Evaluation of the initial construct validity for the Symptom Assessment Questionnaire

(SAQ) in primary care

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CONTRIBUTION OF CO-AUTHORS

I have conducted the full review, development of objectives, writing and compiling of results and final interpretation of results for this thesis. For the article, in addition to myself, the co-authors and GB contributed to the conception and design of the work in the article. A research assistant performed the data collection. All co-authors participated in quantitative data analysis; however, I completed all qualitative data analysis and interpretation.

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ABSTRACT

Background: Symptom evaluation and management is a key task in primary care. Symptom management is directly related to how a symptom is assessed or measured. Patients' symptoms accounts provide more diagnostic information than the physical examination. Very few studies, however, have addressed the more frequently occurring daily symptoms. This is despite the fact that such symptoms are the main cause of medical visits and healthcare expenses and are strongly related to disability. Tools that are available for symptom assessment are focused mostly on specific symptoms that are tailored to a specific disease or pathology, for example, considerable research was done on cancer and cardiovascular disease. Considering the high frequency of symptom assessment and evaluation deserve more attention. To fill this gap, we developed a primary care-oriented Symptom Assessment Questionnaire (SAQ) that covers forty-six symptom domains along with a severity scale. Our objective was to assess the initial construct validity of a general symptom assessment questionnaire (SAQ) in primary care and resolve any issues with comprehension for the SAQ.

Methods: The project was divided into two phases. In Phase I, a cross sectional survey was completed. In Phase II, focus groups were used in a cognitive debriefing exercise to improve comprehension issues identified in Phase I. Patients in a primary care clinic in Quebec completed a cross-sectional questionnaire assessing 46 symptom domains indicating the absence or presence of symptoms, symptom duration and severity. All patients were eligible to participate provided that they were at least 18 years of age and were physically and mentally capable of completing the questionnaire (in French or English) without assistance from the research personnel or

accompanying individuals. Participants for the focus groups were selected using convenience sampling and thematic analysis of transcripts were completed.

Results: 410 patients completed the symptom assessment questionnaires over a period of 3 months. Out of them, 202 patients reported symptoms and among them 15 patients also reported 'other symptoms. In the quantitative data analysis, a large number of patients wrote reason for encounter (RFE) as 'other symptoms. Forty eight percent of patients wrote their diagnosis as 'other symptom'. There was no correlation between the high level of educational status and the pattern of answering the 'other symptoms' section.12 participants participated in 3 focus group discussions during phase II. Results of the focus group analysis indicated that the SAQ can be an effective communication tool between physicians and their patients. It was also observed that some of the medical terms that were adapted from the International Classification of Primary Care medical coding were not understood well by the patients. The SAQ performed well as a tool to assess global symptoms in primary care patients. The SAQ has a severity scale that helped to categorize patients for further intervention.

Conclusion: Introducing a patient-reported general symptom assessment questionnaire captured important information. The tool was well received and changes in terminology to enhance comprehension were made. With further development work on the tool, the patient-physician interaction could shift from reporting symptoms to focusing on symptom severity and causality.

Résumé

Contexte: L'évaluation et la gestion des symptoms sont une tâche clé des soins primaires. La gestion des symptoms est directement liée à la façondont un symptôme est évalué ou mesuré. Les comptes rendus des symptômes des patients fournissent plus d'informations diagnostiques que l'examen physique. Ce pendant, très peu d'étude sont abordé les symptoms quotidiens les plus fréquents. Ceci malgré le fait que ces symptômes sont la principale cause des visites médicales et des dépenses de santé et sont forte mentliés au handicap. Les outils disponibles pour l'évaluation des symptoms sont principale mentaxés sur des symptoms spécifique sadaptés à une maladie ou une pathologie spécifique, par exemple, des recherches considerable sont été menées sur le cancer et les maladies cardiovasculaires. Comptetenu de la fréquence élevée des symptoms dans les soins primaires par rapport aux soins tertiaires et du risque de consequences négatives, l'évaluation et l'évaluation des symptoms méritent plus d'attention. Pour combler cette lacune, nous avons développé un questionnaire d'évaluation des symptômes (SAQ) axé sur les soins primaires qui couvre quarante-six domaines de symptômes avec une échelle de gravité. Notre objectif était d'évaluer la validité du concept initial d'un questionnaire general d'évaluation des symptômes (SAQ) en soins primaires et de résoudre tout problème de compréhension pour le SAQ.

Méthodes: Le projet a été divisé en deux phases. Au cours de la phase I, une enquêt et ransversale a été réalisée. Dans la phase II, des groupes de discussion ont été utilizes dans un exercice de debriefing cognitif pour améliorer les problèmes de comprehension identifies lors de la phase I. Les patients d'une clinique de soins primaires au Québec ont rempli un questionnaire transversal évaluant 46 domaines de symptômes indiquant l'absence ou la présence de symptômes, la durée des symptômes. et la gravité. Tous les patients étaient éligibles à la participation à condition d'avoir au moins 18 ans et d'être physiquement et mentalement capables de remplir le

questionnaire (en français ou en anglais) sans l'aide du personnel de recherche ou des personnes accompagnantes. Les participants aux groupes de discussion ont été sélectionnés par échantillonnage de convenance et une analyse thématique des transcriptions a été effectuée.

Résultats: 410 patients ont rempli les questionnaires d'évaluation des symptômes sur une période de 3 mois. Parmieux, 202 patients ont signalé des symptômes et parmieux 15 patients ont également signalé «d'autres symptômes». Dans l'analyse des donné est quantitatives, un grand nombre de patients ont écrit la raison de la rencontre (RFE) comme «autres symptômes». Quarante-huit pour cent des patients ont écritleur diagnostic comme «autre symptôme». Il n'y avait pas de corrélation entre le niveau élevé de scolarité et la façon de répondre à la section «autres symptômes». 12 participants ont participé à 3 groupes de discussion durant la phase II. Les résultats de l'analyse des groupes de discussion indiquent que la SAQ peut être un outil de communication efficace entre les médecins et leurs patients. Il a également été observé que certains des terms médicaux adaptés du codage médical de la Classification internationale des soins primaires n'étaient pas bien compris par les patients. Des modifications des terminologies médicales ont été apportées conformément à la recommandation des participants. Le SAQ a bien fonctionné entant qu'outil d'évaluation des symptoms globaux chez les patients en soins primaires. Le SAQ a une échelle de gravité qui a aidé à catégoriser les patients pour une intervention ultérieure.

Conclusion: l'introduction d'un questionnaire d'évaluation générale des symptoms rapporté par les patients a permis de recueillir des informations importantes. L'outil a été bien accueilli et des changements de terminologie ont été apportés pour améliorer la compréhension. Avec la pour suite des travaux de développement de l'outil, l'interaction patient-médecin pourrait passer de la déclaration des symptômes à la concentration sur la gravité et la causalité des symptômes.

CHAPTER 1. BACKGROUND

Symptom management is an important part of primary care practice which hardly ever resolves into a specific diagnosis[1]. Approximately one in three consultations in primary care are concluded without a specific diagnosis[2]. Symptom management is directly related to how a symptom is assessed or measured. Patient symptoms accounts provide more diagnostic information than the physical examination in a primary care setting[3]. The complexity of primary care management is also increasing daily with the increase in population morbidity[2]. Primary care physicians (PCPs) need to consider a wide range of conditions from minor self-limiting disease to life-threatening disorders, as the first point of care. In primary care practice ~50% of patients present with symptoms rather than an established diagnosis[4]. PCPs found these consultations more burdensome than the ones with a diagnosis [4].

According to World Health Organization 50% of the global burden of disease is chronic illness[5]. Chronic disease is also a significant concern for Canadians, with one-half (51.6%) of the population over the age of 20 having one or more chronic diseases[6]. Reporting of multiple symptoms is now a frequent phenomenon both in general population and population that seek primary care. Nearly 70% of the visits to subspecialists reported only one diagnosis and about 90% of the visits to PCPs reported four diagnoses [7]. 20-50% of the consultations with PCPs are related to unexplained physical symptoms[8][9]. Multi symptomatic patients are a big challenge to health care professionals since these patients are high consumers of health care[3] and managing such patients inadequately is costly for society[10]. Health care systems around the world are continuously struggling with how well to respond to the growing number of people with chronic and multiple conditions[11][12]. There is a tendency to perceive a symptom as 'abnormal' in the presence of additional symptoms which is labeled by the PCPs as symptom burden. Symptom

burden can be explained by the number of symptoms experienced at a given period, the sum of symptom scores or the mean number of symptoms per patients[13]. This is also associated with a person's experienced life stressors during that time. Therefore, PCPs often consider evaluating a patient's spectrum of experiencing symptoms along with the life stressors that may provide the critical information contributing to ill-health. The prognosis of disease, quality of life and performance status of a patient is also related to the burden[9]. The prognosis of an illness depends on the number of other experienced symptoms. Prospective studies have repeatedly demonstrated the value of "number of symptoms" as a predictor of poor health status in case of long-term follow-ups[14]. In a study with patients suffering from Ulcerative Colitis (UC), a strong association was found between the number of symptoms and disease prognosis even when the symptoms were not necessarily presented to the physicians. The study concluded that ineffective symptom management in the presence of multiple symptoms worsens the overall illness experience of a patient[15]. Therefore, it is critical for PCPs to have the ability to understand the symptom that is most disturbing along with other symptoms.

Primary care is the main access point to the healthcare system and PCPs see the widest range of medical conditions[16]. The management of patients in primary care is therefore significantly different from that undertaken by hospital–based doctors[17]. Patients most frequently consult with PCPs when they are prompted by a symptom. PCPs rely on patients' physical, psychological and social factors along with the general physical symptoms for successful management. As each patient is unique by his or her socio-demographic characteristics, it is particularly important to evaluate symptoms from a patient's perspective. Most of the clinical problems encountered in primary care can be effectively dealt with based on accurate data collection as a form of good clinical history[17]. It has been shown that when based only on a good

history taking, diagnosis and management can be accurately done for three-quarters of new patients seen in a primary care clinic[17]. Thus, the success of a PCP's management approach depends on successful management of their patients' experiencing symptoms by addressing them properly. Acknowledging the patients' reason for their visit is still one of the most important ways health care providers can assess and plan treatments for patients. Most physicians allow patients to tell their story but in an unstructured way. The rising number of patients with multiple chronic conditions in a primary care does not provide the PCP with enough time for proper history taking as they spend less time with each patient[18].

Poor history taking and missing noticeable symptoms and signs have been identified as the most important cause for a faulty diagnosis[19] and unnecessary treatment[20]. Consequently, PCPs generate a wide range of differential diagnoses to ensure treatment coverage that typically involves numerous numbers of diagnostic tests with repetitions as well. It has been shown in a study that the cost of test repetitions causes an enormous upsurge on the health care cost for an annual internal cost of \$0.6 to \$2.2 million Canadian dollars which corresponds to population-scaled national estimates for Canada and USA of \$160 million and \$2.4 billion, respectively[21]. Hence, with the help of a tool that can provide the most important and serious information about the decision-making process, PCPs can establish more precise diagnosis[22].

Patient-centered clinical care is essential to satisfy the demand of current healthcare practice settings. Providing the patients appropriate measures to construct acceptable illness narratives is the first step in patient centered care. All the patients' concerns can be collected with the help of a self-reporting tool such as a questionnaire. Symptom experience varies from person to person and each person can interpret the same symptom differently. Hence, the use of a standardized symptom questionnaire can aid patients to describe how they experience symptoms in a more meaningful way. Patients can also communicate effectively with the help of a questionnaire. Completing some parts of the physician/patient interview before an outpatient visit provides more time to be spent on counselling the patient. Furthermore, many patients appreciate filling out a questionnaire due to the sense of active engagement and the capacity to express all their concerns[23]. With the help of a self-reported symptom questionnaire, the physicians can track the symptoms over time to monitor progress and this may improve the doctor-patient communication. Effective doctor-patient communication is directly related to increased patient satisfaction, better patient compliance with treatment and improved clinical outcomes[22].

In addition, engaging the patient in the treatment process increases autonomy and responsiveness to care which is crucial to patients' symptom assessment and management. It has been shown that patients appreciate having more input into their health decisions[24]. In fact, patients disclose sensitive details on paper rather than by verbal communication[25]. This may suggest that symptom reporting in questionnaires does in fact matter, whether the symptoms are presented to health care professionals or not. In order to support this process, many studies have led to the development of numerous instruments for measuring concepts such as health, social support, functional status and quality of life[26].

Considering the high frequencies of symptoms in primary care and the risk of negative consequences, symptom assessment and evaluation deserves more attention. To acknowledge this, a global Symptom Assessment Questionnaire (SAQ) was created to better understand the most frequent general symptoms in primary care practice. This questionnaire covers all the general symptoms along with a severity scale. The questionnaire's language was adapted from the ICPC (International Classification of Primary Care) medical coding. The objective of this thesis is to assess the initial construct validity of the SAQ in the primary care context.

CHAPTER 2. LITERATURE REVIEW

IMPORTANCE OF SYMPTOMS IN PRIMARY CARE

Approximately 80% of front-line medical services are dispensed in primary care. Primary care practice is often the first point of contact to the health care system. With the increasing number of multi-morbidities associated with chronic conditions, PCPs' practices face additional challenges. The 2018 Canadian Community Health Survey found that 18.3% of Canadians over the age of 20 have multiple chronic diseases[27]. In the current health care system, healthcare professionals rely on patients to contact them when they have noticeable symptoms thus creating symptom-focused clinical consultations. In the case of multiple chronic conditions, the patient often comes with more than one symptom to the primary care physicians. To manage complex patients, several approaches have been recommended for the primary care practitioners where symptom management is the mainstay of treatment. Symptom management mainly focuses on symptom prevention as well as ongoing symptom monitoring.

