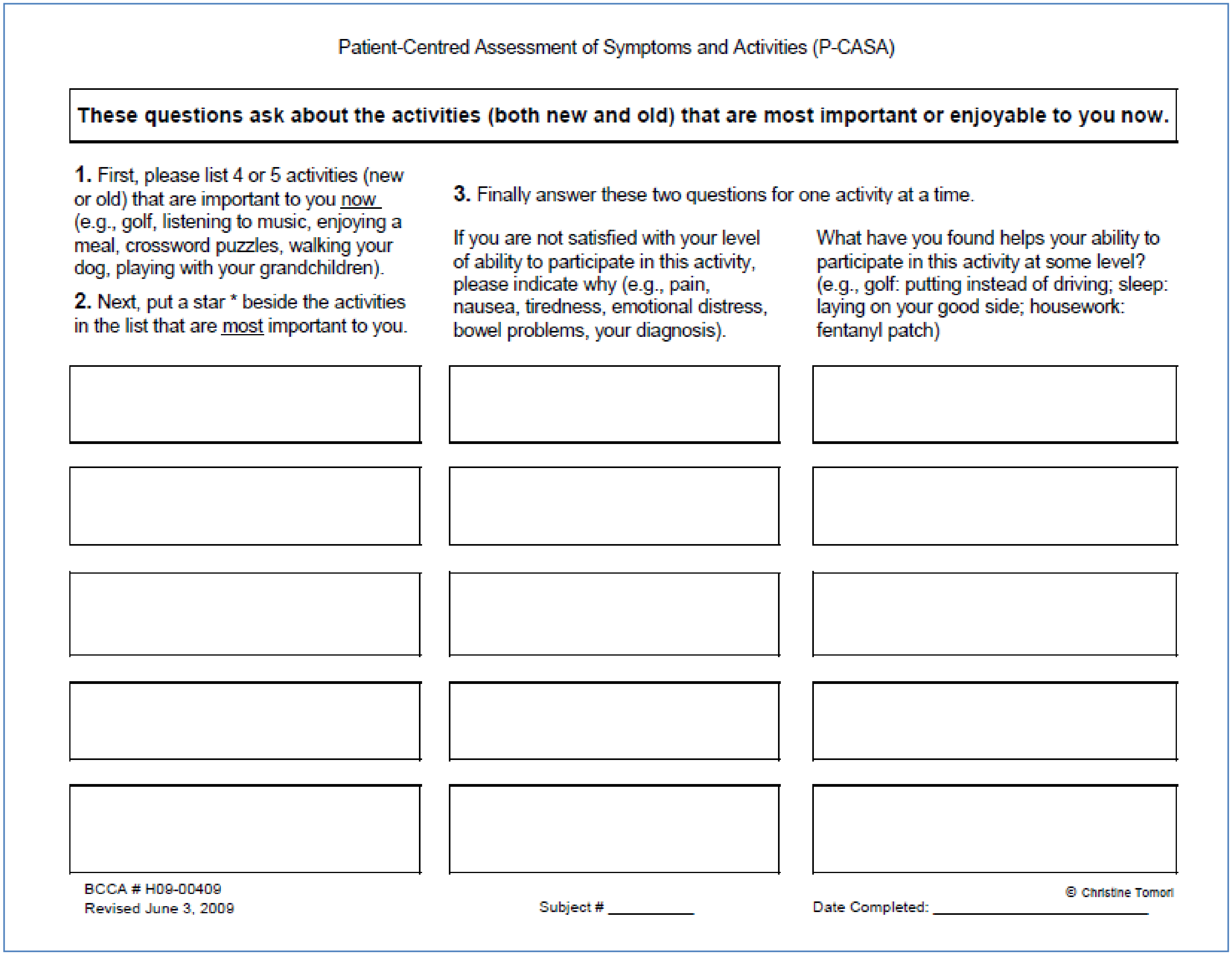
Appendix B

Pain and Symptom Management/Palliative Care Clinic Floor Plan



Appendix C.1

Patient-Centered Assessment of Symptoms and Activities (P-CASA) Form



Patient-Centred Assessment of Symptoms and Activities (P-CASA)

These questions ask about the activities (both new and old) that are most important or enjoyable to you now.

