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Assessing the Performance of a Self-Report Comorbidity Scale

by

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Abstract

This thesis presents the initial evaluation of a self-report comorbidity scale used in the Saskatchewan Health and Back Pain Survey. The relationship of the presence and severity of the six most prevalent health conditions were observed with health-related quality of life (HRQL) and depressive symptomatology as outcomes. HRQL was measured by The Medical Outcomes Study Short-Form 36 (SF-36) using the mental and physical component summary scores (MCS and PCS); and depressive symptomatology was measured by The Center for Epidemiologic Studies Depression (CES-D) scale.

There exists a clear association between presence and severity of most comorbid health conditions with HRQL and depressive symptomatology. The self-report comorbidity scale performed as expected and thus generated increased confidence in its validity. This research is an initial examination of how the self-report comorbidity scale behaves with other measures of health. More research is needed to further examine the validity and reliability of the instrument.

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Chapter 1

Introduction

1.1 Overview

When conducting studies with endpoints such as resource utilization or mortality and morbidity, it is useful to control for confounding factors. In population-based studies, it is common place to collect demographic data, and sometimes smoking status and alcohol use for this purpose. More recently, research has been published indicating that comorbid health conditions are crucial confounding variables that have been omitted from most statistical analyses (Fried et al., 2003). Comorbid conditions can be defined as those conditions which are not a component of the principal disease process, but which increase an individual's total burden of illness and thus place a person in a higher case mix category (Shwartz et al., 1996).

Comorbidity has been demonstrated to alter risk of mortality (Charlson et al., 1987; Sangha et al., 2003) and be a predictor for post-operative complications and functional outcomes (Greenfield et al., 1993). Older age and lower levels of education are also related to the occurrence and degree of comorbidity (van den et al., 1998). It is also estimated that a one point increase in the Charlson comorbidity score is approximately equivalent to being ten years older in terms of overall increased risk of death (Charlson et al., 1994). Based on the strong evidence suggesting that comorbidity is a strong predictor of health outcomes, it is evident that this factor should be taken in to consideration whenever possible.

The primary purpose of this research is to assess the performance of a self-report comorbidity scale (Jaroszynski et al., 1996) that was developed for a population-based survey (the Saskatchewan Health and Back Pain Survey) and utilized in subsequent research studies (Cassidy et al., 1998; Côté et al., 1998; Carroll et al., 2000; Côté et al., 2000b; Côté et al., 2001; Carroll et al., 2002; Côté et al., 2004). This purpose will be addressed by exploring the relationships between the different comorbid conditions and self-reported physical and mental health.

The focus of this chapter is to highlight important background information in the following areas:

(1) Comorbid health conditions

(2) Health-related quality of life and The Medical Outcomes Study SF-36, which was used to assess this construct.

(3) Depression symptomatology and The Center for Epidemiological Studies-Depression Scale (CES-D), which was used to assess depressive symptomatology.

1.2 Literature review: Comorbidity Background Information

1.2.1 Definition

A comorbid condition can be defined as one or more health conditions that exist within an individual that are not a component of their principal disease process (Shwartz et al., 1996). For example, if someone who has diabetes also suffers from back pain, diabetes would be comorbid to back pain, just as back pain would be comorbid to diabetes. For the purposes of the Saskatchewan Health and Back Pain Survey, neck and

back pain were the health conditions that the research team were primarily interested in, therefore any health conditions other than neck or back pain were considered comorbid (Cassidy et al., 1998; Côté et al., 1998; Carroll et al., 2000; Côté et al., 2000b; Côté et al., 2001; Carroll et al., 2002; Côté et al., 2004). Unfortunately it is not always clear whether the comorbid health conditions are in fact a component of the principal disease process or the principal disease itself. Take for instance an individual in acute renal failure who also has diabetes and cardiovascular disease. Research suggests that people who suffer from diabetes (principal disease) are at increased risk for many other health problems, including renal and cardiovascular disease (complications). By definition, comorbid conditions differ from complications which occur as a result of the natural history or treatment history of the principal disease process (Shwartz et al., 1996).

It is not the focus of this thesis to focus on causality that is, which health condition occurred first or in other words, which health condition is the principal disease process. The focus is on recognizing that people do sometimes have more than one health problem that warrants medical attention, which intuitively impacts their health. The importance of recognizing this is further explored in the following section.

It should be noted that the psychiatric community frequently uses the term "comorbidity" in a distinctly different manner. In this sense, the term "comorbidity" is used synonymously with "dual diagnosis", which usually refers to individuals who have, for example, substance abuse disorders (including drugs and/or alcohol) in addition to mental illness (Regier et al., 1990; Currie et al., 2005). Throughout this paper, I will be referring to "comorbidity" in the manner discussed above rather than as a concept used to refer to "dual diagnoses".

1.2.2 Importance of Comorbidities

The ability to control or adjust for different variables is imperative when trying to explain the independent relationship between two factors. Demographic data such as age and gender are usually collected for this purpose. In addition, income level, marital status, education level, smoking status and work status may also be collected for these purposes. Any of the above factors may impact health status, and therefore must be measured and considered when conducting studies.

In the last decade or so, the importance of considering the potential contribution or confounding role of different health conditions became increasingly recognized. Presence of comorbid conditions is an important dimension of an individual's health status (Klabunde et al., 2005) and is a strong predictor that may confound many health outcomes (Fried et al., 2003). The ability to adjust for comorbid disease is essential in health services research and epidemiologic research (Groll et al., 2005).

Another method to 'control' for comorbid health conditions, which does not involve statistical treatment, is to limit inclusion criteria to individuals who do not have certain other health problems. This would in turn limit to whom the results of the study can be generalized to, and thus will not be addressed any further for the purposes of this paper.

It has been demonstrated in the literature that comorbidity is an important determinant of patient costs (Shwartz et al., 1996), mortality (Pompei et al., 1991; Davies et al., 1995; Bagshaw et al., 2005; Miskulin, 2005; Wu et al., 2005), surgical outcomes (Greenfield et al., 1993), functional outcomes (Greenfield et al., 1995), prognostic factor (Piccirillo et al., 2004), and hospital length of stay (Jencks et al., 1988).

Thus, comorbidity appears to have a serious impact on health and must be controlled or adjusted for whenever possible.

1.2.3 Comorbidity Instruments

1.2.3.1 The Charlson Comorbidity Index (CCI)

Adjusting for comorbidity requires data collection with an instrument that is both valid and reliable. The degree to which a measure reflects what it is supposed to measure can be defined as validity, and reliability refers to the extent to which the measure yields the same score every time it is administered, all other things being equal (Hays et al., 1993). The CCI is one of the most highly validated, having been assessed in many different populations (Charlson et al., 1987; Pompei et al., 1991; Charlson et al., 1994; Fried et al., 2003; Ouellette et al., 2004; Bagshaw et al., 2005; Wu et al., 2005). The index assigns different weights for each comorbidity, based on the impact of comorbid diseases on survival (Charlson et al., 1987). In other words, the CCI takes in to account the number and seriousness of comorbid disease present within an individual, along with age. The index was originally created to predict one-year mortality among hospitalized patients and performs well for this purpose; however it is less effective when used to adjust for health conditions when functional status is the outcome of interest (Sangha et al., 2003). Therefore, if the objective of the study is to focus on functional status and other quality of life outcomes rather than mortality in hospitalized patients, this index may not be the best instrument.

Another potential disadvantage of the Charlson comorbidity index is that it relies on obtaining data from medical record abstraction. This reduces its practicality and usefulness in some types of studies. Medical record review by a trained abstractor is expensive and time consuming, and not practical or even possible in large population-based studies, while routine administrative data may not be readily available or accurate in the outpatient setting (Fan et al., 2002; Sangha et al., 2003). Administrative data may be biased by incomplete or inaccurate records and by financial incentives that influence the manner in which certain conditions are reported (Fan et al., 2002). These are certainly concerns if the purpose of the study is to assess presence of comorbidities in the general population.

1.2.4 Importance of Self-Reported Health

Research has shown that patients can accurately assess their current (Mechanic, 1980) and past medical conditions (Colditz et al., 1986; Harlow et al., 1989) including comorbid health status (Greenfield et al., 1995; Katz et al., 1996).

In addition to the aforementioned shortcomings with medical record abstraction, additional evidence suggests that self-report of conditions may be superior for some types of studies. An individual who is not medically ill may still report feeling unwell because they are aware of internal organic problems (Maddox et al., 1973). In a review of 27 studies, Idler et al. (Idler et al., 1997) found consistent results that global self-rated health is an independent predictor of mortality. The focus here is on the one question: 'How would you rate your health, today?' The response options are presented in a likert fashion: excellent, very good, good, fair, poor. Although this is a slightly different focus

than reporting comorbid conditions, it supports the idea that health can be validly measured using self-report, and there is increasing evidence that subjective health is a valid measure of the underlying organic state of health (Chipperfield, 1993).

1.2.5 Self-Report Comorbidity Questionnaires

Self-reported health is especially important when grading the severity level of a condition. Greenfield et al. (Greenfield et al., 1995) demonstrated that a four-level severity classification was significantly able to discriminate and show a clear dose response for each level of mean role physical functioning, for each of the 15 body system diseases. This study was based primarily on patient-reported symptom severity. The surveyed individual should best be able to indicate to what extent a particular condition affects his or her life more accurately than anyone else, based on the all of the other intrinsic factors involved; similar to the idea of global self-rated health as described above. Take, for example, a condition like rheumatoid arthritis. The amount of pain or mobility limitation due to this disease may vary significantly between individuals. Similarly, the physical and mental well-being would be affected to a different extent in each individual. In order to obtain the most accurate representation of how comorbid conditions affect an individual's health, it seems intuitive to ask them directly. Thus, the way a person views his or her health is importantly related to subsequent health outcomes (Mossey et al., 1982).

The availability of self-assessed comorbidity scales is limited. Katz et al. (Katz et al., 1996) developed a questionnaire version of the Charlson index and found it to be reproducible and valid when tested on medical and surgical inpatients over 50 years of

age. The questionnaire attempted to gather severity data on some of the items. The authors estimate that the questionnaire approach is less expensive than medical record review. Shangha et al. (Sangha et al., 2003) evaluated the psychometric properties of a Self-Administered Comorbidity Questionnaire (SCQ) in inpatients over 50 years of age, and concluded that it had modest correlations with the Charlson Index. The SCQ also attempted to measure severity by asking if the individual received treatment for the comorbidity or if the condition limited his or her activities.

A measure by Greenfield et al. (Greenfield et al., 1995) was developed as part of Type II Diabetes Patient Outcomes Research Team project. It uses patients' report of symptoms and conditions, as well as patients' ratings of symptom intensity to characterize total disease burden. A single global measure was developed by aggregating the 15 measures, weighted according to the expected impact of each disease category on functional outcome and disability. The instrument was tested only among individuals with type II diabetes and thus seems to be tailored to this group, possibly affecting its generalizability. It included vision, foot disease, and gastrointestinal autonomic neuropathy, all of which are known complications of diabetes. Mental and emotional problems, cancer and blood problems were not included, therefore this instrument may not be comprehensive and broad enough to assess the general population. No test-retest reliability estimates are available.

A fourth brief self-administered questionnaire, the Seattle Index of Comorbidity, was used by Fan et al., (Fan et al., 2002) to adjust for comorbidity in outpatient studies. Their objective was to determine whether self-reported chronic medical conditions and the SF-36 could be used individually or in combination to assess comorbidity in the

outpatient setting. The primary outcome was all-cause mortality, with a secondary outcome of hospitalization within the Veteran Affairs medical centers.

1.2.6 Self-Report Comorbidity Scale used in the Saskatchewan Health and Back Pain survey

Jaroszynski and colleagues developed a self-report comorbidity scale in order to adjust for case-mix in surveys and other studies using self-reported data (Jaroszynski et al., 1996). A 15-item self-report comorbidity scale was created to measure presence and severity in terms of its self-perceived impact on health in the Saskatchewan sample (Jaroszynski et al., 1996). A description of the creation of this index follows.

The initial strategy for item selection involved a consensus meeting of the authors leading to the creation of a list of diseases or medical conditions that are prevalent in the general population that may impact on the health-related quality of life of individuals (Jaroszynski et al., 1996). Some related conditions were grouped together in order to reduce the number of items. A draft of the different diseases and conditions was sent to a number of health care professionals. At a final consensus meeting, a final version of the questionnaire was agreed upon.

Five response options exist in order to measure the impact that the problem had on their health in the past six months:

1. No, I do not have this condition (move on to the next question). Score 0
2. Not at all: I have the condition but the problem does not affect my health. Score 1
3. Mild: I have the condition and the problem makes my health a little worse than it should be. Score 2

4. Moderate: I have the condition and the problem makes my health worse than it should be. Score 3
5. Severe: I have the condition and the problem makes my health much worse than it should be. Score 4

The study population consisted of ambulatory patients from a primary care community clinic. Ten family physicians, employed by the clinic, volunteered to participate. Entry criteria for the study included age greater than eighteen years and the ability to complete the questionnaire. After interviewing and examining the patient and being unaware of the patient's responses to the questionnaire, the physician filled out the comorbidity questionnaire, the Duke University Severity of Illness Scale (DUSOI) (Parkerson, Jr. et al., 1993), and an analog scale. Ten to 14 days after the clinic visit, a second comorbidity questionnaire was mailed to the patient to assess test-retest reliability.

The DUSOI scale is a physician-generated comorbidity scale that has performed well in reliability and validity studies (Parkerson, Jr. et al., 1993; Shiels et al., 1997). Physician rating of overall health problem severity was assessed using the analog scale that was also used by the authors of the DUSOI scale in their validation study (Parkerson, Jr. et al., 1993). On that scale, 0 means no health problems and 10 means the most severe health problems.

A sample size estimate was computed for the reliability component of the study. The test-retest reliability of the comorbidity questionnaire preformed well with the ICC for each item ranging from 0.8 to 0.98 (Jaroszynski et al., 1996). Initial validation of the comorbidity questionnaire was done against concurrent physician assessment and against

a self-assessed health-related quality of life index (SF-36). There was moderate correlation between the patients' comorbidity score and all of the physician-derived comorbidity measures: the physician-generated comorbidity score, the DUSOI score and the analog score. There was moderate inverse correlation between the comorbidity scores and all of the subscales of the SF-36. Patients with higher comorbidity scores had significantly lower health-related quality of life.

This questionnaire has been widely used (Carroll et al., 2000; Mercado et al., 2000; Côté et al., 2000a) but as yet has not been validated against health-related quality of life in the general population.

1.2.7 Trends

Certain sub-groups of the population have more comorbid health conditions than other sub-groups. Because older people have an increased prevalence of chronic illnesses, it is of increased importance to control for the potential confounding effects of comorbid health conditions when evaluating health outcomes in this population (Extermann et al., 1998; Fan et al., 2002). Older age is so strongly associated with an increased prevalence of medical conditions that it is the simplest proxy for comorbidity and also the most widely used (Van Manen et al., 2003). As mentioned earlier in the introduction, it was found that the relative risk of death from an increased of one in the Charlson comorbidity index was almost equivalent to that from an additional decade of life (Charlson et al., 1994).

Another sub-group of the population who have increased prevalence of comorbid health conditions are those individuals who are on some type of Renal Replacement

Therapy (RRT). Studies show that comorbid conditions are highly prevalent and significant predictors of health outcomes in dialysis patients, continuous ambulatory peritoneal dialysis patients, end-stage renal disease patients and post-kidney transplantation patients (Davies et al., 1995; Miskulin ,2005; Wu et al., 2005). It is actually believed that comorbidity is the single most important determinant of outcome in patients on RRT (Davies et al., 2002). In fact, three different comorbidity indices have been shown to predict mortality in peritoneal patients (Davies et al., 1995; Athienites et al., 2000; Beddhu et al., 2000; Fried et al., 2001; Fried et al., 2003). Intuitively, comorbid health conditions need to be controlled for in this patient population because of the overwhelming impact that they have on health. Another reason to control for comorbid health conditions is when adjustments for case-mix need to be made to allow for fair comparisons between treatment modalities, centers and costs (Davies et al., 2002; Miskulin ,2005). As with older people, people who have serious renal problems have more comorbidities, thus more factors that could essentially be affecting their health.

In addition to increased age and patients on RRT, it is also important to consider comorbid health conditions in cancer patients. Cancer patients often have other medical ailments which do affect their health outcomes. These ailments are being recognized as important attributes (Bang et al., 2000) and important prognostic factors when observing survival rates among cancer patients (Piccirillo et al., 2004). In fact, even a special cancer specific comorbidity instrument, the Adult Comorbidity Evaluation-27, was created in order to better describe comorbidity in patients with cancer (Bang et al., 2000).

There is also literature suggesting that when individuals are affected by comorbid health conditions, they may have concurrent psychiatric problems. Wells et al. found that patients with chronic medical conditions are more likely to have lifetime substance use disorders and anxiety disorders (Wells et al., 1988). In addition, patients who have cognitive disorders suffer from more comorbid medical conditions than patients without cognitive disorders (Lyketsos et al., 2005). This may also be due in part to the increased age of people with cognitive disorders, such as dementia. However, it is still important to consider that the medical conditions may contribute to the progression of patient's cognitive and functional decline (Lyketsos et al., 2005). Another example is diabetes, where patients with more diabetes related complications are at an increased risk of psychological disturbances (Peyrot et al., 1997).

The above illustrates why it is of increased importance to take in to account comorbid health conditions in certain populations who tend to have an increased number of health problems. Because comorbid health conditions can be potential confounders of health outcomes, they should be properly measured and controlled for in any analyses.

1.3 Literature Review: Health-Related Quality of Life

It is interesting to see the definition of health evolve over the years. After realizing that health was more than just mere survival, definitions have changed as times change and life-expectancy increases. Then there was a phase of defining health in terms of freedom of disease, onward to an emphasis on an individual's ability to perform daily activities, and more recently to an emphasis on positive themes of happiness, social and emotional well-being, and quality of life (McDowell et al., 1996).