Symptom can be defined as 'any subjective evidence of a health problem as perceived by the patient'[28]. A symptom can arise from sensitivity to certain combinations of biological, social, and environmental processes and vary in magnitude, severity, persistence, and character. Symptoms can be subjectively reported or can be observed objectively. For example, an individual may not perceive the same disturbance in health as a symptom or reason to concern at different time points of his or her life. If patients are subjectively surveyed about their symptoms, the findings can be established as problematic. In addition, symptoms can be perceived as normal experiences or be ignored for various reasons such as fear of stigmatization, embarrassment, or the expectations of other adverse reactions or consequences from society. Though physical symptoms are often thought to be a sign of poor health, a symptom is not always an indicator of illness. Previous research shows that symptoms are a common daily experience and, in most cases, unassociated with serious illness[29][30].

There are three main types of symptoms. When symptoms improve or resolve completely, they are known as remitting symptoms. For examples, symptoms of the common cold may occur for several days and then resolve without treatment. Chronic symptoms are long-lasting or recurrent symptoms. Chronic symptoms are often seen in ongoing conditions, such as diabetes, asthma, and cancer. Relapsing symptoms are symptoms that have occurred in the past, resolved, and then returned. For instance, symptoms of depression may not occur for years at a time but can then return. Besides these three categories, there are two other types which greatly influence the patient management process which are 'red flag' symptoms and the medically unexplained symptoms.

'Red flag' symptoms are the symptoms that represent something serious and require prompt evaluation. Commonly, physicians use red flag symptoms to find out the definitive diagnosis in a short period of time. Red flag symptoms often help physicians to start immediate management in life-threatening situations such as cancer, myocardial infarction or stroke without any delay to get the maximum benefit of treatment. Red flag symptoms can range between one to a group of benign symptoms that can raise the red flag. While some of them are hard to ignore like the crushing chest pain in myocardial infarction, many concerning symptoms are not as obvious. For an example, headache, vomiting and abdominal pain are the symptoms that can be present in an individual in a different clinical condition such as food poisoning and carbon monoxide poisoning. They, however, do not carry the same importance in the previously mentioned two situations. On the other hand, symptoms like sudden loss of vision or sudden bowel incompetence in an otherwise healthy patient may raise a diagnosis in a physician's mind. This is how red flag symptoms help physicians to diagnose a serious condition without further delay in management[31]. Not recognizing red flag symptoms may cause adverse situations like loss of vision, permanent disability to even death. During the short period of time in a typical clinic visit, these red flag symptoms may be missed due to the challenge of not being able to focus on the history being presented by patients when there is more than one problem at a time. For the physician to proceed further, it is critical to recall all the symptoms that their patients are presenting. The significant challenge for a primary care practitioner is to categorize patients according to their symptoms for further required intervention such as urgent investigation or referral[32]. In fact, people can present "atypically," meaning that the symptoms they experience may be different than the example in the textbook.

In addition, primary care practitioners frequently deal with a large number of patients who present with bodily symptoms but no medical diagnosis[33]. These are called medically unexplained symptoms (MUS). Medically unexplained symptoms are physical symptoms for which there is no pathological explanation. In other words, these are a group of symptoms for which no organic cause is found. These symptoms can be long-lasting and can cause significant distress and impaired functioning. MUS is also known as "bodily distress syndrome", "functional symptoms" and "somatic symptom distress"[7][8]. It has been suggested that around one-fifth of initial appointments with PCPs concern symptoms due to MUS[34]. It is estimated that between 15% and 30% of all primary care consultations are for medically unexplained symptoms, that is approximately one in six primary care consultations[35]. Approximately 35 -52% of patients seeking care in the hospital outpatient department account for MUS. The number of symptoms and the involvement of multiple systems were described as predictors of MUS prognosis. The number of bodily symptoms predicts outcome more accurately than health anxiety in patients attending

neurology, cardiology, and gastroenterology clinics[15]. MUS are also associated with reduced health-related quality of life and increased healthcare use[36][37]. MUS patients have an increased risk of withdrawal from the labor market, which contributed to their low quality of life[38].

A large Canadian community survey revealed the most commonly experienced MUS are musculoskeletal pain, ear, nose, and throat symptoms, abdominal pain, gastrointestinal symptoms, fatigue, and dizziness[9]. MUS often accompany other comorbid conditions such as depression, anxiety, OCD (Obsessive Compulsive Disorder), anorexia nervosa, bulimia nervosa, dysthymia, personality disorders, fibromyalgia, chronic fatigue syndrome, and irritable bowel syndrome. MUS patients often provide a confusing story which might end up with a challenging pattern of consultation. Patients often experience stress, distress, and anxiety because of their unexplained symptoms. They report feeling that their concerns are not taken seriously by their physicians, which can exacerbate the presentation of somatic symptoms. The anxiety associated with symptoms that have not been adequately explained can lead to repeated presentations to their PCPs and/or the emergency department. There are also potentially inappropriate referrals for investigations and specialist opinions or the seeking of alternative therapies- which are costly for both the patient and the health care system[9]. For those successfully managing these symptoms, studies have focused on both the number and pattern of symptoms in multiple body systems[39]. Studies have shown that during the physician-patient encounter related to MUS, the physicians that try to reassure patients often miss the explanation of their condition. This is due to the physicians' poor understanding of the different varieties of symptoms. Acknowledging patients' symptoms and providing them with better explanations, by using their own language, has been shown to improve the management process[40][41]. If symptoms are addressed satisfactorily by their PCPs, people usually do not develop multiple symptoms or become frequent attendees at the

clinics[42]. It is, therefore, imperative that we understand the pattern of symptoms from a patient's perspective for improved patient management.

MEASURING SYMPTOMS DURING A CLINICAL ENCOUNTER

'Illness behavior' has been studied by the health sociologists in order to understand the way people perceive, evaluate and act on symptoms[43]. They found that people respond differently to symptoms that are intermittent as opposed to persistent[44]. In the case of symptoms that have spontaneous resolutions, people don't usually seek medical help. There are, however, symptoms that can become more severe over time. People usually sought medical help after recognizing that their symptom episodes become more frequent or changed from intermittent to persistent. Most of the time during a patient-physician encounter, patients express their complaints in the form of a contextual story and not as a list of symptoms[45]. The ability to recall and express symptoms also varies from patient to patient as they sometimes fabricate or combine individual similar types of symptoms into a single generic event referred to as telescoping[46]. For this reason, revealing the most important symptoms from the verbal discussion or story is challenging and time-consuming during a short visit. Usually, physicians measure symptoms by the clinical history and relevant physical examination. Sometimes an assessment may reveal an additional symptom, maybe a more crucial one, which was unrecognized by the patient.

With the growing number of patients there is pressure to maximize physician productivity resulting in brief encounters, with a mean duration in internal medicine of 19.7 minutes[18]. In such a brief clinical encounter, the physicians cannot always manage to ask about all the patients' concerns due to time constraints. It was found that 47% of primary care patients were not asking questions about medication use during office visits[47]. They also found that patients' initial statements were completed only 28% of the time because physicians interrupted the patient, on

average, after 23 seconds of starting the consultation [48]. This could result in not addressing the concerned symptoms by the PCPs. Patients usually track their symptoms by writing them down or memorizing them, however, it can be difficult to track if there is more than one symptom persisting as is the case with multiple chronic conditions. In addition, patients may not report all symptoms to their clinicians or realize that physiological changes may be related to illness. Therefore, the presence, absence, or severity of a symptom may be overlooked. Detecting the key symptoms in each visit is immensely important. Studies suggested that patients look to their PCPs for guidance on symptoms that should be paid attention to. In addition, discrepancies were found between the patient's versus the physician's reporting of symptom and health status[49]. Differences in understanding the terminology of symptoms between the physicians and patients was mentioned as one of the reasons for this discordance. Reasons for the discrepancies were forgetting or choosing not to report symptoms from the patient's side and errors of omission from the physician's side. Patients may also encounter obstacles to communication outside the clinical visit, such as delays on the telephone, difficulty in transmitting messages, or problems in scheduling timely office visits which ultimately affects their reporting of the symptoms [43]. Studies suggested that patients' self-reports often capture side effects that clinicians miss and that the failure of clinicians to note these side effects leads to preventable adverse events[50]. Thereby, a patientreported symptom assessment was recommended to acknowledge the concerning symptom for the visit into the clinical practice[51].

In general, a disease is an entity that is based on the clinical symptoms and /or other objective measures[17]. A symptom is the subjective evidence of a disease that is experienced by an individual who is affected by the disease. To better understand the importance of symptoms regarding the diagnosis of a disease, we can refer to McWhinney who stated, "A symptom is best

seen as the patient's way of communicating with us, and frequent attendance with the same symptom, large numbers of symptoms, or our inability to make sense of the presenting symptom, should alert us to avoid thinking solely about organic disease when attempting to reach a diagnosis" [52]. The patient is the first person who acknowledges symptoms and decides to see a health-care professional regarding the seriousness of the symptoms. PCPs use symptoms as clues that can help determine the most likely diagnosis when a disease is present. However, symptoms are not synonymous with an organic disease all the time. People may have symptoms that might not meet the diagnostic criteria for the disease. As an example, Berger and colleagues could not confirm that biliary pain was consistently related to gallstone disease, even though this symptom is frequently used to determine the requirements for surgical intervention [53]. A symptom of possible serious organic significance, such as unexplained weight loss, loss of appetite, chest pain or palpitations, almost always needs to be ruled out [54]. The diagnostic process is the method by which health professionals select one disease over another, identifying one as the most likely cause of a person's symptoms. Objective symptom evaluation also has disadvantages since the extent, intensity and duration of symptoms may vary over time depending on the disease. Symptoms that appear early during a disease are often vaguer and more undifferentiated than those that arise as the disease progresses, making this the most difficult time to make an accurate diagnosis. Sir William Osler, creator of the residency program in medicine, understood the immense importance of the symptom in a diagnosis: "Just listen to your patient, he is telling you the diagnosis" [55]. To diagnose a disease, collecting clinical information in the form of symptoms from a patient is critical. This diagnostic process usually begins with a patient presenting their history of general physical symptoms[56] followed by clinical examinations by the physician to search for objective evidence of the symptoms known as signs. Symptoms and signs are used to comprise a listing of the possible diagnoses referred to as the differential diagnosis. In order to narrow down possible diagnostic options from differential diagnosis, initial tests are ordered, and an initial treatment is selected. Therefore, diagnosis is an iterative method involving information collection, integration and interpretation. It also relies on the timing and sequence of the symptoms, past medical history and risk factors for certain illnesses, and latest disease exposure. The physician can then proceed to a management plan after a confirmed diagnosis.

Symptom management depends on a variety of elements related to the person who suffers from it. This can be the individual's assessment of the interference of symptoms with his or her life (personal, professional and social life), duration of symptoms, and perceived seriousness and help-seeking behavior from a physician [57]. The first time a person is aware of many asymptomatic conditions is during a visit to a doctor, normally concerning a different problem. For example, a small asymptomatic lung nodule can incidentally be found in a chest x-ray that is done during a routine visit. When a patient fails to recognize a symptom, this might worsen the condition. In the case of serious chronic conditions such as heart failure and diabetes mellitus, people often require frequent hospitalization for symptom management. Furthermore, a common cause of preventable re-admission is when patients fail to recognize and respond to worsening symptoms before they become serious [24], making, the role of the person that tracks the symptom extremely important in symptom management. Several options for symptom management are preferred by people who experience symptoms depending on the duration, frequency, and severity. Studies have been shown that self-management and pharmacy advice were the most favored management types for minor symptoms (diarrhea), whereas PCP consultation was preferred for managing moderate to severe symptoms (back pain)[58]. A substantial number of symptomatic patients tend to use over-the-counter medications as a part of self-management[59]. Symptom monitoring, responding to symptoms and adhering to treatment is part of the self-management where people often maintain a diary/self-log to monitor the fluctuations of symptoms[60]. With the help of monitoring, they often can decide whether to seek medical assistance if symptoms flareup, take additional medication for worsening symptoms or dietary adjustment. Self-management is an integral part of primary health care and emphasized as the key to health promotion and disease prevention. However, people with limited health literacy have poor abilities to engage in selfmanagement[61]. In Canada, about 60% of adults are affected by low health literacy which further limits the ability to access, understand and act on health-related information[62], a fundamental part of self-management. Patients who can recognize early signs and symptoms are more likely to engage in self-management. Some patients with serious symptoms might delay for a long time before seeking medical care, which can compromise their health. Therefore, if the physician can educate a patient regarding an associated symptom, the situation can be managed efficiently. PCPs can assist their patients with symptom management by offering a list of troublesome symptoms as well as instruction on when to contact their office or go to the emergency. They can also encourage patients to maintain daily logs of symptoms and their severity. By providing support to patients so that they can effectively manage their own health, the goal is to limit their visits to hospitals, especially for chronic diseases.

Managing symptoms is the core business for primary care[2]. PCPs are not focused on a single condition as they need to deal with multiple symptoms at a time. With the use of patient self-reporting symptom questionnaires, the patient-physician interaction could shift from reporting symptoms to focusing on symptom severity and management. With the help of a self-reported symptom questionnaire that has a severity scale, the PCPs can easily identify the patients who need more support along with their ongoing treatment. The physician can quickly identify the

deteriorating cases and can reduce the cost for further diagnostic tests. By measuring the severity, progression of a symptom can also be monitored, and the effectiveness of the treatment can be understood in case of a follow up appointment. Sometimes, symptoms can change in severity so when patients have a tool such as a self-reported questionnaire in-hand they can track their symptoms at home. In addition, this may help with symptom recall and communication with their physician should the patient be seeing their physician later. This further aids in decision making for patients who are on waiting lists for several interventions, e.g., surgical decisions can be altered in case of a chronic pain patient while they get improved by medical intervention during the waiting period.

