

DISEASE-SPECIFIC SYMPTOMS AND HEALTH-RELATED QUALITY OF LIFE
IN CHILDREN AND ADOLESCENTS WITH INFLAMMATORY BOWEL DISEASE

A Dissertation

by

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ABSTRACT

This study assesses generic and disease-specific Health-Related Quality of Life (HRQOL) in children and adolescents with Inflammatory Bowel Disease (IBD). More specifically, the purpose of the study is to address the relationship between disease-specific indicators, both on a symptom-by-symptom basis and as a whole, to overall HRQOL. Self- and proxy-report versions of the Pediatric Quality of Life Inventory™ (PedsQL™) Generic Core Scales and the newly developed Pediatric Quality of Life Inventory™ Gastrointestinal Symptoms Module were administered to 187 parent-child dyads at ten study sites across the United States. Disease-specific indicators included: stomach pain, stomach upset, trouble swallowing, heartburn and reflux, gas and bloating, constipation, and diarrhea. It was hypothesized that caregiver- and child-reported disease-specific HRQOL would be positively correlated with generic HRQOL, and that physical disease-specific indicators would contribute the greatest variance in total generic HRQOL scores, for both self and proxy report.

Results confirmed the hypothesis that disease-specific HRQOL would be positively correlated with generic HRQOL for children and caregivers. Multivariate regression results revealed that the Stomach Pain and Hurt, Worry, Medicines, and Communication scales contributed the most variance to overall HRQOL scores for children. The same analysis performed for parent ratings yielded one statistically significant scale: Worry. In essence, intervention efforts aimed at reducing the influence

of worry and anxiety may prove more effective in improving HRQOL outcomes than interventions targeting reduction of physical symptoms.

DEDICATION

I can do all things through Christ who strengthens me.

-Philippians 4:13

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Lastly, my most sincere thanks to the patients and their families who agreed to participate in this study. I understand the toll that this illness can take. Their resiliency is my inspiration.

NOMENCLATURE

| | |
|---------|--------------------------------|
| IBD | Inflammatory Bowel Disease |
| QOL | Quality of Life |
| HRQOL | Health-Related Quality of Life |
| PedsQL™ | Pediatric Quality of Life |
| SES | Socioeconomic Status |
| GI | Gastrointestinal |

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CHAPTER I

INTRODUCTION

Significant research has been devoted to the study of childhood chronic illness and how individuals adapt to accompanying physical and psychological stressors. Children with chronic illnesses are at greater risk for adjustment-related problems relative to children in the general population, particularly with regard to psychological functioning (Detmar, Muller, Schornagel, Wever, & Aaronson, 2002; Phipps, 2005; Rolland, 1994; Varni, Limbers, & Burwinkle, 2007; Wallander & Varni, 1998). On average, children with chronic illness report elevated levels of anxiety and depression when compared with healthy children (McCusker et al., 2007; Patten et al., 2008; Wong et al., 2011). Therefore, the need to study and understand factors that promote or hinder adjustment calls for the development of adaptation models that can be used to conceptualize these relationships.

Although much of the extant literature emphasizes retrospective analysis of adjustment to chronic illness, it is often more useful, from a clinical standpoint, to analyze adjustment from a prevention perspective. The Disability-Stress-Coping Model, proposed by Wallander and Varni in 1992, organized various factors associated with adjustment of children with chronic illness into a “risk and resistance” framework. Wallander, Thompson, and Alriksson-Schmidt (2003) later revised this model, using a non-categorical approach in lieu of the previous risk-resiliency categorization. According to the 2003 model, factors that influenced child adjustment to chronic illness were organized into (a) condition parameters, (b) functional independence,

(c) psychosocial stress, (d) social-ecological factors, (e) intrapersonal factors, and (f) stress processing. This model since has been the basis for widely utilized measures of child adjustment to chronic illness.

Similarities exist between models of psychosocial adaptation in terms of concepts and measurement; however, the overarching concept that often serves as an organizational framework for adaptation outcomes is Health-Related Quality of Life (HRQOL) (Stanton, Revenson, & Tennen, 2006). Therefore, HRQOL provides valuable information about patient outcomes in terms of successful adaptation to chronic illness (Livneh, 2001; Varni, Burwinkle, & Lane, 2005). Although HRQOL is a broad concept that may encompass a number of domains, it most commonly includes aspects of physical, emotional, and psychological well-being. HRQOL measures have been gaining popularity in the field of medicine as more emphasis is placed on the impact of treatments outside the arena of immediate physiological consequences (Fayers & Machin, 2000; Varni, Burwinkle, et al., 2005).

Children with chronic gastrointestinal disorders generally score lower on measures of HRQOL than children in the general population (Bo et al., 2007; Conklin et al., 2009; Cortina, McGraw, deAlarcon, Rothenberg, & Drotar, 2010; Varni et al., 2006; Varni et al., 2007). Within the category of gastrointestinal disorders, Crohn's disease and ulcerative colitis, two conditions subsumed under the overarching disease category of Inflammatory Bowel Disease (IBD), are the most prevalent (Shikhare & Kugathasan, 2010). Throughout the literature, there has been a strong relationship between disease severity and greater impairment in HRQOL in individuals with IBD (Andrews, Barczak,

& Allan, 1987; Borgaonkar, Townson, Donnelly, & Irvine, 2002; Drossman, Leserman, Patrick, Zagami, & Appelbaum, 1991; Perrin et al., 2008; Porcell, Leoci, & Guerra, 1996; Schwarz & Blanchard, 1990). To date, few studies have investigated the impact of specific symptoms on overall HRQOL in children with IBD. In those that have, symptoms are typically grouped into nebulous categories, such as “emotional symptoms” and “physical symptoms.” Further research is needed to provide more specificity and to determine which specific disease-related symptoms are most strongly correlated with HRQOL scores.

The purpose of this study is to determine which disease-specific symptoms of IBD are most predictive of patients’ overall HRQOL. These symptoms will then be explored within the context of how psychological services may be used to improve HRQOL through the use of behavioral planning, treatment adherence strategies, and other preventative efforts aimed at reducing or eliminating the physical and psychological effects of these GI symptoms. The literature review in Chapter II covers these topics in greater depth and identifies the research questions addressed by this study.

CHAPTER II

REVIEW OF LITERATURE

Chronic Illness and Psychological Functioning

As advances are made in medical technology and care, many diseases that were once considered “terminal” now fall into the category of “chronic.” This has resulted in a downward trend in mortality rates and an upward trend in the prevalence of chronic illness (Gartstein, Short, Vannatta, & Noll, 1999). Chronic illnesses, as defined by the Centers for Disease Control and Prevention (CDC, 2009), are illnesses that are prolonged, do not resolve spontaneously, and are rarely cured completely. Prevalence rates for chronic illness among school-age children vary widely, although there appears to be clear consensus that the rates of chronic illness are increasing rapidly (Clay, 2004; Perrin, Bloom, & Gortmaker, 2007; Van Cleave, Gortmaker, & Perrin, 2010). Subsequently, the study of childhood chronic illness is becoming increasingly important for healthcare and mental health providers.

A number of studies have found a relationship between chronic illness and psychological functioning (Detmar et al., 2002; Phipps, 2005; Rolland, 1994). Research suggests that chronic illnesses put children at risk for adjustment-related psychological and behavior problems, particularly internalizing problems (Cortina et al., 2010; Detmar et al., 2002; Rolland, 1994). Pinquart and Shen (2011) conducted a meta-analysis of 322 studies across several disease populations, including asthma, cancer, diabetes, and epilepsy. On average, children with chronic illness reported elevated levels of anxiety relative to controls or test norms, although the effect size was small ($d = .18$). There

were, however, stronger between-group differences in studies that used control groups rather than studies that used test norms as the basis for comparison. As a result, it was concluded that the use of test norms may have attenuated the overall effect size (Pinquart & Shen, 2011).

The relationship between depression and chronic illness is more definitive. A number of studies have documented statistically significant differences in levels of depression between children with chronic illness and healthy controls, though the direction of action is not always clear (Holahan et al., 2011; Livneh, 2001; Newacheck & Taylor, 1992; (Pinquart & Shen, 2011). Depression may either predict the onset of new illnesses, as there are numerous links between high levels of stress and the subsequent development of physical illness, or it may exacerbate existing illness (McCusker et al., 2007; Patten et al., 2008; Wong et al., 2011). Adult research has shown that depression may influence the course of illness, in that the disease course may be prolonged and disease symptoms may be more severe (Burg, Benedetto, & Soufer, 2003; Connerney, Shapiro, McLaughlin, Bagiella, & Sloan, 2001; Ericsson et al., 2002). The bidirectional relationship between depression and physical health underscores the need for medical professionals to consider psychosocial functioning in conjunction with the medical considerations of the disease itself (Rolland, 1994).

The relationship between psychological functioning and chronic illness is complex. Using a cognitive behavioral therapy (CBT) framework, R. D. Thompson and colleagues (2005) hypothesized that, when diagnosed with a chronic illness, individuals undergo a grieving process in which they mourn the loss of the “pre-illness lifestyle” and

attempt to cope with new limitations placed on them by their illness. Individuals may also be influenced by their own personal narrative, or subjective personal feelings, about the illness. Qualitative research with young adults has revealed several common themes in the illness narrative, including embarrassment and shame about symptoms, concern about physical appearance, misattribution about illness causes, desire for independence, and compliance with medical treatment (Grinyer, 2009; McLafferty, Craig, Courtright, Becker, & Szigethy, 2009).

Family functioning has also been shown to be an important influence on child adaptation to chronic illness. Several studies have highlighted the correlation between parental psychological adjustment and the psychosocial functioning of children with chronic illness (Daniels, Moos, Billings, & Miller, 1987; Drotar, 1997; Gil, Williams, Thompson, & Kinney, 1991; Jobe-Shields et al., 2009; Thompson, Gil, Burbach, Keith, & Kinney, 1993). Therefore, family functioning is an important variable in children's adaptation and must be given due consideration. Lastly, limitations in daily functioning as a result of the illness are important to the understanding of psychological well-being in the face of chronic illness. Dietary restrictions, medication side effects, and limited mobility are all examples of changes in daily functioning that have the potential to generate feelings of depression (Phipps, 2005).

Adjustment Theories and Chronic Illness

An abundance of theories have been developed in an attempt to explain the mechanisms of psychological adjustment to chronic illness; however, adjustment is a multifaceted concept that can be difficult to conceptualize. At the most basic level,

adjustment to chronic illness occurs across multiple life domains and changes over time as a function of disease state, life stage, and availability of new treatments. Despite the complexities of the term “adjustment” when used in relation to chronic illness, commonalities exist in how individuals adjust to illness (Stanton et al., 2006).

Hamburg and Adams (1984) viewed adjustment to chronic illness as a series of tasks: (a) regulating distress, (b) maintaining personal worth, (c) restoring relations with others, (d) pursuing recovery of bodily functions, and (e) bolstering the likelihood of a personally and socially acceptable situation once physical recovery is attained. Stanton and colleagues (2006) posited that adjustment to chronic illness could be conceptualized in terms of five areas: (a) mastery of disease-related adaptive tasks, (b) preservation of functional status, (c) perceived quality of life, (d) absence of psychological disorder, and (e) low negative affect. While similar to earlier adjustment models, the latter took a more integrative conceptualization of the complex relationships between physical and psychological variables and adjustment to chronic illness.

After reviewing the extant literature on psychosocial adaptation to chronic illness, Livneh (2001) proposed a loose framework for conceptualizing psychosocial adaptation that included three components: antecedent events, process of psychosocial adaptation, and anticipated outcomes. The first, antecedent events, includes implicit and explicit causes of the illness, as well as the context in which it occurred. The second involves the *process* of psychosocial adaptation, not to be confused with psychosocial adaptation as an outcome. The process of psychosocial adaptation involves the individual’s subjective experiences of their illness, as well as the interaction between

those experiences, and medical, sociodemographic, personality, and environmental variables. The third component, anticipated outcomes of the aforementioned process, may be viewed as a separate component of HRQOL and is classified according to an individual's domains of functioning (i. e., intrapersonal and extrapersonal), content areas (i. e., cognitive, affective, or behavioral), and sources of outcome measurement (i. e., self, parent, or medical professional).

In terms of clinical utility, the aforementioned frameworks emphasize retrospective analysis of difficulties with psychosocial adaptation in response to chronic illness; however, analysis from a prevention perspective may be more productive in decreasing the amount of psychological maladjustment among children with chronic illness. Wallander and Varni (1992) proposed a model that expanded previous research on coping and stress by incorporating information about risk and protective factors, with added emphasis placed on the stress associated with having a chronic illness and coping mechanisms used. The Disability-Stress-Coping Model organizes various factors associated with the adjustment of children with chronic illness into a “risk and resistance” framework. Subsumed under the category of risk factors are (a) disease/disability parameters, to include the severity of the physical condition, degree of cognitive impairment, and the visibility of the condition; (b) degree of functional independence; and (c) psychosocial stressors such as disability-related problems, major life events, and daily hassles. Resistance factors include (a) the child's interpersonal style and socioecological factors, both thought to influence adjustment indirectly, and (b) stress processing, or cognitive appraisal and coping strategies, which were hypothesized

to influence adjustment directly (Wallander & Varni, 1992). Wallander et al. (2003) later adapted this model using a non-categorical approach in lieu of the previous risk-resiliency categorization. Factors thought to influence child adjustment to chronic illness were instead organized into: (a) condition parameters, (b) functional independence, (c) psychosocial stress, (d) social-ecological factors, (e) intrapersonal factors, and (f) stress processing.

Similarities exist across these models of psychosocial adaptation in terms of concepts and measurement. Models generally include assessment of functional domains (including intrapersonal and extrapersonal functioning) and assessment of content areas (affective, cognitive, and behavioral). HRQOL can be viewed as the overarching concept that serves as an organizational framework for psychosocial adaptation. HRQOL provides an indication of the degree of successful adaptation to chronic illness and, in so doing, provides valuable information about child outcomes (Livneh, 2001).

HRQOL as an Indicator of Adjustment

In 1952, The World Health Organization (WHO) expanded the conventional concept of “quality of life” (QOL) from one that was associated exclusively with physical functioning to one that included social and mental well-being. The definition of HRQOL, which takes into consideration health-specific functioning, is broad and can encompass a number of domains, depending on the context in which it is being measured. To this day, the precise definition of HRQOL is still contested among researchers. Generally, the concept of HRQOL reflects the following domains: satisfaction and happiness with general health, physical functioning, physical symptoms,

emotional functioning, cognitive functioning, role functioning, social well-being, and existential issues (Alexander, Chaitanya, Grisham, & Boktor, 2010). The inclusion of psychological and social aspects is a fairly recent development, in response to the increasing emphasis being placed on the impact of treatments outside the arena of immediate physiological consequences. Measures of HRQOL provide valuable information for health care practitioners in terms of measuring the overall impact and effectiveness of treatments, functioning, and overall well-being (Coleman & Slonim, 2012; Detmar et al., 2002; Newacheck et al., 1998; Turner et al., 2008; Varni, Burwinkle, et al., 2005). The WHO's stance on HRQOL, as set forth in their constitution, is that objective and subjective experiences of the individual are continuously under the influence of their socioecological environment in relation to their personal values, priorities, and expectations (Schipper, Clinch, & Olweny, 1996).

HRQOL has been studied across a number of childhood illnesses, including asthma (Duerr et al.; Shikhare & Kugathasan, 2010; Stanford, Chambers, Biesanz, & Chen, 2008; Varni, Kay, Limbers, Franciosi, & Pohl, 2012; Varni et al., 1996), epilepsy (Kappelman et al., 2007; Newacheck et al., 1998; Newacheck & Taylor, 1992; Varni et al., 2012; Varni et al., 2007), cancer (Bessell, 2001; Bhat et al., 2005; Bloom, Stewart, Chang, & Banks, 2004; Levi & Drotar, 2000; Zebrack & Chesler, 2002; Zeltzer et al., 2008), obesity (Fontaine & Barofsky, 2001; Kolotkin, Meter, & Williams, 2001; Schwimmer, Burwinkle, & Varni, 2003; Williams, Wake, Hesketh, Maher, & Waters, 2005), ADHD (Escobar et al., 2005; Harpin, 2005; Klassen, DPhil, & Fine, 2004), cerebral palsy (Varni, Burwinkle, et al., 2005), kidney disease (Goldstein et al., 2006)

and gastrointestinal disorders (Rothbarth et al., 2001; Youssef, Murphy, Langseder, & Rosh, 2006). Children and adolescents with chronic illnesses may be at greater risk for impaired HRQOL due to the symptoms and limitations placed upon them by their illness.

Of particular interest to recent research initiatives is the relation between gastrointestinal disease and HRQOL. Research on children with gastrointestinal disease indicates correlations between illness status and scores on measures of HRQOL (Bo et al., 2007; Conklin et al., 2009; Cortina et al., 2010; Varni et al., 2006). Drossman and colleagues (1989) found that individuals with IBD reported greater functional impairment relative to healthy controls, particularly in the social and psychological domains. In a similar vein, Greenley et al. (2010) noted higher rates of internalizing disorders, particularly depression, as well as lower parent- and youth-reported social functioning in children with IBD when compared with healthy children. Findings from this study also revealed lower parent- and youth-reported HRQOL in children with IBD as compared to the control group. The impact of IBD on HRQOL appears to be a function of (a) whether the disease is active or in remission, and (b) the severity of gastrointestinal symptoms (Goldstein et al., 2006; Simrén et al., 2002).

Models of HRQOL

Theoretical models for HRQOL are numerous. *Expectations* models, such as one proposed by Calman (1984), suggest that HRQOL is a function of the perceived discrepancy between the individual's goals and expectations and their present experience, presumably with a wider gap between expectations and experience resulting

in a lower HRQOL. Therapeutic aims are developed in order to narrow the gap by adjusting either the individual's expectation to better match their functional status, or by improving functional status itself. Furthermore, expectations are unique to the individual and may be influenced by social, psychological, socioeconomic, and demographic variables. Additionally, individual expectations can be influenced by disease trajectory; therefore, HRQOL is sensitive to the point along the disease trajectory at which it is measured. For example, individuals who been newly diagnosed may have differing expectations than those who have had the disease for some time and have had greater experience by which to judge their day-to-day functioning. The reference value of expectations may also change over time. Expectations models assume that the accuracy of HRQOL measures depends on an individual's ability to accurately assess their illness, treatment, and the interaction of their illness and treatment over time. Expectations models have not been widely tested, due to the fact that individual expectations as a function of the aforementioned influences are difficult to measure (Graff et al., 2006).

Needs models of HRQOL emphasize that the individual's ability to satisfy needs is the primary means by which HRQOL is measured. Needs generally include those necessary for survival, such as: (a) food intake and sleep; (b) physical needs, such as avoidance of pain; and (c) psychological needs, such as identity, sense of security, and affection (Fayers & Machin, 2000). Hyde and colleagues (2003) categorized needs into those involving control, autonomy, self-realization, and pleasure. They posited that a solid theoretical model of HRQOL should consider the concept independently from

contextual and individual phenomena, such as health, social networks, and material circumstances.

Yet another model that has been used to conceptualize HRQOL is the *Reintegration*, or *Reintegration to normal living* model, introduced by Wood-Dauphinee and Williams (2010). *Reintegration* refers to the ability of the individual to do what they want; however, the separate notion of freedom from illness or symptoms is not a part of reintegration models (Fayers & Machin, 2000). *Reintegration to living* occurs when the individual is able to “reorganize” physical, psychological, and social characteristics so that they can resume “well-adjusted” living after illness. Therefore, an individual may still require assistance for normal, everyday functioning, but is able to retain personal abilities and role performance (Schirbel et al., 2010). Similarly, the *existential* model emphasizes that individual preferences are not fixed and may vary over time (Mauder & Levenstein, 2008). Assessment of “positive attitude” and coping skills is a necessary component of the *existential* model, as HRQOL may be improved by changing an individual’s coping mechanisms and perceptions of their HRQOL (Fayers & Machin, 2000).