In 1958, The World Health Organization defined health in terms of "physical, mental, and social well-being, and not merely the absence of disease and infirmity" (World Health Organization, 1958). Although this definition is more comprehensive than simply measuring survival, it was criticized as immeasurable (McDowell et al., 1996).

A previously ill individual may report feeling better, but have no physiological improvement that can be measured by a clinician. Although the positive change is significant for the individual, it may not be captured by the medical tools available to the physician. Defining health is of utmost important when attempting to measure it. This is an example of why it is important to broaden the definition of health so that it encompasses quality of life.

Health-related quality of life is the most broad and highest level in the taxonomy of health definitions. It includes all the domains of physical, psychological, social, spiritual, and role functioning, as well as general well being (Spilker et al., 1996). Because health-related quality of life encompasses the most information about an individual's health, it seems intuitive that researchers would choose to measure it.

1.3.1 Generic versus Specific

There exist two different types of measurement tools to assess health-related quality of life: generic and specific. Generic instruments are ideal to assess disability and health status in the general population because of their comprehensiveness. Most generic health-related quality of life instruments are able to detect differential effects on different aspects of health status (Guyatt et al., 1993). This allows for convenient comparisons across different disease categories (McDowell et al., 1996).

Some argue that health or quality of life is innately multidimensional therefore scores on the different dimensions should be reported separately (McDowell et al., 1996). This is beneficial when it is of interest to observe exactly what aspect of health-related quality of life is impacted; however, it makes for more difficult comparisons when there is more than just one overall score. That said, Osoba (1995) states that an overall score of all health-related quality of life aspects added together, is not informative because it is devoid of detailed information about what the score is comprised of (Osoba, 1995).

When the aim is not descriptive epidemiology of the general population, but to describe a health status in a more specific population, disease specific instruments are sometimes of more value. Because of the nature of this research, I will choose to focus on the generic measurement tool, most appropriate for assessing health-related quality of life in the general population.

1.3.2 Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), a generic measurement tool, is one of the most commonly used instruments internationally to assess health-related quality of life (HRQL). It is a self-report questionnaire of 36 different items that assesses the multidimensionality of health (Ware et al., 1993). The SF-36 consists of eight different health profiles in addition to a single item that measures reported health transition: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in social activities because of physical health problems; 4) bodily pain; 5)

general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); 8) general health perceptions (Ware et al., 1993).

1.3.2.1 Physical and Mental Component Summary Scores

As mentioned earlier, one of the disadvantages of a generic measurement tool is that multiple comparisons must be made because of the large number of different health profiles. The scholars who developed the SF-36 created a Physical component summary (PCS) and Mental component summary (MCS) in order to reduce the number of statistical comparisons (Ware, Jr. et al., 1995). The PCS includes physical functioning, role physical, bodily pain and general health perceptions, while the MCS includes vitality, social functioning, mental health and role emotional. The rationale for creating the two summary scales stems from the discovery that 80-85 percent of the reliable variance in the eight SF-36 scales is accounted for by physical and mental components of health (Ware et al., 1994). The psychometrically sound summary measures allow for simplification in the analysis and interpretation of the SF-36 (Ware et al., 2001) and will be employed for the purposes of this thesis.

1.3.2.2 Validity

The SF-36 has consistently proven to satisfy rigorous psychometric criteria and is considered to be a highly valid instrument when employed in a variety of populations (Garratt et al., 1993). The literature supports that the SF-36 has increased construct validity in terms of distinguishing between groups with expected health differences

(Brazier et al., 1992); and has increased discriminative and responsive validity (McHorney et al., 1994; Kosinski et al., 1999; Gandek et al., 2004) more so than other generic HRQL measures such as the Sickness Impact Profile (SIP) (Stucki et al., 1995) and the Nottingham Health Profile (Brazier et al., 1992).

1.3.2.3 Reliability

The SF-36 has increased internal consistency of the different health profiles and summary measures (Garratt et al., 1993; Jenkinson et al., 1993) where reliability coefficients ranged from a low of 0.65 to a high of 0.94 across scales with a median of 0.85 (McHorney et al., 1994); above 0.70, the minimum standard for group comparisons, for all scales but Social Functioning (Gandek et al., 1998); reliability coefficients greater than 0.75 for all dimensions except social functioning (Brazier et al., 1992); and above 0.70 for group comparisons for all scales and summary measures, across all subgroups (Gandek et al., 2004). Two-week test-retest estimates were also sufficiently high with reliability coefficients ranging from 0.55-0.89 (Wagner et al., 1995) and 0.60-0.81 (Brazier et al., 1992).

1.3.2.4 Scoring

Each multi-item health profile scale is computed by summing scores assigned to item responses and by transforming scores from 0 (worst health state) to 100 (best health state) (Ware, Jr. et al., 1998). The MCS and PCS can be derived from the various health profile scores, as explained in Ware (Ware et al., 1994).

1.3.2.5 Normalization of Data

Normalized health profile scores have a mean of 50 and a standard deviation of ten. Health profiles are normalized to a country's population characteristics therefore it is imperative that the data is valid and based on a well-defined and representative sample of that population (Ware et al., 1993; Hopman et al., 2000). Normative data is the key to determining whether a group or an individual scores above or below the average for their country, age or sex (Hopman et al., 2000). The authors of the Saskatchewan Health and Back Pain study normalized their data to the US population because Canadian norms were not published at this time. Canadian norms are slightly higher than US norms in every domain, but data remains normalized to the US population for comparison purposes (Hopman et al., 2000).

1.3.2.6 Missing Data

Ware et al. (1993) explain how to handle missing data (Ware et al., 1993; Hopman et al., 2000). A health profile score may be calculated if the respondent answered at least half of the items, and missing items are scored as the average scores across completed items in that health profile. If more than half of the items are missing in one of the eight health profiles, that profile is considered incomplete and no calculations may be performed to create the MCS or PCS.

1.3.3 Relationship between HRQL and Comorbidity

It has been consistently demonstrated in the literature that there is a relationship between the SF-36, measuring HRQL and comorbidity. Fan et al (2002) demonstrated

that the comorbidity score had a comparative predictive validity to the SF-36 component scores (MCS and PCS), both being able to significantly predict mortality (Fan et al., 2002). Another study illustrated how scores from one of the SF-36 health profiles correlated well with a case-mix measure used to assess comorbidity in patients with Type II diabetes (Greenfield et al., 1995). A third study demonstrated how the physical function subscale of the SF-36 was used as the outcome of interest to create a comorbidity index (Groll et al., 2005). The relationship between the SF-36 summary scales (MCS and PCS) and different comorbidities reported in the Saskatchewan Health and Back Pain Study will be assessed in Chapter 2 of this thesis.

1.4 Literature Review: Depression

A lack of energy and an inability to concentrate are two common symptoms that a depressed individual may report. Others may feel irritable for no apparent reason. Depressive symptomatology varies from person to person, however if certain symptoms persist for more than two weeks, and are interfering with daily life, clinical depression may be present (the Depression Center, 2006). In 2003, the National Comorbidity Survey Replication reported a lifetime prevalence of major depression of 16.2% (Kessler et al., 2003).

1.4.1 Center for Epidemiologic Studies Depression Scale

Over the past few decades, the Center for Epidemiologic Studies Depression (CES-D) scale has been widely used in a variety of populations to measure depressive symptomatology. This 20-item, self-report scale's primary emphasis is on the affective

component of depression and depressed mood. It is designed to measure current level of depressive symptomatology in the general population, but has also been shown to effectively assess depression in clinical populations (Radloff, 1977).

Each item of the CES-D asks how many times in the past week a certain feeling or behavior was experienced. There are four response options for all questions: (scored zero to four) which are summed to create a final score, taking note that items '4,' '8,' '12,' and '16' are reverse scored. Scores range from 0-60, higher scores indicating increased depressive symptomatology. A validated cut-off point of 16 (16 or above) is recommended for population-based studies of depression, indicating significant depressive symptomatology (Radloff ,1977).

The literature has suggested a few different cut-off points, above and below Radloff's (1977) cut-point of 16, depending on the population studied.

Many researchers have used the cut-off of 16 to identify clinically depressed individuals of a variety of different ages and backgrounds (Barnes et al., 1984; Beekman et al., 1997b; Caracciolo et al., 2002; Herrman et al., 2002; Burns et al., 2003; Haringsma et al., 2004). Adequate sensitivity accompanied by lower specificity were often reported: sensitivity of 1.0 and specificity of 0.88 (Beekman et al., 1997a); sensitivity of 1.0, specificity 0.55 (Beekman et al., 1997b); sensitivity 0.93, specificity 0.29 (Haringsma et al., 2004), demonstrating that the instrument was very sensitive at identifying those with increased depressive sypmtomatology, but at the expense of high false positives. Other literature suggests cut-off points below Radloff's (1977) cut-point of 16: a cut-point of 12 was optimal for identifying major depression and dysthymia combined in a large sample of US drivers over 50 years of age with sensitivity of 0.76 and specificity of 0.77

(Lewinsohn et al., 1997); a cut-point of 12 was seen as optimal in a sample of American elderly (Watson et al., 2004). However, most often a higher cut-point was identified as being more sensitive and specific in a variety of populations: a cut-point of 20 was recommended by Himmelfarb & Murrell (1983) when discriminating between a community and clinical sample of elders (Himmelfarb et al., 1983); Robison et al. (2002) found that a cut-point of 21 was adequate with a sensitivity of 0.81 and specificity of 0.70 in a sample of middle aged and older Puerto-Rican primary care patients (Weingartner et al., 2002; Robison et al., 2002); a cut-point of 20 was identified as optimal in a sample of community dwelling Dutch individuals over the age of 55, with a sensitivity of 0.94 and specificity of 0.74 (Beekman et al., 1997b); in another sample aged 55 and older, a cut-point of 22 yielded sensitivity of 0.84 and specificity of 0.60; in chronic pain patients, a cut-point of 19 was suggested for diagnosing depression (Turk et al., 1994); and Haringsma (2004) found that the optimal cut-off to diagnose clinically relevant depression was 22 with a sensitivity of 84% and specificity of 60%, but when attempting to diagnose major depressive disorder, a higher cut-point of 25 with a sensitivity of 85% and specificity of 64% was listed (Haringsma et al., 2004).

The validated cut-point of $\geq$16 is recommended for population-based studies of depression (Radloff ,1977) and over time, many researchers have used the cut-off of 16 to identify clinically depressed individuals of a variety of different ages and backgrounds (Beekman et al., 1997b; Caracciolo et al., 2002; Herrman et al., 2002; Burns et al., 2003; Haringsma et al., 2004). Therefore, the conventional threshold of $\geq$16 identified initially by Radloff (1977) will be used when assessing the presence of significant depressive symptomatology in the current study.

1.4.1.1 Psychometric Properties of CES-D

The scale correlates well with clinical ratings of depression and its internal consistency, test-retest reliability, concurrent validity and construct validity were good (Spijker et al., 2004).

Caracciolo (2002) found that the CES-D achieved a satisfactory level of criterion validity for depressive disorders in a sample of rehabilitation inpatients (Caracciolo et al., 2002). Similarly, Haringsma (2004) found that the criterion validity of the CES-D for major depressive disorder and clinically relevant depression was satisfactory in a semi-clinical sample of elders (Haringsma et al., 2004). The CES-D scale correlates highly with clinician rating measures of depression such as the Hamilton, the Beck Depression Inventory and the SCL-90 (HAMILTON, 1960; Beck et al., 1961; Radloff ,1977; Weingartner et al., 2002; Arrindell et al., 2003). Finally, Beekman (1997) stated that criterion validity for major depression was very good (Beekman et al., 1997a).

The CES-D also demonstrated convergent validity with other measures of depressive symptoms ($r>0.50$) with the Hamilton Rating Scale for Depression (Devins & Orme, 1985). Similarly, the CES-D agrees well with more lengthy self-report scales used in clinical studies and with clinician interview ratings (Weissman et al., 1977) as well as correlates with trait anxiety (Orme et al., 1986).

In psychiatric populations, the CES-D is a sensitive tool to be able to detect depressive symptoms and change in symptoms over time (Weissman et al., 1977) and has demonstrated temporal stability in individuals with chronic physical disorders where the CES-D has successfully been used to examine how distress changes in this population (Sheehan et al., 1995).

Radloff (1977) found that the CES-D possesses good internal consistency ($\alpha >$ 0.84) and test-retest reliability (0.67) at four weeks . Schroevers (2000) has confirmed that the CES-D has good reliability in terms of internal consistency when they proved that the 16 items of the depressed affect were weakly correlated with the 4 items of positive affect (Schroevers et al., 2000).

The psychometrically sound CES-D is one of the most widely used self-report instruments to measure current depressive symptomatology in population-based studies. For this reason, there is increased confidence for using the CES-D as an outcome measure.

1.4.2 Relationship between Depression and Comorbidity

The WHO estimates that by 2020, unipolar major depression will become the second leading cause of disease burden worldwide, second only to ischemic heart disease (Simon, 2003). In a prospective, community-based study in a Canadian population, Patten (2001) described an increased risk of developing depression with almost any long-term condition and reported that, alternatively, depression may increase the risk of chronic medical conditions (Patten, 2001). This is important because a review study by Katon (2003) concluded that there was a 50% increased in medical costs for patients with comorbid major depression and chronic medical conditions, compared with patients with chronic conditions alone (Katon, 2003).

Research has indicated a positive association between depression symptoms and medical conditions such as diabetes (Ciesla et al., 2001; Katon ,2003); stoke (Pohjasvaara

et al., 1998); myocardial infarction (Frasure-Smith et al., 1993; Carney et al., 2003); congestive heart failure (Koenig, 1998); and cancer (Holland et al., 1998).

1.5 Conclusion

In conclusion, this thesis will assess the performance of the self-report comorbidity scale that was used in the Saskatchewan Health and Back Pain survey. Chapter two will examine the relationship between different self-reported health items and health-related quality of life, using the SF-36 mental and physical component summary scores as the outcomes. Chapter three will examine the relationship between different self-reported health items and depressive symptomatology. Increased confidence in the self-reported comorbidity scale will be gained if presence and severity of the health conditions are associated with decreased mental and physical health, and increased depressive symptomatology.

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Chapter 2

Evaluating the Performance of a Self-Report Comorbidity Questionnaire with Health- Related Quality of Life as the Outcome

2.1 Synopsis

When completing studies with health-related outcomes, it is necessary to control for confounding factors. In population-based studies, it is common place to adjust for sociodemographic characteristics, however comorbid health conditions are beginning to be recognized as crucial confounding variables that must be measured and controlled for during data analyses. The purpose of this research is to begin to assess the validity of the self-report comorbidity scale used in a large population-based survey, with health-related quality of life as the outcome. The relationship between presence and severity of comorbid health conditions and health-related quality of life will be examined.

Data for this study were taken from the Saskatchewan Health and Back Pain Survey, a population-based survey conducted in 1995-96 of adults over the age of 20 years. This study yielded a 55% response rate at baseline (n=1131). Multivariable linear regression was used to determine the relationship between presence and severity of different health conditions and health-related quality of life. The outcome was measured by The Medical Outcomes Study Short-Form 36 (SF-36) using the mental and physical component summary scores (MCS and PCS). Sociodemographic factors were identified and controlled for. Crude and adjusted models were reported for the six most prevalent health conditions and diabetes.

The most common health conditions that were reported in both genders were headache (55%), allergy (41%), respiratory problems (29%), musculoskeletal problems (27%), digestive problems (27%), and mental health problems (24%). Increasing severity of each reported health problem coincided with decreased MCS and PCS scores, indicating decreased health-related quality of life. When multivariate linear regression models were built, presence and severity of each health condition was associated with decreased MCS and PCS scores in most adjusted and non-adjusted models.

We report a clear association between presence and severity of several comorbid health conditions and health-related quality of life. The self-report comorbidity scale performed as expected and thus generated increased confidence in its validity. This research is an initial examination of how the self-report comorbidity scale behaves with regards to health-related quality of life. More research is needed to further examine the validity and reliability of the instrument.

2.2 Introduction

When conducting studies with endpoints such as resource utilization or mortality and morbidity, it is useful to adjust for different variables. In population-based studies, it is commonplace to collect demographic data, smoking status and alcohol use for this purpose. More recently, research has been published indicating that comorbid health conditions are crucial confounding variables that have been omitted from most statistical analyses (Fried et al., 2003).

A comorbid health condition can be defined as one or more health conditions that exist within an individual that are not a component of their principal disease process

(Shwartz et al., 1996). Presence of comorbid conditions is an important dimension of an individual's health status (Klabunde et al., 2005) and is a strong predictor that may confound many health outcomes (Fried et al., 2003). It has been demonstrated in the literature that comorbidity is an important determinant of patient costs (Shwartz et al., 1996), mortality (Pompei et al., 1991; Davies et al., 1995; Bagshaw et al., 2005; Miskulin, 2005; Wu et al., 2005), surgical outcomes (Greenfield et al., 1993), functional outcomes (Greenfield et al., 1995), hospital length of stay (Jencks et al., 1988), a risk measure for adults (Hornbrook et al., 1996) and considered to be an important prognostic factor (Piccirillo et al., 2004). One could conclude that comorbidity has a serious impact on health and must be controlled or adjusted for whenever possible.

A *self-report* comorbidity scale is a logical choice when conducting large population-based studies. Medical record review by a trained abstractor is expensive and time consuming, and not practical or even possible in large population-based studies, while routine administrative data may not be readily available or accurate in the outpatient setting (Fan et al., 2002; Sangha et al., 2003). In addition, administrative data may be biased by incomplete or inaccurate records and by financial incentives that influence the manner in which certain conditions are reported (Fan et al., 2002).