AVAILABLE SYMPTOM ASSESSMENT TOOLS

Most of the tools that are available to use in primary care to assess symptom are related to psychological assessment and psychiatric disorder. Examples include PHQ-9, PHQ-2, PHQ-15, EAT-26, SDQ, BDI-II, AUDIT-C, BDS checklist, Informant AD8, SOMS-2, NPI-Q, 4DSQ, SCL-90-R,SHQ, HSCL-25, SRQ-20, GPCOG, DAS, DSI-SS and SF-36. The Patient Health Questionnaire-9 (PHQ-9) is a tool that measures brief depression severity with nine depression related symptoms[63, p. 9]. The Patient Health Questionnaire-2 (PHQ-2) is same as PHQ-9 which uses two depression symptoms as a brief depression measuring tool. The Patient Health Questionnaire-15 (PHQ-15) is being used to screen somatoform symptoms in primary care settings[64]. The Eating Attitude Test (EAT-26) is used for rapid screening for disordered eating in college-aged females in the primary care setting[65]. The Strength and Difficulties Questionnaire (SDQ) is a brief behavioral five factor instrument developed to assess emotional and behavioral problems in children and adolescents[66]. The Beck Depression Inventory II(BDI-II) is used to diagnose major depressive disorder which uses 21 self-reported questionnaires[67].

The Alcohol Use Disorders Identification Test Consumption (AUDIT-C) is a3-item screening test for alcohol use disorders or risky drinking. It is used in primary care as a brief screen for alcohol misuse symptoms[68]. Bodily distress syndrome (BDS) is a 30 item self-report instrument used in clinical diagnosis for functional disorders[69]. The Informant AD8 is used in primary care to distinguish individuals with very mild dementia from those without dementia. The AD8 contains 8 questions asking the respondent to rate change (yes vs no) in memory, problem-solving abilities, orientation, and daily activities[70]. The Screening for Somatoform Symptoms-2 (SOMS-2) is a 29 symptoms version of the SOMS-2. The 29 items reduced version of the SOMS-2 showed to be a valid tool for detecting CS in primary care settings, specially whenever concomitant disorders such as anxiety and/or depression are present. Thus the R-SOMS-2 is a reliable referral tool for further specialized diagnosis[71]. The Neuropsychiatric Inventory-Questionnaire (NPI-Q) is a brief version that is suitable for use in general clinical practice settings to diagnose neuropsychiatric symptoms such as apathy, disinhibition, depression, psychosis, and agitation commonly accompany progressive cognitive and functional decline in Alzheimer's disease (AD)[72]. The Four-Dimensional Symptom Questionnaire (4DSQ) is a self-report questionnaire that has been developed in primary care to distinguish non-specific general distress from depression, anxiety and somatization[73]. The Hopkins Symptom Checklist-25 (HSCL-25) Self-Reporting Questionnaire-20 (SRQ-20) are tools to diagnose anxiety and depression in primary care[74]. The General Practitioner assessment of Cognition (GPCOG): The GPCOG is a valid, efficient, well accepted instrument for dementia screening in primary care. It has Cognitive test items and historical questions [75]. The Dyadic Adjustment Scale (DAS) is a marital satisfaction assessment scale used in primary care. It is a 32 items self-report tool, to assess couple satisfaction and to evaluate how each partner within the couple perceives his or her relationship[76]. The

Depressive Symptom Inventory - Suicidality Subscale (DSI-SS) is a brief screening tool that assess suicidality in general health settings[77].

Tools that measure symptoms related to quality of life are the Assessment of Quality of Life (AOoL)[78]: the 36-Item Short-Form Health Survey (SF-36) with physical and mental health construct[79]; the COOP/WONCA chart from Dartmouth Coop Functional Health Assessment/ World Organization of National Colleges, Academies and Academic Association of General Practitioners (COOP/WONCA) functional health assessment charts depict levels of function/wellbeing along 5-point ordinal scales in 6 domains: physical fitness, feelings, daily activities, social activities, change in health and overall health. These charts represent a simple and good method for assessing functional status providing valuable, additional information in daily primary care practice[80]. In addition, the Patient Reported Outcome Measurement Information System (PROMIS) that is a self-reported chronic disease reporting measure[81] and the Primary Care Behavioral Health Screen (PCBHS): This is a self-report instrument developed to screen for behavioral health problems in primary care settings which assesses behavioral symptom[82]. Specific symptom assessment tools that have been validated include the HSI for HIV: HIV-risk Screening Instrument (HSI) can be used in health care settings to identify individuals at risk for HIV and to initiate HIV testing, early care, and risk-reduction counseling, necessary goals for effective HIV prevention efforts in primary care[83]. General symptom assessment tools include a health history questionnaire (HHQ) assess general health status along with some specific symptoms[84], Self-Administered Health History Questionnaire (SAHHQ) for major body systems assessment[84], Patient-Reported Outcomes Measurement Information System Global Health Survey (PROMIS-GHS) for general health status and Adapted general Well Being Index (AGWBI)[85] for general well-being. Comparisons of these tools are show in Table 1.

Table 1 Symptom Assessment Tools

Instrument Name	Details	Severity	Purpose/	Validity/
		scale	User	Reliability
				Completed
Self-Administered Health	Related to major body	No	Filled by	Yes
History Questionnaire	system function		Patient	
(SAHHQ)				
Depressive Symptom	Frequency and intensity of			Yes
Inventory—Suicidality	suicidal ideation			
Subscale (DSI-SS)				
Patient Health	9 symptoms related to		Patient	Yes
Questionnaire-9 (PHQ-9)	Depression			
Patient Health	2 symptoms related to		Patient	Yes
Questionnaire-2 (PHQ-2)	Depression			
Beck Depression Inventory-	21 symptoms		Patient	
II(BDI_II)	questionnaire for Major			
	depressive disorder			
Eating Attitude Test (EAT-	Symptoms for eating	No	Patient	Yes
26)	disorders			
General Practitioner	The GPCOG is a valid,	Yes	Physician	Yes
assessment of Cognition	efficient, well accepted			
(GPCOG)	instrument for dementia			
	screening in primary care.			
	It has Cognitive test items			
	and historical questions.			
Dyadic Ajustement Scale	32-item marital adjustment	No	Physicien	Yes
(DAS)	scale			
SDQ (Strength and	Screening children's	-	Children	Yes
difficulties questionnaire)	mental health in primary		with	

Instrument Name	Details	Severity	Purpose/	Validity/
		scale	User	Reliability
				Completed
	health care together with		parents	
	parents, teachers and		and	
	public health nurses.		teachers	
Berlin Questionnaire (BQ)	Obstructive sleep apnea	-	Patient	Yes
	symptom			
The Alcohol Use Disorders	3-item alcohol-screening	-	Patient	Yes
Identification Test	questionnaire			
Consumption (AUDIT-C)				
The three-item ID	Migraine symptoms	-	Patient	Yes
Migraine [™] migraine				
screener				
Bodily Distress Syndrome	30-item questionnaire to	-	Patient	Yes
(BDS)	diagnose functional			
	disorder			
Informant AD8	Dementia: 8 questions to	-	Patient/car	Yes
	check cognitive status		egiver	
Incontinence Questionnaire	Pelvic organ prolapse	-	Patient	Yes
for Vaginal Symptoms	symptoms			
(ICIQ-VS)				
Low Back Pain Treatment	Low back pain symptoms	-	Patient	Yes
Beliefs Questionnaire (LBP-				
TBQ)				
Somatoform Symptoms-2	Somatoform symptoms	-	Patient	Yes
(SOMS-2)				
Neuropsychiatric Inventory-	Non cognitive symptoms	-	Caregiver	Yes
Questionnaire (NPI-Q)	of Dementia			

Instrument Name	Details	Severity	Purpose/	Validity/
		scale	User	Reliability
				Completed
GHQ-12 (General Health	The General Health	-	Patient	Yes
questionnaire)	Questionnaire (GHQ) is a			
	measure of current mental			
	health and			
Four Dimensional Symptom	A measure that uniquely	-	Patient	Yes
Questionnaire (4DSQ)	has separate dimensions			
	for general distress and			
	depressive disorder.			
HIV-risk screening	To develop and test a	-	Physician	-
instrument (HSI)	brief, reliable, and valid			
	HIV-risk screening			
	instrument for use in			
	primary health care			
	settings.			
Adapted general well-being	Psychological well-being,	-	Patient	Yes
index (AGWBI)	the adapted general well-			
	being index (AGWBI).			
Patient Health	Somatoform symptoms	-	Patient	Yes
Questionnaire-15 (PHQ-15)				
Health history	Health history	-	Patient	Yes
questionnaires (HHQs)	questionnaires (HHQs).			
Edmonton Symptom	A 10-item patient-rated	-	Patient	Yes
Assessment Scale (ESAS)	symptom visual analogue			
	scale developed for use in			
	symptom assessment			
Migraine Assessment of	Migraine management and	-	Patient	Yes
Current Therapy (Migraine-	to monitor treatment			
ACT)	effectiveness.			

Instrument Name	Details	Severity	Purpose/	Validity/
		scale	User	Reliability
				Completed
The International Prostatic	The International Prostatic	-	Patient	Yes
Symptom Score (IPSS) The	Symptom Score (IPSS)			
Symptom Problem Index	evaluates urinary disorder			
(SPI)	symptoms			
The Primary Care	Behavioral health	-	Patient	Yes
Behavioral Health Screen	problems in primary care			
(PCBHS)	settings.			
Four-Dimensional Symptom	Non-specific general	-	Patient	Yes
Questionnaire (4DSQ)	distress from depression,			
	anxiety and to measure			
	distress, depression,			
	anxiety and somatization			
	in primary care patients.			
Hopkins Symptom	Tool to diagnose anxiety	-	Patient	Yes
Checklist-25 (HSCL-25)	and depression.			
Self-Reporting				
Questionnaire-20 (SRQ-20)				
the Nottingham Health	Health status	-	Patient	Yes
Profile (NHP)				
COOP/WONCA chart	Functional status	-	Patient	Yes
36-Item Short-Form Health	Physical and mental health	-	Patient	Yes
Survey (SF-36)	construct			
Patient Reported Outcomes	Fatigue, pain interference,	-	Patient	Yes
Measurement Information	physical function,			
System (PROMIS)	depression, and anxiety.			
Assessment of Quality of	Measuring health-related	-	Patient	Yes
Life (AQoL-8D)	quality of life.			

Instrument Name	Details	Severity	Purpose/	Validity/
		scale	User	Reliability
				Completed
PROMIS/GHS	Patient -reported health	No	Patient	Yes
	status for chronic diseases.			
Brief Pain Inventory (BPI)	Results support the	No	Patient	Yes
	validity of the BPI as a			
	measure of pain in patients			
	without cancer and, in			
	particular, as a measure of			
	pain for arthritis and LBP			
	patients.			

Most of the published research is being done on specific symptom assessments, especially in the field of psychiatry and psychological assessment. There is some evidence regarding general symptoms assessment specifically used for assessing most experienced symptoms. Most of the available tools are focused on specific symptoms that are tailored to a specific disease or pathology rather than global symptoms.

We found that the available tools for symptom assessment are focused mostly on specific symptoms that are tailored to a specific disease or pathology. For example, considerable research was done on cancer and cardiovascular disease. Very few studies have addressed the more frequently occurring daily symptoms. This is despite the fact that these symptoms are the main cause of medical visits and healthcare costs and are strongly related to disability[14]. On the other hand, the available wide range of tools presents with several problems. Some instruments lack psychometric properties which make it difficult to assess the quality of those questionnaires. Furthermore, it is not always clear to what extent a domain is covered by the existing instruments.

Additional confusion is created by the possibility of many different versions of some questionnaires. It may be difficult to determine which version is the original one, and which versions are adaptations, made intentionally or not, of the original questionnaire. Uncertainty about the comparability of multiple existing questionnaires hampers comparison of results across studies. In addition to that, very few of them have a severity scale for symptom assessment. One of them is the Health History Questionnaire (HHQ) that was developed mainly as a medical history questionnaire to capture some commonly presenting symptoms [86]. 'Family Medicine Picklist' is another online tool that was developed very recently by the utilization of several questionnaires at one place[87]. The validity and reliability of this tool, however, could not be verified. To address the limitations of other available tools, we developed the SAQ to be a complete tool to assess global symptoms. Along with the symptoms, SAQ has a severity scale. The initial construct validity of this instrument needs to be evaluated.

The specific questions that address the thesis objective of evaluating the initial construct validity of the symptom assessment questionnaire in a primary care context are:

- 1. What is the acceptability and initial construct validity of the Symptom Assessment Questionnaire (SAQ) in a primary care clinic?
- 2. What are the issues with comprehension for the SAQ with primary care patients?

CHAPTER 3. MANUSCRIPT

PREFACE

The manuscript that follows to be submitted for publication in a peer-review open access journal, targeting primary care providers. It summarizes the main results for the thesis. Please see the co-authors contribution detailed at the beginning of the thesis. All authors gave their approval of the final version included here.

Symptom Assessment Questionnaire: Pilot testing of a measure for common symptoms in

primary care

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ABSTRACT

Background: The presence of physical symptoms is an important issue in primary care practice and research. A better understanding of how physical symptoms present could mitigate the costs and negative outcomes associated with these symptoms and provide a framework to begin improving the detection and management of alarm symptoms.

Objective: To assess the initial construct validity of a general symptom assessment questionnaire (SAQ) in primary care.