1. First, please list 4 or 5 activities (new or old) that are important to you now (e.g., golf, listening to music, enjoying a meal, crossword puzzles, walking your dog, playing with your grandchildren).

2. Next, put a star * beside the activities in the list that are most important to you.

3. Finally answer these two questions for one activity at a time.

If you are not satisfied with your level of ability to participate in this activity, please indicate why (e.g., pain, nausea, tiredness, emotional distress, bowel problems, your diagnosis).

What have you found helps your ability to participate in this activity at some level? (e.g., golf: putting instead of driving; sleep: laying on your good side; housework: fentanyl patch)

BCCA # H09-00409
Revised June 3, 2009

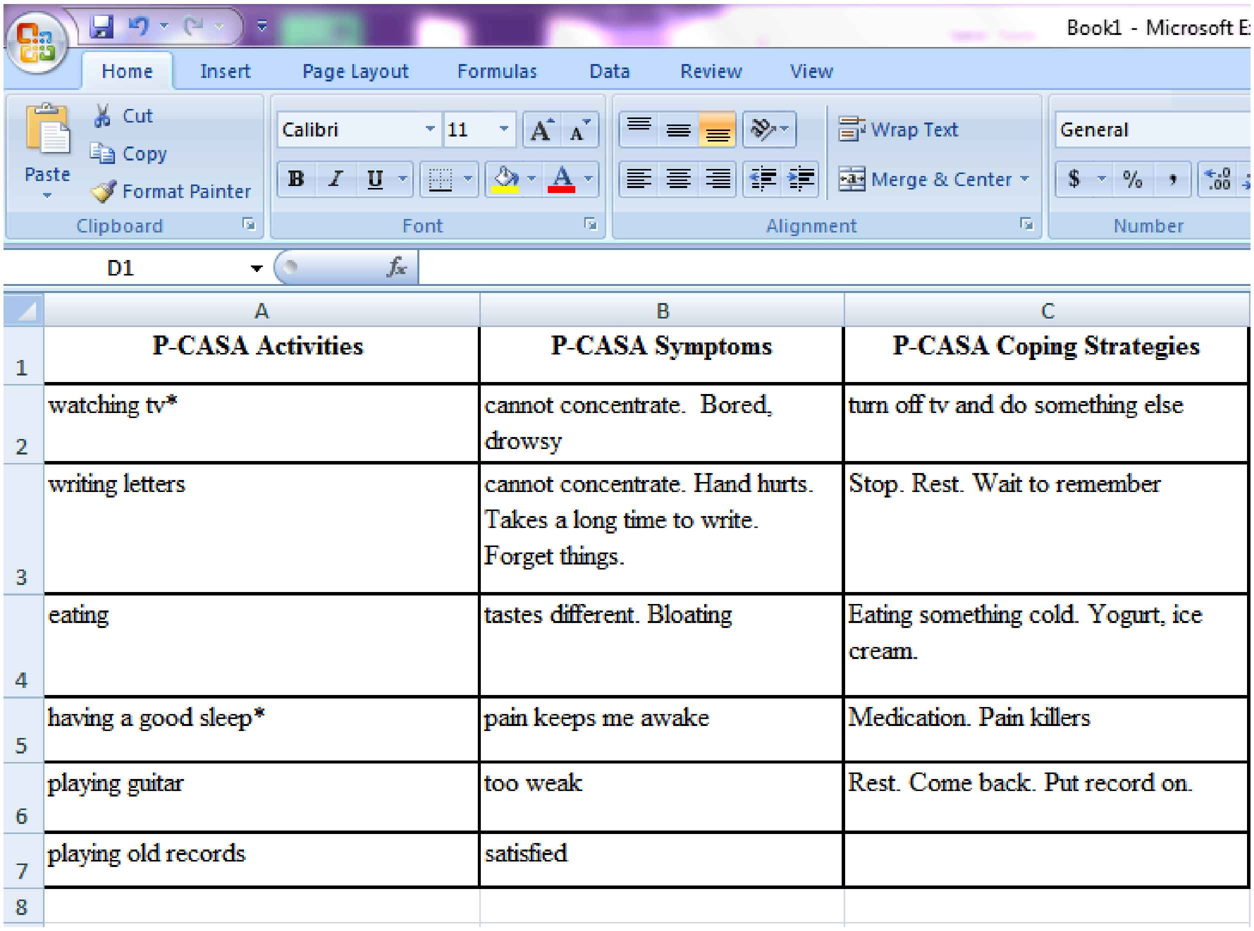
Subject # ___________

© Christine Tomori

Date Completed: ___________________________

Appendix C.2

P-CASA Responses in Excel Spreadsheet



	A	B	C
1	**P-CASA Activities**	**P-CASA Symptoms**	**P-CASA Coping Strategies**
2	watching tv*	cannot concentrate. Bored, drowsy	turn off tv and do something else
3	writing letters	cannot concentrate. Hand hurts. Takes a long time to write. Forget things.	Stop. Rest. Wait to remember
4	eating	tastes different. Bloating	Eating something cold. Yogurt, ice cream.
5	having a good sleep*	pain keeps me awake	Medication. Pain killers
6	playing guitar	too weak	Rest. Come back. Put record on.
7	playing old records	satisfied	
8			

Appendix D

Ethics

Note: We originally named the assessment as the Victoria Inventory of Symptoms and Activities (VISA), therefore, the original recruitment script and consent form refers to the assessment as VISA.

Appendix D.1

Recruitment Script

Hello, my name is (Christine Tomori/insert name) and I am a (researcher/volunteer) at the BCCA. Today I am handing out questionnaire for (my) study (by Christine Tomori). You might recognize (me/her name) because she has been doing a practicum here at the BCCA for some time. (I/She) generally sit(s) in the pain clinic and observes. (This/her) study aims to make a connection between the pain and symptom ratings, or numbers, on our Edmonton System Assessment System (ESAS) form (show