The literature indicates that individuals can accurately assess their current (Mechanic, 1980), and past medical conditions (Colditz et al., 1986; Harlow et al., 1989) including comorbid health status (Greenfield et al., 1995; Katz et al., 1996).

Today, there exists several generic and disease specific self-report comorbidity scales (Greenfield et al., 1995; Katz et al., 1996; Silliman et al., 1999; Fan et al., 2002; Selim et al., 2004; Groll et al., 2005). However, at the time of the Saskatchewan Health

and Back Pain Survey, there were no instruments available to measure comorbidity in a population-based survey. Jaroszynski et al. (1996) developed a self-report comorbidity scale that was used for this purpose (Jaroszynski et al., 1996). This questionnaire has been widely used (Carroll et al., 2000; Mercado et al., 2000; Côté et al., 2000a) but as yet has not been validated against health-related quality of life (HRQL) in the general population.

2.2.1 Health-Related Quality of Life and Comorbidity

It has been consistently demonstrated in the literature that there is a relationship between HRQL and comorbidity (Greenfield et al., 1995; Parkerson, Jr. et al., 2001; Fan et al., 2002; Selim et al., 2004; Groll et al., 2005). Additionally, many health conditions have an independent association with HRQL. Some examples are as follows: chronic obstructive pulmonary disease (Carrasco et al., 2006); cancer (Visser et al., 2006; Bowker et al., 2006); diabetes (Bowker et al., 2006); end-stage renal disease (Davison et al., 2006); rheumatoid arthritis (Kempen et al., 1997); hypertension (Krousel-Wood et al., 1994); depression (Coulehan et al., 1997); epilepsy (Vickrey et al., 1992); migraine headaches (Osterhaus et al., 1994); gastrointestinal problems (Wolfe et al., 2000; Kanazawa et al., 2004); allergies (Cvetkovski et al., 2006a; Cvetkovski et al., 2006b); and asthma (Ekici et al., 2006). Thus, the purpose of this analysis is to assess the convergent validity of the self-report comorbidity scale with HRQL, as measured by the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). Given the abundance of literature indicating that there is a clear association between HRQL and comorbid health conditions (see above), we would expect to find that presence and severity of comorbid

health conditions, as they are measured on the current scale, are association with poorer HRQL scores, that is, the comorbidity scale will demonstrate construct validity. If we find that presence and severity of comorbidity is associated with HRQL, we will have increased confidence in the self-report comorbidity scale as a valid measure.

2.3 Methods

Data for this research study were obtained by the Saskatchewan Health and Back Pain Survey, a population-based survey with six month and one-year follow-up (Cassidy et al., 1998; Côté et al., 1998; Carroll et al., 2000; Mercado et al., 2000; Côté et al., 2000a; Côté et al., 2000b; Côté et al., 2001; Carroll et al., 2002; Côté et al., 2004). This database includes demographic and socioeconomic factors, health-related factors (HRQL, depressive symptomatology, and presence and severity of comorbid health conditions), pain measures and pain coping measures. The measures that will be of interest in this study are the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) and the self-report comorbidity scale.

2.3.1 Measures: The Medical Outcomes Study 36-Item Short Form Health Survey

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) is one of the most common instruments used internationally to assess HRQL. It is a generic self-report questionnaire with 36 different items assessing the multidimensionality of health (Ware et al., 1993). The SF-36 consists of eight different health profiles in addition to a single item that measures reported health transition: 1) limitations in physical activities because of health problems; 2) limitations in social activities because

of physical or emotional problems; 3) limitations in social activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); 8) general health perceptions (Ware et al., 1993).

2.3.1.1 Physical and Mental Component Summary Scores

In order to reduce the number of statistical comparisons using the above eight different profiles, the authors of the SF-36 created a physical component summary (PCS) and mental component summary (MCS) (Ware, Jr. et al., 1995). The PCS includes physical functioning, role physical, bodily pain and general health perceptions, where the MCS includes vitality, social functioning, mental health and role emotional. The rationale for creating the two summary scales stems from the discovery that 80-85 percent of the reliable variance in the eight SF-36 scales is accounted for by physical and mental components of health (Ware et al., 1994). The MCS and PCS scales are scored using norm-based methods where the means and standard deviations are derived from the general U.S. population. A linear T-score transformation method is used so that both the PCS and MCS have a mean of 50 and a standard deviation of 10 (Ware et al., 1994). The psychometrically sound summary measures allow for simplification in the analysis and interpretation of the SF-36 (Ware et al., 2001). The MCS and PCS measures will constitute the outcomes for this analysis.

2.3.1.2 Validity and Reliability of the SF-36

The SF-36 has consistently proven to satisfy rigorous psychometric criteria and is considered to be a highly valid instrument when employed in a variety of populations (Garratt et al., 1993). The literature supports that the SF-36 has increased construct validity in terms of distinguishing between groups with expected health differences (Brazier et al., 1992); and has increased discriminative and responsive validity (McHorney et al., 1994; Kosinski et al., 1999; Gandek et al., 2004) more so than other generic HRQL measures such as the Sickness Impact Profile (SIP) (Stucki et al., 1995) and the Nottingham Health Profile (Brazier et al., 1992).

The SF-36 has increased internal consistency of the different health profiles and summary measures (Garratt et al., 1993; Jenkinson et al., 1993). Two-week test-retest estimates were also sufficiently high with reliability coefficients ranging from 0.55-0.89 (Wagner et al., 1995) and 0.60-0.81 (Brazier et al., 1992).

2.3.2 Measures: Self-report Comorbidity Scale

A 15-item self-report comorbidity scale was created to measure presence and severity in terms of its self-perceived impact on health in the Saskatchewan sample (Jaroszynski et al., 1996).

The initial strategy for item selection involved a consensus meeting of the authors leading to the creation of a list of diseases or medical conditions that are prevalent in the general population that may impact on the health related quality of life of individuals (Jaroszynski et al., 1996). Some related conditions were grouped together in order to reduce the number of items. A draft of the different diseases and conditions was sent to a

number of health care professionals. At a final consensus meeting, a final version of the questionnaire was agreed upon. Five response options were used to assess the impact of the chronic health condition on respondents' health in the past six months:

1. No, I do not have this condition (move on to the next question). Score 0
2. Not at all: I have the condition but the problem does not affect my health. Score 1
3. Mild: I have the condition and the problem makes my health a little worse than it should be. Score 2
4. Moderate: I have the condition and the problem makes my health worse than it should be. Score 3
5. Severe: I have the condition and the problem makes my health much worse than it should be. Score 4

This instrument was then subjected to initial study of its validity and reliability as described in Chapter One of this Thesis.

Covariates: The following covariates were assessed concurrently with the SF-36 and the self-report comorbidity scale: age, gender, income, education, smoking status, working status, exercise, body mass index, location of residence and marital status.

2.3.3 Study Sample

For the current study, data were taken from the baseline data of the Saskatchewan Health and Back Pain Survey. The target population was all Saskatchewan residents between the ages of 20 and 69 years who held a valid Saskatchewan Health Services card on August 31, 1995. Excluded from the target population were inmates, residents under the Office of the Public Trustee, foreign students and workers holding employment and

immigration visas, and residents of special care homes. From this population, a weighted, age-stratified random sample of residents was formed using the Saskatchewan Health Insurance Registration File (HIRF) as the sampling frame. The HIRF provides more than 99% coverage of the Saskatchewan population and contains basic demographic data that allowed for the assessment of the representativeness of the study sample and the impact of nonresponse bias. The Health Insurance Registration Branch of Saskatchewan Health conducted the randomization in order to preserve the confidentiality of the HIRF.

A comparison of age group, gender and geographic location between the random sample and the target population yielded no important differences, suggesting no selection bias due to randomization on the population characteristics. To assess selection bias due to selective responding to the questionnaire, demographic factors in the study sample and factors in non-respondents in the survey were compared. Older people, females and married people were slightly more likely to respond to the survey and individuals living on reserves were much less likely to respond (Côté et al., 1998). However, there was no apparent selection bias due to depression status (Carroll et al., 2000).

2.3.4 Data Collection

The study included three waves of mailings at each time point: the original questionnaire, a card reminding the recipients to complete the questionnaire (1 week later), and a second mailing of the questionnaire (3.5 weeks after the outset of the study) to non-respondents only. Consent was implied if the questionnaire was completed and

sent back. Additionally, if the individual did not respond to the second or third questionnaire after the reminder cards and second mailing of the questionnaire, the individual was assumed to have withdrawn from the study. 1131 individuals responded to the first questionnaire, which resulted in a response rate of 55%.

2.4 Analysis

The data were analyzed using multivariable linear regression to model the associations between the six most prevalent health conditions (headache, allergy, respiratory problems, musculoskeletal problems, gastro-intestinal disorders and mental health problems) and diabetes; and health-related quality of life (MCS and PCS scores) which were the dependent variables. Seven models were built, one for each of the most prevalent health conditions as well as diabetes. The prevalence of the most common disorders in the sample ranged from 55.3% to 23.7%, respectively. However, only 8% of the sample reported having diabetes.

The five different response options that exist in the original comorbidity questionnaire were collapsed into three categories because of small cell sizes. The three different categories are as follows: 1) do not have the health condition; 2) health condition is present but it does not affect or mildly affects my health; 3) health condition is present and moderately or severely affects my health. Dummy variables were created for the second and third category, while not having the health condition was defined as the reference category.

I initially assessed the crude relationship between each health condition level (level 2 and 3) and the each SF-36 summary measure (MCS and PCS) as the outcome,

compared to the reference category of not having the health condition. In order to determine the independent association between each of the health conditions and the SF-36 summary measure, I then assessed the potential effects of each of the listed sociodemographic variables (covariates) by entering them individually into a model that included the comorbid condition of interest. A covariate was considered to explain an important amount of the relationship between the health condition and the summary measure if it changed the magnitude of the estimate of the estimate (at either level of the health condition) by more than 10%. I then built a model which included all covariates, regardless of the bivariate analysis, and assessed the aggregate effect of the association between both health condition levels and the summary measures by removing and then replacing each variable one at a time. If the removal of a covariate affected the estimate of either health condition by 10% or more, that variable was considered to have a significant effect on the relationship between the health condition and the outcome. The final model adjusted for all significantly important covariates identified in either the bivariate analysis or in the aggregate model.

Non-response bias to the SF-36 was assessed by simple logistic regression by evaluating each sociodemographic variable and comorbid health condition independently with response or no response as the outcome. Any variable that had a significant association with the outcome (in the bivariate model) was entered into a multivariate logistic regression model, where significant associations ($p<.05$) were deemed to be associated with response to the SF-36.

2.5 Ethical Approval

Ethical approval for the original study was obtained from the University of Saskatchewan Advisory Committee on Ethics in Human Experimentation. The Health Research Ethics Board at the University of Alberta approved the current research that is the subject of this paper.

2.6 Results

There were 99 missing cases from both the MCS and PCS. An analysis of non-response indicated that younger individuals were less likely to respond to the SF-36 (adjusted OR = 0.96, 95% CI 0.94-0.98) and more educated individuals more likely to respond (adjusted OR = 1.84, 95% CI 1.09-3.10). Response to the SF-36 survey did not differ by any of the other sociodemographic variables or by any of the comorbid health conditions.

The following groups obtained lower MCS scores: females, younger individuals, those who were unmarried, had lower education, lower income, those not working, current smokers and obese individuals. Furthermore, lower PCS scores were found in older individuals, those with lower education, lower income, those not working, current smokers and the obese (Table 2-1).

Table 2-1 Subject characteristics and mean Mental Component Summary (MCS) and Physical Component Summary (PCS) scores. (N=1032)*

Factor	N (%)	MCS* mean (s.d.)†	PCS* mean (s.d.)†
Gender:			
Male	484 (46.9)	50.9 (9.1)	50.7 (9.0)
Female	548 (53.1)	49.6 (10.4)	49.1 (10.0)
Age group:			
20-29	157 (15.2)	48.5 (10.2)	52.3 (7.4)
30-39	229 (22.2)	49.6 (10.2)	52.3 (7.9)
40-49	294 (28.5)	49.2 (9.6)	50.6 (8.8)
50-59	199 (19.3)	52.5 (8.4)	48.4 (10.1)
60-69	153 (14.8)	51.9 (10.3)	44.2 (11.7)
Marital Status:			
Married	771 (75.4)	51.1 (9.3)	49.7 (9.6)
Separated/Divorced	80 (7.8)	45.7 (12.2)	48.0 (10.1)
Widowed	26 (2.5)	51.2(8.5)	47.0 (10.4)
Single	146 (14.3)	48.2 (10.1)	51.9 (8.8)
Education Level:			
University	146 (14.3)	51.8 (8.5)	52.6 (8.0)
Post Secondary	323 (31.6)	50.0 (9.4)	51.4 (8.6)
High School Grad	262 (25.6)	50.2 (10.0)	50.2 (9.4)
> Grade 8	229 (22.4)	50.2 (10.5)	47.0 (10.4)
< Grade 8	63 (6.2)	48.0 (11.2)	43.8 (10.9)
Income:			
Above 60K	201 (21.0)	51.5 (8.2)	52.2 (7.8)
40-60K	226 (23.6)	50.9 (9.1)	51.0 (8.6)
20-40K	324 (33.8)	51.3 (9.2)	49.7 (9.9)
0-20K	208 (21.7)	45.9 (11.8)	46.8 (10.8)
Location of residence:			
Large city	381 (37.0)	49.7 (9.8)	50.8 (9.3)
Small city	188 (18.3)	50.1 (10.2)	50.1 (8.3)
Town	165 (16.0)	50.8 (9.5)	48.9 (10.0)
Village	77 (7.5)	51.5 (9.2)	47.0 (11.7)
Rural municipality	207 (20.1)	50.9 (9.5)	49.7 (9.6)
Reserve	12 (1.2)	40.5 (11.4)	46.4 (12.2)
Smoking Status:			
Never smoked	517 (51.9)	50.4 (9.4)	51.0 (9.2)
Ex smoker	234 (23.5)	52.4 (8.9)	48.7 (10.0)
Current smoker <1pack/day	166 (16.6)	48.7 (10.6)	48.9 (9.2)
Current smoker >1pack/day	80 (8.0)	47.9 (11.1)	47.4 (10.8)
Body mass index:			
< 18.5 (underweight)	17 (1.6)	50.2 (8.4)	50.0 (9.0)
18.5-24.9 (normal)	408 (39.6)	50.1 (9.6)	51.3 (8.4)
25.0-29.9 (overweight)	406 (39.4)	50.8 (9.4)	50.2 (9.4)
>30.0 (obese)	200 (19.4)	49.2 (11.1)	46.0 (11.1)
Exercise frequency/week:			
0-2 times/week	494 (49.1)	49.3 (10.4)	49.1 (9.9)
3-7 times/week	513 (51.4)	51.3 (9.0)	50.6 (9.2)
Work Status:			
Working	941 (92.8)	50.9 (9.2)	50.5 (9.0)
Not working	73 (7.2)	41.4 (12.9)	42.1 (12.8)

*Some missing data: 9 subjects missing from marital status; 9 subjects missing from education level; 73 subjects missing from income; 2 subjects missing from location of residence; 35 subjects missing from smoking status; 1 subjects missing from body mass index; 25 subjects missing from exercise frequency/week; 18 missing subjects from working status.
† s.d. refers to standard deviation.

The most common health condition reported was headache. At the time of the survey, 55% (n=625) of the sample reported that they experienced headache in the last six months. Allergy (41%), respiratory problems (29%), musculoskeletal problems (27%), digestive problems (27%), gynecological problems among women respondents only (25%), mental health problems (24%), kidney problems (18%), high blood pressure (16%), cardiovascular problems (15%), other problems (12%), neurological problems (8%), diabetes (7%) and cancer (5%) follow in prevalence, respectively. The least common health condition identified was blood problems, with 4.3% (n=48) of the sample indicating that they had experienced this health problem in the last six months. For all health conditions, increasing severity of reported health problem coincided with a decrease in mean MCS and PCS scores (Table 2-2).