Methods: Patients in a primary care clinic in Quebec completed a cross-sectional questionnaire assessing 46 symptom domains indicating the absence or presence of symptoms, symptom duration and severity. Patients also completed a visual analogue scale (VAS) of general health and the EuroQoL five dimensions questionnaire (EQ-5D) on quality of life. Descriptive statistics were used to analyze the data. Cognitive debriefing with focus groups were used to improve readability of the wording of the SAQ.

Results: 410 patients completed the survey over 3 months. The average age of the sample was 57.3 years, and 65.3% were women. 202 patients (52.9%) reported symptoms, for a total of 790 symptoms. Of the possible 46 symptom domains, 28 were reported. The most common reported symptoms among all patients with reported symptoms were pain in different parts of the body (48.5%), general weakness/tiredness (29.7%), and back symptom/complaints (28.4%). The majority of patients indicated that they had more than one symptom (N=154, 76.2%). The SAQ correlated well with the VAS and EQ5D. 12 patients participated in the focus groups and provided detailed information which was used to modify the SAQ wordings.

Conclusion: The SAQ performed well in capturing a range of symptoms in primary care patients although there were still some issues with medical jargon. These results provide a framework for

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the design and implementation of future research to determine the psychometric properties of SAQ.

BACKGROUND

General physical symptoms account for more than half of outpatient visits in the United States, or almost 400 million clinic visits each year[88]. More than 80% of the time, these symptoms prompted respondents to see a health care professional, take medication, or reduce normal activities[89]. In primary care clinics, 14 common physical symptoms account for approximately 40% of all visits and only 16%-41% were found to have an organic diagnosis that explained the presenting symptom at the end of 1- year period[90][30].

Even without a diagnosis identified, physical symptoms produce impairment in patient functioning and quality of life similar to that seen as a result of identified medical and psychiatric diseases[88]. Clinic surveys show that the prevalence of many common symptoms exceeds 10-20%[91], and that 35% of patients identify more than one bothersome symptom[92]. In addition to being the leading reason for ambulatory care visits, there is no common mechanism to evaluate a comprehensive profile of symptoms and as a result some go unaddressed, eventually having a large impact on individuals health and function[92]. Even in specialty care where initial referral may be because of a primary symptom(s), the symptom profile of the remains incomplete resulting in suboptimal treatment planning to address full spectrum and impact of symptoms on health[93].

Even minor physical symptoms generate considerable health care expenditures in terms of clinic visits, laboratory testing, medications, and other therapies and subspecialty referrals[88]. Pharmaceutical and non-pharmaceutical therapy for physical symptoms, however, is often disappointing, causing patient and provider dissatisfaction[93]. Since up to 70% of patients with any given symptom improve within several weeks and have self-limiting disease[94], it makes

clinical and economic sense to reserve more intensive investigation and management strategies for those whose symptoms persist. The length of time the practitioner waits to see the patient for follow-up will be decided by the natural history of the suspected possibly serious disease, from a few hours to several weeks[95]. Despite efforts to identify the high-risk symptoms, to determine the incidence of so called alarm symptoms, and how they relate to serious life threatening diagnoses, there has been little success so far[96].

Biomedical research has typically focused on the end state – a specific disease – rather than the generic symptom and then worked backwards to examine the symptoms[97]. This retrospective research has often led to exaggerated sensitivities and specificities of these symptoms[98]. What is new are diseases defined by new agents and new mechanisms such as genetic or proteomic approaches, and not by purely clinical criteria[97]. Our reliance on tests means we are less diligent in taking a history to assess symptoms, and we are doubtful of a symptom when we cannot find objective confirmation[99]. For confirmation, repetition of tests can cost from \$0.6 to \$2.2 million Canadian dollars annually that corresponds to population-scaled national estimates for Canada of \$160 million[21].

The costs and prevalence caused by and the diagnostic and therapeutic uncertainty surrounding common symptoms make these symptoms a priority for primary care research. Symptom research in primary care is a long neglected field, one that may now be poised to produce important new insights that will improve the functional status of patients and enable the health care providers to work more efficiently in providing quality care[97]. The basis for our work is that the most common question a family physician will ask themselves during a clinic is still "what is the cause of symptom x?"[100]. From the patients' perspective, monitoring symptoms and being

able to link them to daily triggers is key for self-management and to be able to mitigate the impact of symptoms on daily function and participation.

In clinical and research settings, symptoms have been collected retrospectively from the medical records or elicited by questionnaires or interviews. Reliance on what is noted in the patient's chart probably underestimates the symptoms' incidence because symptoms often go unrecorded[88]. In addition, many symptom questionnaires focus on one problem[63][101][102]. Utilizing existing taxonomy and a validated assessment tool for symptom severity[103] with an added time scale, we developed a general symptom assessment questionnaire (SAQ) to be developed as a clinical decision aid and to facilitate needed research into red-flag symptoms. The purpose of this pilot project was to assess the potential use of SAQ in primary care for documentation of symptom prevalence and severity.

METHODS

The project was divided into two phases. In Phase I, a cross sectional survey was completed. In Phase II, focus groups were used in a cognitive debriefing exercise to improve comprehension issues identified in Phase I.

Phase I Study Design and Population

Data were in a cross-sectional survey collected via paper questionnaire. Participants were patients in the waiting room of a family medicine clinic in the Queen Elizabeth Health Complex in Montreal, Quebec. Patients were eligible providing that they were at least 18 years of age and were physically and mentally capable of completing the questionnaire (in French or English) without assistance from the research personnel or accompanying individuals. After registering with the receptionist, but before seeing a physician, patients were given a questionnaire by a trained research assistant, who recorded the number of refusals and ineligible patients as well as the reason

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for the ineligibilities and refusals. Attached to the questionnaire was a short statement describing the general goals of the study, as well as an attestation that participation was voluntary, and responses were anonymous. After participants completed the questionnaire (about 15-20 minutes), documents were collected by the research assistant.

Phase I Measures

The symptom questionnaire assesses 46 symptom domains. The initial page collects demographic information including age, gender, languages spoken, marital status, educational level, work status, and occupation. On the second page, patients complete the EuroQoL five dimensions questionnaire (EQ-5D) on quality of life[104]. This measure assesses five domains: mobility, self-care, usual-activities, pain/discomfort, and anxiety/depression, in which patients indicate the presence or absence and severity of each item with a yes-no response. The third page contains a visual analog scale (VAS) of current overall health status from 0 to 100 ("worst to best imaginable state of health"). The questionnaire begins with an open-ended question on the patient's symptom ("What are the reasons you have for coming to see your doctor today?"). The next portion of the questionnaire contains closed questions on 46 main symptoms assessed in two steps. Step one requires a categorical yes-no response to the question, "Is the reason that you came to the doctor today Symptom X?" For those who respond affirmatively, the severity of the symptom is graded into one of three categories (mild: can be ignored if not thought of; moderate: cannot be ignored but does not stop you from doing things; severe: stops you from doing things) and symptom duration is chosen (numbers of days, weeks, months, years). The last item asked patients to indicate if they had any other symptoms not previously listed, as well as their duration and severity.

Phase I Data-analysis

Descriptive statistics were used to analyze the data to assess whether the questionnaire would provide a valid framework to address the psychometric properties of the questionnaire in future studies. Additionally, correlations between the VAS and EQ-5D scores and the total SAQ scores and corresponding symptoms were measured. To detect a strong correlation (>80%) with a Type I error rate of 0.05 and a Type II error rate of 0.20, we would need a sample of 10 respondents. Since the instrument contained 46 domains, we multiplied this number by that factor and increased it by 10% to account for incomplete questionnaires to reach a sample size of 506 respondents.

Phase II Study Design and Population

In the second phase, results from the first phase were used to identify comprehension issues with terminology with a qualitative descriptive study using focus groups as the data collection method. The purpose of the focus groups was to understand the perception regarding the usability of the SAQ by the participants. According to Sandelowski, qualitative descriptive studies offer a comprehensive summary of an event in the everyday terms of those events[105]. Our theoretical orientation was naturalistic[106] as it indicates only a commitment to studying something in its natural state. This methodology has the advantage helping to focus on the experiences of patients' and their views on using the SAQ[107].

The participants were invited using general announcements in the primary care clinic. Inclusion criteria for the participants to participate in the focus group were that they must be residing in Montreal or its vicinity; be fluent in either English or French; be at least 18 years of age; and be willing to provide written consent.

Phase II Data Collection and Analysis

A purposeful sampling technique [106] with maximum variation was used to select the 5 participants. To have maximum variation sample [105] we recruited participants randomly. The

basic principle behind maximum variation sampling is to gain better understanding into the phenomenon by looking at it from all angles. The focus group took place at the location of Montreal, Quebec.

Data were collected using open-ended questions in a focus group to enable debriefing. The duration for the focus group was approximately 45-60 minutes. Interview was audio-recorded and conducted in the preferred language of the participants, specifically, English or French. The session in French was conducted with the help of an interpreter and notes were taken by the interpreter in English immediately after the session. The notes were briefly verified with each participant at the end of the group session. During the session, rephrasing of responses was frequently used as a means of verification.

Data analysis was performed using qualitative content analysis which is a dynamic form of analysis of verbal and visual data that is oriented toward summarizing the informational content of that data[108]. The objective in qualitative content analysis is to systematically transform a large amount of text into a highly organized and concise summary of key results. The initial analysis step was to read and re-read the interviews to get a sense of the whole. Then the texts were divided into smaller parts, namely, into meaning units, which were then condensed further. Then the meaning units were labelled by formulated codes and then grouping these codes into categories. This was a continuous process of coding and categorizing then returning to the raw data to reflect on the initial analysis. Themes and wording corrections are presented in the results.

PHASE I RESULTS

Four hundred and ten patients completed the symptom assessment questionnaires over 3months. Twenty-eight (7%) were excluded due to missing or incomplete information. This occurred when patients were called in by the physician or nurse for their clinical visit and were unable to complete the questionnaire and were therefore considered missing at random. Participants were more likely to be female (65.2%), English-speaking (70.9%), employed (46.6%), and married (60.7%). The average age of all patients was 57.3 years, with average ages of 57.0 and 57.6 years for patients with and without symptoms, respectively. Although females comprised the majority in both groups, the proportion of females was higher among patients with symptoms (73.8%) than patients without symptoms (55.6%). Patients without symptoms indicated higher VAS scores than patients with symptoms (82.8 vs 70.0, respectively). Table 2 summarizes patient characteristics by symptom status.

Commonly reported reasons for the clinical encounter were regular check-ups (39.5%) and blood and lab tests (17.8%). Among patients with symptoms, symptom complaints (94.7%) and administrative requests (e.g. request for referral or completion of administrative forms) (63.8%) were the most cited reasons for clinic visits. Other reasons given for clinic visits for all patients and patients with symptoms are also summarized in Table 2.

Characteristics	All Patients	Patients with	Patients without
	Completing	Symptoms	Symptoms
	SAQ	N=202	N=180
	N =382	n (%)	n (%)
	n (%)		
Age (years)	57.3	57.0	57.6
State of health (VAS: 0 worst - 100 best)	76.0	70.0	82.8
Gender			•
Female	249 (65.2)	149 (73.8)	100 (55.6)
Male	133 (34.8)	53 (26.2)	80 (44.4)
Language preference		~	
English	271 (70.9)	139 (68.8)	132 (73.3)

Table 2 Patient characteristics by symptom status and their reason for clinical visit

French	55 (14.4)	31 (15.3)	24 (13.3)
Other	56 (14.7)	32 (15.8)	24 (13.3)
Employment status			
Employed	178 (46.6)	92 (45.5)	86 (47.8)
Unemployed	55 (14.4)	28 (14.0)	27 (15.0)
Retired	149 (39.0)	82 (40.5)	67 (37.2)
Marital status	·		-
Single	63 (16.5)	33 (16.3)	30 (16.7)
Married/living with partner	232 (60.7)	122 (60.4)	110 (61.1)
Widowed or separated/divorced	87 (22.8)	47 (23.3)	40 (22.2)
Education			
Did not complete high school	52 (13.6)	27 (13.4)	25 (13.9)
Reason for Visit			
Regular check-up	151 (39.5)	87 (43)	-
Symptom complaint	57 (14.9)	191 (94.7)	-
Chronic disease follow-up	53 (13.9)	107 (52.8)	-
Blood and lab tests	68 (17.8)	68 (33.8)	-
Obtain test results	29 (7.6)	125 (62.1)	-
Administrative requests	11 (2.9%)	129 (63.8)	-
Not specified	13 (3.4)	109 (53.8)	-

Symptom frequency, severity, and duration

Two-hundred and two patients (52.9%) reported symptoms, for a total of 790 symptoms. Of the possible 46 symptom domains, 28 were reported. Fifteen patients selected "Other Symptom/Complaint", and of those, 9 fit into one of the 46 symptom domains. The most common symptoms reported were pain in different parts of the body (48.5%), general weakness/tiredness (29.7%), and back symptoms/complaints (28.4%). Patients whose main reason for visiting the clinic was a symptom most frequently reported pain in different parts of the body (50.0%), back symptoms/complaints (25.9%), and feeling anxious/nervous/tense (24.1%). The most frequent symptoms reported are summarized in Table 3.