form) to what they actually mean when it comes to activities in patients' lives. Your participation in this study involves reading and signing a consent form to indicate that you volunteer to participate and filling out a new study questionnaire which is being tested called the Victoria Inventory of Symptoms and Activities (VISA) form that aims to make this connection. The consent form is also to give permission for the researcher (me) to look at your medical chart and your ESAS form for this study.

Please take your time to read this consent form and the questionnaire (hand to patient) and if you decide to participate in the study, please sign it and complete the questionnaire (VISA). If you not sure whether or not you would like to participate in the study, you may take the documents home to read. When you return to the Pain and Symptom Management Clinic for your next appointment, you can then decide if you would like to participate in the study. Whether or not you choose to participate in this study will not affect your treatment at the Pain and Symptom Management Clinic in any way.

If patient decides to participate:
Once you have filled out the ESAS form, then I am going to take it from you and give you time to read the consent form for the study and the study VISA questionnaire to fill out (show form). When you have filled out the VISA, then I will come back, take that form off your hands, and then you will be finished. Do you have any questions? (If yes, answer them. If no, continue)

If you have any questions while you are filling out the forms, please do not hesitate to ask me. And if you decide half way through filling out the VISA that you do not want to continue, we will destroy your form with no questions asked.

Thanks for considering to participate. Thank you.

Appendix D.2

Consent Form

University of Victoria

BC Cancer Agency
CARE & RESEARCH

Subject Information and Consent Form

Victoria Inventory of Symptoms and Activities (VISA)

BCCA Principal Investigator:	Dr. Grant MacLean
Vancouver Island Centre:	Telephone: (250) 519-5572

Sponsor(s): A Canadian Institute for Health research New Emerging Team (CIHR-NET) grant and a Sara Spencer Award from the University of Victoria.