Non-categorical Approach to Assessing HRQOL

Debates over how to conceptualize and measure the effects of chronic illness in children have been ongoing since the 1950s (Phipps, 2005). In the past, one of the more prominent questions posed by researchers in the field has been whether to study groups of children with chronic illnesses across diagnoses (non-categorical models) or, conversely, to investigate aspects of each chronic illness in isolation from other illness

groups (discrete models). The rationale for the latter is that each diagnosis has a unique presentation that influences psychological functioning. Mixed-model approaches, which combine aspects of discrete and non-categorical approaches, have been proposed, as well (Barakat & Kazak, 1999; Rolland, 1994).

In terms of an optimal organizational framework for measurement of HRQOL, a non-categorical approach may be most informative due to homogeneity of adjustment factors across chronic illness groups (Stein & Lambert, 1984; Stein & Jessop, 1982; Stein & Jessop, 1989; Wallander & Varni, 1998). Pless and Pinkerton (1975) asserted that disease chronicity and *overall* impact of disease on everyday aspects of life are most important for determining the relationship between chronic illness and functioning. These aspects may be common to all forms of chronic illness, as opposed to being differentially associated with specific illnesses. Therefore, a non-categorical approach to assessing outcomes of chronic illness based on “generic dimensions of their conditions” may be more practical.

Gartstein and colleagues (Gartstein et al., 1999) compared the utility of discrete, non-categorical, and mixed model approaches for assessing HRQOL across several chronic illness groups, including cancer, sickle cell disease, hemophilia, and juvenile rheumatoid arthritis. Their consensus was that non-categorical models were most appropriate in examining the impact of chronic illness on children, given that emotional and behavioral adjustment was found to be similar across disparate illness groups. This finding was presented with the caveat that a significant number of factors may influence an individual child’s adjustment to chronic illness.

Generic and Disease-Specific Measures of HRQOL

Disease-specific measures may be used in conjunction with generic measures to provide a more complete picture of chronic health conditions; therefore, an integrated approach has great utility for assessing HRQOL outcomes (Stein & Jessop, 1982).

While generic measures allow for comparison across disease groups, an extremely valuable function in chronic illness research, disease-specific measures can capture more subtle changes in HRQOL that may be due to variations in specific disease symptoms and treatment side effects. In other words, disease-specific measures inform clinical management of specific diagnoses, while generic measures allow for screening in healthy populations and comparison in HRQOL across illness groups (Varni, Burwinkle, Katz, Meeske, & Dickinson, 2002; Varni, Burwinkle, Seid, & Skarr, 2003).

The Pediatric Quality of Life Inventory (PedsQL™) measurement model utilizes this non-categorical approach by assessing functioning across physical, psychological, and social areas (Varni, Seid, & Rode, 1999). The Peds QL™ also includes disease-specific measures. Both generic and disease-specific measures assess chronicity and overall impact of illness on daily life domains and can provide valuable information necessary for meeting the needs of children with chronic illnesses, such as those with Inflammatory Bowel Disease (IBD).

Inflammatory Bowel Disease

IBD is a term used to describe a constellation of chronic, relapsing conditions that are characterized by digestive tract inflammation, diarrhea, intestinal bleeding, and abdominal pain (Banez & Cunningham, 2009). Approximately 1.1 million people in the

United States have IBD. In 20 to 30 percent of cases, IBD is diagnosed in childhood or adolescence (Cuffari & Darbari, 2002; Loftus et al., 2007). It is important to distinguish between Irritable Bowel Syndrome (IBS) and IBD to avoid confusion between functional bowel problems (IBS) and the disease (IBD). In individuals with IBS, the digestive tract appears normal, but does not function properly at times. Furthermore, IBS does not cause inflammation or intestinal damage. In contrast, IBD is characterized by chronic inflammation, thought to be caused by an abnormal response of the body's immune system. This inflammation can potentially result in further intestinal damage (Banez & Cunningham, 2009).

Prevalence/Incidence

According to the Centers for Disease Control (CDC), it is difficult to obtain accurate prevalence and incidence rates for IBD due to (a) lack of “gold standard” criteria for diagnosis; (b) inconsistent case ascertainment; and (c) disease misclassification. It is estimated that IBD affects nearly 71 in 100,000 youth in the United States (Kappelman et al., 2007). Three separate diagnostic categories are subsumed under IBD: Crohn's disease (CD), ulcerative colitis (UC), and indeterminate colitis (IC). Crohn's disease and ulcerative colitis are the most commonly diagnosed of the three and are usually the focus of research with IBD populations (Delaini, 2006). The worldwide incidence rate of ulcerative colitis varies between 0.5 and 24.5 per 100,000 persons, while the worldwide incidence rate of Crohn's disease varies between 0.1 and 16 per 100,000. The overall prevalence rate of IBD is roughly 396 per 100,000 persons (CDC, 2011).

Gender differences exist between ulcerative colitis and Crohn's disease, with a slightly higher number of males diagnosed with ulcerative colitis and a slightly higher number of females diagnosed with Crohn's disease. Although it was once thought that IBD, as a whole, occurred more frequently in individuals of Caucasian origin than in all other ethnic groups, this gap is quickly narrowing (Loftus, 2004). Geographically, IBD is more common in developed countries, with higher incidence rates occurring in urban communities (Hanauer, 2006).

Etiology

The etiology of IBD is still uncertain, although a number of theories exist as to possible predisposing factors. The predominant theory at this time is that inflammation in IBD is the result of an abnormal immune response. More specifically, T cells may be inappropriately activated and attack naturally occurring bacteria and healthy tissue in the intestine. A secondary hypothesis is that IBD may be a result of deficiency of the innate intestinal mucosal barrier in acting as a line of defense to protect the host from organisms that breach the epithelial barrier. Therefore, this lining acts as a secondary immune response. In individuals with IBD, this inadequate response would require a T and B cell response to compensate. The innate immune system dysfunction brought about by environmental and genetic factors may, in turn, cause an abnormal T cell response that causes inflammation (Korzenik, 2005). Weinstock and colleagues (2002) proposed that modern living has led to a reduction in intestinal parasites that act as T cell regulatory mechanisms.

There is also speculation that certain forms of bacteria might be causative agents of IBD. Of these, the *myobacteria avium papratuberculosis* (MAP) bacterium has gained the most research support due to its connection with a condition known as Johne's disease. Johne's disease, a chronic MAP infection of the intestinal tract, presents with symptoms similar to those of IBD, namely diarrhea and weight loss; however, research evidence of MAP as a causative agent for IBD is inconclusive. Measles has also been proposed to be a "cofactor" that increases the risk of IBD, particularly Crohn's disease, but has not been established as a causative agent (Korzernik, 2005).

Sulfur intake has been linked to ulcerative colitis; excess sulfur may pass through the stomach and into the colon, where sulfate-reducing bacteria subsequently metabolize it. These bacteria have been identified as being much more numerous in individuals with ulcerative colitis, particularly during flares (Korzenik, 2005). The most recent evidence supporting sulfur intake as a possible causative agent comes from a study by Jowett et al. (2004), in which individuals with a sulfur-containing diet had a higher risk for flares of ulcerative colitis.

Ulcerative Colitis

Ulcerative colitis is characterized by inflammation and ulceration of the innermost lining of the colon, causing abdominal pain, intestinal bleeding, diarrhea, fever, and weight loss. Less common symptoms include nausea, vomiting, and extracolonic ulcers. Inflammation usually begins in the lower part of the colon and progresses to other areas of the colon over time (Banez & Cunningham, 2009).

According to a study by Griffiths and colleagues (1999), children diagnosed with ulcerative colitis report more severe symptoms and complications than adults, perhaps due to the fact that the range of associated symptoms is wider, making it more difficult to pinpoint a diagnosis and provide necessary treatment. Although it is commonly thought that ulcerative colitis is caused by an abnormal immune response, stress and certain foods may trigger symptoms. Individuals with ulcerative colitis are often advised to avoid spicy or high-fiber foods that may cause additional irritation in the gastrointestinal tract (Korzenik, 2005).

Ulcerative colitis is generally diagnosed via colonoscopy with biopsy. Individuals with ulcerative colitis are at a greater risk for developing colon cancer, and therefore must receive screenings at regular intervals for life. Life-long screening is particularly crucial, given that post-diagnosis, risk for developing colorectal cancer increases with each decade of life. Disease complications of ulcerative colitis are numerous and can be life-threatening. Individuals with ulcerative colitis are at risk for developing perforations in the colon, massive bleeding in the colon, and intestinal obstruction due to narrowing of the colon walls. Ulcerative colitis accounts for nearly half of all IBD diagnoses (Itzkowitz & Present, 2005).

Crohn's Disease

As with ulcerative colitis, Crohn's disease is marked by symptoms of abdominal pain, fever, fatigue, loss of appetite, diarrhea, intestinal bleeding, and unintentional weight loss; however, Crohn's disease may manifest in any part of the digestive tract and generally involves inflammation of the entire bowel wall. In addition, Crohn's disease is

more “systemic” in nature and can involve tissues and organs outside the gastrointestinal tract (Banez & Cunningham, 2009). Peak ages of diagnosis are between 15 and 35. Currently, no evidence exists for a link between diet and Crohn’s disease symptoms; however, it is not uncommon for health care providers to encourage patients to make dietary modifications specific to the patient’s nutritional needs, as individuals with Crohn’s disease often suffer from malnutrition due to problems with absorption in the intestine (Korzenik, 2005).

Symptoms of Crohn’s disease may vary based on the location where pathological changes occur. In most cases, the disease is confined to the ileum, or the final section of the small intestine (Crohn, Ginzburg, & Oppenheimer, 1952). Ninety percent of patients with right colon and ileocecal involvement will require surgery at some point, as opposed to individuals for whom the disease is confined to the ileum (Delaini, 2006). Diagnosis of Crohn’s disease is complex and usually involves endoscopic, laboratory, and radiological testing. Although individuals with Crohn’s disease are at greater risk for developing colon cancer compared with the general population, the risk is not as high as with individuals with ulcerative colitis. Therefore, regular screening is not considered as urgent for patients with Crohn’s disease, although it is still advised (White & Miller, 2007).

Disease complications are similar to those associated with ulcerative colitis, although individuals with Crohn’s disease may suffer additional complications due to the development of fistulas, or small tracts that develop between parts of the intestine and adjacent organs. Malnutrition in childhood may result in delayed growth and sexual

development (Gupta et al., 2010). As mentioned earlier, Crohn's disease may be systemic and can result in difficulties in multiple organ systems, such as the respiratory and lymphatic systems (Alexander et al., 2010).

Course and Prognosis

The disease course of IBD is unpredictable and therefore difficult to characterize. Relapse is common in children, with a 40 to 50% chance of relapse in the first year after remission; only 1% go into remission and never relapse again following diagnosis (Ballinger, 2000; Turner et al., 2008). Factors that affect disease course include: age at onset, medication adherence, location of disease, severity of complications, frequency and severity of relapses, and overall health. Currently, no cure exists for Crohn's disease. Surgical intervention may alleviate symptoms for a period of time, but the disease almost always returns in adjacent sections of the intestine. For individuals with ulcerative colitis, colectomy can be curative. Nearly 26% of children presenting with severe ulcerative colitis will undergo colectomy within five years of diagnosis (Hyams, 2000; Turner et al., 2008)

Clinical Management and Monitoring

As IBD is a disease with variable symptoms, disease course, and prognosis, there is no standard treatment regimen. Medical treatments for IBD can be organized into five categories: aminosalicylates, corticosteroids, immunomodulators, antibiotics, and biologic therapies. Aminosalicylates, or 5-ASA, are compounds that interfere with the body's inflammatory response. This category of medication is especially effective for individuals with mild to moderate IBD. Some patients have difficulty tolerating the side

effects of 5-ASA, which include headache, nausea, fatigue, and, in some cases, hair loss. Nevertheless, 5-ASAs are relatively inexpensive and are effective for many individuals with IBD. There is some debate as to whether 5-ASAs may have a role in the prevention of colorectal cancer (Riyaz, Hamlin, & Everett, 2011).

Corticosteroids are typically used during acute flares to provide rapid relief of symptoms; they have both anti-inflammatory and immunosuppressant effects, simultaneously reducing inflammation and suppressing the abnormal immune response that sustains inflammation. Corticosteroids work by mimicking cortisol, an endogenous hormone that is known to reduce inflammation. Long-term use of corticosteroids is not advised, as individuals who take the medication for long periods of time may develop serious side effects that mimic symptoms of Cushing's disease, a malfunction of the adrenal glands that can result in excess amounts of cortisol in the body. Corticosteroids are administered in small doses, when possible, due to their wide range of unpleasant side effects, which can include high blood pressure, increased risk of infection, "moon face" or rounding of the face, mood swings, symptoms of psychosis, osteoporosis, insomnia, increased facial hair, and weight gain. Frequent, short-term therapy with corticosteroids is also not recommended (Graham, 2007).

Immunomodulators work by modulating the activity of the immune system, thereby decreasing the body's inflammatory response. Immunomodulators are not usually considered a first line of treatment and are reserved for individuals who do not respond to or tolerate 5-ASAs, antibiotics, or corticosteroids. Drugs in this class are used to treat individuals with other autoimmune disorders, such as rheumatoid arthritis.

They are also used to decrease the likelihood of organ rejection in individuals who have undergone organ transplantation. Immunomodulators are sometimes used in conjunction with corticosteroids to achieve faster therapeutic response or to reduce the likelihood of negative side effects from corticosteroid use, which can include weight gain, loss of bone density, mood swings, and increased risk of infection (Bar-Meir et al., 1998; Graham, 2007).

Although their exact mechanism of action for reducing symptoms of IBD is unknown, antibiotics are frequently used in the treatment of IBD, particularly Crohn's disease. Antibiotics may work to reduce intestinal inflammation by decreasing the amount of bacteria in the digestive tract that may trigger an abnormal immune response. There is some evidence to suggest that antibiotics may be effective long-term maintenance therapy for individuals with Crohn's disease. Antibiotics are generally not considered effective for maintenance in individuals with ulcerative colitis (Hviid, Svanström, & Frisch, 2011).

Biologic therapies, the newest class of medications for the treatment of IBD, are genetically engineered medications made from antibodies found in living organisms. Their role in reducing the body's inflammatory response is to target specific molecules such as cytokines, tumor necrosis factor alpha, interleukins, adhesion molecules, and colony-stimulating factors, all of which play roles in inflammation. The primary advantage of biologic therapies over other forms of treatment for IBD is their targeted mechanism of action: they act selectively on certain molecules or proteins in the body. Biologic agents are typically administered intravenously or subcutaneously. Common

side effects include fatigue, upper respiratory infections, headache, rash, and nausea. Biologic therapies are usually reserved for individuals with moderate to severe IBD. While very effective, biologic therapies can be cost prohibitive and also increase an individual's risk of developing serious bacterial and fungal infections, lymphoma, and blood disorders. For this reason, patients on biologic therapies must be monitored closely (Graham, 2007).

In terms of ongoing monitoring patients with IBD, it is recommended that individuals with ulcerative colitis be screened for colon cancer eight to ten years after the onset of symptoms. Patients with extensive colitis or left-sided colitis should undergo a surveillance examination every one to two years. After two years of negative examinations, the next surveillance examination may be performed at one- to three-year intervals. Colorectal cancer risk increases with longer duration of colitis (Jess, Rungoe, & Peyrin-Biroulet, 2012; Kiran et al., 2010; Lashner, Provencher, Bozdech, & Brzezinski, 1995). Individuals with Crohn's disease are at lesser risk for developing colorectal cancer if the disease is not present in the colon. Screening for individuals with Crohn's disease with colonic involvement is similar to what is advised for patients with ulcerative colitis (Itzkowitz & Present, 2005).

Psychosocial Factors

In addition to coping with a chronic illness, children and adolescents with IBD must cope with issues unique to their disease. These issues include (a) unpredictability of disease course; (b) unknown etiology of the illness; (c) embarrassment about symptoms related to urgency to use the bathroom, stoma, and so on; and (d) delayed

physical and sexual development. These issues may be distressing to children and adolescents and therefore may be associated with depression and anxiety. Children with IBD have higher rates of internalizing symptoms than children in the general population (Engsörm, 1999; Greenley et al., 2010; Mackner & Crandall, 2006). Estimated prevalence rates of depressive and anxiety disorders vary widely (25 to 60%) among those with “longstanding illness” and those in remission (Burke, Neigut, Kocoshis, Sauer, & Chandra, 1994; Engström & Lindquist, 1991; Iglesias et al., 2009 ; Loftus et al., 2011; Mackner & Crandall, 2005). Among children and adolescents who have been recently diagnosed, rates are much lower (14 to 28%), but still substantial (Burke et al., 1994). Szigethy and colleagues found that later age of diagnosis was associated with greater depressive symptoms, although overall age was not significantly associated with greater depressive symptoms (2004). Other factors associated with depressive symptoms among children and adolescents with IBD include greater parental depression, greater frequency of stressful life events, and higher family conflict. Findings from studies using the Child Behavior Checklist (CBCL) to evaluate emotional symptoms in children and adolescents with IBD are mixed, as are findings related to externalizing disorders (Achenbach, 2001; Gold, Issenman, Roberts, & Watt, 2000; Ondersma, Lumley, Corlis, Tojek, & Tolia, 1997; Szajnberg, Krall, Davis, Treem, & Hyams; Szajnberg, Krall, Davis, Treem, & Hyams, 1993; Wood et al., 1987).

Social functioning also may be affected in children with IBD. Mackner and Crandall (2006) found that 22% of parents of children with IBD reported that their children had problems with social competence, as opposed to 2% of parents with healthy

children. Similarly, Moody, Eaden, and Mayberry (1999) found that children and adolescents with Crohn's disease had more problems interacting with peers and had decreased involvement in sports-related activities compared with healthy children. Children diagnosed during adolescence also have been found to have significantly lower social competence scores than those diagnosed earlier (Mackner & Crandall, 2006). Therefore, adolescence is a particularly sensitive time for youth with IBD, with higher risk for psychosocial maladjustment than in other stages of life.

HRQOL in Individuals with IBD

Individuals with IBD generally report lower HRQOL relative to individuals in the general population (Cunningham, Drotar, Palermo, McGowan, & Arendt, 2007; Greenley et al., 2010; van der Zaag-Loonen, Grootenhuis, Last, & Derkx, 2004). The impact of having IBD on HRQOL appears to be partly a function of whether or not the disease is active or in remission, and the severity of gastrointestinal symptoms (Goldstein et al., 2006; Hommel, Denson, & Baldasano, 2011; Kunz, Hommel, & Greenley, 2010; Perrin et al., 2008; Simrén et al., 2002). Some researchers have suggested that individuals with Crohn's disease experience lower HRQOL than those with ulcerative colitis, further confirming the role of disease severity in HRQOL, as individuals with Crohn's disease typically have more persistent, severe, and systemic symptoms (Drossman et al., 1991; Guthrie et al., 2002; Mitchell et al., 1988; Pizzi et al., 2006).