Symptom	No.	Patients	No. of	Mean	Durati	on by sev	verity
	patients	with most	patients	duration			
	N=202	frequent	reporting	in			
	n (%)	symptom	duration	months			
		as reason			Mild	Mode	Severe
		for visit				rate	
		N=54					
		n (%)					
Pain*	98 (48.5)	27 (50.0)	67	32.0	10.1	22.2	73.5
Weakness/tiredn	60 (29.7)	10 (18.5)	37	28.9	50.7	42.0	39.0
ess*							
Chest pain	19 (9.4)		10	22.6	5.0	14.7	24.1
Abdominal	30 (14.9)	11 (20.4)	18	6.9	5.0	6.8	12.4
pain*							
Heartburn	20 (9.9)		12	25.1	3.0	78.4	84.5
Diarrhea	1 (0.5)		0	-	-	-	-
Gas/flatulence/b	24 (11.9)		11	22.7	0.1	17.6	10.1
elching							
Ear pain/earache	14 (6.9)		7	24.6	-	78.4	0.7
Palpitation	17 (8.4)		12	6.3	-	10.0	12.0
Neck	24 (11.9)		17	21.6	3.1	46.5	78.9
Back*	58 (28.7)	14 (25.9)	34	46.3	-	67.5	95.7
Upper limb*	44 (21.8)	9 (16.7)	27	23.2	5.5	24.5	76.4
Lower limb*	50 (24.8)	9 (16.7)	39	53.7	52.3	28.4	122.4

 Table 3 Symptom frequency, duration and severity

Anxiety/nervous	45 (22.3)	13 (24.1)	27	22.3	2.0	31.4	16.6
/tense*							
Depression*	38 (18.8)	8 (14.8)	25	31.1	61.7	16.3	24.7
Sexual problems	14 (6.9)		0	-	-	-	-
Dyspnea/short	30 (14.9)	8 (14.8)	16	52.5	9.2	20.1	24.8
of breath*							
Cough	25 (12.4)		0	-	-	-	-
Nose	26 (12.9)		0	-	-	-	-
Throat	20 (9.9)		12	19.0	1.1	30.5	32.6
Skin*	36 (17.8)	8 (14.8)	0	-	-	-	-
Eye	23 (11.4)		13	29.8	1.0	6.2	34.7
Thirst	7 (3.5)		3	6.3	-	12.1	-
Weight change*	29 (14.4)	11 (20.4)	20	19.1	-	36.2	14.7
Urinary	26 (12.9)		0	-	-	-	-
Female genital	3 (1.5)		0	-	-	-	-
Female breast	8 (4.0)		0	-	-	-	-
Male genital	1 (0.5)		0	-	-	-	-
Notes. * indicates the symptoms that were most commonly reported							

Many patients with symptoms indicated that they had more than one symptom (N=154, 76.2%). The frequency of multiple symptoms reported was: one (N=48, 24%), two (N=42, 21%), or three (N=36, 18%) and 12 patients reported over 10 symptoms (6%), with a maximum of 20 reported symptoms (Table 3). Patients with symptoms had an average of 3.9 symptoms/patient (95% CI 3.4-4.4), while patients whose reason for encounter was a symptom complaint had on average 3.6 symptoms/patient (95% CI 2.7-4.5).

Pain (N=18), lower-limb problems (N=14), and weakness (N=11) were the most reported among patients reporting only one symptom. For patients who presented with two total symptoms,

the most common combinations were pain+lower limb problems (N=8), pain+back problems (N=5), and pain+upper limb problems (N=2). Among patients with three symptoms, the most common combination was pain+back problems+lower limb problems, reported by 4 patients, followed by pain+upper limb problems+lower limb problems and weakness+depression+anxiety, reported by 2 patients each.

The mean duration for individual symptoms ranged from 6.3 months (palpitation) to 53.7 months (lower limb problem). No symptom had a 100% response rate for severity, with an average response rate of 60.8%. Table 3 also lists average duration and severity for each symptom. *Correlations with EuroOoL five dimensions questionnaire/ visual analogue scale (VAS)*

Table 4 summarizes the frequency and severity of each EQ-5D item. The majority of patients reporting symptoms reported pain/discomfort (N=144, 71.3%) on EQ-5D, with most of those (N=126) indicating moderate severity. For all EQ-5D items, patients most frequently reported moderate severity.

EQ ^a	No. Patients	EQ-5D Severity			
	N=202	No	Moderate	Severe	Missing
	n (%)	problem			
Mobility	60 (29.7)	138	60	0	4
Self-care	10 (5.0)	188	10	0	4
Usual activities	58 (28.7)	142	53	5	2
Pain/discomfort	144 (71.3)	55	126	18	3
Anxiety/depression	94 (46.5)	101	87	7	7

Table 4 EuroQol five dimensions questionnaire frequency and severity

^aEQ is a binary variable with yes/no

Measure	Total Symptoms ^b
EQ-5D Item ^b	
Mobility	0.18 (0.01)
Self-Care	0.27 (0.0001)
Usual activities	0.32 (<0.0001)
Pain/discomfort	0.11 (0.001)
Anxiety/depression	0.30 (<0.0001)
Total EQ5°	0.42 (<0.0001)
VAS ^d	-0.35 (<0.0001)

Table 5 Correlations between EQ-5D/VAS and number of total symptoms

^a Total number of symptoms, value of 1-20

^bEQ-5D Items (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) value of 1, 2, or 3

^cTotal EQ-5D: sum of EQ1 to EQ5, value of 0-5

^dVAS: value of 0-100 with 100 being the best

Described in Table 5, patients' total EQ-5D scores showed a moderate positive (0.42, <0.0001) correlation with total number of symptoms reported, VAS scores showed a moderate negative (-0.35, <0.0001) correlation. Of the individual EQ-5D items, mobility (0.18, 0.01), self-care (0.27, 0.001), and pain/discomfort (0.11, 0.001) showed weak positive correlations with total number of reported symptoms, and usual activities (0.32, <0.0001) and anxiety/depression (0.3, <0.0001) showed moderate positive correlations.

In terms of specific symptoms, total EQ-5D scores showed a moderate positive correlation to the severity of reported general pain (0.41, <0.0001). VAS scores showed a moderate negative correlation to the severity of reported chest pain (-0.66, 0.01), and a weak negative correlation to severity of reported general pain (-0.24, 0.03).

PHASE II RESULTS

Twelve (12) participants took part in 3 focus groups. From Phase I, the focus groups dealt with improving comprehension due to patient noting symptoms in "Other" when there was a category for it. The focus groups also considered the utility of the SAQ. Seven themes were identified in the sessions which are described below.

The first theme was that a symptom could be a state of health where medical intervention is required and that is perceived differently by different people. When participants were asked what they think about the word 'symptom', one participant described a symptom as:

"everything that is wrong with me."

While another participant responded,

"something that bothers you that you feel you have to pursue."

One of them mentioned using a cell phone to track the symptoms:

"everything that leads up to final diagnosis, different formats, what comes before final puzzle-I keep track on my cellphone."

Participants agreed that they seek professional assistance for 'bothersome' symptoms.

A second important theme was that, despite translating the ICD-10 domains into lay language, there was still a lot of jargon and these medical terminologies were not always comprehensible. When the contents of the SAQ were discussed, most participants agreed that they had difficulty understanding some of the labelling that was used in the SAQ. One participant stated that 'abdomen' was unclear while perhaps 'tummy' might be more acceptable. The participant also said,

"What if there is different educational level, different ethnic groups-what would they call it, abdomen?" One participant's observation was that "upper/lower limbs" may not be understandable and to use "arms and legs" instead. Another opinion was about symptoms related to heart:

"Do people understand what is a palpitation? Not always."

"irregular heartbeat as feeling of your heart pounding or racing or skipping" The participants recommended using simple language as much as possible. Such as using 'heart pounding' or 'heart racing' in place of 'irregular heartbeat.' For better understanding, they also recommended to mention symptoms besides the image of the concerning organ/system.

The third theme was around the utility of names of body parts versus pictures. Participants recommended that it would be beneficial to add more pictures of different parts of the body rather than listing of names. According to one participant,

"people think kidneys are at the back.... instead of listing names maybe a picture-since they don't know the anatomy."

In addition, another participant suggested,

"Pictures may be more accurate. Front, side and back view all are important. They could go over parts with cursor in case of an online version and see the names."

One participant mentioned people cannot differentiate between liver and kidney a lot of times; therefore, placing a picture would be a reasonable option.

A fourth theme occurred around a better explanation of pain. To describe pain better, the participants recommended to use images of different body parts to show pain along with color variation,

"pale red to dark red according to severity in case of an online version"

One of the ideas identified by members of the focus groups was to add pain scale instead of using mild, moderate or severe. In fact, one participant discussed that using a pain scale from 0-10 might be more accurate.

The fifth theme was around how the SAQ could act as a symptom tracking tool. Participants felt that the SAQ can act as a tracking tool for the patients who are suffering from chronic conditions. Participants noted that patients are often the first people who track their symptoms. According to one participant, infection should not be added as this is not a symptom but a diagnosis. They discussed the idea of adding duration of symptom along with the pattern whether it is continuous or intermittent.

Another theme touched on self-management of symptoms. The participants agreed that having a self-management option where they could write down their strategies to manage symptoms in the case of chronic symptoms. They would like to inform their physician on how they are managing the symptoms before they seek help. In fact, one participant noted,

"Therefore, when you see a doctor, I have tried doing this, this and this and it hasn't helped; current management+ action plan+ date for each, what I have tried to alleviate the symptom, supplements, meds, name+ quantity, allergies. This will give the physician a clear idea of what aspects were tried before."

They recommended having a free text box where they could write all this information.

When exploring the utility of the SAQ, the theme of using the tool for effective communication emerged. One participant stated,

"Because you don't remember-sometimes you see many doctors, months apart and it's very hard to manage this."

One participant indicated,

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"A tool on my iPhone I can put everything on. Would it be possible for doctors to access, so the patient does not always have to say?"

They also emphasized that to have an operative tool through which they can interconnect with their health care provider would be ideal. As an example, a participant mentioned,

"Doctors can see how much you've done yourself-patients managing their own health is a

full-time job-they do their share and can share with their doctors."

Modifications to the questionnaire wordings that were made to the original SAQ are included in Table 6 (also see the instrument in the Appendix with changes highlighted).

Page	Current Wording	Proposed modification
04	Black box mentioning "Your own	A blank box to write the score
	state of health today"	
06	List of Symptoms	No. 5: within brackets (Tummy/Belly)
		No.16: Within bracket (Heart racing/pounding)
		No 20: Upper limb=Arm (Shoulder to Finger);
		Lower limb=Leg (Hip to toes)
		No 28: Shortness of breath/Dyspnea: Should go
		after chest pain on number 5
07	No 1. No picture	Use BPI with picture
08	4(b): No Picture	Picture/ along with left and right, should add
		center and below the chest
12	12: Rectal/anal pain	Can be added in the first picture of pain
14	16: Palpitation	Heart racing/pounding along with an image
15	17: Swollenankles/edema	17: Removal of the term edema; feet swelling
	18: Neck pain	can be added along with ankle
		18: In case of pain refer to First page BPI
16	19: Back symptoms	If pain add in BPI

Table 6 Recommended Correction of the SAQ

17	20: Upper limb	Arm (Shoulder to fingers)
18	21: Lower limb	Leg (Hip to toes)
21	26: Sleep disturbance	Sleep problem
	(a)Sleep apnea	(a)Breathing problem during sleeping
23	28: Shortness of breath/ Dyspnea	Dyspnea can be removed; can be placed under
		chest problems
24	29: cough	Can be placed under throat
25	30(b): Nose bleed/epistaxis, Post	Remove epistaxis,
	nasal drip	Remove Rhinorrhea, explain postnasal drip,
	Rhinorrhea, Sinus pain	add a picture of sinus area
26	31: Throat symptoms	Voice and cough will fall under this
27	33: Lymph glands/nodes	Add swelling (painful or not) along with
		Pictures of throat, armpit and groin
28	34(b) Pruritus,	Replace with itching
	Erythema,	Replace with redness
33	39(b) Dysuria	Remove and replace with less amount of urine
	Urinary incontinence/involuntary	Maybe with a picture of the area
	urination/stress incontinence	
	Anuria/Oliguria	
	Renal colic/Kidney pain	
34	40(b)Amenorrhea, oligomenorrhea	Replace with absence of period and
		light/irregular periods
35	41 : Premenstrual symptoms	Can be added under menstrual problem
35	42 : Menopausal symptoms	Add within bracket: Irregular periods, Vaginal
		dryness, hot flashes, Chills, Night sweats, Sleep
		dryness, hot flashes, Chills, Night sweats, Sleep problems, Mood change
36	43(b)Vaginal discharge	dryness, hot flashes, Chills, Night sweats, Sleepproblems, Mood changeAdd consistency (Thick/thin/watery)
36	43(b)Vaginal discharge Vulvar pruritus	dryness, hot flashes, Chills, Night sweats, Sleepproblems, Mood changeAdd consistency (Thick/thin/watery)Replace with Vulvar itching
36	43(b)Vaginal discharge Vulvar pruritus 44(b) Nipple fissure,	dryness, hot flashes, Chills, Night sweats, Sleepproblems, Mood changeAdd consistency (Thick/thin/watery)Replace with Vulvar itchingReplace with cracking

	Retraction	Replace with inward deviation of the nipple
37	(Page no 38)	Replace with no 40
38	Perineum /pelvis	Addition of a picture
38	Urethral discharge	Replace with discharge from urinary output

DISCUSSION

The SAQ performs well in capturing a range of symptoms, and patients were able to complete the assessment. Additionally, most symptoms exhibited a range of severity, indicating that SAQ spans severity for most symptoms. The correlations between total symptoms reported and EQ-5D/VAS scores suggest that SAQ is a valid measure of general health and wellness, although further analysis is warranted to verify the extent of its validity.

The majority of patients reporting symptoms, reported more than one symptom, which is consistent with previous research showing that outpatients typically identify more than one bothersome symptom[92]. Because physician visits in primary care clinics are often limited in terms of time, patients may not have time to discuss all of their present symptoms[109]. Furthermore, the reasons patients visit their physicians may primarily concern one major symptom or condition (as opposed to a collection of symptoms or general unwellness), leaving secondary symptoms undiscussed. A patient-completed general symptom questionnaire completed prior to the visit could provide a means for patients to organize their thoughts and guide discussions with their physicians.