Table 2-2 Presence and severity of comorbid conditions and mean Mental Component Summary (MCS) and Physical Component Summary (PCS) scores (N=1032)*

Comorbid Health Condition	n (%)	MCS mean (s.d.)†	PCS mean (s.d.)†
Headaches:			
None	445 (44)	52.6 (8.1)	51.4 (9.1)
Yes, no effect on health	86 (9)	51.0 (8.6)	52.7 (8.9)
Yes, mild effect on health	308 (30)	50.0 (9.5)	49.5 (9.3)
Yes, moderate effect on health	139 (14)	44.3 (12.2)	46.5 (9.7)
Yes, severe effect on health	37 (4)	43.4 (12.0)	39.5 (9.5)
Allergies:			
None	583 (58)	50.7 (9.3)	50.8 (9.1)
Yes, no effect on health	74 (7)	52.7 (8.1)	51.0 (8.5)
Yes, mild effect on health	233 (23)	50.7 (9.3)	48.8 (9.9)
Yes, moderate effect on health	100 (10)	45.3 (12.5)	47.3 (10.6)
Yes, severe effect on health	19 (2)	47.5 (11.9)	40.7 (8.9)
Respiratory Problems:			
None	719 (71)	51.2 (9.1)	51.0 (9.0)
Yes, no effect on health	49 (5)	52.0 (8.6)	51.8 (7.5)
Yes, mild effect on health	169 (17)	48.4 (10.2)	47.7 (10.1)
Yes, moderate effect on health	64 (6)	43.7 (11.7)	41.1 (11.1)
Yes, severe effect on health	9 (1)	41.1 (17.7)	46.4 (8.7)
Musculoskeletal Problems:			
None	733 (73)	50.5 (9.6)	51.9 (8.3)
Yes, no effect on health	27 (3)	52.8 (8.7)	50.7 (8.0)
Yes, mild effect on health	136 (14)	49.3 (10.0)	48.8 (7.6)
Yes, moderate effect on health	80 (8)	48.8 (11.4)	39.2 (9.1)
Yes, severe effect on health	25 (3)	47.9 (11.3)	27.5 (7.3)
Gastrointestinal Problems:			
None	742 (73)	51.3 (9.3)	51.3 (8.6)
Yes, no effect on health	44 (4)	51.8 (7.2)	48.3 (12.1)
Yes, mild effect on health	137 (14)	48.0 (10.1)	48.2 (9.7)
Yes, moderate effect on health	79 (8)	44.7 (12.3)	42.4 (10.3)
Yes, severe effect on health	11 (1)	38.5 (7.5)	38.2 (13.6)
Mental Health Problems:			
None	776 (76)	53.0 (7.2)	50.7 (8.9)
Yes, no effect on health	42 (4)	50.3 (10.4)	49.5 (9.4)
Yes, mild effect on health	130 (13)	42.1 (9.9)	47.0 (11.5)
Yes, moderate effect on health	56 (6)	35.7 (11.0)	46.0 (11.3)
Yes, severe effect on health	12 (1)	27.1 (11.4)	48.5 (10.0)
Kidney Problems:			
None	838 (83)	50.8 (9.6)	50.7 (9.1)
Yes, no effect on health	44 (4)	47.0 (9.6)	46.5 (9.9)
Yes, mild effect on health	101 (10)	49.0 (10.8)	46.0 (10.7)
Yes, moderate effect on health	28 (3)	44.5 (11.8)	44.4 (10.0)
Yes, severe effect on health	4 (1)	43.0 (8.3)	28.6 (8.6)

Comorbid Health Condition	n (%)	MCS mean (s.d.)†	PCS mean (s.d.)†
High Blood Pressure:			
None	858 (85)	50.2 (9.6)	50.7 (8.9)
Yes, no effect on health	46 (5)	52.1 (8.3)	47.4 (10.0)
Yes, mild effect on health	64 (6)	48.2 (10.6)	45.3 (11.5)
Yes, moderate effect on health	36 (4)	48.1 (10.4)	42.5 (12.4)
Yes, severe effect on health	6 (1)	35.1 (16.4)	34.1 (7.2)
Heart Problems:			
None	869 (86)	50.7 (9.6)	50.6 (9.2)
Yes, no effect on health	40 (4)	50.7 (9.4)	49.5 (8.7)
Yes, mild effect on health	66 (7)	48.4 (9.8)	45.8 (10.3)
Yes, moderate effect on health	30 (3)	41.9 (12.6)	42.0 (10.7)
Yes, severe effect on health	9 (1)	48.4 (13.1)	34.2 (10.9)
Gynecological Problems‡:			
None	405 (75)	50.8 (9.8)	49.2 (10.2)
Yes, no effect on health	29 (5)	46.3 (11.0)	49.9 (9.7)
Yes, mild effect on health	63 (12)	45.7 (12.9)	50.2 (7.8)
Yes, moderate effect on health	31 (6)	48.7 (7.6)	46.0 (9.6)
Yes, severe effect on health	11 (2)	45.3 (12.3)	47.4 (9.9)
Other Health Problems:			
None	869 (88)	50.9 (9.5)	50.7 (9.0)
Yes, no effect on health	27 (3)	47.8 (10.8)	49.1 (9.0)
Yes, mild effect on health	39 (4)	47.7 (11.4)	47.6 (8.9)
Yes, moderate effect on health	34 (3)	45.8 (10.9)	41.9 (11.3)
Severe effect	18 (2)	45.5 (10.2)	36.0 (11.6)
Neurological Problems:			
None	938 (92)	50.5 (9.6)	50.3 (9.3)
Yes, no effect on health	32 (3)	49.7 (10.1)	49.4 (7.4)
Yes, mild effect on health	30 (3)	48.0 (11.1)	41.8 (11.9)
Yes, moderate effect on health	13 (1)	42.5 (16.2)	36.5 (14.6)
Yes, severe effect on health	2 (.2)	24.7 (14.1)	42.2 (11.0)
Diabetes:			
None	934 (93)	50.2 (9.9)	50.3 (9.3)
Yes, no effect on health	25 (3)	50.5 (8.1)	49.7 (7.7)
Yes, mild effect on health	28 (3)	52.7 (8.8)	44.0 (12.0)
Yes, moderate effect on health	11 (1)	48.2 (13.1)	36.7 (12.7)
Yes, severe effect on health	3 (.3)	38.8 (4.7)	33.8 (3.7)
Cancer:			
None	976 (95)	50.4 (9.7)	50.0 (9.6)
Yes, no effect on health	32 (3)	48.4 (10.0)	48.1 (8.2)
Yes, mild effect on health	9 (1)	47.6 (14.7)	49.8 (8.7)
Yes, moderate effect on health	5 (1)	44.2 (15.0)	37.5 (13.9)
Yes, severe effect on health	1 (.1)	40.0 (N/A)	31.7 (N/A)
Blood problems:			
None	977 (96)	50.4 (9.7)	50.0 (9.6)
Yes, no effect on health	23 (2)	50.6 (7.8)	47.6 (8.8)
Yes, mild effect on health	14 (1)	44.0 (14.1)	49.4 (10.6)
Yes, moderate effect on health	5 (1)	42.3 (14.2)	42.5 (7.8)
Yes, severe effect on health	2 (.2)	29.8 (18.6)	38.6 (0.8)

*Some missing data. 17 subjects missing from headaches; 23 subjects missing from allergies; 22 subjects missing from respiratory problems; 31 subjects missing from musculoskeletal problems; 19 subjects missing from gastrointestinal problems; 16 subjects missing from mental health problems; 17 subjects missing from kidney problems; 22 subjects missing from high blood pressure problems; 18 subjects missing from heart problems; 66 subjects missing from gynecological problems (women only); 45 subjects missing from other health problems; 17 subjects missing from neurological problems; 31 subjects missing from diabetes; 9 subjects missing from cancer; and 11 subjects missing from blood problems.
† s.d. refers to standard deviation
‡ women respondents only, n=605

Multivariable linear regression models were built to describe the relationship between the six most commonly reported comorbid health conditions as well as diabetes, and the two SF-36 summary scores. The six most common health conditions in both genders were headache, allergy, respiratory problems, musculoskeletal problems, gastrointestinal problems and mental health problems. The presence and severity of nearly each health condition was associated with decreased MCS and PCS scores in both adjusted and non-adjusted models. Crude and adjusted models are reported in Tables 2-3 and 2-4.

Table 2-3: Crude and adjusted association between health item and MCS: Beta values and their 95% confidence intervals

Health item*	β Unadjusted (95%CI)	β Adjusted † (95% CI)
Headache ‡		
No effect/mild effect on health	-2.41 (-3.68, -1.14)	-2.41 (-3.68, -1.14)
Moderate/severe effect on health	-8.57 (-10.21, -6.93)	-8.57 (-10.21, -6.93)
Allergy §		
No effect/mild effect on health	0.43 (-0.91, 1.77)	0.43 (-0.92, 1.78)
Moderate/severe effect on health	-5.09 (-7.00, -3.18)	-4.06 (-5.98, -2.15)
Respiratory Problems ¶		
No effect/mild effect on health	-2.05 (-3.51, -0.60)	-2.05 (-3.51, -0.60)
Moderate/severe effect on health	-7.90 (-10.21, -5.59)	-7.90 (-10.21, -5.59)
Musculoskeletal Problems ||		
No effect/mild effect on health	-0.57 (-2.24, 1.10)	-1.37 (-3.11, 0.38)
Moderate/severe effect on health	-1.93 (-3.94, 0.09)	-2.50 (-4.67, -0.33)
Gastrointestinal Problems **		
No effect/mild effect on health	-2.41 (-3.97, -0.85)	-2.72 (-4.27, -1.17)
Moderate/severe effect on health	-7.39 (-9.49, -5.28)	-6.41 (-8.54, -4.27)
Mental Health ††		
No effect/mild effect on health	-8.91 (-10.26, -7.55)	-8.91 (-10.26, -7.55)
Moderate/severe effect on health	-18.83 (-20.86, -16.80)	-18.83 (-20.86, -16.80)
Diabetes §§		
No effect/mild effect on health	1.46 (-1.27, 4.19)	0.51 (-2.32, 3.35)
Moderate/severe effect on health	-4.02 (-9.23, 1.18)	-3.68 (-9.23, 1.87)

* Reference category for each is not having that particular health condition. Separate models were built for each health condition.
† N in adjusted models = 1016 for headache; 932 for allergy; 1011 for respiratory problems; 888 for musculoskeletal problems; 937 for gastrointestinal problems; 1017 for mental health problems; 890 for diabetes.
‡ No covariate met the criteria for inclusion in the model.
§ Adjusted model adjusts for the following covariates: income and work status.
¶ No covariate met the criteria for inclusion in the model.
|| Adjusted model adjusts for the following covariates: smoking status, marital status, income, amount of exercise, age and work status.
** Adjusted model adjusts for the following covariates: income, age and work status.
†† No covariate met the criteria for inclusion in the model.
§§ Adjusted model adjusts for the following covariates: smoking status, body mass index, marital status, education, income, amount of exercise, location of residence, age, gender and work status.

Table 2-4: Crude and adjusted association between health item and PCS: Beta values and their 95% confidence intervals

Health item*	β Unadjusted (95%CI)	β Adjusted † (95% CI)
Headache ‡		
No effect/mild effect on health	-1.16 (-2.43, 0.11)	-1.01 (-2.64, 0.24)
Moderate/severe effect on health	-6.34 (-7.97, -4.70)	-5.68 (-7.31, -4.05)
Allergy §		
No effect/mild effect on health	-1.48 (-2.79, -0.16)	-1.54 (-2.78, -0.30)
Moderate/severe effect on health	-4.51 (-6.39, -2.64)	-3.47 (-5.24, -1.70)
Respiratory Problems ¶		
No effect/mild effect on health	-2.36 (-3.78, -0.95)	-1.46 (-2.87, -0.06)
Moderate/severe effect on health	-9.25 (-11.49, -7.01)	-7.69 (-9.93, -5.45)
Musculoskeletal Problems ‖		
No effect/mild effect on health	-2.77 (-4.20, -1.35)	-2.77 (-4.20, -1.35)
Moderate/severe effect on health	-15.48 (-17.19, -13.76)	-15.48 (-17.19, -13.76)
Gastrointestinal Problems **		
No effect/mild effect on health	-3.06 (-4.55, -1.57)	-2.31 (-3.77, -0.85)
Moderate/severe effect on health	-9.40 (-11.40, -7.39)	-8.59 (-10.55, -6.63)
Mental Health ††		
No effect/mild effect on health	-3.07 (-4.63, -1.50)	-2.42 (-4.02, -0.82)
Moderate/severe effect on health	-4.20 (-6.55, -1.85)	-2.08 (-4.52, 0.36)
Diabetes §§		
No effect/mild effect on health	-3.65 (-6.25, -1.05)	-0.64 (-3.32, 2.05)
Moderate/severe effect on health	-14.30 (-19.25, -9.34)	-11.91 (-17.05, -6.77)

* Reference category for each is not having that particular health condition. Separate models were built for each health condition.

† N in adjusted models = 1000 for headache; 995 for allergy; 941 for respiratory problems; 1002 for musculoskeletal problems; 1015 for gastrointestinal problems; 976 for mental health problems; 932 for diabetes.

‡: Adjusted model adjusts for work status.

§: Adjusted model adjusts for the following covariates: age and work status.

¶: Adjusted model adjusts for the following covariates: age and income.

‖: No covariate met the criteria for inclusion in the model.

**: Adjusted model adjusts for the following covariates: age.

††: Adjusted model adjusts for the following covariates: work status and smoking status.

§§: Adjusted model adjusts for the following covariates: age and income.

2.6.1 Mental Component Summary (MCS) Score

The association between headaches and the MCS was not significantly affected by any of the sociodemographic factors considered, including factors associated with non-response to the survey. In comparison with no headaches, the MCS score of individuals who reported having headaches with no or a mild effect on health decreased by 2.41 points (95%CI -3.68, -1.14). Individuals who reported experiencing headaches that had a moderate or a severe effect on health had a decrease in MCS score of 8.57 points (95% CI -10.21, -6.93) compared to non-headache suffers.

Compared with no allergy, individuals who reported allergy with no or a mild effect on health had an MCS score that increased 0.43 points (95% CI -0.92, 1.78). However, the MCS score of individuals who reported having allergy with a moderate to severe effect on health decreased 4.06 points (CI -5.98, -2.15) compared to those who did not suffer from allergy problems. The above relationships are adjusted for income and work status.

The association between respiratory problems and MCS was not affected significantly by any of the sociodemographic variables. In comparison with no respiratory problems, individuals who suffer from respiratory problems with no or a mild effect on health have a decreased MCS score of 2.05 (95% CI -3.51, -0.60). Additionally, the MCS score of individuals whose respiratory problems have a moderate to severe effect on health decreases by 7.90 points (95% CI-10.21, -5.59) when compared to those who do not have respiratory problems.

The final MSK model adjusted for income, working status, marital status, exercise category, age and current smoking status. Those respondents who reported MSK

problems with no or a mild effect on health had a decreased MCS score of 1.37 (95% CI -3.11, 0.38) compared to those who did not have MSK problems. Those who reported MSK problems to have a moderate to severe effect on health had a decreased MCS score of 2.50 (95% CI -4.67, -0.33) compared to those who did not have MSK problems.

The association between gastrointestinal (GI) problems and the MCS was affected significantly by age, working status and income which were adjusted for in the final models. In comparison with those who did not have GI problems, individuals who were experiencing GI problems with no or a mild effect on health had a decreased MCS score of 2.72 (95% CI -4.27,-1.17). Whereas, those who reported GI problems with a moderate to severe effect on health had a decreased MCS score of 6.41 (95% CI -8.54, -4.27) compared to those who did not have GI problems.

The strongest relationship observed in these analyses was between mental health problems and the MCS. In comparison with those who did not experience mental health problems, individuals who had mental health problems that did not or mildly affected health had a decreased MCS score of 8.91 (95% CI -10.26, -7.55). Those who reported mental health problems with a moderate or severe effect on health had a decreased MCS score of 18.83 (95% CI -20.86, -16.80) when compared to those with no mental health problems. There were no covariates that significantly affected this relationship.

When the relationship between diabetes and MCS was observed, statistical significance was not achieved at either level of diabetes when compared to no diabetes (see Table 2-3). Unfortunately, there was not enough power to be able to accurately assess these relationships.

2.6.2 Physical Component Summary (PCS) Score

The association between headaches and the PCS was significantly affected by work status which was adjusted for in analysis. In comparison with no headaches, the PCS score of individuals who reported having headaches with no or a mild effect on health decreased by 1.01 points (95%CI -2.64, 0.24). Individuals who reported experiencing headaches that had a moderate or a severe effect on health had a decrease in PCS score of 5.68 points (95% CI -7.31, -4.05) compared to non-headache suffers.

Compared with no allergy, individuals who reported allergy with no or a mild effect on health had a PCS score that decreased by 1.54 points (95% CI -2.78, -0.30). The PCS score of individuals who reported having allergy with a moderate to severe effect on health decreased 3.47 points (CI -5.24, -1.70) compared to those who did not suffer from allergy problems. The above relationships are adjusted for age and work status.

The association between respiratory problems and PCS was significantly affected by age and income which were adjusted for in the final models. In comparison with no respiratory problems, individuals who suffer from respiratory problems with no or a mild effect on health have a decreased PCS score of 1.46 (95% CI -2.87, -0.06). Additionally, the PCS score of individuals whose respiratory problems have a moderate to severe effect on health decreases by 7.69 points (95% CI -9.93, -5.45) when compared to those who do not have respiratory problems.

The strongest relationship observed with PCS as the outcome was with musculoskeletal (MSK) problems. This relationship was not significantly affected by any of the sociodemographic variables. Those respondents who reported MSK problems with

no or a mild effect on health had a decreased PCS score of 2.77 (95% CI -4.20, -1.35) compared to those who did not have MSK problems. Those who reported MSK problems to have a moderate to severe effect on health had a decreased PCS score of 15.48 (95% CI -17.19, -13.76) compared to those who did not have MSK problems.

The association between gastrointestinal (GI) problems and the MCS was significantly affected by age which was adjusted for in the final models. In comparison with those who did not have GI problems, individuals who were experiencing GI problems with no or a mild effect on health had a decreased PCS score of 2.31 (95% CI -3.77, -0.85). Whereas, those who reported GI problems with a moderate to severe effect on health had a decreased PCS score of 8.59 (95% CI -10.55, -6.63) compared to those who did not have GI problems.

In comparison with those who did not experience mental health problems, individuals who had mental health problems that did not or mildly affected health had a decreased PCS score of 2.42 (95% CI -4.02, -0.82). Those who reported mental health problems with a moderate or severe effect on health had a decreased PCS score of 2.08 (95% CI -4.52, 0.36) when compared to those who did not experience mental health problems. This relationship was significantly affected by work and smoking status which were adjusted for in the final models.

Age and income were identified as significantly affecting the relationship between diabetes and PCS. The two variables were adjusted for in the final models. Those who reported diabetes to have no or a mild effect on health had a decreased PCS score of -0.64 (95% CI -3.32, 2.05) when compared those who did not have diabetes. A stronger relationship existed for those who reported that their diabetes had a moderate to strong

effect on their health. Compared to those with no diabetes, the preceding group had a decreased PCS score of 11.91 (95% CI -17.05, -6.77).