Kunz and colleagues recently performed a study in which 136 youths with IBD and their parents completed self and proxy reports of the PedsQL™ Generic Core

Scales. Scores were compared with chronically ill, acutely ill, and healthy comparison groups using independent samples *t*-tests. As predicted, youth with IBD reported significantly lower HRQOL relative to the healthy comparison group; however, overall HRQOL in the IBD group was similar to that of the chronically ill and acutely ill comparison groups. Notably, youth with IBD reported lower HRQOL in the school domain relative to all three comparison groups. Parents' ratings of HRQOL were also significantly lower for the IBD group relative to the healthy comparison group. Finally, youth with active disease reported lower HRQOL than youth with inactive disease (Kunz et al., 2010).

The role of disease severity in HRQOL for individuals with IBD has been investigated in multiple studies (Andrews, Barczak, & Allan; Borgaonkar, Townson, Donnelly, & Irvine, 2002; Drossman et al., 1991; Perrin et al., 2008; Porcell, Leoci, & Guerra, 1996; Schwarz & Blanchard, 1990). Smirén and colleagues (2002) measured HRQOL in adults with IBD who had been in remission (i.e., no active inflammation) for over a year and found that, overall, their HRQOL scores were similar to those of the general population. Upon closer investigation, however, adults with IBD who continued to experience IBS symptoms (e.g., abdominal pain, bloating, abdominal distention, diarrhea, urgency, and constipation), despite being in remission, reported greater levels of anxiety and depression and lower levels of well-being than adults with IBD who were not experiencing these symptoms. It was not known whether anxiety and depression preceded or followed development of IBS symptoms. These differences remained even when controlling for disease type (Porcell et al., 1996; Smirén et al., 2002).

In terms of the pediatric literature, a recent study by Greenly and colleagues (2013) investigated the role of abdominal pain in parent- and child-reported HRQOL of children and adolescents with active disease and in remission. Ratings of abdominal pain and HRQOL were collected at baseline and six-month follow-up. Abdominal pain was prevalent in the sample, with 50 percent of participants reporting pain at either time point. Reports of abdominal pain appeared to be independent of disease status, with roughly fifty percent of participants with active disease reporting abdominal pain and fifty percent of participants deemed in clinical remission reporting abdominal pain, as well. Chronic abdominal pain was found to have a particularly profound impact on HRQOL. Given that youth-perceived stress and internalizing symptoms predict higher levels of pain in other pediatric chronic illness populations, there is a continued need for research on the extent to which these variables influence pain perception, and therefore HRQOL, in children with IBD (Stanford et al., 2008; Varni et al., 1996).

With regard to the relationship between disease severity and psychological functioning in adults, Nordin and colleagues (2002) investigated HRQOL and psychological distress in a sample of Swedish individuals with IBD and found that individuals with Crohn's disease reported significantly lower levels of HRQOL in all dimensions when compared with individuals with ulcerative colitis. When adjusting for symptom severity in the analysis of covariance, differences in HRQOL scores between those with Crohn's disease and those with ulcerative colitis disappeared. Thus, it could be concluded that the lower HRQOL scores in the Crohn's disease group could potentially be explained by the presence of more severe physical symptoms.

Interestingly, “bowel function” explained a significant amount of variance in anxiety and depression, which strengthens the assumption that symptom severity is related to anxiety and depression in patients with IBD (Nordin et al., 2002). These results are consistent with a similar study in which individuals with IBD reported that physical symptoms, namely frequent or loose stools, abdominal pain, and intestinal bleeding, had the greatest impact on HRQOL (Irvine, 1996).

Statement of the Problem

The current study aims to address gaps in the literature by assessing relationships between parent- and self-reported severity of gastrointestinal symptoms and overall HRQOL in children and adolescents with a physician’s diagnosis of IBD. The relationship between disease severity and HRQOL in children with IBD has been strongly established. Research indicates that the more active (or severe) the disease, the lower children’s overall HRQOL (Drossman et al., 1991; Mitchell et al., 1988; Nordin et al., 2002; Simrén et al., 2002). Heretofore, measures used to assess disease severity have typically been unidimensional, assessing only the physical symptoms associated with the disease. The PedsQL™ GI Symptoms Module assesses additional disease-specific areas of HRQOL, to include food and drink limits, worry, medicines, and communication. Moreover, the PedsQL™ GI Symptoms Module is intended for use in conjunction with the PedsQL™ Generic Core Scales; it uses similar instructions and response scales. To date, no research has been done with this population using “compatible” disease-specific and overall HRQOL measures. Furthermore, no studies have addressed the relationship between domains of disease-specific HRQOL and

overall HRQOL in children and adolescents with IBD. Knowledge of this relationship will facilitate the development of more targeted preventative, behaviorally based interventions that mental health practitioners can use to improve HRQOL for these individuals.

Research Questions and Hypotheses

Research Question 1: Is greater self-reported disease-specific HRQOL, as measured by the PedsQL™ GI Symptoms Module Total Score, associated with greater self-reported generic HRQOL, as measured by the PedsQL™ Generic Core Scales Total Health score? This association was tested using Pearson's Product Moment Correlation between the self-report PedsQL™ GI Symptoms Module Total score and the self-report PedsQL™ Generic Core Scales Total Health score. It was hypothesized that disease-specific HRQOL would be positively correlated with overall HRQOL.

Research Question 2: Is greater proxy report disease-specific HRQOL, as measured by the PedsQL™ GI Symptoms Module Total Score, associated with greater generic HRQOL, as measured by the PedsQL™ Generic Core Scales Total Health score? This association was tested using Pearson's Product Moment Correlation between the proxy report PedsQL™ GI Symptoms Module Total score and the proxy report PedsQL™ Generic Core Scales Total Health score. It was hypothesized that disease-specific HRQOL would be positively correlated with overall HRQOL.

Research Question 3: Are self-reported physical disease-specific symptoms more strongly related to impaired HRQOL in children and adolescents with IBD? This association was tested using linear regression to determine which scales of the self-

report PedsQL™ GI Symptoms Module contributed the most variance to overall HRQOL, as measured by the self-report PedsQL™ Generic Core Scales Total Health score. It was hypothesized that physical disease-specific domains of HRQOL, specifically stomach pain; stomach upset; trouble swallowing; heartburn and reflux; gas and bloating; constipation; and diarrhea would contribute most to variance in overall HRQOL.

Research Question 4: Are physical disease-specific symptoms more strongly related to impaired HRQOL in children and adolescents with IBD, according to proxy report? This association was tested using linear regression to determine which scales of the proxy report PedsQL™ GI Symptoms Module contributed the most variance to overall HRQOL, as measured by the proxy report PedsQL™ Generic Core Scales Total Health score. It was hypothesized that physical disease-specific domains of HRQOL, specifically stomach pain; stomach upset; trouble swallowing; heartburn and reflux; gas and bloating; constipation; and diarrhea would contribute most to variance in overall HRQOL.

Clinical Significance and Implications

Although there is evidence to suggest a relationship between symptom severity and HRQOL in children with gastrointestinal disorders, it is not yet known which disease-specific symptoms have the greatest impact on HRQOL. In clinical practice, it is often to the advantage of physicians to make quick and accurate assessments of treatment outcomes and their overall effects on patients' well-being; however, as time constraints increase in healthcare settings, it may not be feasible to administer HRQOL

inventories in their entirety. For this reason, it may be more beneficial to administer streamlined versions of disease-specific HRQOL inventories to assess only the symptoms that have been found to have the greatest potential impact on overall HRQOL. Preventative therapies aimed at alleviating the physical and psychological burden of these specific symptoms may prove to be extremely valuable in reducing the probability of long-term adverse consequences.

CHAPTER III

METHOD

Research Design

This study uses a cross-sectional multisource research approach using parent/caregiver- and child-completed rating scales relating to children's HRQOL. This questionnaire format study focuses on the child and parent ratings of disease-specific symptoms and overall HRQOL. No adverse events were expected, as participants were not participating in any randomization or experimental conditions. Participation in this study was voluntary. Approval was obtained from the Institutional Review Boards of the following sites: Primary Children's Medical Center in Salt Lake City, Cincinnati Children's Hospital Medical Center, Children's Memorial Hospital in Chicago, Texas Children's Hospital, Boston Children's Hospital, Goryeb Children's Hospital/Morristown Memorial Hospital, Nationwide Children's Hospital in Columbus, and Children's Medical Center of Dallas.

Participants

Participants were English-speaking children and adolescents ages 5-18 with a physician's diagnosis of IBD ($N = 187$) and their parents/guardians. This age range was chosen in order match the age range of the PedsQL™ Generic Core and GI Module self report. The average age of the sample was 14.32 years ($SD = 2.93$). The majority of participants fell within the 13 to 18 age group, consistent with the age distribution reflected in epidemiological studies (Loftus, 2011). Of the 187 child participants, 102 (54.5%) were male, and 85 (45.5%) were female. With respect to race/ethnicity of child

participants, 143 (76.5%) identified as White non-Hispanic, 23 identified as Black non-Hispanic (12.3%), 10 identified as Hispanic (5.3%), 6 identified as Asian or Pacific Islander (3.2%), 1 identified as American Indian/Alaskan Native (.5%), and 4 identified as “other” (2.1%). One caregiver per child was also asked to participate in the study. The majority of caregiver participants were mothers (83.4%), followed by fathers (11.2%), grandmothers (2.1%), legal guardians (.5%), and two caregiver participants who identified as “other” (1.1%). Three caregivers (1.6%) did not report their relationship to the child participants. Mean socioeconomic status (SES) based on the Hollingshead index was 50.43 (SD = 11.88), indicating, on average, a middle to upper class sample (Hollingshead, 1975); however, only 31% of caregiver participants provided SES data. In summary, participants were fairly evenly distributed with regard to gender. The majority of the sample was Caucasian, and the majority of caregiver reporters were mothers.

Table 1

Demographic Characteristics of Participants

| | Frequencies | % |
|---|-------------|------|
| <i>Gender</i> | | |
| Male | 102 | 54.5 |
| Female | 85 | 45.5 |
| <i>Ethnicity</i> | | |
| White, non-Hispanic | 143 | 76.5 |
| Black non-Hispanic | 23 | 12.3 |
| Hispanic | 10 | 5.3 |
| Asian/Pacific Islander | 6 | 3.2 |
| American Indian/Alaskan Native | 1 | 0.5 |
| Other | 4 | 2.1 |
| <i>Language</i> | | |
| English | 187 | 100 |
| <i>Diagnosis</i> | | |
| Crohn's Disease | 139 | 74.3 |
| Ulcerative Colitis | 48 | 25.7 |
| <i>Site</i> | | |
| Primary Children's Medical Center | 7 | 3.7 |
| Cincinnati Children's Hospital Medical Center | 30 | 16.0 |
| Children's Memorial Hospital | 30 | 16.0 |
| Texas Children's Hospital | 42 | 22.5 |
| Boston Children's Hospital | 5 | 2.7 |
| Goryeb Children's Hospital | 5 | 2.7 |
| Nationwide Children's Hospital | 56 | 29.9 |
| Children's Medical Center of Dallas | 12 | 6.4 |

Participants were recruited as part of a larger study aimed at developing and field testing the PedsQL™ GI Symptoms Module for use across a range of functional and organic GI diagnoses. Participants were enrolled at eight sites nationwide: Primary Children's Medical Center, Cincinnati Children's Hospital Medical Center, Children's Memorial Hospital, Texas Children's Hospital, Boston Children's Hospital, Goryeb Children's Hospital/Morristown Memorial Hospital, Nationwide Children's Hospital, and Children's Medical Center of Dallas. For purposes of the current study, children

and adolescents were required to have a physician's diagnosis of IBD, specifically Crohn's disease or ulcerative colitis, to be eligible to participate. The mean number of months since IBD diagnosis for the sample was 25.1 months (SD = 27.8; Range = 0 to 147). Exclusionary criteria for children and adolescents included the presence of comorbid GI diagnoses, inability to read, and non-English speaking. Inclusion and exclusion criteria were evaluated through screening and demographic questionnaires completed by the parents/guardians, as well as medical chart reviews.

Procedures

Data collection took place between June 2011 and July 2012. Texas A&M IRB approval was obtained for the current study in July of 2011, prior to the start of data collection, and was renewed in July of 2012. Participants were recruited at hospitals through pediatric gastroenterology clinics. Caregivers were initially approached by gastroenterologists and/or their research staff to determine caregivers' interest in participating in the study. Families were informed that their decision to participate in this study was voluntary and would not affect their medical care or insurance coverage.

Upon agreement to participate, caregivers and children were provided with information concerning the research study. Once parent consent and child assent were obtained, participants were given a packet containing the PedsQL™ Family History Form, the PedsQL™ Generic Core Parent and Child forms, and the PedsQL™ Gastrointestinal Symptoms Module Parent and Child forms. Additionally, participants were provided contact information for the primary investigator. Participants were given the option of leaving completed packets at their physicians' offices or returning them via

mail to the primary investigator. Depending on funding availability at each site, participants who returned completed packets received monetary compensation. Once returned, each packet was assigned a unique identification number for purposes of data entry and analysis. All forms were stored in secured locations to ensure confidentiality. Likewise, all computer-entered information was stored in secure, password-protected files. Only researchers involved in this project had access to identifying information.

Measures

Health-Related Quality of Life

Overall HRQOL was measured using the Pediatric Quality of Life Inventory™ Generic Core Scales (PedsQL™; Varni, 2001), an empirically validated measure of HRQOL that is widely used in the medical field as a measure of intervention and treatment effectiveness. The PedsQL™ consists of four scale scores measuring functioning across physical, emotional, social, and school domains, which collectively form three summary scores: Physical, Psychosocial, and Total Health. The 23-item PedsQL™ is available as both a self and proxy report. Item content is the same for both parent and child forms; however, each is worded according to the perspective of the respondent. Forms are age-specific. The Young Child form is intended for ages 5-7, the Child form for ages 8-12, and the Teen form for ages 13-18. Responses to each item are presented on a four-point Likert-type scale. Responses indicate “how much of a problem” each of the items have been for the child during the previous month (0=Never to 4=Almost Always). Items are reverse-scored and linearly transformed to a 0 to 100 scale, with higher scores indicating better HRQOL. Internal consistency estimates for

the PedsQL™ range from .75 to .90 for the parent report and .71 to .88 for the child report, based on standardization data. The Total Health score was used for purposes of the current study.

In addition to information from the PedsQL™ Generic Core Scales, the PedsQL™ Gastrointestinal Symptoms Module (Varni et al., 2012) provided information on disease-specific symptoms related to IBD. The PedsQL™ GI Symptoms Module consists of 76 items and includes a self-report measure for children ages 5-18 and a proxy measure for caregivers with children ages 2-18. Item content is the same for both parent and child form; however, each is worded according to the perspective of the respondent. Responses to each item are presented on a five-point Likert-type scale. Participants are asked to indicate “how much of a problem” each of the items have been for the child during the previous month (0=never a problem to 5=almost always a problem). The measure is designed to assess symptoms across a range of pediatric GI disorders.

Consistent with the FDA guidelines for patient-reported outcome instruments, the PedsQL™ GI Symptoms Module was developed using qualitative methods such as focus groups/individual interviews and cognitive interviewing techniques to inform content and item development. Eleven domains were derived from the aforementioned qualitative methods: Stomach Pain and Hurt (5 items), Stomach Upset (8 items), Food and Drink Limits (6 items), Trouble Swallowing (3 items), Heartburn and Reflux (8 items), Gas and Bloating (7 items), Constipation, (15 items), Diarrhea (7 items), Worry (8 items), Medicine (4 items), and Communication (5 items). These domains are

subsumed under the broad domains of “upper GI symptoms” and “lower GI symptoms.” The PedsQL™ GI Symptoms Module is currently in the final stages of field-testing; therefore, reliability and validity data are not yet available. All scales of the PedsQL™ GI Symptoms Module were used in this study.

The PedsQL™ Generic Core Scales demonstrate good internal consistency, with Cronbach alpha coefficients approaching or exceeding the minimum standard of .70 (Varni, Seid, & Kurtin, 2001). In the present study, alpha coefficients for the self-report Core scales ranged from .80 to .84, while parent report coefficients ranged from .80 to .90. Cronbach alpha coefficients for self-report GI scales ranged from .59 to .93. The majority of alpha coefficients fell in the .80 to .90 range. Similarly, alpha coefficients for parent-report GI scales ranged from .74 to .95. The majority of alpha coefficients fell in the .80 to .90 range.

Item-internal consistency for this sample was computed by correlating each individual GI symptom scale with the overall GI Total scale, for both self and caregiver reports, to assess the relationships between the GI symptom scales and the Total GI scale. Pearson product-moment correlations of the GI symptom scales with the GI Total scale for child self-reports were as follows: Stomach Pain and Hurt ($r = .73, p < .001$), Stomach Upset ($r = .81, p < .001$), Food and Drink Limits ($r = .57, p < .001$), Trouble Swallowing ($r = .42, p < .001$), Heartburn and Reflux ($r = .70, p < .001$), Gas and Bloating ($r = .72, p < .001$), Constipation ($r = .82, p < .001$), Diarrhea ($r = .71, p < .001$), Worry ($r = .72, p < .001$), Medications ($r = .31, p < .001$), and Communication ($r = .49, p < .001$). Correlations of the GI symptom scales with the GI Total scale for

parent reports were: Stomach Pain and Hurt ($r = .73, p < .001$), Stomach Upset ($r = .78, p < .001$), Food and Drink Limits ($r = .60, p < .001$), Trouble Swallowing ($r = .35, p < .001$), Heartburn and Reflux ($r = .68, p < .001$), Gas and Bloating ($r = .71, p < .001$), Constipation ($r = .83, p < .001$), Diarrhea ($r = .72, p < .001$), Worry ($r = .78, p < .001$), Medications ($r = .31, p < .001$), and Communication ($r = .32, p < .001$).

Demographics

Demographic information was collected using the PedsQL™ Family Information Form (Varni et al., 2001). The questionnaire includes children's date of birth, gender, race/ethnicity, parental education, and occupation: information necessary to calculate the Hollingshead four-factor SES index (Hollingshead, 1975). The demographic questionnaire may be used in conjunction with any PedsQL™ measure.

Disease-Specific Indicators

The following information was retrieved from children's medical charts by research assistants: IBD diagnosis, category of co-morbid diagnoses, and date of IBD diagnosis. Participants were told during the informed consent process that their medical records would be reviewed to determine their eligibility for the study and to provide information about the length of time that had passed since their diagnosis.

Data Analyses

To test hypothesis 1, an analysis of Pearson's Product Moment Correlations between the self report of the PedsQL™ Generic Core Total scale and the self report PedsQL™ GI Symptoms Module Total scale was conducted to determine the degree of correlation between disease-specific domains of HRQOL and overall HRQOL. Pearson

Product Moment Correlation coefficient effect sizes are designated as small (.10-.29), medium (.30-.49) and large ($\geq .50$; Cohen, 1988). It was hypothesized that higher disease-specific HRQOL scores, as measured by the PedsQL™ GI Symptoms Module Total Score, would be associated with higher self-reported generic HRQOL scores, as measured by the PedsQL™ Generic Core Scales Total Health score.

Similarly, to test hypothesis 2, an analysis of Pearson's Product Moment Correlations between the PedsQL™ GI Symptoms Module Total scale and the PedsQL™ Generic Core Total scale for parent proxy reports was conducted to determine the degree of correlation between disease-specific domains of HRQOL and overall HRQOL. Pearson Product Moment Correlation coefficient effect sizes are designated as small (.10-.29), medium (.30-.49) and large ($\geq .50$; Cohen, 1988). It was hypothesized that higher disease-specific HRQOL scores, as measured by the PedsQL™ GI Symptoms Module Total score, would be associated with higher self-reported generic HRQOL scores, as measured by the PedsQL™ Generic Core Scales Total Health score.