Pain was the most frequently reported symptom, and the most frequently included symptom in common symptom clusters. Several studies have highlighted the high frequency of general pain experienced in clinic populations[110]. The frequency with which patients reported general pain may indicate that this item is redundant, however, we felt it was important to include this item to differentiate pain from related (but distinct) complaints. For example, the "pain" category may refer to pain in the arm, but the "arm symptom/complaint" may refer to tingling or other sensations, which are not necessarily painful. Future studies will address this issue as well as any other possible redundancies among measures on SAQ.

Symptoms including experience of pain create significant impairment in patient functioning and generate considerable financial costs in healthcare systems[88]. Although symptoms account for over half of outpatient visits, patients and providers often report dissatisfaction with treatment related to these issues[111]. The frequency of symptoms and their influence on function, general health perceptions, and in turn quality of life in primary care patients[112] make symptoms a priority in primary care research. Current research and even tools for clinical practice rarely consider general physical symptoms, instead focus on end-state, diseasespecific issues such as lab results[97]. A symptom assessment questionnaire could provide a starting point to gather information about physical "red flag" symptoms to determine how they predict specific diseases and improve patient and provider satisfaction in treating physical symptoms.

Limitations of this research related primarily to the methods of administration and preliminary nature of the study. Of note, nine patients who completed the survey listed symptoms in the "Other Symptom/Complaint" which fit into one of the previously listed symptom domains. This may indicate that the language used in the questionnaire may be too advanced for some primary care patients. In addition, many patients who listed symptoms failed to indicate the severity level of each symptom, which may indicate that the survey was too long (40 pages, or about 20 minutes), causing participants to become disinterested or fatigued. Paper surveys might

be considered cumbersome, and an electronic version of the survey could be a better way to keep participants engaged for the length of the survey. Future research could determine an appropriate length, and gauge interest in an electronic version of the questionnaire in order to aid in a revision of the current SAQ. Another limitation is the generalizability of our results; the sample was limited to one primary care clinic in Quebec and may not be representative of Canadian primary care patients at large. It is not clear if and to what extent the use and applicability of the questionnaire would apply to different age groups, such as children, young adults, or geriatric populations, and non-English or French speakers. Finally, there are several symptoms (namely sexual problems, diarrhea, genital problems, thirst, and breast problems) with very few respondents. A larger and more varied sample would likely provide a larger number of respondents for each symptom, which would better allow more robust statistical analyses relating to these particular symptoms.

This is the first step to providing a validated instrument for comprehensive symptom assessment in primary care. The next step is to assess the psychometric test characteristics of SAQ, including determining more fully its validity and discriminative properties. As discussed previously, further analysis will assess the construct validity for each of the symptom domains beyond clarifying medical terminology for better comprehension, to identifying any redundancy between the items, and assessing the items' internal consistency.

Previous studies have shown that primary care patients have positive attitudes about providing information about their symptoms prior to their visit in order to assist their physicians' diagnostic process, and that over half preferred to do so via a web-based platform[23]. These studies, along with the present results, suggest that patients' self-reports could be a valuable and easily obtained resource for symptom monitoring. This method has the benefit of engaging patients in their own care, which has been shown to correlate with positive health outcomes and greater

treatment compliance[113]. Furthermore, patients who report adequate communication with their physicians about symptoms report greater satisfaction with care, less worry, fewer unmet expectations, and better symptom outcomes after two weeks[4].

The goal of this research was to adapt the questionnaire into a format that can be incorporated into electronic health records and to evaluate the impact of this process on patient care and safety. This information will also provide valuable information on the prevalence and incidence of symptoms across patient populations, including which patterns of alarm symptoms predict adverse events and specific diseases.

SAQ performs well in capturing a range of symptoms in primary care patients, and participants can understand and complete the survey. These results provide a framework for the design and implementation of future research to determine the psychometric properties of SAQ and its use in primary care settings including a comparison to other primary care tools used in clinics.

DECLARATIONS

Ethical approval and consent to participate

The study was performed with the approval of the McGill Institutional Review Board of the McGill University Health Complex (MUHC). Informed consent was not obtained as responses were completely anonymous.

Competing interests

The authors have no conflicts to disclose.

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CHAPTER 4. DISCUSSION

In the initial evaluation of the SAQ, 94.7% of people referred to symptoms as their 'Reason For Encounter', which is a common trend seen in the primary care encounters[114]. PCPs reported seeing more patients with chronic illness having multiple symptoms along with the routine health maintenance issues. Due to time constraints, PCPs often manage the appointment time by limiting one or two complaints per visit. In the end, this resulted to less comprehension of the primary reason for consultation of patients. However, worsening and additional symptoms are well-known causes for seeking medical assistance, most of which are not reported[115].

Amongst the many reasons listed for non-reporting, failure to elicit the patients' agenda due to short clinic time and interruption by the physicians were the most common[116]. On the other hand, the five most common reasons for non-reporting by the patients are not wanting to be judged, not wanting to be embarrassed, not wanting to develop an image of a difficult patient and not wanting to consume more of the physicians' time[117]. Therefore, it has been recommended[118] to use written formats of standardized tools to provide more personalized information. We found that when patients are given appropriate tools and enough time to inform their health concerns, they can pin-point the bothering symptoms along with the severity.

PCPs are the forefront to managing patients' physical along with psychosocial well-being which is an integral part of primary care practice. Sometimes patients come to see the PCP for reasons such as discussing about a new treatment option or a new research that the patient saw or read in an article. In addition to that, a patient might be interested in addressing other emotional and psychosocial issues. These 'other' symptom' complaints do not always match with the ICPC (International Classification of Primary Care) code. Hence, it has been recommended to develop appropriate tools that provide a list of choices for both active and non-active problems[119]. To capture these, we included the 'other symptoms' section in the SAQ. About >48% of patients wrote their diagnosis as an 'other symptom'. This is a common phenomenon to mention diagnosis which is evident in the development ICPC codes[120]. For example, one patient wrote 'people or work-related issues' in the 'other symptoms' section. Hence, the 'other symptom' can be the section to capture the non-active/non-physical concerns of the patients.

We were interested to know whether the literacy of our patient population had bearing on their patterns of answering the questions. To answer that, we observed their educational status and spotted that the lowest level of education was 8th grade or less for only one patient out of the 15. Hence, we could not find any co-relation between the high level of educational status and the pattern of their answering the 'other symptoms' section. The questionnaire covered nearly all body parts and symptoms, and this could be the reason why no other symptoms were written. This enables us to consider a change in the questionnaire from 'other symptoms' to 'other concerns.'

In addition to that, results of the focus group analysis indicated that the SAQ can be a good source of communication tool between the physician and patient that was emphasized by previous research[50]. The questionnaire was an effective tool for tracking and managing symptoms by the participants as well. Patients' self-reports frequently capture side effects that were missed by the clinicians, and those failures result in the occurrence of preventable adverse events[47][121].

We observed that some of the medical terms that were adapted from the ICPC medical coding were difficult to understand by the patients, which is a common phenomenon in medical practices. Our participants were agreed upon changing the difficult medical terminologies and recommended the addition of more images for better comprehension. We therefore changed the medical terminologies to lay terms according to the participants' recommendations. The corrected SAQ according to the focused group recommendation is added to the appendix. It is important to

note that symptoms might arise in a person due to the effect of a medication. These are the unwanted or unexpected events or reactions to a medication that can be named as side effects or adverse drug reactions. Both prescription and over-the-counter (OTC) drugs can produce these effects. These symptoms can vary from minor problems like a runny nose to life-threatening events, such as an increased risk of a heart attack. They can be life-threatening if an individual is unable to recognize them. In a study of 661 primary care patients reporting symptoms, 179 (27%) reported 286 symptoms were related to medications [47]. In those reported symptoms, 37% occurred with every dose, and 93% were persisted for 1 month or more. The most frequently identified medication symptoms in that group were gastrointestinal problems, fatigue, dizziness and problems with balance, and rash or itching. However, patients continued to take the drugs that accounted for 55% of medication symptoms and consulted with their physicians for 69% of medication symptoms. Of these, 22% were sufficiently serious to require a visit to a medical facility e.g., physician's office, clinic, or emergency department. Besides, there was a correlation between use of multiple medications and medication related symptoms. Patients who take multiple medications are more likely to have had a prior experience of a medication related symptom and thus may be more aware of the risks. They may also have more physician encounters and more opportunities to report symptoms. Patients were least likely to report symptoms like incontinence, perhaps because they were embarrassed. On the other hand, patients might not understand the significance of medication-related symptoms in case of the presence of multiple symptoms. Therefore, any future work would need to account for medication histories or be specially adapted to the introduction of new medications.

The ultimate objective of this research is to develop a standardized general symptom assessment questionnaire that is aimed at collecting information on the incidence and prevalence of general symptoms across primary care patient population. The SAQ can be used as a potential tracking tool for disease process, red flag symptoms and adverse events. From our comparison to the available tools with the SAQ, we also found that it can be a complete tool to manage all symptoms which can be further added to an electronic medical record (EMR).

LIMITATIONS

As with all research, this thesis has limitations. Firstly, the study was done in one primary care clinic with a limited number of samples which might not be representative of other clinics or the general population. For the initial validation work, however, the results provide encouraging initial validation findings. Future research could involve the potentials of incorporating the SAQ to the EMR as well as transforming into an electronic version. This is only the initial validation work and more needs to be done with a more diverse sample.

CONCLUSION

A successful management of symptoms in primary care depends on successful evaluation and interpretation of the presenting symptoms. Poorly controlled symptoms adversely affect the illness experiences of patients. In addition, a disease can be managed efficiently by treating the bothering symptom effectively. Patients rarely present a single symptom to their clinicians. It is therefore important for PCPs to understand the patients' perceptions regarding the symptoms to provide a comprehensive explanation to discuss the symptoms. Yet, there is little evidence on optimal evaluation and management of general symptoms and that reflects a critical gap in symptom science. With raising attention to personalized care, research aimed at the identification of symptom assessment is essential to the development and testing of targeted interventions. Introducing patient-reported general symptom assessment questionnaire will improve physicians' awareness of their patients' symptom burden, and facilitate timely changes in the management, whenever necessary. By collecting data related to the patients' symptom right from the start the PCPs will be able to improve the full spectrum of patient care. It will help the physicians to focus more time and attention to the patient as the symptoms need to be managed will already be present. With the help of patient self-reporting, the patient-physician interaction could shift from reporting symptoms to focusing on symptom severity and causality. Patients' positive attitude towards the SAQ may facilitate its implementation and contribute to its clinical utility. The SAQ can also be used as a tool to track disease process, red flag symptoms and adverse events by incorporating it into the electronic medical records. By sharing this information with other physicians who are involved in the patient's circle of care, the management process will be more efficient and less error prone.

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APPENDIX: THE SAQ WITH HIGHLIGHTED CHANGES

The Symptom Assessment Study

We are doing a study to improve the care provided by family physicians to their patients. We want to better understand the reasons why patients, such as you, visit their family physician and what physical symptoms may be present at the time of this visit.

To answer this question, we are asking all patients who attend this clinic if they would be willing to complete a short questionnaire while waiting to see the physician. Your participation in this study is voluntary and you can drop out of the study at any time. The information that you provide is completely confidential. We will not put your name on the questionnaire or provide your individual response to your doctor or anyone else. At the end of the study, we will summarize everyone's responses and use this information to identify ways to improve patient care.

This study was approved by the McGill Institutional Review Board. The principal investigators are:

Gillian Bartlett, PhD Martin Dawes, MD Dept. of Family Medicine McGill University 515-517 Pine Avenue West Montreal, Quebec H2W 1S4

www.medicine.mcgill.ca/familymed/

a li	ttle background information from ev	veryone, as covered	in the follov	ving questions.
1.	Are you: Male Female $\%$ $\%$	2. If you would	know your po you please w	ostal code, rrite it here:
3.	What is your age in years?			
4.	What language do you prefer to spea	ak?		
	French	%0		PLACE A CHECK IN
	English	%0		THE APPROPRIATE
	Arabic	%0		BOX
	Italian	%0		
	Portuguese	%0		
	Greek	%00		BOX
	Chinese	%00		
	Hebrew	%00		
	Other (please specify)	%0		
		Yes	No	
5.	Are you currently employed?	%0	%0	
	If No, are you retired?	%	%0	PLACE A CHECK IN THE APPROPRIATE BOX
6.	What is (was) your occupation?			DOX
7.	How many years of education have	ou completed?		
	8 th grade or less some high	· %o		
	school araduated high school	%0		
	some college or university	%0		
	graduated college or	%00		PLACE A CHECK IN THE
	university postgraduate	%0		BOX
		%0		
8.	What is your current marital status?			
	single	%0		
	married	%0		
	unmarried but living with a	%0		APPROPRIATE BOX
	partner widowed	%0		
	separated or divorced	%00		

All replies are anonymous. It will help us to understand your answers better if we have

By placing a check-mark in one box in each group below, please indicate which statements best describe your own state of health today.

Mobility	
I have no problems walking	%0
I have some problems walking	%00
Self-Care	
I have no problems with self-care	%0
I have some problems washing or dressing	%0
myself I am unable to wash or dress myself	%0
Usual Activities (e.g. work, study, housework, family or leisure activities)	
I have no problems performing my usual activities	0/00
I have some problems performing my usual	%o
activities I am unable to perform my usual activities	%o
Pain/Discomfort	
I have no pain or discomfort	M
I have moderate pain or discomfort	%00 ~
I have extreme pain or discomfort	%00
	%00
Anxiety/Depression	
I am not anxious or depressed	~
I am moderately anxious or depressed I	%00
am extremely anxious or depressed	%0
	<i>‰</i>

Best imaginable state of health

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the black box below to whichever point on the scale indicates how good or bad your state of health is today.





what are the reasons you have for coming to see your doctor today	What are the reasons y	you have for	coming to see	your doctor today?
---	------------------------	--------------	---------------	--------------------

- 5 -

Please fill in the symptoms that are the reason for this visit. To help you, this is a list of possible symptoms and the page number.