Background

We are asking you to volunteer to participate in this study because pain and other cancer-related symptoms are personal experiences that you have. Pain and symptoms are often measured by questionnaires that ask you to rate your symptoms on a scale from zero to ten, where zero is no experience of the symptom and ten is the worst possible experience of the symptom. A form that uses these types of ratings is the Edmonton Symptom Assessment System (ESAS). The Pain and Symptom Management (PSM) clinic uses the ESAS, so you may have already experienced rating your symptoms in this way. You are the only person who can explain how your numerical pain and symptom ratings effect your ability to take part in activities that are important to you, which is the aim of this study. If this study is successful, then this information could be gathered routintely, in order to help health care providers provide the best treatment options for future patients.

Purpose

The main purpose of this study is to test a questionniare form that gathers information about activities that are important to you and how these activities are effected by pain and other cancer-related symptoms that you may experience. The questionnaire form being tested is called the Victoria Inventory of Symptoms and Activities (VISA). We are going to compare the VISA to another questionniare that measures the pain and other cancer related symptoms called the Edmonton Symptom Assessment System (ESAS) which is routinely filled out at the PSM clinic. We would like to find out if the ESAS form is collecting all of the necessary information in order to make the best treatment decisions. For example, suppose a patient's rating of nausea on the ESAS is only moderate, but they report on the new VISA form that this level of nausea interferes with most of their favourite activities. This research is important because it makes a connection between the numerical pain and symptom ratings to what these levels actually mean in an individual patient's life (i.e., important activities). The secondary purpose of this study is to determine if the information that the VISA gathers already exists within patients' charts. This will help the researchers to determine whether the information the VISA collects is already being gathered by health care providers or not.

If you agree to participate in this study, you will be consenting to the researcher having access to your medical chart, including your current and previously completed ESAS forms.

Benefits and Risks

The benefits of participation in this study are that people often find it interesting to think about what is important or enjoyable to them. However, one risk of participating in the study is that you may feel upset if you are not able to take part in some activities you enjoy at the level you would like. If this should happen, you should stop filling out the VISA form and discuss your distress with your physician during the consultation.

Costs or inconveniences

The cost or inconvenience of participating is that it takes about 20 minutes to fill our the questionnaire form. Other possible inconveniences are that you might not feel up to answering these types of questions on the day of your appointment.

Compensation

You will not be paid for taking part in this study.

Your rights

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent. Your identity will not be used in any reports about the study.Your participation in this study is entirely voluntary, and you are free to withdraw at any time. You would not need to explain your reasons for withdraw and you will continue to be offered the best available medical care.

Whether or not you choose to participate in this study will not affect your treatment at the Pain and Symptom Management clinic in any way. All of the information that is collected from your medical chart, the ESAS, or the VISA will not have your name or other identifiable information on it. Notice that this means that if you decide later that you want to withdraw your data from the study, we will not be able to identify what information or assessment you filled out because it is anonymous to us. All hard copies of the assessment forms will be kept either at the BC Cancer Agency or at the University of Victoria in a locked cabinet or office.

There is a possibility that, in the future, we will want to use the data gathered in this study (in an anonymous form) for another analysis. If the data is used for other research that what is described above, approval will first be obtained from a properly consituted Research Ethics Board.

You can request a copy of the results of the study when it is finished. The findings may be disseminated to others through publication in a journal or book, at scholorly meetings, on the internet, and at workshops for training physicians and other health care pratctioners. Your rights to privacy are legally protected by federal and provincial laws that required safeguards to insure that your privacy is respected. Further details about these laws are available on request of the UBC BCCA Research Ethics Board.

Contacts

If you have any questions or concerns about the study and its procedures, you can ask the principal investigator, Dr. Grant MacLean at (250) 519-5572; gmaclean@bccancer.bc.ca, or the co-investigators Christine Tomori at (250)507-7084; ctomori@uvic.ca, and Dr. Bavelas: (250) 721-7550; 250-727-6573; bavelas@uvic.ca. In addition, you can verify the University's or Agency's ethical approval of this study by contacting the Human Research Ethics Office at the University of Victoria: (250) 472-4545; ethics@uvic.ca, or by contacting the Research Subject Line in the UBC office of Research Services: (604) 882-8598; RSIL@ors.ubc.ca.