To test Hypothesis 3, a regression analysis was conducted to determine which self-reported disease-specific symptoms explained the most variance in scores on the Total Health subscale of the self-report PedsQL™ Generic Core Scales. It was hypothesized that physical disease-specific domains of HRQOL, specifically stomach pain, stomach upset, trouble swallowing, heartburn and reflux, gas and bloating, constipation, and diarrhea would contribute most to variance in overall HRQOL.

To test Hypothesis 4, a regression analysis was conducted to determine which caregiver-reported disease-specific symptoms explained the greatest variance in scores

on the Total Health subscale of the proxy report PedsQL™ Generic Core Scales. It was hypothesized that physical disease-specific domains of HRQOL, specifically stomach pain, stomach upset, trouble swallowing, heartburn and reflux, gas and bloating, constipation, and diarrhea would contribute most to variance in overall HRQOL.

CHAPTER IV

RESULTS

Descriptive Statistics

The means, standard deviations, and other statistics of normality for independent variables (i.e., self- and proxy-report GI scales) were computed, with results listed in Table 2. PedsQL™ Symptom scores range from 0 to 100 (higher scores indicate better HRQOL). Both children's and parents' scores on the PedsQL™ Generic Core Total scale were below the mean scores of children in a healthy normative sample, confirming prior research evidence that children with IBD report poorer health-related quality of life than healthy children (Varni et al., 2003).

Table 2

Descriptive Statistics for Measures of Independent Variables, Self-Reported GI Symptoms

| | N | Min | Max | M | SD | Skewness | SE | Kurtosis | SE |
|-----------------------|-----|-------|-------|-------|-------|----------|-----|----------|-----|
| <i>Measure</i> | | | | | | | | | |
| Stomach Pain and Hurt | 183 | 10.00 | 100.0 | 68.06 | 21.49 | -.34 | .18 | -.48 | .36 |
| Stomach Upset | 183 | 18.75 | 100.0 | 75.47 | 18.59 | -.72 | .18 | -.14 | .36 |
| Food and Drink Limits | 184 | 4.17 | 100.0 | 70.51 | 23.85 | -.47 | .18 | -.75 | .36 |
| Trouble Swallowing | 184 | 50.00 | 100.0 | 95.04 | 9.78 | -2.18 | .17 | 4.41 | .36 |
| Heartburn and Reflux | 183 | 43.75 | 100.0 | 85.62 | 13.28 | -.95 | .17 | .25 | .36 |
| Gas and Bloating | 181 | 3.57 | 100.0 | 66.64 | 21.03 | -.53 | .18 | -.33 | .36 |
| Constipation | 181 | 13.33 | 100.0 | 74.93 | 19.81 | -.72 | .18 | -.05 | .36 |
| Diarrhea | 183 | .00 | 100.0 | 78.66 | 23.40 | -1.19 | .18 | .76 | .36 |
| Worry | 183 | .00 | 100.0 | 75.26 | 20.75 | -1.10 | .18 | .98 | .36 |
| Medicine | 182 | 18.75 | 100.0 | 75.27 | 19.48 | -.69 | .18 | -.15 | .36 |
| Communication | 183 | .00 | 100.0 | 71.68 | 22.45 | -.73 | .18 | -.02 | .36 |
| Total | 183 | 32.24 | 99.01 | 75.61 | 14.67 | -.67 | .18 | -.02 | .36 |

Note. PedsQL™ scores are presented as linearly transformed scores. Higher values equal better HRQOL. Min = Minimum, Max = Maximum, M = Mean, SD = Standard Deviation, SE = Standard Error.

Table 3 presents the means, standard deviations, and other statistics of self- and proxy-report PedsQL™ GI Symptom Module scales. Assumptions of multiple regression were met with regard to multicollinearity, linear distribution of scores, and

independence of residuals. Data for the overall sample was negatively skewed, as were the distributions of scores for each scale. The decision was made to proceed with data analysis, given that this is a non-normative clinical sample and that some degree of non-normality is to be expected.

Table 3

Descriptive Statistics for Measures of Independent Variables, Proxy Report GI Symptoms

| | N | Min | Max | M | SD | Skewness | SE | Kurtosis | SE |
|-----------------------|-----|-------|-------|-------|-------|----------|-----|----------|-----|
| <i>Measure</i> | | | | | | | | | |
| Stomach Pain and Hurt | 182 | .00 | 100.0 | 62.58 | 24.48 | -.28 | .18 | -.67 | .36 |
| Stomach Upset | 182 | .00 | 100.0 | 68.59 | 23.63 | -.54 | .18 | -.32 | .36 |
| Food and Drink Limits | 183 | .00 | 100.0 | 69.30 | 26.74 | -.54 | .18 | -.70 | .36 |
| Trouble Swallowing | 183 | 50.00 | 100.0 | 95.08 | 10.81 | -2.34 | .18 | 4.96 | .36 |
| Heartburn and Reflux | 183 | 18.75 | 100.0 | 83.87 | 16.15 | -1.00 | .18 | .65 | .36 |
| Gas and Bloating | 180 | .00 | 100.0 | 67.72 | 23.91 | -.62 | .18 | -.03 | .36 |
| Constipation | 179 | 11.67 | 100.0 | 76.45 | 19.78 | -.72 | .18 | -.13 | .36 |
| Diarrhea | 180 | 7.14 | 100.0 | 75.14 | 23.45 | -.63 | .18 | -.59 | .36 |
| Worry | 181 | .00 | 100.0 | 73.14 | 22.74 | -.83 | .18 | .21 | .36 |
| Medicine | 182 | .00 | 100.0 | 77.63 | 20.68 | -1.33 | .18 | 1.76 | .36 |
| Communication | 181 | 15.00 | 100.0 | 72.57 | 22.72 | -.50 | .18 | -.51 | .36 |
| Total | 181 | 25.33 | 100.0 | 74.18 | 15.60 | -.64 | .18 | .14 | .36 |

Note. PedsQL™ scores are presented as linearly transformed scores. Higher values equal better HRQOL. Min = Minimum, Max = Maximum, M = Mean, SD = Standard Deviation, SE = Standard Error.

Prior to addressing the research questions, an exploratory analysis of PedsQL™ Generic Core Scale scores across age forms (5-7, 8-12, 13-18) was conducted utilizing analysis of variance with Tukey post-hoc tests to determine if there were systematic differences across age groups. There was no significant difference in self-report scores for ages 5-7 and ages 8-12 [$t(56)=.12, p=.91$]. Likewise, there was no significant difference between children who completed the 5-7 form and children who completed the 13-18 form [$t(124)=.36, p=.72$]. Lastly, no significant differences existed between children who completed the 8-12 form and the 13-18 form [$t(178)=1.40; p=.30$]. The same analysis was conducted for proxy reports across age forms. Similarly, there were

no significant differences in proxy report scores for ages 5-7 and ages 8-12 [$t(56)=.68$, $p=.50$], nor ages 5-7 and ages 13-18 [$t(119)=.58$, $p=.57$]. No significant differences in parent proxy report scores existed for ages 8-12 and ages 13-18 [$t(171)=-.29$, $p=.77$]. In summary, no systematic differences across age groups were found. These results are presented in Table 4.

Table 4

Comparison of Means by Age Group for PedsQL™ Generic Core Scales

| | 5-7 years | 8-12 years | 13-18 years | Significant Differences |
|--------------------------------|------------------|------------------|------------------|---------------------------------|
| Number of Participants (n) | 2 | 57 | 128 | |
| Child Report | 82.60 (9.22) | 81.68 (10.70) | 79.90 (9.22) | No comparisons were significant |
| Proxy Report | 81.52 (16.01) | 74.85 (16.65) | 75.67 (17.41) | No comparisons were significant |

Correlations with the PedsQL™ 4.0 Generic Core Scales

Research Question 1: Is greater overall self-reported disease-specific HRQOL, as measured by the PedsQL™ GI Symptoms Module Total score, associated with greater generic HRQOL, as measured by the PedsQL™ Generic Core Scales Total Health score? This relationship was tested using Pearson’s Product Moment Correlation between the self-report PedsQL™ GI Symptoms Module Total score and the self-report PedsQL™ Generic Core Scales Total Health score. It was hypothesized that disease-specific symptom severity would be positively correlated with overall HRQOL. Tables 5 and 6 show the correlations among the PedsQL™ GI Symptoms Module and the PedsQL™ 4.0 Generic Core Total scale.

Table 5

Correlations between Self Report GI Symptoms Module Scales and Generic Core Total Scale

| Scale | r |
|-----------------------|-------|
| Stomach Pain and Hurt | .55** |
| Stomach Upset | .48** |
| Food and Drink Limits | .41** |
| Trouble Swallowing | .34** |
| Heartburn and Reflux | .45** |
| Gas and Bloating | .43** |
| Constipation | .51** |
| Diarrhea | .41** |
| Worry | .56** |
| Medicine | .35** |
| Communication | .42** |
| Total | .63** |

Note. Sig = Level of significance. * $p < .05$, ** $p < .001$.

Higher child self-report scores on the PedsQL™ GI Symptoms Module Total Scale were associated with higher generic HRQOL scores. All PedsQL™ GI Symptoms Module scales were significantly correlated with the PedsQL™ 4.0 Generic Core Total scale, with the largest correlations demonstrated on Worry ($r = .56, p < .001$) and Stomach Pain and Hurt ($r = .55, p < .001$). Pearson’s Product Moment Correlations between scales of the PedsQL™ GI Symptoms Module and the PedsQL™ 4.0 Generic Core Total Scale were all within the medium range (see Table 5).

Research Question 2: Is greater overall disease-specific HRQOL, as measured by the proxy report PedsQL™ GI Symptoms Module Total Score, associated with greater generic HRQOL, as measured by the proxy report PedsQL™ Generic Core Scales Total Health score? This relationship was tested using Pearson’s Product Moment Correlation between the proxy report PedsQL™ GI Symptoms Module Total score and the proxy report PedsQL™ Generic Core Scales Total Health score. It was

hypothesized that disease-specific symptom HRQOL scores would be positively correlated with overall HRQOL scores. Results are provided in Table 6.

Table 6

Correlations between Proxy Report GI Symptoms Module Scales and Generic Core Total Scale

| Scale | r |
|-----------------------|-------|
| Stomach Pain and Hurt | .48** |
| Stomach Upset | .50** |
| Food and Drink Limits | .44** |
| Trouble Swallowing | .21** |
| Heartburn and Reflux | .33** |
| Gas and Bloating | .39** |
| Constipation | .41** |
| Diarrhea | .36** |
| Worry | .50** |
| Medicine | .14 |
| Communication | .38** |
| Total | .56** |

Note. Sig = Level of significance. * $p < .05$, ** $p < .001$.

Higher proxy report scores on the PedsQL™ GI Symptoms Module Total Scale were associated with higher generic HRQOL scores, as well (Table 6). All proxy report PedsQL™ GI Symptoms Module scales were significantly correlated with the PedsQL™ 4.0 Generic Core Total scale, with the exception of the Medicines scale ($r = .14$, $p = .06$). Largest correlations were demonstrated on the Upset ($r = .50$, $p < .001$) and Pain and Hurt ($r = .48$, $p < .001$) scales. In summary, Pearson's Product Moment Correlations between proxy report scales of the PedsQL™ GI Symptoms Module and the PedsQL™ 4.0 Generic Core Total Scale were in the medium range, with only one scale, Medicines, falling within the small correlation range.

Contribution of Variance

Research Question 3: Are self-reported physical disease-specific symptoms more strongly related to impaired HRQOL in children and adolescents with IBD than non-physical disease-specific symptoms? It was hypothesized that physical disease-specific domains of HRQOL, specifically stomach pain, stomach upset, trouble swallowing, heartburn and reflux, gas and bloating, constipation, and diarrhea would contribute the most variance in overall HRQOL scores.

This relationship was tested using linear regression to determine which scales of the self-report PedsQL™ GI Symptoms Module contributed the most variance to overall HRQOL, as measured by the self-report PedsQL™ Generic Core Scales Total Health score. Linear regression analyses were used to determine the extent to which scores on the PedsQL™ Generic Core Total scale could be predicted by Stomach Pain and Hurt, Stomach Upset, Food and Drink Limits, Trouble Swallowing, Heartburn and Reflux, Gas and Bloating, Constipation, Diarrhea, Worry, Medications, and Communication subscales of the PedsQL™ GI Symptoms Module. The eleven subscales of the PedsQL™ GI Symptoms Module were included as the independent variables, and the PedsQL™ Generic Core Total scale was employed as the dependent variable. Results are presented in Table 7.

Table 7

Regression Analysis of Self Report GI Symptoms Scales

| Variable | B | SE B | B | Sig |
|-----------------------|------|------|------|-------|
| Stomach Pain and Hurt | .16 | .07 | .23 | <.05* |
| Stomach Upset | -.01 | .08 | -.01 | .93 |
| Food and Drink Limits | .05 | .05 | .07 | .31 |
| Trouble Swallowing | .06 | .11 | .04 | .55 |
| Heartburn and Reflux | .09 | .09 | .08 | .30 |
| Gas and Bloating | -.05 | .06 | -.06 | .46 |
| Constipation | .12 | .07 | .16 | .09 |
| Diarrhea | -.09 | .06 | -.14 | .10 |
| Worry | .19 | .07 | .26 | <.05* |
| Medicine | .01 | .05 | .13 | <.05* |
| Communication | .12 | .05 | .17 | <.05* |

Note. B = Unstandardized coefficient; SE B = Standard Error of the Unstandardized Coefficient; B = Standardized Coefficient; Sig = Level of significance. * $p < .05$, ** $p < .001$.

Regarding children’s perceptions of HRQOL, results indicated that a significant amount of variance in self-reported overall HRQOL, as measured by the PedsQL™ Generic Core Scale Total score, was accounted for by these predictors [$F(11,167) = 13.04, p < .01, R^2 = 46.2\%$]. Taken together, the physical symptom scales (Stomach Pain and Hurt, Stomach Upset, Food and Drink Limits, Trouble Swallowing, Heartburn and Reflux, Gas and Bloating, Constipation, Diarrhea) explained a marginally greater amount of variance in the Generic Core Scale Total score [$F(8,179) = 13.78, p < .01, R^2 = 39.2\%$] than the combined Communication, Medicines, and Worry scales [$F(3,180) = 37.07, p < .01, R^2 = 38.6\%$].

Research Question 4: Are parent-reported physical disease-specific symptoms predictive of impaired HRQOL in children and adolescents with IBD? It was hypothesized that physical disease-specific domains of HRQOL, specifically stomach pain, stomach upset, trouble swallowing, heartburn and reflux, gas and bloating,

constipation, and diarrhea would contribute most to variance in overall HRQOL.

Results are presented in Table 8.

Table 8

Regression Analysis of Proxy Report GI Symptoms Scales

| Variable | B | SE B | <i>B</i> | Sig |
|-----------------------|------|------|----------|----------|
| Stomach Pain and Hurt | .12 | .08 | .19 | .13 |
| Stomach Upset | .01 | .09 | .01 | .92 |
| Food and Drink Limits | .03 | .05 | .05 | .56 |
| Trouble Swallowing | -.03 | .11 | -.02 | .82 |
| Heartburn and Reflux | .08 | .09 | .08 | .42 |
| Gas and Bloating | .00 | .06 | .00 | .99 |
| Constipation | .15 | .08 | .19 | .06 |
| Diarrhea | .02 | .06 | .03 | .72 |
| Worry | .27 | .05 | .42 | < .001** |
| Medicine | -.10 | .05 | -.13 | .07 |
| Communication | .05 | .05 | .08 | .27 |

Note. B = Unstandardized coefficient; SE B = Standard error of the Unstandardized Coefficient; *B* = Standardized Coefficient; Sig = Level of significance. * $p < .05$, ** $p < .001$.

Similar to Question 3, this relationship was tested using linear regression to determine which scales of the proxy report PedsQL™ GI Symptoms Module contributed the most variance to overall HRQOL, as measured by the proxy report PedsQL™ Generic Core Scales Total Health score. With respect to parents' perceptions of their children's HRQOL, results indicated that a significant amount of the variance in parent ratings of children's overall HRQOL was accounted for by this set of predictors [$F(11,160) = 9.472, p < .01, R^2 = 39.4\%$]; however, the non-physical symptom scales (Worry, Communication, Medicines) explained a greater amount of variance in parent ratings of children's overall HRQOL [$F(3,175) = 12.746, p < .01, R^2 = 42.6\%$] than did the physical symptom scales (Pain and Hurt, Stomach Upset, Food and Drink Limits,

Trouble Swallowing, Heartburn and Reflux, Gas and Bloating, Constipation, Diarrhea)

[$F(8.174) = 5.433, p < .01, R^2 = 20.8\%$].

Parent/Child Agreement

Although not a research question, the extent to which parents and children agreed in their report of symptoms was of interest. Intraclass correlations (ICC) between pediatric self-report and parent proxy-report across the PedsQL™ GI Symptoms Module are provided in Table 9.

Table 9

Intraclass Correlations

| Variable | R | <i>p</i> |
|-----------------------|-----|------------|
| Stomach Pain and Hurt | .74 | $p < .001$ |
| Stomach Upset | .65 | $p < .001$ |
| Food and Drink Limits | .66 | $p < .001$ |
| Trouble Swallowing | .37 | $p < .001$ |
| Heartburn and Reflux | .61 | $p < .001$ |
| Gas and Bloating | .57 | $p < .001$ |
| Constipation | .67 | $p < .001$ |
| Diarrhea | .74 | $p < .001$ |
| Worry | .72 | $p < .001$ |
| Medicine | .57 | $p < .001$ |
| Communication | .25 | $p < .001$ |
| Total | .74 | $p < .001$ |

All scales were significantly intercorrelated. The greatest agreement was found between parents and children on Stomach Pain and Hurt, while the lowest agreement was demonstrated between parents and children on Communication. Children reported higher HRQOL across all PedsQL™ GI Symptoms Module scales, with the exception of Gas and Bloating, Constipation, and Medicine subscales.

CHAPTER V

SUMMARY AND CONCLUSIONS

The group of disorders known as Inflammatory Bowel Disease (IBD) affects nearly 1.1 million individuals in the United States. Of these, a substantial number of cases are diagnosed in childhood and early adolescence. IBD is thought to be an autoimmune disease and is characterized by a constellation of symptoms, which may include severe abdominal pain, fever, diarrhea, fistulas, intestinal bleeding, joint pain, and extreme fatigue. The physical and psychological effects of IBD are pervasive and can cause significant impairment in physical, social, and academic functioning. Ongoing efforts are being made to investigate the specific mechanisms by which various disease factors impact overall functioning and individuals' HRQOL.

Although prior research has suggested a relationship between physical disease-specific symptom indicators, particularly pain, and HRQOL in children with gastrointestinal disorders, questions remain as to which disease-specific symptoms have the greatest impact on overall HRQOL and how best to intervene to improve functioning. The purpose of this study was twofold: to assess the relationship of overall disease-specific HRQOL with generic HRQOL and, secondly, to explore which disease-specific symptom scales explained the most variance in generic HRQOL scores. With managed care a growing trend within the healthcare world, findings to this effect are of great value for healthcare providers who strive for greater diagnostic precision in detecting the presence and severity of symptoms most likely to influence HRQOL.