If the reason that you came to the doctor today is not found in the list below, pleas	<u>e go to</u>
question 47 (page 40)	
1: Pain in different parts of your body	7
2: Fever	7
3: General weakness/tiredness	8
4: Chest Pain	8
5: Abdominal Pain	9
6: Heartburn	9
7: Nausea	10
8: Vomiting	<mark>10</mark>
9: Diarrhea	11
10: Constipation	11
11: Rectal bleeding	<mark>12</mark>
12: Rectal / anal pain (the external opening in your bottom)	<mark>12</mark>
13: Flatulence / gas / belching	13
14: Ear pain/earache	13
15: Hearing problem or deafness	14
16: Palpitation	14
17: Swollen ankles/ edema	15
18: Neck symptom /complaint	15
19: Back symptom/complaint	16
20: Upper limb symptom / complaint	17
21: Lower limb symptom / complaint	18
22: Headache	19
23: Vertigo / dizziness	19
24: Feeling anxious/nervous/tense	20
25: Feeling depressed	20
26: Sleep disturbance	21
27: Sexual problems	22
28: Shortness of breath/dyspnea	23
29: Cough	24
30: Nose symptom/complaint	25
31: Throat symptom/complaint	26
32: Voice symptom/complaint	26
33: Lymph glands enlarged/painful	27
34: Skin symptom/complaint	28
35: Eye symptom/complaint	30
36: Excessive thirst	31
37: Change in appetite	31
38: Change in weight	32
39: Urinary symptom/complaint	33
WOMEN ONLY	34
40: Menstrual symptom/complaint	34
41: Premenstrual symptom/complaint	35
42: Menopausal symptom/complaint	35
43: Genital symptom/complaint (sex organs)	36
44: Breast symptom/complaint	37
MEN ONLY	38
45:Genital symptom/complaint (sex organs)	38
46: Breast symptom/complaint	39
47: Other symptom/complaint	40

We would like to know if you have any of the following symptoms. Please place a firm tick in the box which is most applied to you. It is important that you answer all the questions.

1: Pain in different parts of your body

(a) Is the reason that you came to the doctor today: <u>Persistent aches and pains in several different parts of your body</u>?

[] No (if no, please go to question 2)

Days (please enter number)

Weeks (please enter number)

Months (please enter number)

Years (please enter number)

[] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?

(c) How bad is it ?

[] <u>mild</u>: can be ignored if you don't think about it

[] moderate: cannot be ignored, but does not stop you from doing things

[] <u>severe</u>: stops you from doing things

2: Fever

or

or

or

(a) Is the reason that you came to the doctor today: <u>fever or high temperature</u>?

- [] No (if no, please go to question 3)
- [] Yes

[] Don't know

(b) How long has it lasted (the time from the beginning of the problem until now)?

or _____ Days (please enter number) or _____ Weeks (please enter number) or _____ Months (please enter number) or _____ Years (please enter number)

(c) How bad is it ?

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

[] Don't know

3: General weakness/tiredness

- (a) Is the reason that you came to the doctor today: physical fatigue, which is, <u>feeling</u> <u>tired out</u>, fatigued, or lacking enough energy to do the things you normally do ?
 - [] No. (if no , please go to question 4)
 - [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?		(c) How bad is it?	
	Days (please enter number)	[] mild: can be ignored if you don't think	
or		about it	
	Weeks (please enter number)		
or		[] <u>moderate</u> : <i>cannot be ignored, but does not</i>	
	Months (please enter number)	stop you from doing things	
or			
	Years (please enter number)	[] <u>severe</u> : stops you from doing things	
	Don't Imory		

4: Chest Pain

- (a) Is the reason that you came to the doctor today: <u>ache, pain, or discomfort in</u> <u>the chest</u>?
 - [] No (if no, please go to question 5)
 - [] Yes

(b) Do you have it :

- [] in your left chest
- [] in your right chest
- [] both left ant right chest

(c) How long has it lasted (the time from the beginning of the problem until now)?

or _____ Days (please enter number) or _____ Weeks (please enter number) or _____ Months (please enter number) or _____ Years (please enter number)

[] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

5: Abdominal Pain

(a) Is the reason that you came to the doctor today: ache, pain, or discomfort in your stomach or belly?

- [] No (if no, please go to question 6)
- [] Yes

(b) Has this ache or pain been?

- [] Above the navel, in the upper abdomen
- [] Below the navel, in the lower abdomen
- [] In both upper and lower abdomen

(c) How long has it lasted (the time from the beginning of the problem until now)?



(d) How bad is it?

- [] mild: can be ignored if you don't think about it
- [] moderate: cannot be ignored, but does not stop you from doing things
- [] severe: stops you from doing things

6: Heartburn

- (a) Is the reason that you came to the doctor today: feeling burning or ache in the chest (heartburn)?
 - [] No (if no, please go to question 7)
 - [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?

- Days (please enter number) or
- Weeks (please enter number) or
- Months (please enter number)
 - Years (please enter number)
 - [] Don't know

or

- [] mild: can be ignored if you don't think about it
- [] moderate: *cannot be ignored*, *but does not* stop you from doing things
- [] severe: *stops you from doing things*

7: Nausea

(a) Is the reason that you came to the doctor today: <u>feeling sick (nausea)</u>?

- [] No (if no, please go to question 8)
- [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?		(c) How bad is it ?		
	Days (please enter number)	[] <u>mild</u> : can be ignored if you don't think about it		
or	Weeks (please enter number)	[] moderate: cannot be ignored, but does not stop you from doing things		
or	Months (please enter number)	[] severe: stops you from doing things		
	Years (please enter number)	[] <u>bevere</u> . stops you'll om doing hungs		
	[] Don't know			

8: Vomiting

(a) Is the reason that you came to the doctor today: <u>being sick (vomiting)</u>?

- [] No (if no, please go to question 9)
- [] Yes

(b) How long has it lasted (the time from the		(c) How bad is it ?		
beginni	ng of the problem until now)?	[] mild: can be ignored if you don't think		
	Days (please enter number)	about it		
or	Weeks (please enter number)	[] moderate: cannot be ignored, but does not		
or	Months (please enter number)	[] severe: stops vou from doing things		
	Years (please enter number)			
[] Don't know			

- 10 -

9: Diarrhea

(a) Is the reason that you came to the doctor today: <u>watery stools or</u> <u>frequent/loose bowel movements (diarrhea)?</u>

- [] No (if no, please go to question 10)
- [] Yes

(b) How long has it lasted (the time from the		has it lasted (the time from the	(c) How bad is it ?	
beginn	ing of	The problem until now)? Days (please enter number)	[] <u>mild</u> : can be ignored if you don't think about it	
or		Weeks (please enter number)	[] moderate: cannot be ignored, but does not	
or		Months (please enter number)	stop you from doing things	
or	Years (please enter number)		[] <u>severe</u> : stops you from doing things	

[] Don't know

10: Constipation

(a) Is the reason that you came to the doctor today: <u>hard stool and difficult to</u> <u>pass (constipation) ?</u>

- [] No (if no, please go to question 11)
- [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?

or Days (please enter number)

Weeks (please enter number)

- _____ Months (please enter number)
- or

or

- ____ Years (please enter number)
- [] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: stops you from doing things

11: Rectal bleeding

(a) Is the reason that you came to the doctor today: <u>fresh blood in stool?</u>

- [] No (if no, please go to question 12)
- [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?

- Days (please enter number) or
 - _____ Weeks (please enter number)
- or Months (please enter number)
 - Years (please enter number)
 - [] Don't know

(c) How bad is it ?

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: stops you from doing things

12: Rectal / anal pain (the external opening in your bottom)

(a) Is the reason that you came to the doctor today: <u>pain in your anus/rectum (the external opening in your bottom)?</u>

- [] No (if no, please go to question 13)
- [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?

____ Days (please enter number)

Weeks (please enter number)

or

or

or

- Months (please enter number)
- or
- _____ Years (please enter number)
- [] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] severe: stops you from doing things

13: Flatulence / gas / belching

(a) Is the reason that you came to the doctor today: <u>belching, bloating, gas</u> <u>pains gaseous distension ?</u>

- [] No (if no, please go to question 14)
- [] Yes

 (b) How long has it lasted (the time from the beginning of the problem until now)?
 (c) How bad is it ?

 beginning of the problem until now)?
 [] mild: can be ignored if you don't think about it

 or
 Days (please enter number)

 or
 Weeks (please enter number)

 or
 Months (please enter number)

 or
 Months (please enter number)

 or
 [] moderate: cannot be ignored, but does not stop you from doing things

[] Don't know

14: Ear pain/earache

(a) Is the reason that you came to the doctor today: pain in your ear?

[] No (if no, please go to question 15)

Years (please enter number)

[] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?



[] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: stops you from doing things

15: Hearing problem or deafness

(a) Is the reason that you came to the doctor today: hearing problem?

- [] No (if no, please go to question 16)
- [] Yes

(b) Do you have: (you can choose more than one answer)

- [] Decrease in your hearing
- [] Ringing in the ears (tinnitus)
- [] Plugged feeling ear

(c) How long has it lasted (the time from the beginning of the problem until now)?



(d) How bad is it?

- [] mild: can be ignored if you don't think about it
- [] moderate: cannot be ignored, but does not stop you from doing things
- [] severe: stops you from doing things

16: Palpitation

(a) Is the reason that you came to the doctor today: feeling your heart pounding or racing?

- [] No (if no, please go to question 17)
- [] Yes

or

or

(b) How long has it lasted (the time from the beginning of the problem until now)?

- Days (please enter number)
- or Weeks (please enter number)
- Months (please enter number)
 - Years (please enter number)
 - [] Don't know

- [] mild: can be ignored if you don't think about it
- [] moderate: cannot be ignored, but does not stop you from doing things
- [] severe: *stops you from doing things*

17: Swollen ankles/ edema

(a) Is the reason that you came to the doctor today: swollen feet, ankles, or lower legs ?

- [] No (if no, please go to question 18)
- [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?



[] Don't know

(c) How bad is it ?

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: stops you from doing things

18: Neck symptom /complaint

(a) Is the reason that you came to the doctor today: <u>problem</u> or pain in your neck?

- [] No (if no, please go to question 19)
- [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?

- or _____ Days (please enter number) or _____ Weeks (please enter number) or _____ Months (please enter number) or _____ Years (please enter number)
 - [] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: cannot be ignored, but does not stop you from doing things
- [] <u>severe</u>: stops you from doing things

19: Back symptom/complaint

(a) Is the reason that you came to the doctor today: problem or pain in your back ?

- [] No (if no, please go to question 20)
- [] Yes

(b) Is this problem in the?

- [] Middle back
- [] Low back
- [] Non other specified



(c) How long has it lasted (the time from the beginning of the problem until now)?

- or _____ Days (please specify in number) Weeks (please specify in number) or
- _____ Months (please specify in number)
 - Years (please specify in number)
 - [] Don't know

(d) How bad is it ?

or

- [] <u>mild</u>: can be ignored if you don't think about it
- [] moderate: cannot be ignored, but does not stop you from doing things
- [] severe: stops you from doing things

20: Upper limb symptom / complaint

(a) Is the reason that you came to the doctor today: <u>problem or pain in your upper limb (from</u> <u>shoulder down to finger)?</u>

- [] No (if no, please go to question 21)
- [] Yes

(b) Do you have it in your: (you can choose more than one answer)

- [] Shoulder
- [] Arm
- [] Elbow
- [] Wrist
- [] Hand / finger

(c) How long has it lasted (the time from the beginning of the problem until now)?



[] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

21: Lower limb symptom / complaint

(a) Is the reason that you came to the doctor today: <u>problem or pain in your lower limb (from</u> <u>hip down to toe) ?</u>

- [] No (if no, please go to question 22)
- [] Yes

(b) Do you have it in your: (you can choose more than one answer)

- [] Hip
- [] Leg/thigh
- [] Knee
- [] Ankle
- [] Foot/toe)

(c) How long has it lasted (the time from the beginning of the problem until now)?

or _____ Days (please enter number) or _____ Weeks (please enter number) or _____ Months (please enter number) or _____ Years (please enter number) [] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

22: Headache

(a) Is the reason that you came to the doctor today: <u>headache</u>?

- [] No (if no, please go to question 23)
- [] Yes

(b) How long has it lasted (the time from the		(c) How bad is it ?	
beginn	ning of the problem until now)?	[] mild on he impered if you don't think	
	Days (please enter number)	about it	
or	Weeks (please enter number)	[] moderate: cannot be ignored, but does not	
or	Months (please enter number)	stop you from doing things	
or	Years (please enter number)	[] <u>severe</u> : <i>stops you from doing things</i>	
	[] Don't know		

23: Vertigo / dizziness

- (a) Is the reason that you came to the doctor today: <u>giddiness</u>, <u>feeling lightheaded</u>, <u>and</u> <u>loss of balance</u>?
 - [] No (if no, please go to question 24)
 - [] Yes

((b) How long has it lasted (the time from the beginning of the problem until now)?



- or
- Years (please enter number)
- [] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

24: Feeling anxious/nervous/tense

(a) Is the reason that you came to the doctor today: feeling anxious, tense or frightened ?