2.7 Discussion

The aim of this analysis was to describe the relationship between the presence and severity of comorbid health conditions and health-related quality of life, as measured by the MCS and PCS. Our findings that a lower MCS score is more common in the female gender, younger age, being unmarried, having lower education, lower income, not working, being a current smoker and being obese are consistent with reports in the literature (Weissman et al., 1984; Ross et al., 1989; Gallo et al., 1994; Weissman et al., 1996; Carroll et al., 2000; Piccinelli et al., 2000; Rodriguez et al., 2001; Murphy et al., 2003; Muennig et al., 2006; Rejeski et al., 2006). Furthermore, lower PCS scores are more common in older age, having lower education, lower income, not working, being a current smoker and being obese. This is also consistent with the literature (Grimby et al., 1994; Kazis et al., 1998; Cheng et al., 2003; Garces et al., 2004; Salaffi et al., 2005; Rejeski et al., 2006; Blissmer et al., 2006).

The self-report comorbidity scale performed as expected by demonstrating that individuals who report the presence of a health condition have both decreased scores of MCS and PCS, compared to individuals who do not have the health condition. The analyses also indicated an association between the severity of different health conditions and the MCS and PCS scores. This suggests that individuals who have a heavier burden of illness correspondingly have decreased MCS and PCS scores. To summarize, our findings are consistent with the literature that comorbid health conditions are associated

with health-related quality of life (Greenfield et al., 1995; Parkerson, Jr. et al., 2001; Fan et al., 2002; Selim et al., 2004; Groll et al., 2005). These findings generate increased confidence that the self-report comorbidity questionnaire is a valid instrument.

It should be noted that causality cannot be established due to the cross-sectional design of the study. However, as mentioned above, our study does describe a gradient relationship between presence and severity of health conditions and health-related quality of life. This finding strengthens the noted relationship.

2.7.1 Mental Component Summary (MCS) Score

We observe clinically important differences between those who report moderate to severe effects on health from headaches, respiratory problems, gastrointestinal problems, and mental health problems compared to those who do not report these conditions. A change in β coefficient of five or more equates to over half of a standard deviation, which indicates a clinically important difference (Norman et al., 2003). This informs us that most moderate or severe health problems affect mental HRQL in a clinically important adverse way.

An interesting finding was that MSK did not have as strong and significant a relationship with MCS as we had expected. A reason for this may be because respondents were instructed that the MSK item included rheumatoid arthritis; osteoarthritis of the knee, hip or hand; osteoporosis or thin bones; and fracture. The MSK item did not include neck pain or back pain, two items under the umbrella of MSK problems that are highly associated with depressive symptomatology (Carroll et al.,

2000). It is plausible that because neck and back pain were excluded from the MSK item, that the item performed differently than if it had included all MSK pain.

The mental health item was the most strongly associated item with the MCS, as the β coefficients for both levels of reported mental health problems are much higher than any of the other comorbid health items (see Table 2-3). This may be due in part to the fact that depression is the most common mental health problem that is reported (Wang et al., 2000; Enns et al., 2001). We had hypothesized that this item would have a strong relationship with depressive symptomatology because both are measuring similar traits; thus highlighting the validity of the mental health item.

2.7.2 Physical Component Summary (PCS) Score

Headaches, respiratory problems, MSK problems, gastrointestinal problems and diabetes that were reported to have a moderate to severe effect on health demonstrated a clinically important difference compared to those who did not report these health conditions. As stated earlier, because these health conditions (that have a moderate to severe effect on health) have β coefficients that are higher than half of a standard deviation, they are considered to be clinically different from those who do not report these health conditions. This informs us that most moderate or severe health problems affect physical HRQL in a clinically important adverse way.

The MSK health item was the most strongly associated item with the PCS, as the β coefficients for both levels of reported MSK problems are much higher than any of the other comorbid health items (see Table 2-4). We expected MSK problems and the PCS scores to be strongly associated because of the intrinsic physical component to both of the

scales. This gives us increased confidence that MSK item is performing as it should, thus highlighting validity of this item.

The diabetes health item was difficult to evaluate because of the low prevalence in the sample. Statistical significance was not achieved for either level with MCS as the outcome; therefore no conclusions can be made in these analyses. However, there is evidence to suggest that diabetes and depression are associated in other populations (Brown et al., 2006). Diabetes that affects health moderately or severely had a large effect (β = -11.91) on the PCS score, however the confidence intervals around the estimate were larger (95% CI -17.05, -6.77), indicating a lack of precision due to the small proportion of respondents to this item. The literature also supports that there is an association between diabetes and physical HRQL (Maddigan et al., 2003).

The self-report comorbidity questionnaire is a brief but comprehensive tool that has demonstrated its ability to identify presence and severity of comorbid health conditions in a large population-based study. The questionnaire can be easily appended to any population-based survey to 1) determine the burden of different health conditions in the population, and 2) to be able to adjust for different health conditions in statistical analyses.

2.8 Strengths and Limitations

It is important to highlight some strengths and limitations of our study. The Saskatchewan Health and Back Pain Survey was a large population based mail out survey with 1131 respondents at baseline. Although a response rate of 55% was attained, we have increased confidence in our results (Carroll et al., 2000). An accurate and complete

sampling frame was ensured using the Saskatchewan Health Insurance Registration File where Saskatchewan adults were randomly sampled (Côté et al., 1998; Carroll et al., 2000). Previous analyses identified that non-respondents were younger, male and not married, therefore these individuals are slightly underrepresented (Côté et al., 1998). However, other than the aforementioned traits, logistical regression and wave analysis determined that the non-respondents and respondents were from the same population (Côté et al., 1998). Although we have some information that was provided by Saskatchewan Health on respondents and non-respondents with respect to factors that influenced participation in the study (age group, gender, marital status and location of residence), we cannot say for certain if different comorbid health conditions differed among respondents and non-respondents. In addition, because some health conditions were not very prevalent in the study sample, the number of models that we were able to build using multiple linear regression was limited. It would have been informative to observe a relationship between presence and severity of all comorbid health conditions and HRQL. Response to the SF-36 survey did not differ by comorbid health conditions; only by age and level of education where younger individuals and less educated individuals were less likely to respond. While non-response bias is always a concern with large mail-out surveys, attempts were made to explain the differential response rates in order to guide interpretation.

2.9 Conclusion

In conclusion, we report a clear association between presence and severity of several comorbid health conditions and HRQL. The self-report comorbidity scale

performed as expected and thus generated increased confidence in its validity. This paper is an initial examination of how the self-report comorbidity scale behaves with regards to HRQL. More research is needed to further examine the validity and reliability of the instrument.

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Chapter 3

Evaluating the Performance of a Self-Report Comorbidity Questionnaire with Depressive Symptomatology as the Outcome

3.1 Synopsis

When completing studies with health-related outcomes, it is necessary to control for confounding factors. In population-based studies, it is common place to adjust for sociodemographic characteristics, however comorbid health conditions are beginning to be recognized as crucial confounding variables that must be measured and controlled for during data analyses. The purpose of this research is to begin to assess the validity of the self-report comorbidity scale used in a large population-based survey, with depressive symptomatology as the outcome. The relationship between presence and severity of comorbid health conditions and depressive symptomatology will be examined.

Data for this study were taken from the Saskatchewan Health and Back Pain Survey, a population-based survey conducted in 1995-96 of adults over the age of 20 years. This study yielded a 55% response rate at baseline (n=1131). Multivariable logistic regression was used to determine the relationship between presence and severity of different health conditions and depressive symptomatology. The outcome, depressive symptomatology, was measured by The Center for Epidemiologic Studies Depression (CES-D) scale where a score $\geq$ 16 indicated increased depressive symptomatology. Sociodemographic factors were identified and controlled for. Crude and adjusted models were reported for the six most prevalent health conditions.

The most common health conditions that were reported in both genders were headache (55%), allergy (41%), respiratory problems (29%), musculoskeletal problems

(27%), digestive problems (27%), and mental health problems (24%). Increasing severity of each reported health problem coincided with an increase in mean CES-D scores. When multivariate logistic regression models were built, presence and severity of each health condition was associated with increased frequency of depressive symptomatology in most adjusted and non-adjusted models.

We report a clear association between presence and severity of several comorbid health conditions and depressive symptomatology. The self-report comorbidity scale performed as expected and thus generated increased confidence in its validity. This research is an initial examination of how the self-report comorbidity scale behaves with regards to presence or absence of depressive symptomatology. More research is needed to further examine the validity and reliability of the instrument.

3.2 Introduction

When conducting studies with endpoints such as resource utilization or mortality and morbidity, it is important to control for confounding factors. In population-based studies, for example, it is commonplace to collect demographic data, smoking status and alcohol use for this purpose. More recently, research has been published indicating that comorbid health conditions are crucial confounding variables that have been omitted from most statistical analyses (Fried et al. 2003). Comorbid conditions can be defined as those conditions which are not a component of the principal disease process, but which increase an individual's total burden of illness and thus place a person in a higher case mix category (Shwartz et al. 1996). Comorbidity has been demonstrated to alter risk of mortality (Charlson et al. 1987;Sangha et al. 2003) and be a predictor for post-operative

complications and functional outcomes (Greenfield et al. 1993). Older age and lower levels of education are also related to the occurrence and degree of comorbidity (van den et al. 1998).

Comorbid chronic medical conditions are also associated with depressive symptomatology. In a prospective, community-based study in a Canadian population, Patten (2001) described an increased risk of developing depression with almost any long-term condition and reported that, alternatively, depression may increase the risk of chronic medical conditions (Patten 2001). Based on this information, it is plausible to suggest that comorbid illness together with depression may place a heavy burden on the healthcare system. This is illustrated in a review by Katon (2003) who concluded that there was a 50% increase in medical costs for patients with major depression and chronic medical conditions, compared with patients with chronic conditions alone (Katon 2003). Furthermore, research has indicated a positive association between symptoms of depression and medical conditions such as diabetes (Ciesla and Roberts 2001;Katon 2003;Brown et al. 2006); stroke (Pohjasvaara et al. 1998); myocardial infarction (Frasure-Smith et al. 1993;Lesperance et al. 1996;Bush et al. 2001;Carney and Freedland 2003); congestive heart failure (Koenig 1998); coronary artery bypass surgery (Blumenthal et al. 2003); and cancer (Holland et al. 1998;Capuron et al. 2001;Goodwin et al. 2004).

Depression is an important health issue globally and nationally. The WHO estimates that, by 2020, unipolar major depression will become the second leading cause of disease burden worldwide, second only to ischemic heart disease (Simon 2003). To

illustrate the Canadian perspective, a recent study reported that lifetime prevalence of major depressive episode in the Canadian population was 12.2% (Patten et al. 2006).

One of the goals of The Saskatchewan Health and Back Pain survey, conducted in 1995-96, was to determine the incidence and prevalence of neck and back pain, and to observe the relationship between these health conditions and depression (Carroll et al. 2000). In order to determine the independent relationship between neck and back pain and depression, other factors which may have impacted this relationship, such as comorbid health conditions, needed to be adjusted for. Comorbid health conditions were assessed based on the respondent's answers on a self-report comorbidity scale, a scale that was created exclusively for the purpose of this large population-based study and is described in a later section. Thus, the purpose of this analysis is to assess the performance of the self-report comorbidity scale by observing its relationship with depressive symptomatology as measured by the CES-D. Given the abundance of literature indicating that there is a clear association between depressive symptomatology and comorbid health conditions (see above), we would expect to have similar findings in our study. If we find that presence and severity of comorbidity is associated with depressive symptomatology, we will have increased confidence in the self-report comorbidity scale as a valid measure.

3.3 Methods

Data for this research study was obtained by the Saskatchewan Health and Back Pain Survey, a population-based survey with six month and one-year follow-up (Cassidy et al. 1998;Côté et al. 1998;Carroll et al. 2000;Mercado et al. 2000;Côté et al. 2000a;Côté

et al. 2000b;Côté et al. 2001;Carroll et al. 2002;Carroll et al. 2003;Côté et al. 2004;Carroll et al. 2004;Cassidy et al. 2005;Mercado et al. 2005). This database includes demographic and socioeconomic factors, health-related factors, pain measures and pain coping measures. The measures of interest in this study are the CES-D and the self-report comorbidity scale.

3.3.1 Measures: The Center for Epidemiologic Studies Depression (CES-D) scale

The Center for Epidemiologic Studies Depression (CES-D) scale has been widely used to measure depressive symptomatology in epidemiologic research. This self-report scale includes 20-items with scores ranging from 0-60, where a score of $\geq$ 16 suggests the presence of significant depressive symptomatology (Radloff 1977;Boyd et al. 1982;Orme et al. 1986;Devins et al. 1988). This validated cut-point of $\geq$16 is recommended for population-based studies of depression (Radloff 1977) and over time, many researchers have used the cut-off of 16 to identify clinically depressed individuals of a variety of different ages and backgrounds (Barnes and Prosen 1984;Beekman et al. 1997;Caracciolo and Giaquinto 2002;Herrman et al. 2002;Burns et al. 2003;Haringsma et al. 2004). Therefore, the conventional threshold of $\geq$16 identified initially by Radloff (1977) will be used when assessing the presence of significant depressive symptomatology in the current study.

The CES-D has consistently demonstrated good criterion validity (Beekman et al. 1997;Caracciolo and Giaquinto 2002;Haringsma et al. 2004) and correlates highly with clinician rating measures of depression such as the Hamilton, the Beck Depression Inventory and the SCL-90 (Hamilton 1960;Beck et al. 1961;Radloff 1977;Weingartner et

al. 2002;Arrindell and Ettema 2003). The CES-D is also a reliable tool and possesses good internal consistency ($\alpha > 0.84$) and test-retest reliability (r=0.67) at four weeks (Radloff 1977).

As stated above, the psychometrically sound CES-D is one of the most widely used self-report instruments to measure current depressive symptomatology in population-based studies. For this reason, there was confidence in applying the CES-D to the Saskatchewan Health and Back Pain Survey.

3.3.2 Measures: Self-Report Comorbidity Scale

A 15-item self-report comorbidity scale was created to measure presence and severity in terms of its self-perceived impact on health in the Saskatchewan sample (Jaroszynski et al. 1996).

The initial strategy for item selection involved a consensus meeting of the developers of the scale leading to the creation of a list of diseases or medical conditions that are prevalent in the general population that may impact on the health-related quality of life of individuals (Jaroszynski et al. 1996). Some related conditions were grouped together in order to reduce the number of items. A draft of the different diseases and conditions was sent to a number of health care professionals. At a final consensus meeting, a final version of the questionnaire was agreed upon. Five response options were used to assess the impact of the chronic health condition on respondents' health in the past six months:

1. No, I do not have this condition (move on to the next question). Score 0
2. Not at all: I have the condition but the problem does not affect my health. Score 1

3. Mild: I have the condition and the problem makes my health a little worse than it should be. Score 2
4. Moderate: I have the condition and the problem makes my health worse than it should be. Score 3
5. Severe: I have the condition and the problem makes my health much worse than it should be. Score 4

This instrument was then subjected to initial study of its validity and reliability as described in Chapter One of this Thesis.

3.3.3 Study Sample

For the current study, data were taken from the baseline data of the Saskatchewan Health and Back Pain Survey. The target population was all Saskatchewan residents between the ages of 20 and 69 years who held a valid Saskatchewan Health Services card on August 31, 1995. Excluded from the target population were inmates, residents under the Office of the Public Trustee, foreign students and workers holding employment and immigration visas, and residents of special care homes. From this population, a weighted, age-stratified random sample of residents was formed using the Saskatchewan Health Insurance Registration File (HIRF) as the sampling frame. The HIRF provides more than 99% coverage of the Saskatchewan population and contains basic demographic data that allowed for the assessment of the representativeness of the study sample and the impact of nonresponse bias. The Health Insurance Registration Branch of Saskatchewan Health conducted the randomization in order to preserve the confidentiality of the HIRF.

A comparison of age group, gender and geographic location between the random sample and the target population yielded no important differences, suggesting no selection bias due to randomization on the population characteristics. To assess selection bias due to selective responding to the questionnaire, demographic factors in the study sample and factors in non-respondents in the survey were compared. Older people, females and married people were slightly more likely to respond to the survey and individuals living on reserves were much less likely to respond (Côté et al. 1998). However, there was no apparent selection bias due to depression status (Carroll et al. 2000).

3.3.4 Data Collection

The study included three waves of mailings at each time point: the original questionnaire, a card reminding the recipients to complete the questionnaire (1 week later), and a second mailing of the questionnaire (3.5 weeks after the outset of the study) to non-respondents only. Consent was implied if the questionnaire was completed and sent back. Additionally, if the individual did not respond to the second or third questionnaire after the reminder cards and second mailing of the questionnaire, the individual was assumed to have withdrawn from the study. 1131 individuals responded to the first questionnaire, which resulted in a response rate of 55%.

3.4 Analysis

The data were analyzed using multivariable logistic regression to model the associations between the six most prevalent health conditions (headache, allergy,

respiratory problems, musculoskeletal problems, gastro-intestinal disorders and mental health problems) and presence of depressive symptomatology which was the dependent variable. Six models were built, one for each of the most prevalent health conditions. The prevalence of these disorders in the sample ranged from 55.3% to 23.7%, respectively.

The five different response options that exist in the original questionnaire were collapsed into three different categories as follows: 1) do not have the health condition; 2) health condition is present but it does not affect or mildly affects my health; 3) health condition is present and moderately or severely affects my health. Collapsing these categories was necessary because of small cell sizes and also improved the linear relationship between the continuous CES-D scores and the health conditions.

In order to assess the independent relationship between health conditions and depressive symptomatology, I initially assessed the crude relationship between each health condition and the CES-D as the outcome. I then assessed the potential significant effects of each sociodemographic variable (covariate) by entering it into a model that included the comorbid condition of interest. A sociodemographic variable was considered to explain an important amount of the relationship between the health condition and depressive symptomatology, if it changed the magnitude of the estimate of the effect by more than 10%. I then built a model which included all sociodemographic variables, and assessed the effect of the association between the health condition and depressive symptomatology by removing and then replacing each covariate one at a time. If the removal of a covariate affected the estimate by 10% or more, it was included in the

final model. The final model adjusted for all covariates thus identified in either the bivariate analysis or in the aggregate model.