Previous research has emphasized the importance of obtaining data from multiple informants (Kazak, 1997). The current study included data from both children and their caregivers. As has traditionally been the case in pediatric research, the majority of caregivers were mothers, despite the fact that any caregiver was eligible to participate in the study. Mothers are widely considered to be the ideal caregiver informants for children with chronic illness, provided that they take the primary caregiving responsibility (Brown & Barbarin, 1996; Kazak & Nachman, 1991; Koch, Harter, Jakob, & Siegrist, 1996; Kolbrun-Svavarsdottir, 2005). That said, consideration must be given to the fact that mothers demonstrate higher levels of parenting stress when caring for a chronically ill child than when other family members fill the role of primary caregiver, which may influence their ratings of child adjustment. A strength of the current study lies in the fact that information was collected across a more ethnically diverse group than most previous studies with this population.

Four hypotheses were made regarding the relationship between disease-specific HRQOL and overall HRQOL, from both child and caregiver report. First, it was hypothesized higher self-reported disease-specific HRQOL scores, as measured by the PedsQL™ GI Symptoms Module Total Score, would be associated with higher self-reported generic HRQOL, as measured by the PedsQL™ Generic Core Scales Total Health score. Indeed, a strong positive correlation was found between self-reported disease-specific HRQOL and overall HRQOL. This finding was not surprising, given that prior research has demonstrated strong ties between self-reported disease-specific symptoms and HRQOL. It stands to reason that, when children report better control of

physical and emotional symptoms specific to their illnesses, the resultant improved well-being will be reflected in overall HRQOL. As mentioned earlier, this finding was not surprising, given that prior research has demonstrated strong ties between self-reported disease-specific symptoms and HRQOL. It stands to reason that, when children report better control of physical and emotional symptoms specific to their illnesses, the resultant improved well-being will be reflected in overall HRQOL.

A second hypothesis was that higher proxy report disease-specific HRQOL scores, as measured by the PedsQL™ GI Symptoms Module Total Score, would be associated with higher proxy report generic HRQOL scores, as measured by the PedsQL™ Generic Core Scales Total Health score. Once again, a strong positive correlation existed between the two variables, indicating that, as caregivers' perceptions of children's disease-specific HRQOL improve, their perceptions of children's overall HRQOL improve, as well. The correlation between the proxy report measures was not as strong as the correlation between self-report measures, however.

Third, it was hypothesized that physical disease-specific symptoms would explain more variance in overall HRQOL scores than non-physical disease-specific symptoms. In contrast to what was hypothesized, the Worry subscale contributed the most variance in overall HRQOL, followed closely by Medicine and Communication subscales. Stomach Pain and Hurt was the only symptom among the physical symptom scales that explained a significant amount of variance in the Generic PedsQL™ Total score. This is consistent with previous research on adults with GI disorders that pointed toward pain being a major contributor to reduced HRQOL (Graff et al., 2006; Schirbel et

al., 2010). Unlike prior research studies that have cited other symptoms such as food and drink limitations, upset, and diarrhea as key players, none of these symptom scales emerged as statistically significant in the current study. Rather, the more psychosocially oriented scales, Communication, Worry, and Medications, contributed most to variance in overall HRQOL. Results are, however, taken with considerations from previous studies that have found that increases in physical symptoms corresponded with increases in anxiety and depression (Graff, Walker, & Bernstein, 2009; Maunder & Levenstein, 2008). Thus, it is possible that the presence of physical symptoms does impact HRQOL directly; however, worry may be a moderating factor, in that greater physical discomfort may perpetuate concerns about the duration of the physical symptoms/illness, severity of the illness, functional limitations, and so on. In turn, this may bring more acute awareness of the impact of illness on overall well-being, or HRQOL.

Another unexpected finding was that, as children perceive themselves to be less able to communicate with others about their illness, their sense of overall well-being is affected. The ability to communicate with parents, medical professionals, other people, and friends about concerns related to having a chronic illness such as IBD was summarized in the Communication scale. Though beyond the scope of the current study, it would be reasonable to hypothesize, based on findings here, that the Communication subscale of the GI Symptoms Module could contribute a significant amount of variance to the Social Scale on the Core Module. Fear related to disclosing information about one's illness to others significantly impacts social functioning, particularly when social engagement is limited by disease symptoms. The feeling of isolation that may

accompany the perception or feeling that one is unable to communicate about a chronic illness with others may also contribute to anger and sadness, which would be reflected in the Emotional scale of the Core Module.

Lastly, it was hypothesized that caregiver-reported physical disease-specific symptoms would explain the most variance in overall HRQOL in children and adolescents with IBD. Consistent with results from the analysis with the self-report, Worry explained the most variance in Total HRQOL scores. In contrast to self-report results, Pain and Upset, Communication, and Medicines scales of the caregiver reports were not statistically significant. One possible explanation for this finding is that children may not readily articulate concerns about pain, communication, and medication; caregivers may instead perceive these concerns as general worry about their condition. Furthermore, in response to potential concerns that children are not accurate self-reporters, the value of self-report measures for children cannot be underestimated. Elevated scores on these scales indicate distress, or problem areas that need to be explored further for clarification. In this sense, the use of patient-reported outcome inventories is, in and of itself, a mechanism of improving communication, which was a large contributor to variance in self-reported HRQOL.

In considering these results, once again, worry may function as a moderating factor between caregivers' perceptions of physical symptoms and overall HRQOL. Though none of the physical symptom scales contributed a significant amount of variance to proxy report overall HRQOL scores, it cannot necessarily be presumed that these factors did not contribute to caregiver perceptions of child worry. Mean self-report

scores of worry were slightly higher than caregiver-reported scores of worry; the same pattern existed with regard to the Total GI Symptoms scale. While this difference may appear to be slight, it nevertheless reflects the trend typically found with parent and child report HRQOL scores, in which parents and caregivers report lower HRQOL than children.

Intraclass correlations between child and parent reports were higher than expected on a number of the physical symptom scales, as well as the Worry scale. Although this study did not purport to assess parent-child agreement, it is hypothesized that higher agreement on disease-specific measures may be due in part to the fact that parents of patients with a chronic illness, particularly one with such intrusive symptoms as IBD, may be more attuned to the disease-specific difficulties that impair children's HRQOL. Frequent medical appointments provide opportunities for children to share disease-specific information with parents and, in turn, for parents to confirm and/or expand upon children's reports of disease-specific activity to physicians. The strong agreement between children and parents on the Worry scale is particularly notable. Intraclass correlations of internalizing symptoms on multi-informant behavioral rating scales are generally much lower (Achenbach & Rescorla, 2001). This finding indicates that the Worry scale demonstrates good sensitivity to internalizing symptoms that children perceive as relevant and that are easily observable to parents.

In general, this study differed from previous studies in which disease symptom severity accounted for the greatest amount of variance in HRQOL scores. Though the relationship is still unclear, several studies have posited that severity of disease

symptoms co-varies with rates of anxiety and depression, lending support to the supposition that Worry could serve as a moderating factor between pain and overall HRQOL (Drossman et al., 1991; Mikocka-Walus et al., 2007; Nordin et al., 2002). Furthermore, in past studies, depression and anxiety symptoms were considered outcome variables, along with overall HRQOL. Therefore, they were considered apart from physical symptom scales in most models. The few studies that addressed emotional symptom scales did not assess the relative contribution of emotional symptoms versus physical symptoms to overall HRQOL. Until now, no research precedent existed upon which to base a prediction that Worry would contribute more variance in Total HRQOL over and above the physical symptom scales.

Limitations

Limitations of the present study included sample size, sample homogeneity, and the absence of a healthy comparison group. Significant variability existed within the sample with regard to disease-specific indicators such as time since diagnosis, disease severity, length of medication usage, surgical history, and stage of treatment. While the heterogeneity of the sample (Crohn's and ulcerative colitis) may not have implications for internal validity of results for the present study, these differences may differentially impact the generalizability of the findings. Although each patient enrolled in the study had a physician's diagnosis of ulcerative colitis or Crohn's disease, functional status varies greatly for individuals with mild or newly diagnosed forms of IBD versus patients with more severe forms of the disease.

The profiles of individuals with mild disease who take daily oral medications for maintenance of the disease and have few functional limitations likely would look vastly different from patients with severe forms of the disease who must undergo either regularly scheduled infusions of biologic medications administered intravenously or invasive surgical procedures to control symptoms. In addition, manifestations of Crohn's disease often occur outside of the gastrointestinal tract; symptoms may include rheumatoid arthritis, ocular inflammation, anemia, and skin lesions. Although the PedsQL™ GI Symptoms Module does not purport to take these symptoms into account, nor should it, it is nevertheless important to consider that these symptoms may impact patients' subjective experiences of HRQOL.

Although children with comorbid GI symptoms were excluded from the study, other medical and psychiatric comorbidities may have been present within the sample. Caregivers were given the option to list comorbid diagnoses on the family information form, but this information was not used in the present study. Undoubtedly, it would be expected that the presence of comorbid diagnoses would have a detrimental effect on overall HRQOL. Future research may include further investigation of the extent to which scores on the Emotional scale of the generic module are influenced by disease-specific symptoms.

While the present sample size was much larger than the majority of those in existing psychological research on children with IBD, statistical power could be improved with a larger sample size. Furthermore, the cross-sectional nature of the study

prohibits the ability to draw conclusions about directionality and change over time. It is likewise impossible to measure how the burden of the disease changes over time.

Although the study included participants ages 5 to 18, the sample was composed predominately of children in the 11 to 17 age range. The mean age of the sample was 14 years, with a standard deviation of roughly three years. A more even distribution of age groups would allow for better generalizability of findings; however, the distribution of age groups in this study closely approximates those found in epidemiological studies. Additionally, the current sample consisted of predominately Caucasian child-parent dyads; however, it should be noted that the sample was fairly representative of the underlying population of children with IBD, in that IBD is most commonly diagnosed in mid to late adolescence and occurs most frequently among individuals of Caucasian ancestry. Lastly, participants at some sites were provided monetary compensation for their participation, which could have had a differential effect on responding and may have contributed to some degree of systematic bias.

Implications for Future Research and Clinical Practice

These findings revealed several implications for future research. First, as mentioned previously, a larger, more ethnically diverse sample would allow for greater generalizability and would provide information to help determine which children with IBD may be at greatest risk for adjustment difficulties. For example, younger children who suffer from stunted growth due to the effects of IBD may experience more social difficulties than children who are diagnosed in adolescence. The ideal study would be prospective in nature and would include participants at varying stages of time since

diagnosis with varying disease severity, with the ultimate goal of parsing out meaningful differences in GI symptoms and HRQOL scores depending on disease state.

Furthermore, it would be beneficial for future research to further elucidate the relationship between pain, worry, and HRQOL so that more efficacious interventions can be developed. Findings of this nature would have important implications for future pediatric psychology practice with GI patients, in that it would allow practitioners to more closely target services to those in greatest anticipated need. Given that patient scores reveal worry to have more of an impact than pain and other physical symptoms on HRQOL, interventions aimed at targeting anxiety may have much more utility than interventions aimed at developing mechanisms to cope with physical symptoms.

As stated previously, less common symptoms of Crohn's disease and ulcerative colitis exist that may impact HRQOL in certain subgroups of children with IBD more strongly. The presence of extra-intestinal manifestations that often accompany more severe forms of these diseases can severely limit functioning, beyond the severe gastrointestinal symptoms typically present. Future research could examine the role of extra-intestinal symptoms such as joint pain, myalgia, and painful ocular inflammation, to determine if these issues further explain variance in the Pain scale of the GI symptoms module and overall HRQOL. Furthermore, given the fact that many IBD patients are on fairly intensive immunosuppressive therapy regimens, investigating the impact of frequent illness (viruses and infections) on HRQOL might help clarify the relationship between HRQOL and worry. Similarly, worry associated with injections and intravenous infusions of immunosuppressive medications might also lend insight into the

contribution of worry to HRQOL for children with IBD. Assessment of HRQOL related to these issues would provide valuable information for physicians regarding the readiness of patients to proceed with such treatment decisions and, post hoc, the effect that these treatment decisions have on individuals' well-being.

The presence of medical and psychiatric comorbidities may have important implications for HRQOL assessment in pediatric patients with IBD. Given the high rate of comorbid anxiety disorders and depression in this patient population, there is great utility in discerning the nature of the worry children experience in the context of their IBD. Given that worry has such a significant impact on overall HRQOL, more in-depth study of the causal pathways between physical symptoms, worry, communication, and HRQOL are certainly warranted, if such pathways exist. Better identification of the way in which worry is either preceded by or contributes to the development and maintenance of IBD symptoms is key. With more specific knowledge to this end, clinicians may be able to target anxiety and its precipitants using evidence-based interventions aimed at improving these factors before they can adversely impact HRQOL.

Lastly, a longitudinal study design would allow for study of the trajectories of HRQOL in IBD patients. While longitudinal research is costly and time-consuming, it can provide many advantages over cross-sectional designs. Given that ulcerative colitis and Crohn's disease are lifelong, chronic illnesses with no cure yet in existence, research related to changes in HRQOL over time would provide valuable information for determining how functioning changes with progression in age, disease course, and medical treatments.

Conclusions

Crohn's disease and ulcerative colitis, collectively known as IBD, are chronic illnesses that affect approximately 1.1 million people in the United States. Of these cases, 20 to 30 percent of cases were diagnosed in childhood or adolescence. The disease course of IBD is unpredictable and therefore difficult to characterize. Relapse is particularly common in children; currently, no definitive cure exists for IBD. Surgical intervention may improve symptoms temporarily in patients with Crohn's disease, but post-surgical relapse is extremely common.

In addition to coping with a chronic illness, children and adolescents with IBD must cope with issues unique to their disease: (a) unpredictability of disease course; (b) unknown etiology of the illness; (c) embarrassment about symptoms related to urgency to use the bathroom, stoma, and so on; and (d) delayed physical and sexual development. These issues may be distressing to children and adolescents. Therefore, it is not surprising that children with IBD have higher rates of internalizing disorders relative to the general population. Likewise, patients with IBD historically report lower HRQOL than healthy children. To date, the impact of having IBD on HRQOL appears to be a function of, first, whether or not the disease is active or in remission, and second, symptom severity.

The current study aimed to address gaps in the literature by assessing the relationship between parent- and self-reported severity of gastrointestinal symptoms and overall HRQOL in children and adolescents with a physician's diagnosis of IBD. The newly developed PedsQL™ GI Symptoms Module was used to assess disease-specific

areas of HRQOL, to include additional issues not commonly addressed by HRQOL measures for IBD, including food and drink limits, worry, medicines, and communication. Results indicated that higher disease-specific HRQOL scores were associated with higher overall HRQOL scores, for both caregivers and children. Self-report ratings revealed that Worry was the only variable that accounted for significant variance in HRQOL. Caregiver ratings also revealed that Worry contributed the most variance to overall HRQOL scores; however, Pain and Upset, Medications, and Communications scales were also significant.

Although further explanation is needed to determine the precise role of emotional and communication symptoms in relation to physical symptoms, results of this study indicate that interventions targeting emotional symptoms such as worry may be more effective in improving HRQOL than those aimed at helping individuals cope with physical symptoms. Further research is needed to facilitate the development of more targeted preventative, behaviorally based interventions which mental health practitioners can use to improve HRQOL for these patients.

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APPENDIX

ID#:

Date: / /

PedsQL™ Family Information Form

| | | | | | |
|---|--------------|--|---|--|-------------------------|
| INFORMATION ABOUT THE FAMILY | | | | | |
| <i>What is your relationship to this child (please check and/or circle)?</i> | | | | | |
| <input type="checkbox"/> Mother, Step Mother, Foster Mother | | <input type="checkbox"/> Grandmother | | <input type="checkbox"/> Guardian | |
| <input type="checkbox"/> Father, Step Father, Foster Father | | <input type="checkbox"/> Grandfather | | <input type="checkbox"/> Other | |
| INFORMATION ABOUT THE CHILD | | | | | |
| <i>Child's Age is: <u> </u> years, <u> </u> months</i> | | | | | |
| <i>Child is:</i> <input type="checkbox"/> male <input type="checkbox"/> female | | | | | |
| <i>Ethnic Group or Race:</i> | | <input type="checkbox"/> Black, Non-Hispanic | | <input type="checkbox"/> Hispanic | |
| | | <input type="checkbox"/> Asian or Pacific Islander | | <input type="checkbox"/> White, Non-Hispanic | |
| | | | | <input type="checkbox"/> Native American or Alaskan Native | |
| | | | | <input type="checkbox"/> Other _____ | |
| INFORMATION ABOUT MOTHER | | | INFORMATION ABOUT FATHER | | |
| <i>Marital Status:</i> | | | <i>Marital Status:</i> | | |
| <input type="checkbox"/> Single | | | <input type="checkbox"/> Single | | |
| <input type="checkbox"/> Married | | | <input type="checkbox"/> Married | | |
| <input type="checkbox"/> Separated | | | <input type="checkbox"/> Separated | | |
| <input type="checkbox"/> Living with someone | | | <input type="checkbox"/> Living with someone | | |
| <input type="checkbox"/> Divorced | | | <input type="checkbox"/> Divorced | | |
| <input type="checkbox"/> Widowed | | | <input type="checkbox"/> Widowed | | |
| <i>Highest Level of Education:</i> | | | <i>Highest Level of Education:</i> | | |
| <input type="checkbox"/> 6 th grade or less | | | <input type="checkbox"/> 6 th grade or less | | |
| <input type="checkbox"/> 7 th -9 th grade or less | | | <input type="checkbox"/> 7 th -9 th grade or less | | |
| <input type="checkbox"/> 9 th -12 th grade or less | | | <input type="checkbox"/> 9 th -12 th grade or less | | |
| <input type="checkbox"/> High school graduate | | | <input type="checkbox"/> High school graduate | | |
| <input type="checkbox"/> Some college or certification course | | | <input type="checkbox"/> Some college or certification course | | |
| <input type="checkbox"/> College Graduate | | | <input type="checkbox"/> College Graduate | | |
| <input type="checkbox"/> Graduate or Professional Degree | | | <input type="checkbox"/> Graduate or Professional Degree | | |
| <i>Occupation Or Job Title:</i> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> | | | <i>Occupation Or Job Title:</i> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> | | |
| IMPACT SCALE | | | | | |
| <i>In the past 6 months, has your child...</i> | | | | | |
| Had a chronic health condition (defined as a physical or mental health condition that has lasted or is expected to last at least 6 months, and interferes with your child's activities)? <input type="checkbox"/> NO <input type="checkbox"/> YES | | | | | |
| IF YES , What is the name of your child's chronic health condition? <input style="width: 100%;" type="text"/> | | | | | |
| <i>In the past 12 months, has your child had...</i> | | | | | |
| Any OVERNIGHT VISITS to the hospital? | | | Any EMERGENCY ROOM/URGENT CARE visits? | | |
| <input type="checkbox"/> NO <input type="checkbox"/> YES | | | <input type="checkbox"/> NO <input type="checkbox"/> YES | | |
| IF YES , ... How many times? <u> </u> <u> </u> | | | IF YES , ... How many times? <u> </u> <u> </u> | | |
| What was wrong? <input style="width: 100%;" type="text"/> | | | What was wrong? <input style="width: 100%;" type="text"/> | | |
| <i>In the past 30 days...</i> | | | | | |
| How many days did your child miss from school due to physical or mental health? | | | | | <u> </u> <u> </u> |
| How many days was your child sick in bed or too ill to play? | | | | | <u> </u> <u> </u> |
| How many days did your child need someone to care for him/her due to physical or mental health? | | | | | <u> </u> <u> </u> |
| IF YOU WORK OUTSIDE OF THE HOME, PLEASE ANSWER THE FOLLOWING QUESTIONS. | | | | | |
| <i>In the past 30 days</i> , how many days have you missed from work due to your child's physical or mental health? <u> </u> <u> </u> | | | | | |
| <i>In the past 30 days, has your child's health interfered with...</i> | Never | Almost Never | Some-times | Often | Almost Always |
| Your daily routine at work | 0 | 1 | 2 | 3 | 4 |
| Your ability to concentrate at work | 0 | 1 | 2 | 3 | 4 |

| | |
|-------|-------|
| ID# | _____ |
| Date: | _____ |
| | _____ |

PedsQLTM Pediatric Quality of Life Inventory

Version 4.0

YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.