This research project will be used for Christine Tomori's Masters thesis which is a requirement for her to complete her degree at the University of Victoria.

Subject Consent

I understand that participation in this study is entirely voluntary. I authorize access to my medical record and ESAS forms, as described in this consent form. I may choose not to participate or I may withdraw from the study at any time and I will continue to be offered the best available medical care. I understand that I may ask questions about this study in the future.

I will receive a signed copy of this consent form including all attachments, for my own records.

I consent to participate in this study.

____________________________	_____________________		___________
Subject's Signature	Printed name		Date
____________________________	_____________________		___________
Witness' Signature	Printed name		Date
____________________________	_____________________	___________________	____
Signature of Person Obtaining Consent	Printed name	Study Role	Date

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language:______________________

Was the subject assisted during the consent process in one of ways listed below?

☐ Yes ☐ No

If yes, please check the relevant box and complete the signature space below:

☐ The consent form was read to the subject, and the person signing below attests that the study was accurately explained to, and apparently understood by, the subject (**please check if subject is unable to read**).

☐ The person signing below acted as an interpreter/translator for the subject, during the consent process (**please check if an interpreter/translator assisted during the consent process**).

_________________________________	__________________	____________
Signature of Person Assisting in the Consent Discussion	Printed Name	Date

Appendix E.1

Operational Definitions for Symptom Analysis

Symptoms:

Directly out of ASCPRO article (Cleeland & Sloan, 2010)

Webster's Third New International Dictionary: the *subjective evidence of disease or physical disturbance observed by a patient*. Implicit in this definition is the negative nature of symptoms and, most importantly, that symptoms are observations of the person directly experiencing the evidence of disease or physical disturbance. In contrast to "signs" of disease (such as fever or high blood pressure), symptoms can only be known through patient report (Cleeland & Sloan, 2010).

In the second column of the P-CASA, patients often list symptoms as the reason why they are not satisfied with their level of ability to participate in activities that are most important to them (e.g., pain, nausea, tiredness, emotional distress, bowel problems, the diagnosis). That is, patients' provide evidence of their disease or physical disturbance by listing what is causing their dissatisfaction with their ability to participate in their activities.

Non-symptoms:
Patients may also list other reasons why they are not satisfied with their level of ability to participate in activities.

Non-symptoms: reasons why patients are not satisfied with their level of ability to participate in important activities, but are *neither subjective nor physical in nature*. For example, a patient may list *medical appointments* as the reason why they cannot travel out of town. Although the patient observed this disturbance in his life, it is neither a subjective experience nor a physical disturbance.

Non-symptom examples:
Lack of time
Having to deal with appointments
More money
safety issues
Seasonal
chemo treatment
Lots of time driving
Hard to get there

ESAS Symptoms:

List of nine symptoms common in cancer patients:

- *Pain*
- *Tiredness*
- *Nausea*
- *Depression*
- *Anxiety*
- *Drowsiness*
- *Appetite*
- *Wellbeing*
- *Shortness of Breath*

Note: the ESAS guidelines included synonyms for words that may be difficult for some patients to comprehend, however these were not given to patients when they filled out the ESAS at the PSM/PC clinic.

Synonym rule

As a general rule, the original words that patients use to describe their physical disturbance must match the term used to describe the symptom on the ESAS (above). However, patients often list symptoms on the P-CASA that are closely related to ESAS symptoms. The following chart lists various words that patients use to describe their symptoms. The first column lists the exact term on the ESAS or a slight variation of it; we consider all of the symptoms in this column as *ESAS Symptoms*. The symptoms listed under the *ESAS Synonyms* column are close synonyms to the ESAS symptoms listed in the first column. Symptoms we consider to be ESAS synonyms are symptoms that are equivalent to the ESAS symptoms. The final column of the chart are symptoms that may be related to the ESAS symptoms in the first column, but have a different meaning; therefore, we consider these symptoms *Not Equivalent Symptoms* to ESAS symptoms.