3.5 Ethical Approval

Ethical approval for the original study was obtained from the University of Saskatchewan Advisory Committee on Ethics in Human Experimentation. The Health Research Ethics Board at the University of Alberta approved the current research that is the subject of this paper.

3.6 Results

Our findings that depressive symptomatology is more common in the female gender, younger age, being unmarried, having lower education, lower income, not working and being a current smoker are consistent with reports in the literature (Weissman et al. 1984;Ross and Mirowsky 1989;Gallo et al. 1994;Weissman et al. 1996;Carroll et al. 2000;Piccinelli and Wilkinson 2000;Rodriguez et al. 2001;Murphy et al. 2003). Individuals living on reserves reported the highest unadjusted mean CES-D score of 22.5; however caution should be taken when interpreting these results due poor response in this population. See Table 3-1 for descriptive results.

Table 3-1 Subject characteristics and mean CESD scores. (N=1131)*

Factor	N (%)	CESD mean (s.d.)†
Gender:		
Male	526 (46.5)	8.9 (8.4)
Female	605 (53.5)	11.3 (10.3)
Age group:		
20-29	166 (14.7)	13.0 (10.5)
30-39	243 (21.5)	10.8 (10.0)
40-49	312 (27.6)	10.1 (9.3)
50-59	220 (19.5)	8.3 (8.7)
60-69	190 (16.8)	8.9 (8.3)
Marital Status:		
Married	845 (75.4)	9.2 (8.8)
Separated/Divorced	86 (7.7)	15.1 (12.6)
Widowed	31 (2.8)	12.5 (10.2)
Single	158 (14.1)	12.2 (10.2)
Education Level:		
University	150 (13.4)	8.4 (8.7)
Post Secondary	342 (30.6)	9.5 (8.7)
High School Grad	293 (26.2)	10.3 (9.8)
> Grade 8	255 (22.8)	10.8 (9.4)
< Grade 8	79 (7.1)	15.0 (12.0)
Income:		
Above 60K	210 (20.1)	7.4 (7.8)
40-60K	239 (22.9)	8.8 (8.3)
20-40K	361 (34.6)	10.0 (8.7)
0-20K	234 (22.4)	15.2 (11.8)
Location of residence:		
Large city	410 (36.3)	10.2 (9.6)
Small city	211 (18.7)	10.6 (10.2)
Town	176 (15.6)	9.7 (9.3)
Village	83 (7.4)	10.3 (9.2)
Rural municipality	233 (20.6)	9.3 (8.5)
Reserve	16 (1.4)	22.5 (10.2)
Smoking Status:		
Never smoked	557 (51.1)	9.4 (8.6)
Ex smoker	262 (24.0)	8.5 (8.4)
Current smoker <1pack/day	178 (16.3)	12.8 (11.4)
Current smoker >1pack/day	94 (8.6)	13.1 (11.3)
Body mass index:		
< 18.5 (underweight)	19 (1.7)	12.0 (8.9)
18.5-24.9 (normal)	441 (39.0)	10.1 (9.4)
25.0-29.9 (overweight)	449 (39.7)	9.4 (9.0)
>30.0 (obese)	221 (19.6)	11.9 (10.8)
Exercise frequency/week:		
0-2 times/week	534 (48.7)	11.0 (9.9)
3-7 times/week	563 (51.3)	9.3 (9.0)
Work Status:		
Working	1030 (92.9)	9.5 (9.1)
Not working	79 (7.1)	19.2 (11.1)

*Some missing data. 57 missing subjects from CES-D. In addition, 3 subjects missing from marital status; 3 subjects missing from education level; 70 subjects missing from income; 2 subjects missing from location of residence; 35 subjects missing from smoking status; 1 subjects missing from body mass index; 24 subjects missing from exercise frequency/week; 12 missing subjects from working status.
† s.d. refers to standard deviation.

The most common health condition reported was headache. At the time of the survey, 55% (n=625) of the sample reported that they experienced headache in the last six months. Allergy (41%), respiratory problems (29%), musculoskeletal problems (27%), digestive problems (27%), gynecological problems among women respondents only (25%), mental health problems (24%), kidney problems (18%), high blood pressure (16%), cardiovascular problems (15%), other problems (12%), neurological problems (8%), diabetes (7%) and cancer (5%) follow in prevalence, respectively. The least common health condition identified was blood problems, with 4.3% (n=48) of the sample indicating that they had experienced this health problem in the last six months. For all health conditions, increasing severity of the reported health problem coincided with an increase in mean CES-D scores (Table 3-2).

Multivariable logistic regression models were built to describe the relationship between the six most commonly reported comorbid health conditions and depressive symptomatology. The six most common health conditions in both genders were headache, allergy, respiratory problems, musculoskeletal problems, gastrointestinal problems and mental health problems. The presence and severity of each health condition was associated with increased frequency of depressive symptomatology in both adjusted and non-adjusted models. Crude and adjusted models are reported in Table 3-3.

Table 3-2. Presence and severity of comorbid conditions and mean CESD score (N=1131)*

Comorbid Health Condition	n (%)	CESD mean (s.d.)†
Headaches:		
None	451 (43)	7.4 (7.2)
Yes, no effect on health	92 (9)	9.3 (8.8)
Yes, mild effect on health	325 (31)	10.5 (8.7)
Yes, moderate effect on health	146 (14)	16.7 (12.6)
Yes, severe effect on health	43 (4)	17.4 (12.3)
Allergies:		
None	605 (58)	9.4 (8.9)
Yes, no effect on health	74 (7)	8.5 (8.1)
Yes, mild effect on health	242 (23)	10.0 (9.3)
Yes, moderate effect on health	109 (10)	15.3 (12.3)
Yes, severe effect on health	20 (2)	14.4 (10.1)
Respiratory Problems:		
None	734 (70)	9.0 (8.6)
Yes, no effect on health	51 (5)	10.1 (9.5)
Yes, mild effect on health	185 (18)	12.0 (10.1)
Yes, moderate effect on health	72 (7)	17.1 (12.2)
Yes, severe effect on health	10 (1)	19.9 (14.4)
Musculoskeletal Problems:		
None	764 (73)	9.4 (9.3)
Yes, no effect on health	26 (2)	10.5 (8.9)
Yes, mild effect on health	145 (14)	11.4 (9.4)
Yes, moderate effect on health	82 (8)	13.2 (10.7)
Yes, severe effect on health	27 (3)	16.4 (11.9)
Gastrointestinal Problems:		
None	776 (74)	9.1 (8.8)
Yes, no effect on health	46 (4)	8.5 (6.5)
Yes, mild effect on health	143 (14)	12.1 (10.1)
Yes, moderate effect on health	78 (7)	17.0 (12.8)
Yes, severe effect on health	12 (1)	20.8 (9.4)
Mental Health Problems:		
None	805 (76)	7.7 (7.0)
Yes, no effect on health	44 (4)	10.7 (10.4)
Yes, mild effect on health	137 (13)	17.0 (10.2)
Yes, moderate effect on health	59 (6)	23.8 (11.7)
Yes, severe effect on health	13 (1)	30.0 (14.4)
Kidney Problems:		
None	909 (82)	9.5 (9.0)
Yes, no effect on health	50 (5)	12.3 (10.1)
Yes, mild effect on health	115 (10)	13.0 (11.0)
Yes, moderate effect on health	31 (3)	16.4 (12.7)
Yes, severe effect on health	6 (1)	20.0 (7.1)

Comorbid Health Condition	n (%)	CESD mean (s.d.)†
High Blood Pressure:		
None	930 (84)	9.7 (9.0)
Yes, no effect on health	50 (5)	8.9 (8.1)
Yes, mild effect on health	73 (7)	12.6 (11.5)
Yes, moderate effect on health	45 (4)	16.0 (11.6)
Yes, severe effect on health	7 (1)	28.3 (18.4)
Heart Problems:		
None	941 (85)	9.7 (9.1)
Yes, no effect on health	46 (4)	11.0 (9.1)
Yes, mild effect on health	77 (7)	12.9 (11.1)
Yes, moderate effect on health	35 (3)	17.5 (14.0)
Yes, severe effect on health	10 (1)	12.9 (14.5)
Gynecological Problems††:		
None	425 (75)	10.0 (9.2)
Yes, no effect on health	32 (6)	13.0 (11.0)
Yes, mild effect on health	168 (30)	13.7 (11.95)
Yes, moderate effect on health	31 (5)	14.6 (10.0)
Yes, severe effect on health	13 (2)	19.5 (14.8)
Other Health Problems:		
None	952 (88)	9.7 (9.2)
Yes, no effect on health	28 (3)	10.2 (8.5)
Yes, mild effect on health	40 (4)	14.8 (12.6)
Yes, moderate effect on health	36 (3)	13.0 (10.9)
Severe effect	21 (2)	14.7 (9.5)
Neurological Problems:		
None	1024 (92)	9.8 (9.1)
Yes, no effect on health	35 (3)	10.6 (9.5)
Yes, mild effect on health	36 (3)	17.4 (13.8)
Yes, moderate effect on health	13 (1)	15.6 (13.4)
Yes, severe effect on health	2 (0.2)	41.5 (3.5)
Diabetes:		
None	1019 (93)	10.0 (9.3)
Yes, no effect on health	30 (3)	11.9 (11.4)
Yes, mild effect on health	29 (3)	9.4 (10.6)
Yes, moderate effect on health	13 (1)	14.0 (15.2)
Yes, severe effect on health	4 (0.4)	22.5 (5.8)
Cancer:		
None	1065 (95)	10.0 (9.3)
Yes, no effect on health	36 (3)	12.5 (11.2)
Yes, mild effect on health	9 (1)	12.3 (14.2)
Yes, moderate effect on health	6 (0.5)	19.4 (9.4)
Yes, severe effect on health	1 (0.1)	13.0 (n/a)
Blood problems:		
None	1068 (96)	9.9 (9.2)
Yes, no effect on health	26 (2)	11.1 (9.5)
Yes, mild effect on health	14 (1)	19.1 (16.2)
Yes, moderate effect on health	5 (0.4)	12.8 (17.6)
Yes, severe effect on health	3 (0.3)	21.3 (17.9)

* Some missing data; 57 cases missing from CES-D. In addition, 17 missing from headaches; 24 from allergies; 22 from respiratory problems; 30 from musculoskeletal; 19 from gastrointestinal problems; 16 from mental health; 36 from gynecological problems (women only); 20 from kidney problems; 21 from high blood pressure; 17 from heart problems; 49 from other health problems; 16 from neurological problems; 31 from diabetes; 30 from cancer; 12 from blood problems.
† s.d. refers to standard deviation; †† women respondents only, n=605

Table 3-3: Crude and Adjusted OR's of relationship between health item and CES-D

Health item*	Unadjusted OR (95%CI)	Adjusted †OR (95% CI)
Headache ‡		
No effect/mild effect on health	1.68 (1.17-2.41)	1.68 (1.17-2.41)
Moderate/severe effect on health	5.32 (3.58-7.90)	5.32 (3.58-7.90)
Allergy §		
No effect/mild effect on health	.86 (.61-1.22)	.84 (.576-1.21)
Moderate/severe effect on health	2.37 (1.58-3.57)	2.10 (1.36-3.24)
Respiratory Problems ¶		
No effect/mild effect on health	1.91 (1.35-2.69)	1.96 (1.38-2.79)
Moderate/severe effect on health	3.85 (2.39-6.20)	3.98 (2.41-6.59)
Musculoskeletal Problems ||		
No effect/mild effect on health	1.50 (1.02-2.20)	2.09 (1.34-3.28)
Moderate/severe effect on health	1.90 (1.22-2.96)	1.94 (1.11-3.40)
Gastrointestinal Problems **		
No effect/mild effect on health	1.34 (.91-1.97)	1.52 (1.00-2.32)
Moderate/severe effect on health	3.98 (2.53-6.25)	3.91 (2.35-6.51)
Mental Health ††		
No effect/mild effect on health	4.77 (3.32-6.85)	4.12 (2.78-6.11)
Moderate/severe effect on health	16.74 (9.67-28.98)	10.96 (6.05-19.87)

*Reference category for each is not having that particular health condition. Separate models were built for each health condition.
† N in adjusted models = 1057 for headache; 982 for allergy; 1050 for respiratory problems; 944 for musculoskeletal problems; 979 for gastrointestinal problems; 958 for mental health problems.
‡ No covariate met the criteria for inclusion in the model.
§ Adjusted model adjusts for income.
¶ Adjusted model adjusts for the following covariates: age and marital status.
|| Adjusted model adjusts for the following covariates: income, working status, education, age and current smoking status.
** Adjusted model adjusts for the following covariates: age, working status and income.
†† Adjusted model adjusts for the following covariates: current smoking status, income and working status.

The association between headaches and depressive symptomatology was not significantly affected by any of the sociodemographic factors considered, including factors associated with non-response to the survey. In comparison with no headaches, individuals who reported having headaches with no or a mild effect on health were 1.7 times more likely (95%CI 1.2-2.4) to have increased depressive symptomatology.

Individuals who reported experiencing headaches that had a moderate or a severe effect on health were 5.3 times more likely (95% CI 3.6-7.9) than non-headache suffers to have increased depressive symptomatology.

Compared with no allergy, individuals who reported allergy with no or a mild effect on health were 0.84 times more likely (95% CI 0.58-1.2) to have increased depressive symptomatology. However, individuals who reported having allergy with a moderate to severe effect on health were about two times more likely (OR 2.1; CI 1.4-3.2) to have increased depressive symptomatology than those who did not suffer from allergy problems. The above relationships are adjusted for income.

The association between respiratory problems and depressive symptomatology was significantly affected by age and marital status, which were adjusted for in the final models. In comparison with no respiratory problems, individuals who suffer from respiratory problems with no or a mild effect on health are two times more likely (95% CI 1.4-2.8) to have increased depressive symptomatology. Additionally, individuals whose respiratory problems have a moderate to severe effect on health are about four times more likely (95% 2.41-6.59) to have depressive symptomatology than those who do not have respiratory problems.

An unexpected finding was that although smoking is associated with both respiratory problems and depression, current smoking status did not significantly affect the relationship between respiratory problems and depressive symptomatology. To further investigate, a sub-group analysis of the current smokers was performed to observe the relationship between breathing problems and depressive symptomatology after controlling for the number of years smoked and the number of cigarettes smoked per day

(data not reported). Number of cigarettes smoked per day was a significant covariate in this analysis along with age, marital status, income, gender, education, location of residence and working status. Among smokers, when breathing problems were reported as not affecting their health or having a mild effect on health, the odds ratio was 3.3 (95% CI 1.6-6.9) with regards to experiencing depressive symptomatology; and when breathing problems had a moderate to severe effect on health, the odds ratio was 2.9 (95% CI 1.0-8.7). This demonstrates an association between presence but not severity of respiratory problems and depressive symptomatology among smokers, although the precision is poor due to the smaller cell sizes in this subgroup analysis.

Models were also built to describe the relationship between respiratory problems as a dichotomous variable (i.e. present or absent) and depressive symptomatology to achieve more precision among the subgroups of smokers (OR 2.3, 95% CI 1.3-4.4) and non-smokers (OR 2.0, 95% CI 1.4-3.0). This analysis indicated that there is no meaningful difference between smokers and non-smokers with respect to the relationship between respiratory problems and depressive symptomatology. In addition, an interaction term was built for smoking status and respiratory problems, which was not statistically significant.

Income, working status, education, age and current smoking status significantly affected the relationship between musculoskeletal problems (MSK) and depressive symptomatology and were adjusted for in the final models. Those respondents who reported MSK problems with no or a mild effect on health were two times more likely (OR 2.1, 95% CI 1.3-3.3) than those who did not report MSK problems to experience increased depressive symptomatology. Similarly, those who reported MSK problems to

have a moderate to severe effect on health were also about two times more likely (OR 1.9, 95% CI 1.1-3.4) to than non-MSK sufferers to experience increased depressive symptomatology.

The association between gastrointestinal (GI) problems and depressive symptomatology was significantly affected by age, working status and income which were adjusted for in the final models. In comparison with those who did not have GI problems, individuals who were experiencing GI problems with no or a mild effect on health were 1.5 times more likely (95% CI 1.0-2.3) to have increased depressive symptomatology. Whereas, those who reported GI problems with a moderate to severe effect on health were almost 4 times (OR 3.9, 95% CI 2.4-6.5) more likely than non-GI sufferers to experience depressive symptomatology.

The strongest relationship observed in these analyses was between mental health problems and depressive symptomatology. In comparison with those who did not experience mental health problems, individuals who had mental health problems that did not or mildly affected health were more than 4 times (OR 4.1, 95% CI 2.8-6.1) to experience increased depressive symptomatology. Those who reported mental health problems with a moderate or severe effect on health were almost eleven times more likely than those without mental health problems to experience increased depressive symptomatology. This relationship was significantly affected by current smoking status, income and working status which were adjusted for in the final models.

3.7 Discussion

The aim of this analysis was to describe the relationship between the presence and severity of comorbid health conditions and depressive symptomatology. The self-report comorbidity scale performed as expected by demonstrating that individuals who report the presence of a health condition have increased depressive symptomatology compared to individuals who do not have the health condition. The analyses also indicated a positive association between the severity of different health conditions and depressive symptomatology. This suggests that individuals who have a heavier burden of illness correspondingly have increased depressive symptomatology. To summarize, our findings are consistent with the literature that comorbid health conditions are associated with depressive symptomatology (Patten 2001). These findings generate increased confidence that the self-report comorbidity questionnaire is a valid instrument.

It should be noted that causality cannot be established due to the cross-sectional design of the study. However, as mentioned above, our study does describe a gradient relationship between presence and severity of health conditions and depressive symptomatology. This finding strengthens the noted relationship.