Show the child the template and point to the responses as you read.

If it is not at all a problem for you, point to the smiling face

If it is sometimes a problem for you, point to the middle face

If it is a problem for you a lot, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

| | Not at all | Sometimes | A lot |
|--|---|---|---|
| Is it hard for you to snap your fingers |  |  |  |

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

| PHYSICAL FUNCTIONING (problems with...) | Not at all | Some-times | A lot |
|---|-------------------|-------------------|--------------|
| 1. Is it hard for you to walk | 0 | 2 | 4 |
| 2. Is it hard for you to run | 0 | 2 | 4 |
| 3. Is it hard for you to play sports or exercise | 0 | 2 | 4 |
| 4. Is it hard for you to pick up big things | 0 | 2 | 4 |
| 5. Is it hard for you to take a bath or shower | 0 | 2 | 4 |
| 6. Is it hard for you to do chores (like pick up your toys) | 0 | 2 | 4 |
| 7. Do you have hurts or aches (Where?) | 0 | 2 | 4 |
| 8. Do you ever feel too tired to play | 0 | 2 | 4 |

Remember, tell me how much of a problem this has been for you for the last few weeks.

| EMOTIONAL FUNCTIONING (problems with...) | Not at all | Some-times | A lot |
|---|-------------------|-------------------|--------------|
| 1. Do you feel scared | 0 | 2 | 4 |
| 2. Do you feel sad | 0 | 2 | 4 |
| 3. Do you feel mad | 0 | 2 | 4 |
| 4. Do you have trouble sleeping | 0 | 2 | 4 |
| 5. Do you worry about what will happen to you | 0 | 2 | 4 |

| SOCIAL FUNCTIONING (problems with...) | Not at all | Some-times | A lot |
|--|-------------------|-------------------|--------------|
| 1. Is it hard for you to get along with other kids | 0 | 2 | 4 |
| 2. Do other kids say they do not want to play with you | 0 | 2 | 4 |
| 3. Do other kids tease you | 0 | 2 | 4 |
| 4. Can other kids do things that you cannot do | 0 | 2 | 4 |
| 5. Is it hard for you to keep up when you play with other kids | 0 | 2 | 4 |

| SCHOOL FUNCTIONING (problems with...) | Not at all | Some-times | A lot |
|--|-------------------|-------------------|--------------|
| 1. Is it hard for you to pay attention in school | 0 | 2 | 4 |
| 2. Do you forget things | 0 | 2 | 4 |
| 3. Is it hard to keep up with schoolwork | 0 | 2 | 4 |
| 4. Do you miss school because of not feeling good | 0 | 2 | 4 |
| 5. Do you miss school because you have to go to the doctor's or hospital | 0 | 2 | 4 |

How much of a problem is this for you?

Not at all



Sometimes



A lot



ID# _____
Date: _____
_

TM
PedsQL
Pediatric Quality of Life
Inventory

Version 4.0

PARENT REPORT for YOUNG CHILDREN (ages 5-7)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE** month, how much of a **problem** has your child had with ...

| PHYSICAL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Walking more than one block | 0 | 1 | 2 | 3 | 4 |
| 2. Running | 0 | 1 | 2 | 3 | 4 |
| 3. Participating in sports activity or exercise | 0 | 1 | 2 | 3 | 4 |
| 4. Lifting something heavy | 0 | 1 | 2 | 3 | 4 |
| 5. Taking a bath or shower by him or herself | 0 | 1 | 2 | 3 | 4 |
| 6. Doing chores, like picking up his or her toys | 0 | 1 | 2 | 3 | 4 |
| 7. Having hurts or aches | 0 | 1 | 2 | 3 | 4 |
| 8. Low energy level | 0 | 1 | 2 | 3 | 4 |

| EMOTIONAL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Feeling afraid or scared | 0 | 1 | 2 | 3 | 4 |
| 2. Feeling sad or blue | 0 | 1 | 2 | 3 | 4 |
| 3. Feeling angry | 0 | 1 | 2 | 3 | 4 |
| 4. Trouble sleeping | 0 | 1 | 2 | 3 | 4 |
| 5. Worrying about what will happen to him or her | 0 | 1 | 2 | 3 | 4 |

| SOCIAL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Getting along with other children | 0 | 1 | 2 | 3 | 4 |
| 2. Other kids not wanting to be his or her friend | 0 | 1 | 2 | 3 | 4 |
| 3. Getting teased by other children | 0 | 1 | 2 | 3 | 4 |
| 4. Not able to do things that other children his or her age can do | 0 | 1 | 2 | 3 | 4 |
| 5. Keeping up when playing with other children | 0 | 1 | 2 | 3 | 4 |

| SCHOOL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Paying attention in class | 0 | 1 | 2 | 3 | 4 |
| 2. Forgetting things | 0 | 1 | 2 | 3 | 4 |
| 3. Keeping up with school activities | 0 | 1 | 2 | 3 | 4 |
| 4. Missing school because of not feeling well | 0 | 1 | 2 | 3 | 4 |
| 5. Missing school to go to the doctor or hospital | 0 | 1 | 2 | 3 | 4 |

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CHILD REPORT (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for you ...

| ABOUT MY HEALTH AND ACTIVITIES (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. It is hard for me to walk more than one block | 0 | 1 | 2 | 3 | 4 |
| 2. It is hard for me to run | 0 | 1 | 2 | 3 | 4 |
| 3. It is hard for me to do sports activity or exercise | 0 | 1 | 2 | 3 | 4 |
| 4. It is hard for me to lift something heavy | 0 | 1 | 2 | 3 | 4 |
| 5. It is hard for me to take a bath or shower by myself | 0 | 1 | 2 | 3 | 4 |
| 6. It is hard for me to do chores around the house | 0 | 1 | 2 | 3 | 4 |
| 7. I hurt or ache | 0 | 1 | 2 | 3 | 4 |
| 8. I have low energy | 0 | 1 | 2 | 3 | 4 |

| ABOUT MY FEELINGS (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. I feel afraid or scared | 0 | 1 | 2 | 3 | 4 |
| 2. I feel sad or blue | 0 | 1 | 2 | 3 | 4 |
| 3. I feel angry | 0 | 1 | 2 | 3 | 4 |
| 4. I have trouble sleeping | 0 | 1 | 2 | 3 | 4 |
| 5. I worry about what will happen to me | 0 | 1 | 2 | 3 | 4 |

| HOW I GET ALONG WITH OTHERS (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. I have trouble getting along with other kids | 0 | 1 | 2 | 3 | 4 |
| 2. Other kids do not want to be my friend | 0 | 1 | 2 | 3 | 4 |
| 3. Other kids tease me | 0 | 1 | 2 | 3 | 4 |
| 4. I cannot do things that other kids my age can do | 0 | 1 | 2 | 3 | 4 |
| 5. It is hard to keep up when I play with other kids | 0 | 1 | 2 | 3 | 4 |

| ABOUT SCHOOL (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. It is hard to pay attention in class | 0 | 1 | 2 | 3 | 4 |
| 2. I forget things | 0 | 1 | 2 | 3 | 4 |
| 3. I have trouble keeping up with my schoolwork | 0 | 1 | 2 | 3 | 4 |
| 4. I miss school because of not feeling well | 0 | 1 | 2 | 3 | 4 |
| 5. I miss school to go to the doctor or hospital | 0 | 1 | 2 | 3 | 4 |

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PARENT REPORT for CHILDREN (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has your child had with ...

| PHYSICAL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Walking more than one block | 0 | 1 | 2 | 3 | 4 |
| 2. Running | 0 | 1 | 2 | 3 | 4 |
| 3. Participating in sports activity or exercise | 0 | 1 | 2 | 3 | 4 |
| 4. Lifting something heavy | 0 | 1 | 2 | 3 | 4 |
| 5. Taking a bath or shower by him or herself | 0 | 1 | 2 | 3 | 4 |
| 6. Doing chores around the house | 0 | 1 | 2 | 3 | 4 |
| 7. Having hurts or aches | 0 | 1 | 2 | 3 | 4 |
| 8. Low energy level | 0 | 1 | 2 | 3 | 4 |

| EMOTIONAL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Feeling afraid or scared | 0 | 1 | 2 | 3 | 4 |
| 2. Feeling sad or blue | 0 | 1 | 2 | 3 | 4 |
| 3. Feeling angry | 0 | 1 | 2 | 3 | 4 |
| 4. Trouble sleeping | 0 | 1 | 2 | 3 | 4 |
| 5. Worrying about what will happen to him or her | 0 | 1 | 2 | 3 | 4 |

| SOCIAL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Getting along with other children | 0 | 1 | 2 | 3 | 4 |
| 2. Other kids not wanting to be his or her friend | 0 | 1 | 2 | 3 | 4 |
| 3. Getting teased by other children | 0 | 1 | 2 | 3 | 4 |
| 4. Not able to do things that other children his or her age can do | 0 | 1 | 2 | 3 | 4 |
| 5. Keeping up when playing with other children | 0 | 1 | 2 | 3 | 4 |

| SCHOOL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Paying attention in class | 0 | 1 | 2 | 3 | 4 |
| 2. Forgetting things | 0 | 1 | 2 | 3 | 4 |
| 3. Keeping up with schoolwork | 0 | 1 | 2 | 3 | 4 |
| 4. Missing school because of not feeling well | 0 | 1 | 2 | 3 | 4 |
| 5. Missing school to go to the doctor or hospital | 0 | 1 | 2 | 3 | 4 |

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TEEN REPORT (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

- 0** if it is **never** a problem
- 1** if it is **almost never** a problem
- 2** if it is **sometimes** a problem
- 3** if it is **often** a problem
- 4** if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for you ...

| ABOUT MY HEALTH AND ACTIVITIES (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. It is hard for me to walk more than one block | 0 | 1 | 2 | 3 | 4 |
| 2. It is hard for me to run | 0 | 1 | 2 | 3 | 4 |
| 3. It is hard for me to do sports activity or exercise | 0 | 1 | 2 | 3 | 4 |
| 4. It is hard for me to lift something heavy | 0 | 1 | 2 | 3 | 4 |
| 5. It is hard for me to take a bath or shower by myself | 0 | 1 | 2 | 3 | 4 |
| 6. It is hard for me to do chores around the house | 0 | 1 | 2 | 3 | 4 |
| 7. I hurt or ache | 0 | 1 | 2 | 3 | 4 |
| 8. I have low energy | 0 | 1 | 2 | 3 | 4 |

| ABOUT MY FEELINGS (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. I feel afraid or scared | 0 | 1 | 2 | 3 | 4 |
| 2. I feel sad or blue | 0 | 1 | 2 | 3 | 4 |
| 3. I feel angry | 0 | 1 | 2 | 3 | 4 |
| 4. I have trouble sleeping | 0 | 1 | 2 | 3 | 4 |
| 5. I worry about what will happen to me | 0 | 1 | 2 | 3 | 4 |

| HOW I GET ALONG WITH OTHERS (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. I have trouble getting along with other teens | 0 | 1 | 2 | 3 | 4 |
| 2. Other teens do not want to be my friend | 0 | 1 | 2 | 3 | 4 |
| 3. Other teens tease me | 0 | 1 | 2 | 3 | 4 |
| 4. I cannot do things that other teens my age can do | 0 | 1 | 2 | 3 | 4 |
| 5. It is hard to keep up with my peers | 0 | 1 | 2 | 3 | 4 |

| ABOUT SCHOOL (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. It is hard to pay attention in class | 0 | 1 | 2 | 3 | 4 |
| 2. I forget things | 0 | 1 | 2 | 3 | 4 |
| 3. I have trouble keeping up with my schoolwork | 0 | 1 | 2 | 3 | 4 |
| 4. I miss school because of not feeling well | 0 | 1 | 2 | 3 | 4 |
| 5. I miss school to go to the doctor or hospital | 0 | 1 | 2 | 3 | 4 |

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PARENT REPORT for TEENS (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for **your teen**. Please tell us **how much of a problem** each one has been for **your teen** during the **past ONE month** by circling:

- 0** if it is **never** a problem
- 1** if it is **almost never** a problem
- 2** if it is **sometimes** a problem
- 3** if it is **often** a problem
- 4** if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has your teen had with ...

| PHYSICAL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Walking more than one block | 0 | 1 | 2 | 3 | 4 |
| 2. Running | 0 | 1 | 2 | 3 | 4 |
| 3. Participating in sports activity or exercise | 0 | 1 | 2 | 3 | 4 |
| 4. Lifting something heavy | 0 | 1 | 2 | 3 | 4 |
| 5. Taking a bath or shower by him or herself | 0 | 1 | 2 | 3 | 4 |
| 6. Doing chores around the house | 0 | 1 | 2 | 3 | 4 |
| 7. Having hurts or aches | 0 | 1 | 2 | 3 | 4 |
| 8. Low energy level | 0 | 1 | 2 | 3 | 4 |

| EMOTIONAL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Feeling afraid or scared | 0 | 1 | 2 | 3 | 4 |
| 2. Feeling sad or blue | 0 | 1 | 2 | 3 | 4 |
| 3. Feeling angry | 0 | 1 | 2 | 3 | 4 |
| 4. Trouble sleeping | 0 | 1 | 2 | 3 | 4 |
| 5. Worrying about what will happen to him or her | 0 | 1 | 2 | 3 | 4 |

| SOCIAL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Getting along with other teens | 0 | 1 | 2 | 3 | 4 |
| 2. Other teens not wanting to be his or her friend | 0 | 1 | 2 | 3 | 4 |
| 3. Getting teased by other teens | 0 | 1 | 2 | 3 | 4 |
| 4. Not able to do things that other teens his or her age can do | 0 | 1 | 2 | 3 | 4 |
| 5. Keeping up with other teens | 0 | 1 | 2 | 3 | 4 |

| SCHOOL FUNCTIONING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Paying attention in class | 0 | 1 | 2 | 3 | 4 |
| 2. Forgetting things | 0 | 1 | 2 | 3 | 4 |
| 3. Keeping up with schoolwork | 0 | 1 | 2 | 3 | 4 |
| 4. Missing school because of not feeling well | 0 | 1 | 2 | 3 | 4 |
| 5. Missing school to go to the doctor or hospital | 0 | 1 | 2 | 3 | 4 |

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| ID# _____ |
| Date: _____ |

PedsQLTM

Gastrointestinal Symptoms Module

Version 3.0

YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.

Show the child the template and point to the responses as you read.

If it is not at all a problem for you, point to the smiling face

If it is sometimes a problem for you, point to the middle face

If it is a problem for you a lot, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

| | Not at all | Sometimes | A lot |
|--|---|--|---|
| Is it hard for you to snap your fingers |  |  |  |

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

| STOMACH PAIN AND HURT (problems with...) | Not at all | Some-times | A lot |
|---|-------------------|-------------------|--------------|
| 1. Do you feel pain or hurt in your tummy | 0 | 2 | 4 |
| 2. Do you get tummy aches | 0 | 2 | 4 |
| 3. Does your tummy hurt | 0 | 2 | 4 |
| 4. Do you wake up at night with tummy aches | 0 | 2 | 4 |
| 5. Does your tummy hurt when you go poop | 0 | 2 | 4 |

| STOMACH UPSET (problems with...) | Not at all | Some-times | A lot |
|---|-------------------|-------------------|--------------|
| 1. Do you feel sick to your tummy | 0 | 2 | 4 |
| 2. Do you get an upset tummy | 0 | 2 | 4 |
| 3. When you eat do you get sick to your tummy | 0 | 2 | 4 |
| 4. When you eat does your tummy feel bad | 0 | 2 | 4 |
| 5. Does your tummy hurt when you eat | 0 | 2 | 4 |
| 6. Does your tummy feel heavy when you eat | 0 | 2 | 4 |
| 7. Do you feel full as soon as you start to eat | 0 | 2 | 4 |
| 8. Are you not hungry when you need to go poop | 0 | 2 | 4 |

| FOOD AND DRINKS LIMITS (problems with...) | Not at all | Some-times | A lot |
|--|-------------------|-------------------|--------------|
| 1. Are you not able to eat some foods | 0 | 2 | 4 |
| 2. Are you not able to drink some drinks | 0 | 2 | 4 |
| 3. Are you not able to eat what you want | 0 | 2 | 4 |
| 4. Are you not able to drink what you want | 0 | 2 | 4 |
| 5. Are you not able to eat some foods because they make you sick | 0 | 2 | 4 |
| 6. Are you not able to eat the foods that your friends eat | 0 | 2 | 4 |

Remember, think about how you have been doing for the last few weeks...

| TROUBLE SWALLOWING (problems with...) | Not at all | Some-times | A lot |
|--|-------------------|-------------------|--------------|
| 1. Is it hard for you to swallow food | 0 | 2 | 4 |
| 2. Does it hurt when you swallow | 0 | 2 | 4 |
| 3. Does food get stuck going down | 0 | 2 | 4 |

| HEARTBURN AND REFLUX (problems with...) | Not at all | Some-times | A lot |
|---|-------------------|-------------------|--------------|
| 1. Do you get a burning feeling in your throat | 0 | 2 | 4 |
| 2. Do you have pain or hurt in your chest | 0 | 2 | 4 |
| 3. Do you burp a lot | 0 | 2 | 4 |
| 4. Does food comes back up into your mouth after eating | 0 | 2 | 4 |
| 5. Do you feel like throwing up | 0 | 2 | 4 |
| 6. Do you feel like throwing up when you eat | 0 | 2 | 4 |
| 7. Do you feel like throwing up after you eat | 0 | 2 | 4 |
| 8. Do you throw up | 0 | 2 | 4 |

| GAS AND BLOATING (problems with...) | Not at all | Some-times | A lot |
|--|-------------------|-------------------|--------------|
| 1. Does your tummy feel full of gas | 0 | 2 | 4 |
| 2. Does your tummy feel very full | 0 | 2 | 4 |
| 3. Does your tummy get big and hard | 0 | 2 | 4 |
| 4. Do you have a lot of gas | 0 | 2 | 4 |
| 5. Do you pass a lot of gas | 0 | 2 | 4 |
| 6. Does your tummy feel gassy | 0 | 2 | 4 |
| 7. Does your tummy makes noises | 0 | 2 | 4 |

Remember, think about how you have been doing for the last few weeks...

| CONSTIPATION (problems with...) | Not at all | Some-times | A lot |
|---|-------------------|-------------------|--------------|
| 1. Do you feel full after you poop | 0 | 2 | 4 |
| 2. Do you feel like you are not done after you poop | 0 | 2 | 4 |
| 3. Do you feel like you cannot get all the poop to come out | 0 | 2 | 4 |
| 4. Does it hurt when you go poop | 0 | 2 | 4 |
| 5. Is your poop hard | 0 | 2 | 4 |
| 6. Is your poop lumpy | 0 | 2 | 4 |
| 7. Do you have to push hard to poop | 0 | 2 | 4 |
| 8. Does your poop get stuck when you poop | 0 | 2 | 4 |
| 9. Does your bottom hurt after you go poop | 0 | 2 | 4 |
| 10. Does it take a long time for poop to come out | 0 | 2 | 4 |
| 11. Do you have to work hard to make poop come out | 0 | 2 | 4 |
| 12. Do you not want to poop because it hurts | 0 | 2 | 4 |
| 13. Is there blood on your toilet paper after you go poop | 0 | 2 | 4 |
| 14. Is there blood in your poop | 0 | 2 | 4 |
| 15. Do you spend a lot of time on the toilet going poop | 0 | 2 | 4 |

| DIARRHEA (problems with...) | Not at all | Some-times | A lot |
|---|-------------------|-------------------|--------------|
| 1. Do you need to be near the potty a lot | 0 | 2 | 4 |
| 2. Do you have to rush to the potty to poop | 0 | 2 | 4 |
| 3. Do you feel like you are always in the bathroom going poop | 0 | 2 | 4 |
| 4. Do you wake up at night to go poop | 0 | 2 | 4 |
| 5. Is your poop watery | 0 | 2 | 4 |
| 6. Do you have poop accidents in your underwear | 0 | 2 | 4 |
| 7. Do you have to go poop a lot | 0 | 2 | 4 |