- [] No (if no, please go to question 25)
- [] Yes

(b) How long has it lasted (the time from the		(c) How bad is it ?	
begin	nning of the problem until now)?	[] mild on he incord they don't think	
0.4	Days (please enter number)	about it	
or	Weeks (please enter number)	[] <u>moderate</u> : cannot be ignored, but does not	
01	Months (please enter number)	stop you from doing inings	
or	Years (please enter number)	[] <u>severe</u> : <i>stops you from doing things</i>	
	[] Don't know		

25: Feeling depressed

- (a) Is the reason that you came to the doctor today: <u>feeling depressed</u>, <u>down</u>,<u>unhappy or</u> <u>hopeless?</u>
 - [] No (if no, please go to question 26)
 - [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?

- or _____ Days (please enter number) or _____ Weeks (please enter number) or _____ Months (please enter number) or _____ Years (please enter number)
- (c) How bad is it ?
- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

[] Don't know

26: Sleep disturbance

(a) Is the reason that you came to the doctor today: <u>sleep disturbance such as :</u> <u>sleeplessness, nightmares , sleep walking , sleepiness , sleep apnea?</u>

- [] No (if no, please go to question 27)
- [] Yes

(b) How long has it lasted (the time from the		(c) How bad is it ?	
beginni	ing of the problem until now)?	[] mild: can be ignored if you don't think	
or	Days (please enter number)	about it	
	Weeks (please enter number)	[] moderate: cannot be ignored, but does not	
or	Months (please enter number)	stop you from doing things	
or	Years (please enter number)	[] <u>severe</u> : <i>stops you from doing things</i>	

[] Don't know

27: Sexual problems

(a) Is the reason that you came to the doctor today: problem in your sexual activity?

- [] No (if no, please go to question 28)
- [] Yes

(b) Do you have: (you can choose more than one answer)

- [] Loss of sex drive
- [] Impotence or premature ejaculation
- [] Painful intercourse
- [] Difficulty achieving orgasm
- [] Other : please specify

(c) How long has it lasted (the time from the beginning of the problem until now)?



- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] severe: stops you from doing things

28: Shortness of breath/dyspnea

(a) Is the reason that you came to the doctor today: <u>difficulties with your breathing ?</u>

- [] No (if no, please go to question **29**)
- [] Yes

(b) Do you have: (you can choose more than one answer)

- [] difficulties with your breathing when lying down
- [] inspiratory wheeze
- [] abnormal breathing / apnea / holding breath / respiratory distress / snoring /

stridor

[] faster or deeper breathing than normal

(c) How long has it lasted (the time from the beginning of the problem until now)?

(d) How bad is it ?

- or _____ Days (please enter number) or _____ Weeks (please enter number) or _____ Months (please enter number)
- or
- Years (please enter number)

[] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: cannot be ignored, but does not stop you from doing things
- [] <u>severe</u>: *stops you from doing things*

29: Cough

(a) Is the reason that you came to the doctor today: <u>cough?</u>

- [] No (if no, please go to question **30**)
- [] Yes

(b) Do you have:

- [] Dry cough
- [] Moist cough with phlegm or sputum
- [] Coughing blood

(c) How long has it lasted (the time from the beginning of the problem until now)?



- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

30: Nose symptom/complaint

(a) Is the reason that you came to the doctor today: problem in your nose / sinuses ?

- [] No (if no, please go to question **31**)
- [] Yes

(b) Do you have: (you can choose more than one answer)

- [] Nose bleed / epistaxis
- [] Blocked nose , rhinorrhea ,running nose
- [] Pain in nose, postnasal drip, prominent nose, red nose
- [] Blocked sinus , congested sinus , pain / pressure in sinus

(c) How long has it lasted (the time from the beginning of the problem until now)?

- ____ Days (please enter number)
- or _____ Weeks (please enter number)
- or Months (please enter number)
- or
- Years (please enter number)
- [] Don't know

- [] <u>mild</u>: *can be ignored if you don't think about it*
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing thing*

31: Throat symptom/complaint

(a) Is the reason that you came to the doctor today: dry/inflamed/red/sore throat, large tonsils, lump in throat, tonsillar pain?

- [] No (if no, please go to question 32)
- [] Yes

(b) How long has it lasted (the time from the (c) How bad is it ? beginning of the problem until now)? Days (please enter number) about it or Weeks (please enter number) or Months (please enter number)

[] Don't know

- [] mild: *can be ignored if you don't think*
- [] moderate: cannot be ignored, but does not stop you from doing things
- [] <u>severe</u>: *stops you from doing things*

32: Voice symptom/complaint

- (a) Is the reason that you came to the doctor today: absence of voice, aphonia hoarseness ?
 - [] No (if no, please go to question 33)

Years (please enter number)

[] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?

Days (please enter number) or

- Weeks (please enter number)
- or

or

or

- Months (please enter number)
 - Years (please enter number)
 - [] Don't know

- [] mild: can be ignored if you don't think about it
- [] moderate: cannot be ignored, but does not stop you from doing things
- [] <u>severe</u>: *stops you from doing things*

33: Lymph glands enlarged/painful

(a) Is the reason that you came to the doctor today: <u>enlarged or painful lymph node?</u>

- [] No (if no, please go to question 34)
- [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?



- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

34: Skin symptom/complaint

(a) Is the reason that you came to the doctor today: problem in your skin ?

- [] No (if no, please go to question **35**)
- [] Yes

(b) Do you have: (you can choose more than one answer)

- [] Burning sensation, painful lesion or rash, soreness
- [] Skin irritation / pruritus
- [] Verruca / warts
- [] Localized swelling / papule
- [] Generalized swelling / papules in multiple sites
- [] Localized rash , erythema , redness , blotch
- [] Generalized rash , erythema , redness, blotches in multiple sites
- [] Infected finger/toe
- [] Abscess, furuncle
- [] Infected skin post traumatic wound / bite
- [] Insect bite / sting
- [] Animal / human bite
- [] Burn / scald
- [] Bruise / contusion
- [] Laceration / cut of skin
- [] Dry skin, peeling, scaling, wrinkles
- [] Hair loss / baldness
- [] Dry scalp / excessive hairiness
- [] Other : please specify _____

.....Continuation in the next page

(c) How long has it lasted (the time from the beginning of the problem until now)?

~*	 Days (please enter number)
or	 Weeks (please enter number)
or	 Months (please enter number)
or	 Years (please enter number)

[] Don't know

- [] <u>mild</u>: *can be ignored if you don't think about it*
- [] <u>moderate</u>: cannot be ignored, but does not stop you from doing things
- [] <u>severe</u>: *stops you from doing things*

35: Eye symptom/complaint

(a) Is the reason that you came to the doctor today: <u>problem in your eye</u>?

- [] No (if no, please go to question **36**)
- [] Yes

(b) Do you have: (you can choose more than one answer)

- [] Eye pain
- [] Red eye
- [] Eye discharge
- [] Fixed/floating spots in the visual field
- [] Visual disturbance
- [] Burning / dry / itchy eye
- [] Abnormal eye movements
- [] Swollen eye
- [] Eyelid problem)
- [] Other : please specify _____

(c) How long has it lasted (the time from the beginning of the problem until now)?

- or _____ Days (please enter number) or _____ Weeks (please enter number) or _____ Months (please enter number) or _____ Years (please enter number)
 - [] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

36: Excessive thirst

(a) Is the reason that you came to the doctor today: excessive thirst?

- [] No (if no, please go to question **37**)
- [] Yes

(b) How long has it lasted (the time from the		(c) How bad is it ?
beginr	ning of the problem until now)? Days (please enter number)	[] <u>mild</u> : can be ignored if you don't think about it
or	Weeks (please enter number)	 [] moderate: cannot be ignored, but does not stop you from doing things [] severe: stops you from doing things
or	Months (please enter number)	
	Years (please enter number)	

[] Don't know

37: Change in appetite

(a) Is the reason that you came to the doctor today: change in your appetite ?

- [] No (if no, please go to question **38**)
- [] Yes

(b) Do you have:

[] Excessive appetite

[] Loss of appetite

(c) How long has it lasted (the time from the beginning of the problem until now)?



- or
- Years (please enter number)

[] Don't know

- [] mild: can be ignored if you don't think about it
- [] moderate: cannot be ignored, but does not stop you from doing things
- [] <u>severe</u>: *stops you from doing things*

38: Change in weight

(a) Is the reason that you came to the doctor today: <u>change in your weight ?</u>

- [] No (if no, please go to question **39**)
- [] Yes

(b) Do you have:

- [] Weight gain
- [] Weight loss

(c) How long has it lasted (the time from the beginning of the problem until now)?

or _____ Days (please enter number) or _____ Weeks (please enter number) or _____ Months (please enter number) or _____ Years (please enter number) [] Don't know

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: cannot be ignored, but does not stop you from doing things
- [] <u>severe</u>: stops you from doing things

39: Urinary symptom/complaint

(a) Is the reason that you came to the doctor today: problem in urination ?

[] No (if no, please go to question : 40 if you are a woman or 45 if you are a man)

[] Yes

(b) Do you have: (you can choose more than one answer)

- [] Dysuria , burning urination
- [] Urinary frequency / urgency
- [] Urine incontinence / involuntary urination / stress incontinence
- [] Anuria / dribbling urine / oliguria
- [] Blood in urine
- [] Bad odour of urine / dark urine
- [] Urinary retention
- [] Bladder pain / irritable bladder
- [] Renal colic / kidney pain
- Other : please specify

(c) How long has it lasted (the time from the beginning of the problem until now)?



[] Don't know

(d) How bad is it ?

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

If you are a man please skip the next section and go to question 45 (page 36)
WOMEN ONLY

40: Menstrual symptom/complaint

(a) Is the reason that you came to the doctor today: problem in your menstruation ?

- [] No (if no, please go to question 41)
- [] Yes

(b) Do you have: (you can choose more than one answer)

- [] Menstrual pain
- [] Amenorrhea, delayed/late menses, oligomenorrhea
- [] Excessive menstruation
- [] Irregular menstruation
- [] Bleeding between menses

(c) How long has it lasted (the time from the beginning of the problem until now)?

- ____ Days (please enter number)
 - Weeks (please enter number)
- or Months (please enter number)
- or

or

- _____ Years (please enter number)
- [] Don't know

(d) How bad is it ?

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

41: Premenstrual symptom/complaint

- (a) Is the reason that you came to the doctor today: <u>feeling worse before your</u> <u>periods</u> (<u>premenstrual tension</u>)?
 - [] No (if no, please go to question 42)
 - [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?

- or _____ Days (please enter number) or _____ Weeks (please enter number) or _____ Months (please enter number) or _____ Years (please enter number)
 - [] Don't know

(c) How bad is it ?

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] severe: stops you from doing things

42: Menopausal symptom/complaint

(a) Is the reason that you came to the doctor today: menopausal symptom ?

- [] No (if no, please go to question 43)
- [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?

or _____ Days (please enter number) or _____ Weeks (please enter number) or _____ Months (please enter number) or _____ Years (please enter number)

[] Don't know

(c) How bad is it ?

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*

43: Genital symptom/complaint (sex organs)

(a) Is the reason that you came to the doctor today: <u>genital symptom (sex organs)</u> ?

- [] No (if no, please go to question 44)
- [] Yes

(b) Do you have: (you can choose more than one answer)

- [] Vaginal discharge
- [] Pelvic pain/Vulval pain
- [] Vaginal dryness
- [] Vulval pruritus/ vulval dryness
- Other : please specify

(c) How long has it lasted (the time from the beginning of the problem until now)?

- or _____ Days (please enter number)
- Weeks (please enter number)
- or
- _____ Months (please enter number)
- or
- Years (please enter number)
 - [] Don't know

(d) How bad is it ?

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: cannot be ignored, but does not stop you from doing things
- [] <u>severe</u>: *stops you from doing things*

44: Breast symptom/complaint

(a) Is the reason that you came to the doctor today: breast symptom?

- [] No (if no, please go to question 47)
- [] Yes

(b) Do you have: (you can choose more than one answer)

- [] Breast pain
- [] Breast lump/mass
- Nipple discharge, nipple fissure, nipple pain/pruritus, nipple retraction
- [] Other : please specify _____

(c) How long has it lasted (the time from the beginning of the problem until now)?

(d) How bad is it?

- - Days (please enter number)
- or Weeks (please enter number)
- Months (please enter number)
 - Years (please enter number)

[] Don't know

or

or

- [] mild: can be ignored if you don't think about it
- [] moderate: cannot be ignored, but does not stop you from doing things
- [] <u>severe</u>: *stops you from doing things*

Now please go to question 47 (page 38)

MEN ONLY

45:Genital symptom/complaint (sex organs)

(a) Is the reason that you came to the doctor today: genital symptom (sex organs)?

- [] No (if no, please go to question **46**)
- [] Yes

(b) Do you have: (you can choose more than one answer)

- [] Pain in penis
- [] Pain in testis / scrotum / perineum / pelvis
- [] Urethral discharge
- [] Other : please specify _

(b) How long has it lasted (the time from the (c) How bad is it ? beginning of the problem until now)? [] mild: can be ignored if you don't think Days (please enter number) about it or Weeks (please enter number) [] moderate: cannot be ignored, but does not or stop you from doing things Months (please enter number) [] severe: *stops you from doing things* or Years (please enter number) [] Don't know

46: Breast symptom/complaint

(a) Is the reason that you came to the doctor today: breast symptom ?

- [] No (if no, please go to question 47)
- [] Yes

(b) How long has it lasted (the time from the beginning of the problem until now)?



[] Don't know

(c) How bad is it ?

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] severe: stops you from doing things

47: Other symptom/complaint

- (a) Is the reason that you came to the doctor today <u>other than those described</u> <u>above ?</u>
 - [] No
 - [] Yes please specify _____

(b) How long has it lasted (the time from the beginning of the problem until now)?



(c) How bad is it ?

- [] <u>mild</u>: can be ignored if you don't think about it
- [] <u>moderate</u>: *cannot be ignored, but does not stop you from doing things*
- [] <u>severe</u>: *stops you from doing things*