The only exception to this finding was the MSK item where we did not observe a clear gradient relationship due to similar effect sizes for no to mild effect on health and moderate or severe effect on health. Respondents to the questionnaire were instructed that the MSK item included rheumatoid arthritis; osteoarthritis of the knee, hip or hand; osteoporosis or thin bones; and fracture. The MSK item did not include neck pain or back pain, two items under the umbrella of MSK problems that are highly associated with depressive symptomatology (Carroll et al. 2000). It is plausible that because neck and

back pain were excluded from the MSK item, the item performed differently than if it had included all MSK pain.

The mental health item was the most strongly associated item with depressive symptomatology, as the odds ratios for both levels of reported mental health problems are much higher than any of the other comorbid health items (see Table 3-3). This may be due in part to the fact that depression is the most common mental health problem that is reported (Wang et al. 2000;Enns et al. 2001). We had hypothesized that this item would have a strong relationship with depressive symptomatology because both are measuring similar traits; thus highlighting the validity of the health item.

The self-report comorbidity questionnaire is a brief but comprehensive tool that has demonstrated its ability to identify presence and severity of comorbid health conditions in a large population-based study. The questionnaire can be easily appended to any population-based survey to 1) determine the burden of different health conditions in the population, and 2) to be able to adjust for different health conditions in statistical analyses.

3.8 Clinical Implications

Our findings indicated that presence and severity of comorbid health conditions are associated with depressive symptomatology. Clinicians should recognize this relationship and should be aware to assess for this in their practice. A simple evaluation of presence and severity of comorbid health conditions may help clinicians to recognize patients who may also be experiencing depressive symptomatology. In addition, if a health condition is affecting the patient's general health *more* adversely, clinicians need

to acknowledge that patients may have an even higher level of depressive symptomatology. As previously stated, there is an increased risk of developing depression with almost any long-term condition and alternatively, depression may increase the risk of chronic medical conditions (Patten 2001). If depressive symptomatology was screened for, identified, and treated, perhaps patients would not suffer as much from their medical conditions.

3.9 Strengths and Limitations

It is important to highlight some strengths and limitations of our study. The Saskatchewan Health and Back Pain Survey was a large population based mail out survey with 1131 respondents at baseline. Although a response rate of 55% was attained, we have increased confidence in our results (Carroll et al. 2000). An accurate and complete sampling frame was ensured using the Saskatchewan Health Insurance Registration File where Saskatchewan adults were randomly sampled (Côté et al. 1998;Carroll et al. 2000). Previous analyses identified that non-respondents were younger, male and not married, therefore these individuals are slightly underrepresented (Côté et al. 1998). One reason why this may not have a large impact on our research question is that older people, not younger people tend to report comorbid health conditions; and although younger people are more likely to report increased depressive symptomatology, a wave analysis indicated no evidence of selective responding due to depressive symptoms (Carroll et al. 2000). Although we have some information with respect to factors that influenced participation in the study, we cannot say for certain if different comorbid health conditions differed among respondents and non-respondents. In addition, because

some health conditions were not very prevalent in the study sample, the number of models that we were able to build using logistic regression was limited. It would have been informative to observe a relationship between presence and severity of all comorbid health conditions and depressive symptomatology.

3.91 Conclusion

In conclusion, we report a clear association between presence and severity of several comorbid health conditions and depressive symptomatology. The self-report comorbidity scale performed as expected and thus generated increased confidence in its validity. Clinicians should recognize that this association exists and further investigate higher risk patients. This paper is an initial examination of how the self-report comorbidity scale behaves with regards to presence or absence of depressive symptomatology. More research is needed to further examine the validity and reliability of the instrument.

3.92 References

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Chapter 4

General Discussion and Conclusion

4.1 Overview

The previous chapters have reviewed the literature on comorbid health conditions, depressive symptomatology and HRQL; and assessed the relationship between self-reported comorbid health conditions with depressive symptomatology and HRQL. The review of literature, presented in Chapter 1, discussed the definition of comorbidity. It also discussed the importance of adjusting for comorbid health conditions in analyses, as well as different ways that comorbidities are measured. When grading the severity of different health conditions, it is recommended to use a self-assessed comorbidity instrument (Charlson et al., 1987; Greenfield et al., 1995). There is limited availability of relatively generic self-assessed comorbid scales for the purpose of surveying a large population, therefore Jarzsnowski et al. created one for this purpose(Jaroszynski et al., 1996). It was the performance of this self-report comorbidity scale that was the focus of this thesis.

The second chapter (first research paper) begins with stating that according to the literature, there exists a clear relationship between comorbid health conditions and HRQL (Greenfield et al., 1995; Parkerson, Jr. et al., 2001; Fan et al., 2002; Selim et al., 2004; Groll et al., 2005). The basis of the analysis was to confirm that the comorbid health conditions in our database had a similar relationship with HRQL. Specifically, the Summary Component Scales of the SF-36 were defined as the outcomes: Mental Component Scale (MCS) and Physical Component Scale (PCS). The rationale for using

the summary scales is because about 80-85 percent of the reliable variance in the eight SF-36 scales is accounted for by physical and mental components of health (Ware et al., 1994). The six most prevalent health conditions that were reported (headache, allergy, respiratory problems, musculoskeletal problems, gastrointestinal problems, mental health problems) and diabetes were assessed with HRQL as the dependent variable in linear regression models. Although there existed five original response options for reporting the impact that the comorbid condition had on health, categories were combined to increase cell sizes to 1) health condition not present, 2) health condition present, does not affect or mildly affects my health, 3) health condition present, affects my health moderately or severely. The later two categories were entered into the models as dummy variables and were consistently compared to the reference category of not having the health condition. This method was employed for all comorbid health conditions that were assessed. Confounding factors were also identified and controlled for in order to obtain the independent relationship between the variables. Crude and adjusted estimates were reported for the seven comorbid conditions with the MCS and PCS as the outcome. The comorbidity scale performed as we had expected in that the presence and severity of almost all comorbid health conditions were significantly associated with the MCS and PCS.

Clinically important results were observed between the association of the category moderate to severe for headaches, respiratory problems, gastrointestinal problems, and mental health problems with the MCS. The mental health comorbidity item had the strongest relationship with the MCS when mental health mildly or did not affect health (β= -8.91, 95% CI -10.26, -7.55) and when mental health affected health moderately or

severely (β= -18.83, 95% CI -20.86, -16.80) when compared to not having the health condition. In addition, as the severity of all comorbid health conditions worsened, the MCS score decreased accordingly.

Clinically important results were also observed between the association of the category of moderate to severe headaches, respiratory problems, musculoskeletal problems, gastrointestinal problems and diabetes with the PCS. The musculoskeletal comorbidity item had the strongest relationship with the PCS when musculoskeletal problems were present but mildly or did not affect health (β = -2.77, 95% CI -4.20, -1.35) and when musculoskeletal problems affected health moderately or severely (β = -15.48, 95% CI -17.19, -13.76) when compared to not having the health condition. As with the MCS, as the severity of the comorbid health conditions worsened, the PCS score decreased accordingly.

In summary, the aim of this analysis was to describe the relationship between the presence and severity of comorbid health conditions and health-related quality of life, as measured by the MCS and PCS. The self-report comorbidity scale performed as expected by demonstrating that individuals who report the presence of a health condition have decreased scores of MCS and PCS, compared to individuals who do not have the health condition. The analyses also indicated a negative association between the severity of different health conditions and the MCS and PCS scores. This suggests that individuals who have a heavier burden of illness correspondingly have decreased MCS and PCS scores. To summarize, our findings are consistent with the literature that comorbid health conditions are associated with health-related quality of life (Greenfield et al., 1995; Parkerson, Jr. et al., 2001; Fan et al., 2002; Selim et al., 2004; Groll et al.,

2005). These findings generate increased confidence that the self-report comorbidity questionnaire is a valid instrument.

The purpose of the third chapter (second research paper) was to assess the same self-report comorbidity scale with depressive symptomatology as the outcome. Because it was evident from the literature that presence and severity of health conditions and depression are associated, we expected to observe a relationship between scores on the comorbidity items and depressive symptomatology (Patten, 2001), and thus the goal of the analysis was to address this research question.

I used multivariable logistic regression to assess the association of presence and severity of the six most prevalent comorbid health conditions (headache, allergy, respiratory problems, musculoskeletal problems, gastrointestinal problems, mental health problems) with depressive symptomatology as the dependent variable. Depressive symptomatology, was measured by The Center for Epidemiologic Studies Depression (CES-D) scale where a score $\geq$ 16 indicated increased depressive symptomatology (Radloff, 1977). Crude and adjusted models were reported for the six most prevalent health conditions.

For all health conditions, increasing severity of reported health problem coincided with an increase in mean CES-D scores. The strongest relationship observed in these analyses was between mental health problems and depressive symptomatology. In comparison with those who did not experience mental health problems, individuals who had mental health problems that did not or mildly affected health were more than 4 times (OR= 4.1, 95% CI 2.8-6.1) to experience increased depressive symptomatology. Those who reported mental health problems with a moderate or severe effect on health were

almost eleven times more likely than those who did not report mental health problems to experience increased depressive symptomatology. This may be due in part to the fact that depression is the most common mental health problem that is reported (Wang et al., 2000; Enns et al., 2001).

In summary, the aim of this analysis was to describe the relationship between the presence and severity of comorbid health conditions and depressive symptomatology. The self-report comorbidity scale performed as expected by demonstrating that individuals who report the presence of a health condition have increased depressive symptomatology compared to individuals who do not have the health condition. The analyses also indicated a positive association between the severity of different health conditions and depressive symptomatology. This suggests that individuals who have a heavier burden of illness correspondingly have increased depressive symptomatology. To summarize, our findings are consistent with the literature that comorbid health conditions are associated with depressive symptomatology (Patten , 2001). These findings generate increased confidence that the self-report comorbidity questionnaire is a valid instrument.

The ability to control or adjust for different variables is imperative when trying to explain the independent relationship between two factors. Demographic data such as age and gender are usually collected for this purpose. In addition, income level, marital status, education level, smoking status and work status may also be collected for these purposes. Any of the above factors may impact health status, therefore must be measured and considered when conducting studies.

In the last decade or so, the importance of considering the potential contribution or confounding role of different health conditions became increasingly recognized.

Presence of comorbid conditions is an important dimension of an individual's health status (Klabunde et al., 2005) and is a strong predictor that may confound many health outcomes (Fried et al., 2003). The ability to adjust for comorbid disease is essential in health services research and epidemiologic research (Groll et al., 2005).

Thus, this thesis evaluates the self-reported comorbidity scale's performance by assessing its association with HRQL and depressive symptomatology. The self-report comorbidity questionnaire is a brief but comprehensive tool that has demonstrated its ability to identify presence and severity of comorbid health conditions in a large population-based study. The questionnaire can be easily appended to any population-based survey to 1) determine the burden of different health conditions in the population, and 2) to be able to adjust for different health conditions in statistical analyses.

4.2 Recommendations for Future Directions

More research is needed to further examine the validity and reliability of the self-report comorbidity instrument. The existing database, the Saskatchewan Health and Back Pain Survey, would provide an appropriate foundation to answer many more research questions of this nature (Cassidy et al., 1998; Côté et al., 1998; Carroll et al., 2000; Mercado et al., 2000; Côté et al., 2000a; Côté et al., 2000b; Côté et al., 2001; Carroll et al., 2002; Carroll et al., 2003; Côté et al., 2004; Carroll et al., 2004; Cassidy et al., 2005; Mercado et al., 2005). Although the instrument performed as we had expected it to in our analyses, there are many more psychometric properties that can be evaluated.

The aim of the preceding analyses examined the self-report comorbidity scale's construct validity; whether it behaved as it should when assessed with other measures of

health. To further assess this theme; one could examine whether certain combinations of comorbidities within an individual have differential associations on self-reported health-related quality of life (SF-36) and/or depressive symptomatology (CES-D). Because individuals could potentially have a few different comorbid health conditions present at the same time, this interaction of health conditions could have differential effects on their health. This would be particularly interesting to evaluate in older individuals as they tend to have larger numbers of health problems than younger people. In addition, the sheer number of comorbid conditions that an individual has would certainly affect their health status and could be assessed. For example, someone with five health problems may tend to have a heavier burden of illness than someone with only one health problem.

The analyses did not address factors related to reliability which is a very important component in evaluating questionnaires. Test-retest reliability was evaluated when the instrument was initially developed and assessed using ambulatory patients from a doctor's office. The two-week test-retest reliability of the comorbidity questionnaire preformed well with the ICC for each item ranging from 0.8 to 0.98 (Jaroszynski et al., 1996).

In addition to the test-retest reliability, it would be valuable to examine the reporting patterns of different comorbid health conditions over time. This may be accomplished by ascertaining proportions of individuals with congruent or incongruent reports of comorbid conditions over the three time periods. For example, if someone reported having diabetes at the baseline survey, but did not report having diabetes in subsequent follow-up surveys may indicate a problem with reliability of the diabetes item.

A future study that could be pursued could assess the scale's criterion validity by comparing it to another self-reported comorbidity questionnaire. This process was simulated in the development of the scale when it was compared with the DUSOI scale (a physician-generated comorbidity scale) that has performed well in reliability and validity studies (Parkerson, Jr. et al., 1993; Shiels et al., 1997). Initial validation of the comorbidity questionnaire was done against concurrent physician assessment. There was moderate correlation between the patients' comorbidity score and all of the physician-derived comorbidity measures: the physician-generated comorbidity score, the DUSOI score and the corresponding analog score. A future direction that could further assess the comorbidity scale's criterion validity would be to compare it with other self-report comorbidity scales. Individual items could be compared and if similar outcomes result, this would generate increased confidence in the self-report comorbidity scale.

In conclusion, evidence has shown that it is imperative to be able to control for comorbidity due to it's effect on both health and depressive symptomatology. On a broader scope, once a comorbid condition has been identified and/or treated, it may lead to improvements in general health. Comorbidity may impact treatment decision-making, prognosis and quality of care assessment (Piccirillo et al., 2004). A valid and reliable instrument to capture self-reported comorbidity would inevitably be a significant contribution to health care research.

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Appendix 1

Saskatchewan Health and Back Pain Survey

Welcome to...

The Saskatchewan Health and Back Pain Survey

Your participation is important because:

1. It is likely that you or somebody you know suffers from a painful neck or back.
2. To develop helpful and cost-effective treatments for neck and low back pain we need to understand how it affects peoples' lives.
3. Prevention is the best cure. Please help us to find the causes of neck and low back pain by filling out this questionnaire.

Dr. J. David Cassidy | Dr. Linda Carroll | Dr. Ken Yong-Hing | Dr. Pierre Côté

Section A
Your General Health

Section B
Neck and Low Back Pain

Section C
How You Manage Your Pain

Section D
Questions About Your Mood

Section E
About You

Return Date

Please return the completed questionnaire in the enclosed pre-paid envelope **as soon as possible**.

Help and Advice

If you have any questions about this survey or need help completing the questionnaire, please call 966-8465 in Saskatoon or 1-800-667-8505 toll-free outside of Saskatoon.

Section A. Your General Health

In this section, we are interested in your general health. Please answer these questions to the best of your knowledge.

1. Please check the circle "✓" if you currently have any of the following health problems. If you do, to what extent have these problems affected your health in the last six months.

   Not at all: the problem does not affect my health.
   Mild: the problem makes my health **a little worse** than it should be.
   Moderate: the problem makes my health **worse** than it should be.
   Severe: the problem makes my health **much worse** than it should be.

Health Problem	Have it?	Affects your health?
a. **Rheumatoid arthritis; Osteoarthritis of the knee, hip or hand; Osteoporosis or thin bones; Fracture**	Yes O → No O ↓	Not at all . . O Mild . . . . . O Moderate . . O Severe . . . . . O
b. **Allergies** (such as hay fever, dermatitis, eczema, allergies to medication, food allergy, others)	Yes O → No O ↓	Not at all . . O Mild . . . . . O Moderate . . O Severe . . . . . O
c. **Breathing problems** (such as asthma, emphysema, bronchitis, fibrosis, lung scarring, TB, pneumonia, infection, common cold, others)	Yes O → No O ↓	Not at all . . O Mild . . . . . O Moderate . . O Severe . . . . . O
d. **High blood pressure** (hypertension)	Yes O → No O ↓	Not at all . . O Mild . . . . . O Moderate . . O Severe . . . . . O

Health Problem	Have it?	Affects your health?
e. **Heart and circulation problems** (such as angina, heart attack, heart failure, heart valve problem, hardening of arteries, varicose veins, claudication, foot or leg ulcers, others).	Yes O → No O ↓	Not at all . . O Mild ..... O Moderate . . O Severe ..... O
f. **Digestive system problems** (such as ulcer, gastritis, inflammatory or irritable bowel disease, colitis, Crohn's disease, hiatus hernia, gall stones, pancreatitis, others)	Yes O → No O ↓	Not at all . . O Mild ..... O Moderate . . O Severe ..... O
g. **Diabetes**	Yes O → No O ↓	Not at all . . O Mild ..... O Moderate . . O Severe ..... O
h. **Kidney, bladder or urinary problems** (such as kidney failure, nephritis, kidney stones, urinary tract infection, prostate problems, bladder control problems, others)	Yes O → No O ↓	Not at all . . O Mild ..... O Moderate . . O Severe ..... O
i. **Neurological problems** (such as stroke, seizures, multiple sclerosis, Parkinson's, paraplegia, quadriplegia, paralysis, Alzheimer's, dizziness, others)	Yes O → No O ↓	Not at all . . O Mild ..... O Moderate . . O Severe ..... O
j. **Headaches** (such as migraine, tension, stress, sinus, others)	Yes O → No O ↓	Not at all . . O Mild ..... O Moderate . . O Severe ..... O
k. **Mental or emotional problems** (such as depression, anxiety, substance abuse: alcohol, drugs, others)	Yes O → No O ↓	Not at all . . O Mild ..... O Moderate . . O Severe ..... O

Health Problem	Have it?	Affects your health?
l. **Cancer** (such as breast, lung, prostate, cervix, stomach, colon, kidney, bone, metastasis or spread, lymphoma, leukemia, others)	Yes O → No O ↓	Not at all . . O Mild . . . . . O Moderate . . O Severe . . . . . O
m. **Gynecological problems** (such as endometriosis, dysmenorrhea or menstrual problems, fibroids, ovarian cysts, others).	Yes O → No O ↓	Not at all . . O Mild . . . . . O Moderate . . O Severe . . . . . O
n. **Blood problems** (such as AIDS or HIV+, anemia, bleeding problems)	Yes O → No O ↓	Not at all . . O Mild . . . . . O Moderate . . O Severe . . . . . O
o. **Other problems** Please list:_____	Yes O → No O ↓	Not at all . . O Mild . . . . . O Moderate . . O Severe . . . . . O

2. Have you ever smoked at least one cigarette a day for <u>at least one year</u>?

   No . . O → (skip to page 5)
   Yes . O

3. How many years have you smoked at least one cigarette a day? _____ years.

4. Do you still smoke cigarettes?

   No . . O → (skip to page 5)
   Yes . O

5. On average, how many cigarettes do you smoke <u>per day</u>? (one pack equals "25" cigarettes)

   Less than one pack per day . . . . . O
   One pack or more than one pack per day . . . . O

SF-36 HEALTH SURVEY

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

(circle one)

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago, how would you rate your health in general now?