Remember, think about how you have been doing for the last few weeks...

| WORRY (problems with...) | Not at all | Some-times | A lot |
|--|-------------------|-------------------|--------------|
| 1. Do you worry about your tummy aches | 0 | 2 | 4 |
| 2. Do you worry about going poop in your pants | 0 | 2 | 4 |
| 3. Do you worry that you will not make it to the potty in time | 0 | 2 | 4 |
| 4. Do you worry that it will hurt when you go poop | 0 | 2 | 4 |
| 5. Do you worry that your tummy will hurt in school | 0 | 2 | 4 |
| 6. Do you worry that you will have to use the potty at school | 0 | 2 | 4 |
| 7. Do you worry that you will poop in your pants at school | 0 | 2 | 4 |
| 8. Do you get headaches | 0 | 2 | 4 |

| MEDICINES (problems with...) | Not at all | Some-times | A lot |
|---|-------------------|-------------------|--------------|
| 1. Is it hard for you to take your medicines | 0 | 2 | 4 |
| 2. Do you forget to take your medicines | 0 | 2 | 4 |
| 3. Is it hard for you to swallow your medicines | 0 | 2 | 4 |
| 4. Do you not like having to take your medicines all the time | 0 | 2 | 4 |

| COMMUNICATION (problems with...) | Some-times | Often | Almost Always |
|---|-------------------|--------------|----------------------|
| 1. Is it hard for you to tell the doctors and nurses how you feel | 0 | 2 | 4 |
| 2. Is it hard for you to ask the doctors and nurses questions | 0 | 2 | 4 |
| 3. Is it hard for you to explain your illness to other people | 0 | 2 | 4 |
| 4. Is it hard for you to explain your illness to your friends | 0 | 2 | 4 |
| 5. Is it hard for you to talk to your parents about your illness | 0 | 2 | 4 |

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| | _____ |

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Gastrointestinal Symptoms Module

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PARENT REPORT for YOUNG CHILDREN (ages 5-7)

DIRECTIONS

On the following page is a list of things that might be a problem for your child. Please tell us **how much of a problem** each one has been for your child during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for your child ...

| STOMACH PAIN AND HURT (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Feeling pain or hurt in his/her stomach | 0 | 1 | 2 | 3 | 4 |
| 2. Getting stomachaches | 0 | 1 | 2 | 3 | 4 |
| 3. Stomach hurts | 0 | 1 | 2 | 3 | 4 |
| 4. Waking up at night with stomachaches | 0 | 1 | 2 | 3 | 4 |
| 5. Stomach hurts when he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |

| STOMACH UPSET (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Feel sick to his/her stomach | 0 | 1 | 2 | 3 | 4 |
| 2. Gets an upset stomach | 0 | 1 | 2 | 3 | 4 |
| 3. When he/she eats gets sick to his/her stomach | 0 | 1 | 2 | 3 | 4 |
| 4. When he/she eats his/her stomach feels bad | 0 | 1 | 2 | 3 | 4 |
| 5. Stomach hurts when he/she eats | 0 | 1 | 2 | 3 | 4 |
| 6. Stomach feels heavy when he/she eats | 0 | 1 | 2 | 3 | 4 |
| 7. Feels full as soon as soon as he/she starts to eat | 0 | 1 | 2 | 3 | 4 |
| 8. Not hungry when he/she needs to have a bowel movement | 0 | 1 | 2 | 3 | 4 |

| FOOD AND DRINKS LIMITS (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Cannot eat some foods | 0 | 1 | 2 | 3 | 4 |
| 2. Cannot drink some drinks | 0 | 1 | 2 | 3 | 4 |
| 3. Not able to eat what he/she wants | 0 | 1 | 2 | 3 | 4 |
| 4. Not able to drink what he/she wants | 0 | 1 | 2 | 3 | 4 |
| 5. Cannot eat some foods because they make him/her sick | 0 | 1 | 2 | 3 | 4 |
| 6. Cannot eat the foods that his/her friends eat | 0 | 1 | 2 | 3 | 4 |

In the past **ONE month**, how much of a **problem** has this been for your child ...

| TROUBLE SWALLOWING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Hard for him/her to swallow food | 0 | 1 | 2 | 3 | 4 |
| 2. Hurts when he/she swallows | 0 | 1 | 2 | 3 | 4 |
| 3. Food gets stuck going down | 0 | 1 | 2 | 3 | 4 |

| HEARTBURN AND REFLUX (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|--------------|---------------------|------------------|--------------|----------------------|
| 1. Gets a burning feeling in his/her throat | 0 | 1 | 2 | 3 | 4 |
| 2. Has pain or hurt in his/her chest | 0 | 1 | 2 | 3 | 4 |
| 3. Burps a lot | 0 | 1 | 2 | 3 | 4 |
| 4. Food comes back up into his/her mouth after eating | 0 | 1 | 2 | 3 | 4 |
| 5. Feels like throwing up | 0 | 1 | 2 | 3 | 4 |
| 6. Feels like throwing up when he/she eats | 0 | 1 | 2 | 3 | 4 |
| 7. Feels like throwing up after he/she eats | 0 | 1 | 2 | 3 | 4 |
| 8. Throws up | 0 | 1 | 2 | 3 | 4 |

| GAS AND BLOATING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Stomach feels full of gas | 0 | 1 | 2 | 3 | 4 |
| 2. Stomach feels very full | 0 | 1 | 2 | 3 | 4 |
| 3. Stomach gets big and hard | 0 | 1 | 2 | 3 | 4 |
| 4. Has a lot of gas | 0 | 1 | 2 | 3 | 4 |
| 5. Passes a lot of gas | 0 | 1 | 2 | 3 | 4 |
| 6. Stomach feels gassy | 0 | 1 | 2 | 3 | 4 |
| 7. Stomach makes noises | 0 | 1 | 2 | 3 | 4 |

*In the past **ONE month**, how much of a **problem** has this been for your child ...*

| CONSTIPATION (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Still feels full after he/she goes to the bathroom | 0 | 1 | 2 | 3 | 4 |
| 2. Feels like he/she is not done after having a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 3. Feels like he/she cannot get all the bowel movement to come out | 0 | 1 | 2 | 3 | 4 |
| 4. Hurts when he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 5. Bowel movements are hard | 0 | 1 | 2 | 3 | 4 |
| 6. Bowel movements are lumpy | 0 | 1 | 2 | 3 | 4 |
| 7. Having to push hard to have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 8. Poop gets stuck when he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 9. Bottom hurts after he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 10. Takes a long time for poop to come out | 0 | 1 | 2 | 3 | 4 |
| 11. Has to work hard to make poop come out | 0 | 1 | 2 | 3 | 4 |
| 12. Does not want to poop because it hurts | 0 | 1 | 2 | 3 | 4 |
| 13. There is blood on his/her toilet paper after he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 14. There is blood in his/her bowel movement | 0 | 1 | 2 | 3 | 4 |
| 15. Spends a lot of time on the toilet having a bowel movement | 0 | 1 | 2 | 3 | 4 |

| DIARRHEA (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Needs to be near the bathroom a lot | 0 | 1 | 2 | 3 | 4 |
| 2. Has to rush to the bathroom to have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 3. Feels like he/she is always in the bathroom having a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 4. Wakes up at night to have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 5. Bowel movements are watery | 0 | 1 | 2 | 3 | 4 |
| 6. Has poop accidents in his/her underwear | 0 | 1 | 2 | 3 | 4 |
| 7. Has to have a bowel movement a lot | 0 | 1 | 2 | 3 | 4 |

*In the past **ONE month**, how much of a **problem** has this been for your child ...*

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| WORRY (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Worries about his/her stomachaches | 0 | 1 | 2 | 3 | 4 |
| 2. Worries about having a bowel movement in his/her pants | 0 | 1 | 2 | 3 | 4 |
| 3. Worries that he/she will not make it to the bathroom in time | 0 | 1 | 2 | 3 | 4 |
| 4. Worries that it will hurt when he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 5. Worries that his/her stomach will hurt in school | 0 | 1 | 2 | 3 | 4 |
| 6. Worries that he/she will have to use the bathroom at school | 0 | 1 | 2 | 3 | 4 |
| 7. Worries that he/she will have a bowel movement in his/her pants at school | 0 | 1 | 2 | 3 | 4 |
| 8. Gets headaches | 0 | 1 | 2 | 3 | 4 |

| MEDICINES (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Hard for him/her to take his/her medicines | 0 | 1 | 2 | 3 | 4 |
| 2. Forgets to take his/her medicines | 0 | 1 | 2 | 3 | 4 |
| 3. Hard for him/her to swallow his/her medicines | 0 | 1 | 2 | 3 | 4 |
| 4. Does not like having to take his/her medicines all the time | 0 | 1 | 2 | 3 | 4 |

| COMMUNICATION (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Hard for him/her to tell the doctors and nurses how he/she feels | 0 | 1 | 2 | 3 | 4 |
| 2. Hard for him/her to ask the doctors and nurses questions | 0 | 1 | 2 | 3 | 4 |
| 3. Hard for him/her to explain his/her illness to other people | 0 | 1 | 2 | 3 | 4 |
| 4. Hard for him/her to explain his/her illness to his/her friends | 0 | 1 | 2 | 3 | 4 |
| 5. Hard for him/her to talk to his/her parents about his/her illness | 0 | 1 | 2 | 3 | 4 |

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| ID# | _____ |
| Date: | _____ |
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PedsQL™

Gastrointestinal Symptoms Module

Version 3.0

CHILD REPORT (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for you ...

| STOMACH PAIN AND HURT (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|--------------|---------------------|------------------|--------------|----------------------|
| 1. I feel pain or hurt in my stomach | 0 | 1 | 2 | 3 | 4 |
| 2. I get stomachaches | 0 | 1 | 2 | 3 | 4 |
| 3. My stomach hurts | 0 | 1 | 2 | 3 | 4 |
| 4. I wake up at night with stomachaches | 0 | 1 | 2 | 3 | 4 |
| 5. My stomach hurts when I go poop | 0 | 1 | 2 | 3 | 4 |

| STOMACH UPSET (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|--------------|---------------------|------------------|--------------|----------------------|
| 1. I feel sick to my stomach | 0 | 1 | 2 | 3 | 4 |
| 2. I get an upset stomach | 0 | 1 | 2 | 3 | 4 |
| 3. When I eat I get sick to my stomach | 0 | 1 | 2 | 3 | 4 |
| 4. When I eat my stomach feels bad | 0 | 1 | 2 | 3 | 4 |
| 5. My stomach hurts when I eat | 0 | 1 | 2 | 3 | 4 |
| 6. My stomach feels heavy when I eat | 0 | 1 | 2 | 3 | 4 |
| 7. I feel full as soon as I start to eat | 0 | 1 | 2 | 3 | 4 |
| 8. I am not hungry when I need to go poop | 0 | 1 | 2 | 3 | 4 |

| FOOD AND DRINKS LIMITS (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. I cannot eat some foods | 0 | 1 | 2 | 3 | 4 |
| 2. I cannot drink some drinks | 0 | 1 | 2 | 3 | 4 |
| 3. I am not able to eat what I want | 0 | 1 | 2 | 3 | 4 |
| 4. I am not able to drink what I want | 0 | 1 | 2 | 3 | 4 |
| 5. I cannot eat some foods because they make me sick | 0 | 1 | 2 | 3 | 4 |
| 6. I cannot eat the foods that my friends eat | 0 | 1 | 2 | 3 | 4 |

In the past **ONE month**, how much of a **problem** has this been for you ...

| TROUBLE SWALLOWING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. It is hard for me to swallow food | 0 | 1 | 2 | 3 | 4 |
| 2. It hurts when I swallow | 0 | 1 | 2 | 3 | 4 |
| 3. Food gets stuck going down | 0 | 1 | 2 | 3 | 4 |

| HEARTBURN AND REFLUX (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. I get a burning feeling in my throat | 0 | 1 | 2 | 3 | 4 |
| 2. I have pain or hurt in my chest | 0 | 1 | 2 | 3 | 4 |
| 3. I burp a lot | 0 | 1 | 2 | 3 | 4 |
| 4. Food comes back up into my mouth after eating | 0 | 1 | 2 | 3 | 4 |
| 5. I feel like throwing up | 0 | 1 | 2 | 3 | 4 |
| 6. I feel like throwing up when I eat | 0 | 1 | 2 | 3 | 4 |
| 7. I feel like throwing up after I eat | 0 | 1 | 2 | 3 | 4 |
| 8. I throw up | 0 | 1 | 2 | 3 | 4 |

| GAS AND BLOATING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. My stomach feels full of gas | 0 | 1 | 2 | 3 | 4 |
| 2. My stomach feels very full | 0 | 1 | 2 | 3 | 4 |
| 3. My stomach gets big and hard | 0 | 1 | 2 | 3 | 4 |
| 4. I have a lot of gas | 0 | 1 | 2 | 3 | 4 |
| 5. I pass a lot of gas | 0 | 1 | 2 | 3 | 4 |
| 6. My stomach feels gassy | 0 | 1 | 2 | 3 | 4 |
| 7. My stomach makes noises | 0 | 1 | 2 | 3 | 4 |

In the past **ONE month**, how much of a **problem** has this been for you ...

| CONSTIPATION (problems with...) | Never | Almost Never | Some- times | Often | Almost Always |
|---|--------------|-------------------------|------------------------|--------------|--------------------------|
| 1. I still feel full after I poop | 0 | 1 | 2 | 3 | 4 |
| 2. I feel like I am not done after I poop | 0 | 1 | 2 | 3 | 4 |
| 3. I feel like I cannot get all the poop to come out | 0 | 1 | 2 | 3 | 4 |
| 4. It hurts when I go poop | 0 | 1 | 2 | 3 | 4 |
| 5. My poop is hard | 0 | 1 | 2 | 3 | 4 |
| 6. My poop is lumpy | 0 | 1 | 2 | 3 | 4 |
| 7. I have to push hard to poop | 0 | 1 | 2 | 3 | 4 |
| 8. My poop gets stuck when I poop | 0 | 1 | 2 | 3 | 4 |
| 9. My bottom hurts after I go poop | 0 | 1 | 2 | 3 | 4 |
| 10. It takes a long time for poop to come out | 0 | 1 | 2 | 3 | 4 |
| 11. I have to work hard to make poop come out | 0 | 1 | 2 | 3 | 4 |
| 12. I do not want to poop because it hurts | 0 | 1 | 2 | 3 | 4 |
| 13. There is blood on my toilet paper after I go poop | 0 | 1 | 2 | 3 | 4 |
| 14. There is blood in my poop | 0 | 1 | 2 | 3 | 4 |
| 15. I spend a lot of time on the toilet going poop | 0 | 1 | 2 | 3 | 4 |

| DIARRHEA (problems with...) | Never | Almost Never | Some- times | Often | Almost Always |
|---|--------------|-------------------------|------------------------|--------------|--------------------------|
| 1. I need to be near the bathroom a lot | 0 | 1 | 2 | 3 | 4 |
| 2. I have to rush to the bathroom to poop | 0 | 1 | 2 | 3 | 4 |
| 3. I feel like I am always in the bathroom going poop | 0 | 1 | 2 | 3 | 4 |
| 4. I wake up at night to go poop | 0 | 1 | 2 | 3 | 4 |
| 5. My poop is watery | 0 | 1 | 2 | 3 | 4 |
| 6. I have poop accidents in my underwear | 0 | 1 | 2 | 3 | 4 |
| 7. I have to go poop a lot | 0 | 1 | 2 | 3 | 4 |

In the past **ONE month**, how much of a **problem** has this been for you ...

| WORRY (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. I worry about my stomachaches | 0 | 1 | 2 | 3 | 4 |
| 2. I worry about going poop in my pants | 0 | 1 | 2 | 3 | 4 |
| 3. I worry that I will not make it to the bathroom in time | 0 | 1 | 2 | 3 | 4 |
| 4. I worry that it will hurt when I go poop | 0 | 1 | 2 | 3 | 4 |
| 5. I worry that my stomach will hurt in school | 0 | 1 | 2 | 3 | 4 |
| 6. I worry that I will have to use the bathroom at school | 0 | 1 | 2 | 3 | 4 |
| 7. I worry that I will poop in my pants at school | 0 | 1 | 2 | 3 | 4 |
| 8. I get headaches | 0 | 1 | 2 | 3 | 4 |

| MEDICINES (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. It is hard for me to take my medicines | 0 | 1 | 2 | 3 | 4 |
| 2. I forget to take my medicines | 0 | 1 | 2 | 3 | 4 |
| 3. It is hard for me to swallow my medicines | 0 | 1 | 2 | 3 | 4 |
| 4. I do not like having to take my medicines all the time | 0 | 1 | 2 | 3 | 4 |

| COMMUNICATION (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. It is hard for me to tell the doctors and nurses how I feel | 0 | 1 | 2 | 3 | 4 |
| 2. It is hard for me to ask the doctors and nurses questions | 0 | 1 | 2 | 3 | 4 |
| 3. It is hard for me to explain my illness to other people | 0 | 1 | 2 | 3 | 4 |
| 4. It is hard for me to explain my illness to my friends | 0 | 1 | 2 | 3 | 4 |
| 5. It is hard for me to talk to my parents about my illness | 0 | 1 | 2 | 3 | 4 |

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| ID# | _____ |
| Date: | _____ |
| | _____ |

PedsQL™

Gastrointestinal Symptoms Module

Version 3.0

PARENT REPORT for CHILDREN (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for your child. Please tell us **how much of a problem** each one has been for your child during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for your child ...

| STOMACH PAIN AND HURT (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Feeling pain or hurt in his/her stomach | 0 | 1 | 2 | 3 | 4 |
| 2. Getting stomachaches | 0 | 1 | 2 | 3 | 4 |
| 3. Stomach hurts | 0 | 1 | 2 | 3 | 4 |
| 4. Waking up at night with stomachaches | 0 | 1 | 2 | 3 | 4 |
| 5. Stomach hurts when he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |

| STOMACH UPSET (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Feel sick to his/her stomach | 0 | 1 | 2 | 3 | 4 |
| 2. Gets an upset stomach | 0 | 1 | 2 | 3 | 4 |
| 3. When he/she eats gets sick to his/her stomach | 0 | 1 | 2 | 3 | 4 |
| 4. When he/she eats his/her stomach feels bad | 0 | 1 | 2 | 3 | 4 |
| 5. Stomach hurts when he/she eats | 0 | 1 | 2 | 3 | 4 |
| 6. Stomach feels heavy when he/she eats | 0 | 1 | 2 | 3 | 4 |
| 7. Feels full as soon as he/she starts to eat | 0 | 1 | 2 | 3 | 4 |
| 8. Not hungry when he/she needs to have a bowel movement | 0 | 1 | 2 | 3 | 4 |

| FOOD AND DRINKS LIMITS (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Cannot eat some foods | 0 | 1 | 2 | 3 | 4 |
| 2. Cannot drink some drinks | 0 | 1 | 2 | 3 | 4 |
| 3. Not able to eat what he/she wants | 0 | 1 | 2 | 3 | 4 |
| 4. Not able to drink what he/she wants | 0 | 1 | 2 | 3 | 4 |
| 5. Cannot eat some foods because they make him/her sick | 0 | 1 | 2 | 3 | 4 |
| 6. Cannot eat the foods that his/her friends eat | 0 | 1 | 2 | 3 | 4 |