ESAS Symptoms	**ESAS Synonyms examples**	**Not Equivalent Symptoms examples**
Pain	Sore; knots; cramps; hurt; spasms; burns; cuts; scratch; ache	Stiffness
Tiredness; tired	fatigue; energy; energy not there; lack of energy; no energy; too tired; more energy; not as much energy; energy to do it; exhausted	Stamina; weakness; weak; strength; no strength; more endurance; lack of strength; not as much endurance; too weak
Nausea		
Depression; depressed		Not feeling up to it; lack of motivation; lack of ambition; motivation; lack of motivation; bored; lost interest; not interested;

Anxiety; anxious		inability to concentrate; distress; lack of concentration; hard to focus; cannot concentrate; forget things; increases restlessness; mind wandering; nervous
Drowsiness; drowsy	dozee; sleepy; fall asleep	Eyes blur; eye strain
Appetite		Eating; enjoying a meal; tastes different; doesn't taste good; 1 big meal - needs more planning; can't swallow it. Burns esophagus and cuts and scratches.
Wellbeing		Discomfort; Feel too physically overwhelmed; not feeling as confident; can't get into a comfortable position; no comfortable position
Shortness of Breath; SOB	breath	

Additional (more specific) information
Patients often provide additional information about a symptom or synonym. That is, a patient may indicate where on their body or in what situations the symptom occurs. For example: "*Chest* pain", "*Not able to drive if feeling* tiredness", "*light-headed* [because of] breath", and "*Can only actively play for a short time* 'tired out.'"

ESAS Symptoms	**ESAS symptom + additional information examples:**	**ESAS synonym + additional information examples:**
Pain	discomfort in stomach/back area [because of] pain; pain when standing; pain keeps me awake; sitting up pain;	Sore back; backache; leg knots
Tiredness	Can't travel very far due to tiredness; eyes become tired;	fatigued quickly
Nausea	Constantly nausea	
Depression		
Anxiety		
Drowsiness	Sometimes fall asleep [because of] drowsiness; drowsiness from pain medication	
Appetite		
Wellbeing		
Shortness of Breath		light-headed [because of] breath