(circle one)

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same as one year ago	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

ACTIVITIES	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking more than a kilometre	1	2	3
h. Walking several blocks	1	2	3
i. Walking one block	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	YES	NO
a. Cut down on the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Were limited in the kind of work or other activities	1	2
d. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(circle one number on each line)

	YES	NO
a. Cut down the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(circle one)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

7. How much bodily pain have you had during the past 4 weeks?

(circle one)

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

(circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the time
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc)?

(circle one)

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

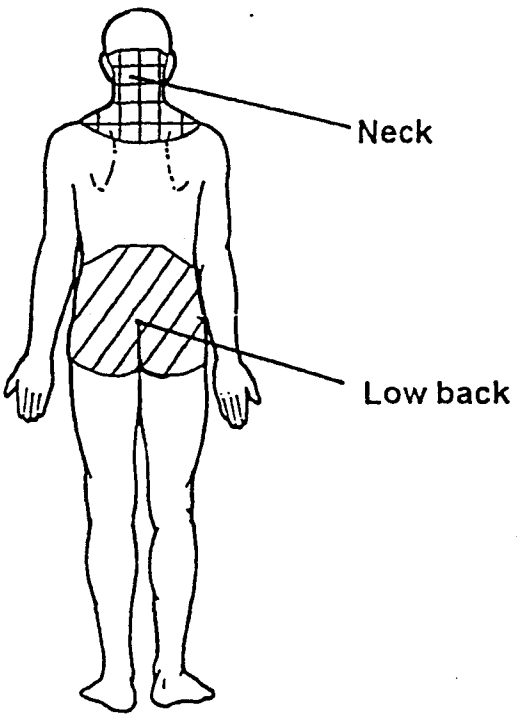
11. How TRUE or FALSE is each of the following statements to you?

(circle one number on each line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

Section B. Neck and Low Back Pain

In this section, we will ask you about neck and low back problems. What we mean by neck and low back is illustrated on this diagram. When answering questions about neck and low back pain, please refer to the diagram.



1. Have you ever <u>injured</u> your neck or low back in a motor vehicle accident?

   a) Neck ..... Yes O No O

   b) Low back..... Yes O No O

2. Have you ever injured your neck or low back <u>at work</u>?

   a) Neck..... Yes O No O

   b) Low back..... Yes O No O

If yes, have you ever had to <u>take time off work or perform light duties at work</u> because of a work injury?

   a) Neck injury..... Yes O No O

   b) Low back injury.. Yes O No O

Neck Pain (please refer to body diagram on page 10)

1. In your lifetime, have you ever had neck pain? No . . O → (skip to page 13)
   Yes . O

2. About how many days in the past six months have you had neck pain ?

   0 days...O 1-30 days...O 31-89 days...O 90-180 days...O

3. Do you have neck pain at the present time, that is right now? No . . O
   Yes . O

   If you have neck pain right now, does it travel into your arm(s)? No . . O
   Yes . O

In the next section, you will be asked to describe your neck pain. Please answer by circling the appropriate number from 0 to 10. Answer all questions by circling only one number.

1. How would you rate your neck pain on a 0-10 scale at the present time, that is right now, where 0 is "no neck pain" and 10 is "neck pain as bad as could be"?

No pain — Pain as bad as could be

0 1 2 3 4 5 6 7 8 9 10

2. In the past 6 months, how intense was your worst neck pain rated on a 0-10 scale where 0 is "no neck pain" and 10 is "neck pain as bad as could be"?

No pain — Pain as bad as could be

0 1 2 3 4 5 6 7 8 9 10

3. In the past 6 months, on the average, how intense was your neck pain rated on a 0-10 scale where 0 is "no neck pain" and 10 is "neck pain as bad as could be"?

No pain — Pain as bad as could be

0 1 2 3 4 5 6 7 8 9 10

4. About how many days in the last 6 months have you been kept from your usual activities (work, school, or housework) because of neck pain? (please check appropriate circle)

0-6 days	O	15-30 days	O
7-14 days	O	31 or more days	O

5. In the past 6 months, how much has your neck pain interfered with your daily activities rated on a 0-10 scale where 0 is "no interference" and 10 is "unable to carry on any activities"?

No interference — Unable to carry on any activities

0 1 2 3 4 5 6 7 8 9 10

6. In the past 6 months, how much has your neck pain changed your ability to take part in recreational, social and family activities where 0 is "no change" and 10 is "extreme change"?

No change — Extreme change

0 1 2 3 4 5 6 7 8 9 10

7. In the past 6 months, how much has your neck pain changed your ability to work (including housework) where 0 is "no change" and 10 is "extreme change"?

No change — Extreme change

0 1 2 3 4 5 6 7 8 9 10

Low Back Pain (please refer to body diagram on page 10)

1. In your **lifetime**, have you ever had low back pain? No O → (skip to page 15)
   Yes O

2. About how many days in the **past six months** have you had low back pain ?

   0 days...O 1-30 days...O 31-89 days...O 90-180 days...O

3. Do you have low back pain at the present time, that is **right now**? No ..... O
   Yes ..... O

   If you have low back pain **right now**, does it travel into your leg(s)? No ..... O
   Yes ..... O

Now, we would like to know a bit more about your low back pain. Please answer by circling the appropriate number from 0 to 10. Answer all questions by circling only one number.

1. How would you rate your low back pain on a 0-10 scale at the present time, that is right now, where 0 is "no low back pain" and 10 is "low back pain as bad as could be"?

No pain — Pain as bad as could be

0 1 2 3 4 5 6 7 8 9 10

2. In the past 6 months, how intense was your worst low back pain rated on a 0-10 scale where 0 is "no low back pain" and 10 is "low back pain as bad as could be"?

No pain — Pain as bad as could be

0 1 2 3 4 5 6 7 8 9 10

3. In the past 6 months, on the average, how intense was your low back pain rated on a 0-10 scale where 0 is "no low back pain" and 10 is "low back pain as bad as could be"?

No pain — Pain as bad as could be

0 1 2 3 4 5 6 7 8 9 10

4. About how many days in the last 6 months have you been kept from your usual activities (work, school, or housework) because of low back pain? (please check appropriate circle)

0-6 days	O	15-30 days	O
7-14 days	O	31 or more days	O

5. In the past 6 months, how much has your low back pain interfered with your daily activities rated on a 0-10 scale where 0 is "no interference" and 10 is "unable to carry on any activities"?

No interference — Unable to carry on any activities

0 1 2 3 4 5 6 7 8 9 10

6. In the past 6 months, how much has your low back pain changed your ability to take part in recreational, social and family activities where 0 is "no change" and 10 is "extreme change"?

No change — Extreme change

0 1 2 3 4 5 6 7 8 9 10

7. In the past 6 months, how much has your low back pain changed your ability to work (including housework) where 0 is "no change" and 10 is "extreme change"?

No change — Extreme change

0 1 2 3 4 5 6 7 8 9 10

Section C. How you manage your pain

Answer this section (page 15-17) if you have had neck or low back pain.

1. In the past four weeks, have you used medication every day for at least seven days because of your neck pain or back pain? No....O → (skip to question 2)
   Yes...O

If yes, did you use prescription medication, non-prescription medication or both ?

a) Neck pain..... Non-prescription medication O Prescription medication O

b) Low back pain... Non-prescription medication O Prescription medication O

2. In the past four weeks, have you seen a health care professional for neck pain or low back pain?

Neck pain	Yes O No O
Low back pain	Yes O No O

If you have seen any health care professionals for neck pain or low back pain in the past four weeks, who did you see? (please check all that apply)

	For your neck pain	For your low back pain
Family Doctor	Yes O	Yes O
Chiropractor	Yes O	Yes O
Physiotherapist	Yes O	Yes O
Orthopedic Surgeon	Yes O	Yes O
Neurologist or Neurosurgeon	Yes O	Yes O
Rheumatologist	Yes O	Yes O
Massage therapist	Yes O	Yes O
Counsellor/Psychologist	Yes O	Yes O
Other: (please specify) _____	Yes O	Yes O

3. If you have ever been treated for neck pain or low back pain, please indicate whether the treatment helped or not?

	Neck pain	Low back pain
Pills (medication)	Helped O Did not help O	Helped O Did not help O
Chiropractic	Helped O Did not help O	Helped O Did not help O
Physiotherapy	Helped O Did not help O	Helped O Did not help O
Bed rest	Helped O Did not help O	Helped O Did not help O
Massage Therapy	Helped O Did not help O	Helped O Did not help O
Back brace (corset)	Helped O Did not help O	Helped O Did not help O
Injection(s)	Helped O Did not help O	Helped O Did not help O
Surgery	Helped O Did not help O	Helped O Did not help O
Back School	Helped O Did not help O	Helped O Did not help O
Counselling or Psychotherapy	Helped O Did not help O	Helped O Did not help O
Exercise	Helped O Did not help O	Helped O Did not help O
Neck Collar	Helped O Did not help O	Helped O Did not help O
Other: (please specify) _____	Helped O Did not help O	Helped O Did not help O

Have you ever suffered from moderate neck or back pain? No....O → (skip to page 18)
Yes...O

We would like to know how frequently you have the following thoughts or engage in the following behaviours only when your pain is at a MODERATE level of intensity or greater. Please indicate how frequently you do the following when experiencing pain by checking the appropriate circle next to each statement.

Check ① Never do when in pain
Check ② Rarely do when in pain
Check ③ Occasionally do when in pain
Check ④ Frequently do when in pain
Check ⑤ Very frequently do when in pain

1. Engaging in physical exercise or physical therapy.....	①	②	③	④	⑤
2. Saying to yourself, "I wish my doctor would prescribe better pain medication for me".....	①	②	③	④	⑤
3. Staying busy or active.....	①	②	③	④	⑤
4. Clearing your mind of bothersome thoughts or worries.	①	②	③	④	⑤
5. Thinking, "This pain is wearing me down.".....	①	②	③	④	⑤
6. Talking to others about how much your pain hurts.....	①	②	③	④	⑤
7. Restricting or cancelling your social activities.....	①	②	③	④	⑤
8. Participating in leisure activities (such as hobbies, sewing, stamp collecting etc.).....	①	②	③	④	⑤
9. Thinking, "I can't do anything to lessen this pain".....	①	②	③	④	⑤
10. Distracting your attention from the pain (recognizing you have pain, but putting your mind on something else).....	①	②	③	④	⑤
11. Focusing on where the pain is and how much it hurts..	①	②	③	④	⑤

Section D. Questions about your mood.

Using the scale below, indicate the number which best describes how often you felt or behaved this way – DURING THE PAST WEEK.

0 = Rarely or none of the time (less than 1 day)
1 = Some or a little of the time (1-2 days)
2 = Occasionally or a moderate amount of time (3-4 days)
3 = Most or all of the time (5-7 days)

DURING THE PAST WEEK:

_____ 1. I was bothered by things that usually don't bother me.
_____ 2. I did not feel like eating; my appetite was poor.
_____ 3. I felt that I could not shake off the blues even with help from my family or friends.
_____ 4. I felt that I was just as good as other people.
_____ 5. I had trouble keeping my mind on what I was doing.
_____ 6. I felt depressed.
_____ 7. I felt that everything I did was an effort.
_____ 8. I felt hopeful about the future.
_____ 9. I thought my life had been a failure.
_____ 10. I felt fearful.
_____ 11. My sleep was restless.
_____ 12. I was happy.
_____ 13. I talked less than usual.
_____ 14. I felt lonely.
_____ 15. People were unfriendly.
_____ 16. I enjoyed life.
_____ 17. I had crying spells.
_____ 18. I felt sad.
_____ 19. I felt that people disliked me.
_____ 20. I could not get "going".

How satisfied would you say you are with your life? (please check the **most appropriate** answer)

Very dissatisfied..... O
Dissatisfied..... O
Neither satisfied nor dissatisfied.... O
Satisfied..... O
Very satisfied ..... O

Section E. About You.

1. Male O Female O → Are you currently pregnant? Yes O
   No O

2. Date of Birth: day_____ month____ year_____

3. Height: Feet _____ Inches_____ Weight: Pounds _____

4. Check your current marital status:

Married/Common Law.....	O
Separated/Divorced.....	O
Widowed.....	O
Single.....	O

5. Check your highest education level:

Grade 8 or less.....	O
Higher than Grade 8, but did not graduate from high school...	O
High School Graduate.....	O
Post secondary or some university.....	O
University Graduate.....	O

6. What is your household's total yearly income before taxes?

$0 - $20,000.....	O
$20,001-$40,000.....	O
$40,001-$ 60,000.....	O
Above $60,000.....	O

7. What is your present employment status?

Full-time	O	Part-time.....	O
Homemaker.....	O	Student.....	O
Unemployed.....	O	Retired.....	O
Maternity leave.....	O	Disability leave.....	O
Compensation.....	O		

8. Main work activity: (please check main one)

Heavy labour	O	Light labour.....	O
Mostly sitting at desk	O	Driving, operating a vehicle.....	O
Mostly standing.....	O	Mostly walking, moving around.....	O

9. What is your main occupation. _____
(Please Print)

10. If you are currently employed, how satisfied would you say you are with your job? (please check the most appropriate answer)

Very dissatisfied	O
Dissatisfied	O
Neither satisfied nor dissatisfied	O
Satisfied	O
Very satisfied	O

11. During the last 6 months, on average, how many days a week have you engaged in 30 minutes or more of exercise? (please circle the appropriate number of days)

0 1 2 3 4 5 6 7 days/week

12. Where do you currently live? (please check one)

Large city (population more than 100,000).....	O
Small city (population 5,000 - 100,000).....	O
Town (population 500 - 4,999).....	O
Village (population 100 - 499).....	O
Rural municipality but not in city, town or village.....	O
Reserve.....	O

Comments

If you have any comments about this study, please write them below.

Thank you for your participation.

Please fold this questionnaire, place it in the enclosed stamped self-addressed envelope and return it as soon as possible. Thank you for helping us.

Appendix 2

University of Saskatchewan Ethical Approval

UNIVERSITY ADVISORY COMMITTEE ON ETHICS IN HUMAN EXPERIMENTATION

(Behavioral Sciences)

NAME AND EC #: J.D. Cassidy (P. Cote, L. Carroll, K. Yong-Hing)
Department of Surgery (Orthopaedics)

95-64

DATE: March 31, 1995

The University Advisory Committee on Ethics in Human Experimentation (Behavioral Sciences) has reviewed your study "A Population-Based Survey of the Prevalence and Incidence of Neck and Low Back Pain in Saskatchewan" (95-64).

1. Your study has been APPROVED.

2. Any significant changes to your protocol should be reported to the Director of Research Services for Committee consideration in advance of its implementation.

fo [redacted]
Dr. C. von Baeyer, Chair
University Advisory Committee
on Ethics in Human Experimentation, Behavioral Science

Appendix 3

University of Alberta Ethical Approval

213 Heritage Medical Research Centre
University of Alberta, Edmonton, Alberta T6G 2S2
p.780.492.9724 (Biomedical Panel)
p.780.492.0302 (Health Panel)
p.780.492.0459
p.780.492.0839
f.780.492.7808

HEALTH RESEARCH ETHICS APPROVAL FORM

Date: March 2006

Name of Applicant: **Dr. Linda Carroll**

Organization: **University of Alberta**

Department: **PHS, Epidemiology**

Project Title: **Assessing the performance of a self-report comorbidity scale.**

The Health Research Ethics Board (HREB) has reviewed the protocol for this project and found it to be acceptable within the limitations of human experimentation. The HREB has also reviewed and approved the subject information letter and consent form.

The approval for the study as presented is valid for one year. It may be extended following completion of the yearly report form. Any proposed changes to the study must be submitted to the Health Research Ethics Board for approval. Written notification must be sent to the HREB when the project is complete or terminated.

Special Comments:

The Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. The REB Panel determined that the research described in the ethics application is a secondary analysis of de-identified data for which subject consent for access to personally identifiable health information would not be reasonable, feasible or practical. Subject consent therefore is not required for access to the personally identifiable health information described in the ethics application..

MAR 0 2 2006

Dr. Glenn Griener, PhD
Chair of the Health Research Ethics Board
(B: Health Research)

Date of Approval Release

File Number: B-180306

UNIVERSITY OF ALBERTA

Capital Health

CARITAS HEALTH GROUP

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