In the past **ONE month**, how much of a **problem** has this been for your child ...

| TROUBLE SWALLOWING (<i>problems with...</i>) | Never | Almost Never | Some- times | Often | Almost Always |
|---|--------------|-------------------------|------------------------|--------------|--------------------------|
| 1. Hard for him/her to swallow food | 0 | 1 | 2 | 3 | 4 |
| 2. Hurts when he/she swallows | 0 | 1 | 2 | 3 | 4 |
| 3. Food gets stuck going down | 0 | 1 | 2 | 3 | 4 |

| HEARTBURN AND REFLUX (<i>problems with...</i>) | Never | Almost Never | Some- times | Often | Almost Always |
|---|--------------|-------------------------|------------------------|--------------|--------------------------|
| 1. Gets a burning feeling in his/her throat | 0 | 1 | 2 | 3 | 4 |
| 2. Has pain or hurt in his/her chest | 0 | 1 | 2 | 3 | 4 |
| 3. Burps a lot | 0 | 1 | 2 | 3 | 4 |
| 4. Food comes back up into his/her mouth after eating | 0 | 1 | 2 | 3 | 4 |
| 5. Feels like throwing up | 0 | 1 | 2 | 3 | 4 |
| 6. Feels like throwing up when he/she eats | 0 | 1 | 2 | 3 | 4 |
| 7. Feels like throwing up after he/she eats | 0 | 1 | 2 | 3 | 4 |
| 8. Throws up | 0 | 1 | 2 | 3 | 4 |

| GAS AND BLOATING (<i>problems with...</i>) | Never | Almost Never | Some- times | Often | Almost Always |
|---|--------------|-------------------------|------------------------|--------------|--------------------------|
| 1. Stomach feels full of gas | 0 | 1 | 2 | 3 | 4 |
| 2. Stomach feels very full | 0 | 1 | 2 | 3 | 4 |
| 3. Stomach gets big and hard | 0 | 1 | 2 | 3 | 4 |
| 4. Has a lot of gas | 0 | 1 | 2 | 3 | 4 |
| 5. Passes a lot of gas | 0 | 1 | 2 | 3 | 4 |
| 6. Stomach feels gassy | 0 | 1 | 2 | 3 | 4 |
| 7. Stomach makes noises | 0 | 1 | 2 | 3 | 4 |

*In the past **ONE month**, how much of a **problem** has this been for your child ...*

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| CONSTIPATION (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Still feels full after he/she goes to the bathroom | 0 | 1 | 2 | 3 | 4 |
| 2. Feels like he/she is not done after having a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 3. Feels like he/she cannot get all the bowel movement to come out | 0 | 1 | 2 | 3 | 4 |
| 4. Hurts when he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 5. Bowel movements are hard | 0 | 1 | 2 | 3 | 4 |
| 6. Bowel movements are lumpy | 0 | 1 | 2 | 3 | 4 |
| 7. Having to push hard to have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 8. Poop gets stuck when he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 9. Bottom hurts after he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 10. Takes a long time for poop to come out | 0 | 1 | 2 | 3 | 4 |
| 11. Has to work hard to make poop come out | 0 | 1 | 2 | 3 | 4 |
| 12. Does not want to poop because it hurts | 0 | 1 | 2 | 3 | 4 |
| 13. There is blood on his/her toilet paper after he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 14. There is blood in his/her bowel movement | 0 | 1 | 2 | 3 | 4 |
| 15. Spends a lot of time on the toilet having a bowel movement | 0 | 1 | 2 | 3 | 4 |

| DIARRHEA (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Needs to be near the bathroom a lot | 0 | 1 | 2 | 3 | 4 |
| 2. Has to rush to the bathroom to have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 3. Feels like he/she is always in the bathroom having a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 4. Wakes up at night to have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 5. Bowel movements are watery | 0 | 1 | 2 | 3 | 4 |
| 6. Has poop accidents in his/her underwear | 0 | 1 | 2 | 3 | 4 |
| 7. Has to have a bowel movement a lot | 0 | 1 | 2 | 3 | 4 |

*In the past **ONE month**, how much of a **problem** has this been for your child ...*

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| WORRY (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Worries about his/her stomachaches | 0 | 1 | 2 | 3 | 4 |
| 2. Worries about having a bowel movement in his/her pants | 0 | 1 | 2 | 3 | 4 |
| 3. Worries that he/she will not make it to the bathroom in time | 0 | 1 | 2 | 3 | 4 |
| 4. Worries that it will hurt when he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 5. Worries that his/her stomach will hurt in school | 0 | 1 | 2 | 3 | 4 |
| 6. Worries that he/she will have to use the bathroom at school | 0 | 1 | 2 | 3 | 4 |
| 7. Worries that he/she will have a bowel movement in his/her pants at school | 0 | 1 | 2 | 3 | 4 |
| 8. Gets headaches | 0 | 1 | 2 | 3 | 4 |

| MEDICINES (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Hard for him/her to take his/her medicines | 0 | 1 | 2 | 3 | 4 |
| 2. Forgets to take his/her medicines | 0 | 1 | 2 | 3 | 4 |
| 3. Hard for him/her to swallow his/her medicines | 0 | 1 | 2 | 3 | 4 |
| 4. Does not like having to take his/her medicines all the time | 0 | 1 | 2 | 3 | 4 |

| COMMUNICATION (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Hard for him/her to tell the doctors and nurses how he/she feels | 0 | 1 | 2 | 3 | 4 |
| 2. Hard for him/her to ask the doctors and nurses questions | 0 | 1 | 2 | 3 | 4 |
| 3. Hard for him/her to explain his/her illness to other people | 0 | 1 | 2 | 3 | 4 |
| 4. Hard for him/her to explain his/her illness to his/her friends | 0 | 1 | 2 | 3 | 4 |
| 5. Hard for him/her to talk to his/her parents about his/her illness | 0 | 1 | 2 | 3 | 4 |

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| ID# | _____ |
| Date: | _____ |
| | _____ |

PedsQL™

Gastrointestinal Symptoms Module

Version 3.0

TEEN REPORT (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for you ...

| STOMACH PAIN AND HURT (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. I feel pain or hurt in my stomach | 0 | 1 | 2 | 3 | 4 |
| 2. I get stomachaches | 0 | 1 | 2 | 3 | 4 |
| 3. My stomach hurts | 0 | 1 | 2 | 3 | 4 |
| 4. I wake up at night with stomachaches | 0 | 1 | 2 | 3 | 4 |
| 5. My stomach hurts when I go poop | 0 | 1 | 2 | 3 | 4 |

| STOMACH UPSET (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. I feel sick to my stomach | 0 | 1 | 2 | 3 | 4 |
| 2. I get an upset stomach | 0 | 1 | 2 | 3 | 4 |
| 3. When I eat I get sick to my stomach | 0 | 1 | 2 | 3 | 4 |
| 4. When I eat my stomach feels bad | 0 | 1 | 2 | 3 | 4 |
| 5. My stomach hurts when I eat | 0 | 1 | 2 | 3 | 4 |
| 6. My stomach feels heavy when I eat | 0 | 1 | 2 | 3 | 4 |
| 7. I feel full as soon as I start to eat | 0 | 1 | 2 | 3 | 4 |
| 8. I am not hungry when I need to have a bowel movement | 0 | 1 | 2 | 3 | 4 |

| FOOD AND DRINKS LIMITS (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. I cannot eat some foods | 0 | 1 | 2 | 3 | 4 |
| 2. I cannot drink some drinks | 0 | 1 | 2 | 3 | 4 |
| 3. I am not able to eat what I want | 0 | 1 | 2 | 3 | 4 |
| 4. I am not able to drink what I want | 0 | 1 | 2 | 3 | 4 |
| 5. I cannot eat some foods because they make me sick | 0 | 1 | 2 | 3 | 4 |
| 6. I cannot eat the foods that my friends eat | 0 | 1 | 2 | 3 | 4 |

In the past **ONE month**, how much of a **problem** has this been for you ...

| TROUBLE SWALLOWING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. It is hard for me to swallow food | 0 | 1 | 2 | 3 | 4 |
| 2. It hurts when I swallow | 0 | 1 | 2 | 3 | 4 |
| 3. Food gets stuck going down | 0 | 1 | 2 | 3 | 4 |

| HEARTBURN AND REFLUX (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. I get a burning feeling in my throat | 0 | 1 | 2 | 3 | 4 |
| 2. I have pain or hurt in my chest | 0 | 1 | 2 | 3 | 4 |
| 3. I burp a lot | 0 | 1 | 2 | 3 | 4 |
| 4. Food comes back up into my mouth after eating | 0 | 1 | 2 | 3 | 4 |
| 5. I feel like throwing up | 0 | 1 | 2 | 3 | 4 |
| 6. I feel like throwing up when I eat | 0 | 1 | 2 | 3 | 4 |
| 7. I feel like throwing up after I eat | 0 | 1 | 2 | 3 | 4 |
| 8. I throw up | 0 | 1 | 2 | 3 | 4 |

| GAS AND BLOATING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. My stomach feels full of gas | 0 | 1 | 2 | 3 | 4 |
| 2. My stomach feels very full | 0 | 1 | 2 | 3 | 4 |
| 3. My stomach gets big and hard | 0 | 1 | 2 | 3 | 4 |
| 4. I have a lot of gas | 0 | 1 | 2 | 3 | 4 |
| 5. I pass a lot of gas | 0 | 1 | 2 | 3 | 4 |
| 6. My stomach feels gassy | 0 | 1 | 2 | 3 | 4 |
| 7. My stomach makes noises | 0 | 1 | 2 | 3 | 4 |

*In the past **ONE month**, how much of a **problem** has this been for you ...*

| CONSTIPATION (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|--------------|---------------------|------------------|--------------|----------------------|
| 1. I still feel full after I go to the bathroom | 0 | 1 | 2 | 3 | 4 |
| 2. I feel like I am not done after I have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 3. I feel like I cannot get all the bowel movement to come out | 0 | 1 | 2 | 3 | 4 |
| 4. It hurts when I have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 5. My bowel movements are hard | 0 | 1 | 2 | 3 | 4 |
| 6. My bowel movements are lumpy | 0 | 1 | 2 | 3 | 4 |
| 7. I have to push hard to have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 8. My poop gets stuck when I have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 9. My bottom hurts after I have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 10. It takes a long time for poop to come out | 0 | 1 | 2 | 3 | 4 |
| 11. I have to work hard to make poop come out | 0 | 1 | 2 | 3 | 4 |
| 12. I do not want to poop because it hurts | 0 | 1 | 2 | 3 | 4 |
| 13. There is blood on my toilet paper after I have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 14. There is blood in my bowel movement | 0 | 1 | 2 | 3 | 4 |
| 15. I spend a lot of time on the toilet having a bowel movement | 0 | 1 | 2 | 3 | 4 |

| DIARRHEA (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. I need to be near the bathroom a lot | 0 | 1 | 2 | 3 | 4 |
| 2. I have to rush to the bathroom to have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 3. I feel like I am always in the bathroom having a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 4. I wake up at night to have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 5. My bowel movements are watery | 0 | 1 | 2 | 3 | 4 |
| 6. I have poop accidents in my underwear | 0 | 1 | 2 | 3 | 4 |
| 7. I have to have a bowel movement a lot | 0 | 1 | 2 | 3 | 4 |

*In the past **ONE** month, how much of a **problem** has this been for you ...*

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| WORRY (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. I worry about my stomachaches | 0 | 1 | 2 | 3 | 4 |
| 2. I worry about having a bowel movement in my pants | 0 | 1 | 2 | 3 | 4 |
| 3. I worry that I will not make it to the bathroom in time | 0 | 1 | 2 | 3 | 4 |
| 4. I worry that it will hurt when I have a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 5. I worry that my stomach will hurt in school | 0 | 1 | 2 | 3 | 4 |
| 6. I worry that I will have to use the bathroom at school | 0 | 1 | 2 | 3 | 4 |
| 7. I worry that I will have a bowel movement in my pants at school | 0 | 1 | 2 | 3 | 4 |
| 8. I get headaches | 0 | 1 | 2 | 3 | 4 |

| MEDICINES (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|--------------|---------------------|------------------|--------------|----------------------|
| 1. It is hard for me to take my medicines | 0 | 1 | 2 | 3 | 4 |
| 2. I forget to take my medicines | 0 | 1 | 2 | 3 | 4 |
| 3. It is hard for me to swallow my medicines | 0 | 1 | 2 | 3 | 4 |
| 4. I do not like having to take my medicines all the time | 0 | 1 | 2 | 3 | 4 |

| COMMUNICATION (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. It is hard for me to tell the doctors and nurses how I feel | 0 | 1 | 2 | 3 | 4 |
| 2. It is hard for me to ask the doctors and nurses questions | 0 | 1 | 2 | 3 | 4 |
| 3. It is hard for me to explain my illness to other people | 0 | 1 | 2 | 3 | 4 |
| 4. It is hard for me to explain my illness to my friends | 0 | 1 | 2 | 3 | 4 |
| 5. It is hard for me to talk to my parents about my illness | 0 | 1 | 2 | 3 | 4 |

| | |
|-------|-------|
| ID# | _____ |
| Date: | _____ |
| | _____ |

PedsQL™

Gastrointestinal Symptoms Module

Version 3.0

PARENT REPORT for TEENS (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for your teen. Please tell us **how much of a problem** each one has been for your teen during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for your child ...

| STOMACH PAIN AND HURT (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Feeling pain or hurt in his/her stomach | 0 | 1 | 2 | 3 | 4 |
| 2. Getting stomachaches | 0 | 1 | 2 | 3 | 4 |
| 3. Stomach hurts | 0 | 1 | 2 | 3 | 4 |
| 4. Waking up at night with stomachaches | 0 | 1 | 2 | 3 | 4 |
| 5. Stomach hurts when he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |

| STOMACH UPSET (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Feel sick to his/her stomach | 0 | 1 | 2 | 3 | 4 |
| 2. Gets an upset stomach | 0 | 1 | 2 | 3 | 4 |
| 3. When he/she eats gets sick to his/her stomach | 0 | 1 | 2 | 3 | 4 |
| 4. When he/she eats his/her stomach feels bad | 0 | 1 | 2 | 3 | 4 |
| 5. Stomach hurts when he/she eats | 0 | 1 | 2 | 3 | 4 |
| 6. Stomach feels heavy when he/she eats | 0 | 1 | 2 | 3 | 4 |
| 7. Feels full as soon as soon as he/she starts to eat | 0 | 1 | 2 | 3 | 4 |
| 8. Not hungry when he/she needs to have a bowel movement | 0 | 1 | 2 | 3 | 4 |

| FOOD AND DRINKS LIMITS (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Cannot eat some foods | 0 | 1 | 2 | 3 | 4 |
| 2. Cannot drink some drinks | 0 | 1 | 2 | 3 | 4 |
| 3. Not able to eat what he/she wants | 0 | 1 | 2 | 3 | 4 |
| 4. Not able to drink what he/she wants | 0 | 1 | 2 | 3 | 4 |
| 5. Cannot eat some foods because they make him/her sick | 0 | 1 | 2 | 3 | 4 |
| 6. Cannot eat the foods that his/her friends eat | 0 | 1 | 2 | 3 | 4 |

In the past **ONE month**, how much of a **problem** has this been for your child ...

| TROUBLE SWALLOWING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Hard for him/her to swallow food | 0 | 1 | 2 | 3 | 4 |
| 2. Hurts when he/she swallows | 0 | 1 | 2 | 3 | 4 |
| 3. Food gets stuck going down | 0 | 1 | 2 | 3 | 4 |

| HEARTBURN AND REFLUX (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|---|-------|--------------|-----------|-------|---------------|
| 1. Gets a burning feeling in his/her throat | 0 | 1 | 2 | 3 | 4 |
| 2. Has pain or hurt in his/her chest | 0 | 1 | 2 | 3 | 4 |
| 3. Burps a lot | 0 | 1 | 2 | 3 | 4 |
| 4. Food comes back up into his/her mouth after eating | 0 | 1 | 2 | 3 | 4 |
| 5. Feels like throwing up | 0 | 1 | 2 | 3 | 4 |
| 6. Feels like throwing up when he/she eats | 0 | 1 | 2 | 3 | 4 |
| 7. Feels like throwing up after he/she eats | 0 | 1 | 2 | 3 | 4 |
| 8. Throws up | 0 | 1 | 2 | 3 | 4 |

| GAS AND BLOATING (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|-------|--------------|-----------|-------|---------------|
| 1. Stomach feels full of gas | 0 | 1 | 2 | 3 | 4 |
| 2. Stomach feels very full | 0 | 1 | 2 | 3 | 4 |
| 3. Stomach gets big and hard | 0 | 1 | 2 | 3 | 4 |
| 4. Has a lot of gas | 0 | 1 | 2 | 3 | 4 |
| 5. Passes a lot of gas | 0 | 1 | 2 | 3 | 4 |
| 6. Stomach feels gassy | 0 | 1 | 2 | 3 | 4 |
| 7. Stomach makes noises | 0 | 1 | 2 | 3 | 4 |

*In the past **ONE month**, how much of a **problem** has this been for your child ...*

| WORRY (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Worries about his/her stomachaches | 0 | 1 | 2 | 3 | 4 |
| 2. Worries about having a bowel movement in his/her pants | 0 | 1 | 2 | 3 | 4 |
| 3. Worries that he/she will not make it to the bathroom in time | 0 | 1 | 2 | 3 | 4 |
| 4. Worries that it will hurt when he/she has a bowel movement | 0 | 1 | 2 | 3 | 4 |
| 5. Worries that his/her stomach will hurt in school | 0 | 1 | 2 | 3 | 4 |
| 6. Worries that he/she will have to use the bathroom at school | 0 | 1 | 2 | 3 | 4 |
| 7. Worries that he/she will have a bowel movement in his/her pants at school | 0 | 1 | 2 | 3 | 4 |
| 8. Gets headaches | 0 | 1 | 2 | 3 | 4 |

| MEDICINES (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Hard for him/her to take his/her medicines | 0 | 1 | 2 | 3 | 4 |
| 2. Forgets to take his/her medicines | 0 | 1 | 2 | 3 | 4 |
| 3. Hard for him/her to swallow his/her medicines | 0 | 1 | 2 | 3 | 4 |
| 4. Does not like having to take his/her medicines all the time | 0 | 1 | 2 | 3 | 4 |

| COMMUNICATION (problems with...) | Never | Almost Never | Sometimes | Often | Almost Always |
|--|--------------|---------------------|------------------|--------------|----------------------|
| 1. Hard for him/her to tell the doctors and nurses how he/she feels | 0 | 1 | 2 | 3 | 4 |
| 2. Hard for him/her to ask the doctors and nurses questions | 0 | 1 | 2 | 3 | 4 |
| 3. Hard for him/her to explain his/her illness to other people | 0 | 1 | 2 | 3 | 4 |
| 4. Hard for him/her to explain his/her illness to his/her friends | 0 | 1 | 2 | 3 | 4 |
| 5. Hard for him/her to talk to his/her parents about his/her illness | 0 | 1 | 2 | 3 | 4 |