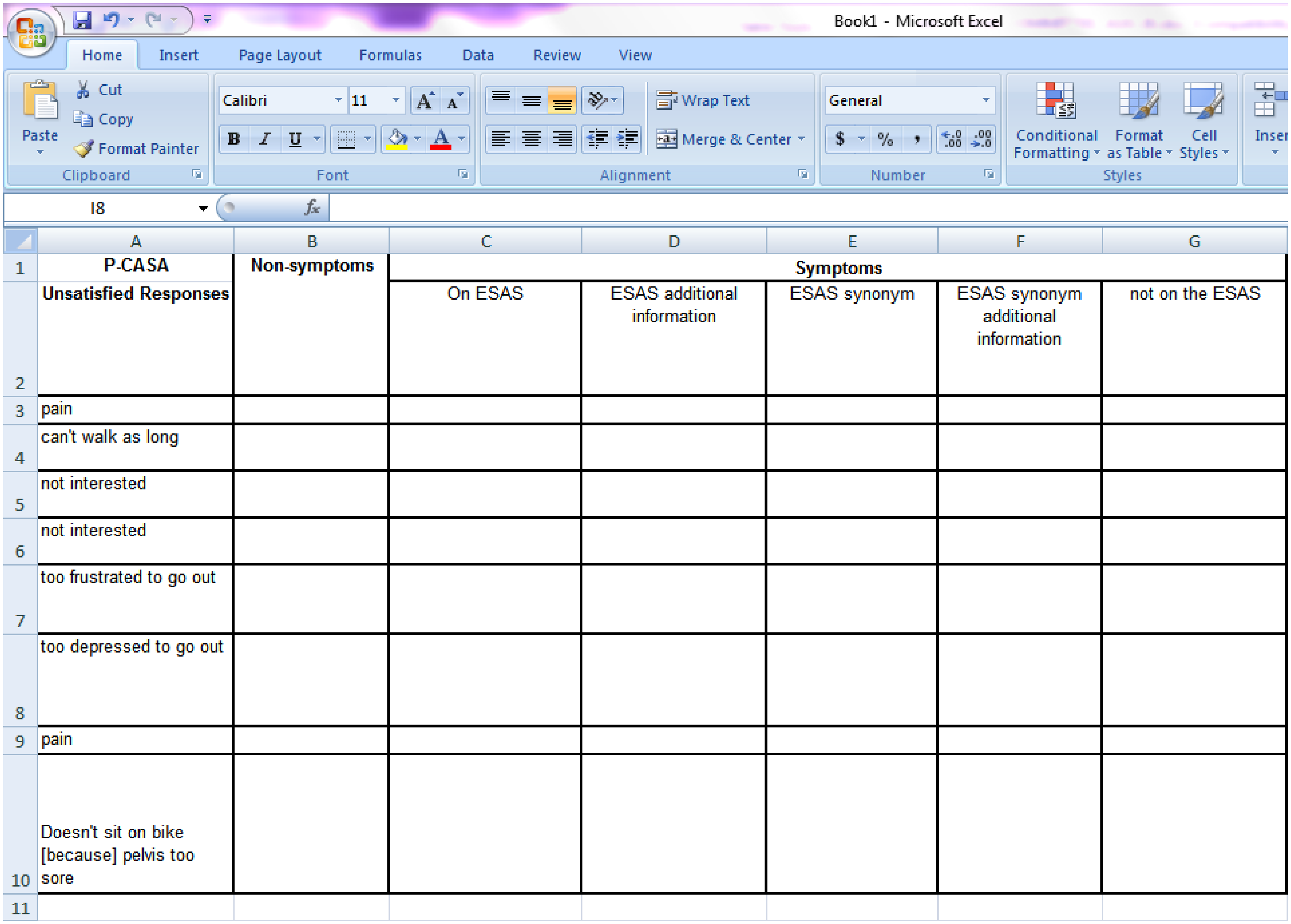
P-CASA Symptoms:

In the second column of the P-CASA, patients list the reasons why patients are not satisfied with their level of ability to participate in activities that are most important to them. However, patients often list other symptoms that are neither on the ESAS nor close synonyms of them. Below is a list of symptoms that are considered P-CASA symptoms, that is, symptoms that are not on the ESAS in anyway.

Symptoms not on the ESAS examples:
Irritability
Unable to concentrate
Weakness in the legs
Physical discomfort
Not enough control over motor movements
bowel problems
Unable to stand
No strength
distress
eye sight
motivation
bored
Tastes different
Bloating
wheelchair
lost interest

Appendix E.2

P-CASA Symptom Analysis Sheet



	A	B	C	D	E	F	G
1	**P-CASA**	**Non-symptoms**			**Symptoms**		
2	**Unsatisfied Responses**		On ESAS	ESAS additional information	ESAS synonym	ESAS synonym additional information	not on the ESAS
3	pain						
4	can't walk as long						
5	not interested						
6	not interested						
7	too frustrated to go out						
8	too depressed to go out						
9	pain						
10	Doesn't sit on bike [because] pelvis too sore						
11							

Appendix E.3

Rules for Symptom Analysis and Decision Tree

Testing the hypothesis: P-CASA obtains symptoms that are not on the ESAS

Procedure

Materials

You will need the following in order to do this analysis:

- Operational definitions (i.e., symptoms, non-symptoms, ESAS symptoms, P-CASA symptoms: equivalent, not equivalent, and additional information than ESAS symptoms)
- Excel file which includes
    a. The list of each patient's symptoms on the P-CASA
    b. Table for analysis

Symptom analysis

Start with the ESAS kiosk group.
Step 1: Review the operational definitions.
Step 2: Open the excel file for the patient you are analyzing. Using the operational definitions, examine the symptoms that are listed for that patient and answer the questions in the following decision tree:

Decision Tree: symptom analysis