

THE OASIS: DEVELOPMENT OF A SIMPLIFIED QUESTIONNAIRE FOR PATIENTS
WITH OVERACTIVE BLADDER

by

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Abstract

Overactive bladder (OAB) refers to a complex of symptoms characterized by urgency, frequency, and nocturia, with or without urge incontinence (Ellsworth, 2013a; Heesakkers, 2015). The prevalence of OAB increases with age, and primary care practitioners can expect to see patients with symptoms of OAB frequently in practice (Hou & Zimmern, 2015). This condition can negatively affect physical, sexual, psychological, domestic, and social aspects of patients' lives, decreasing quality of life (Ellsworth, 2013a). Several questionnaires exist to evaluate OAB. However, no comprehensive questionnaire exists that evaluates patients' responses to OAB treatment while also addressing medication side effects and lifestyle modifications. The purpose of this culminating project was to design a user-friendly, simplified, brief, patient-centered questionnaire that assesses the symptoms of OAB, quality of life concerns, and response to treatment, including medication side effects. Three separate literature reviews were completed to develop the Overactive-Bladder Assessment of Symptoms, Interventions, and Satisfaction (OASIS) questionnaire. The OASIS questionnaire was developed and adapted from pre-existing questionnaires, with the goal to have real-world application in the offices of busy healthcare clinicians, overall improving affected patients' lives. It will be presented at the 2017 Graduate Students in Nursing Association student research symposium and distributed to Urologists and primary care practitioners for feedback on use in actual practice.

Keywords: Overactive bladder, questionnaire, instrument design

The OASIS: Development of a Simplified Questionnaire for Patients with Overactive Bladder

The term overactive bladder (OAB) refers to a complex or constellation of symptoms characterized by urgency, frequency, and nocturia, with or without urge incontinence (Barkin, 2011; Ellsworth, 2013a; Heesakkers, 2015). Urgency must be present for a diagnosis of OAB, and refers to “the sudden compelling desire to void that is difficult to defer” (Ellsworth, 2013a, p. 12). Urgency is distinct from urge (the normal sensation felt when the bladder is full); urge can be deferred while urgency cannot (Ellsworth, 2013a). Overactive bladder is estimated to affect between 11.8% and 18.1% of Canadians (Herschorn, Gajewski, Schultz & Corcos, 2007) and is present in similar numbers of men and women (Barkin, 2011). The prevalence of OAB increases with age, and primary care practitioners can expect to see patients with symptoms of OAB more frequently than ever before (Hou & Zimmern, 2015).

Among patients with probable OAB, less than half actually discuss their symptoms with a health care provider (Ellsworth, 2013a). This occurs for several reasons: patients are often embarrassed or anxious regarding treatment, physicians are too busy to ask about OAB symptoms, health care practitioners do not understand the impact OAB can have on a patient’s quality of life, and as OAB is not life threatening, it is not a priority (Ellsworth, 2013a; Ellsworth 2013b). Furthermore, many physicians assume that patients will mention their symptoms if significantly bothersome (Ellsworth, 2013a). In reality, OAB can negatively affect physical, sexual, psychological, domestic, and social aspects of a patient’s life, decreasing quality of life (Ellsworth, 2013a). It is important to identify and treat OAB because it is also associated with anxiety, depression, sleep disturbances, urinary tract infections, falls, and fractures (Stewart et al., 2003; Wagner et al., 2002). Early diagnosis and treatment can prevent these complications (Ellsworth, 2013a).

As OAB is primarily a symptom-based diagnosis, patient-reported outcomes are critical to understand its impact (Coyne, Thompson, Lai, & Sexton, 2015). Several questionnaires exist to evaluate OAB that address specific symptoms and their effect on quality of life (Matza et al., 2005). Furthermore, many of these questionnaires have been validated to demonstrate responsiveness and thus can be used to monitor treatment outcomes (Coyne, Matza & Thompson, 2005; Matza et al., 2005). Treatments for OAB include lifestyle modifications (such as weight loss and smoking cessation) and pharmacologic therapy (Hou & Zimmern, 2015). The most common first-line medications are anticholinergic/antimuscarinic medications, however the presence of side effects such as dry mouth, constipation, and blurry vision can cause patients to discontinue pharmacotherapy (White & Iglesia, 2016). As medication side effects are a key reason patients cease treatment, it is imperative that these must be monitored.

Self-completed questionnaires are thought to be the most suitable method to assess patients' perspectives of their OAB symptoms (Singh & Khullar, 2015), yet no questionnaire exists that evaluates all aspects of patients' responses to OAB treatment with the intention of being completed in a busy clinician's office. Thus, the purpose of this N596 culminating project is to design a brief, practical questionnaire that thoroughly assesses patients' symptoms of OAB, quality of life, and their response to treatment, including medication side effects.

Rationale for Project

This project is important to primary care Nurse Practitioners (NPs) because, as stated above, OAB is common in the Canadian population and is a condition NPs will certainly encounter in practice. This questionnaire will improve the care received by patients with OAB as it will be a way to consistently monitor patients' progress throughout their treatment for OAB, regardless of what that treatment is. It will be brief enough for the patient to fill out prior to an

encounter with a healthcare professional and will allow the NP to focus on what is most important to the patient during their visit, while still being able to objectively track patients' response to treatment.

Scope of Project

Three separate literature reviews were conducted to complete this project. The first literature review answered the question of what OAB is, and encompassed an analysis of OAB, including its most recognized definitions, consequences, and first- and second-line treatments, including side effects. The second literature review looked at what OAB questionnaires currently exist. The final and third literature review answered the question of what constitutes an ideal patient questionnaire. The information obtained in the above literature searches was used to develop a questionnaire for patients with OAB that addresses their symptoms, their quality of life, and their response to treatment, including medication side effects.

Literature Review 1: What is Overactive Bladder?

In order to develop an effective questionnaire and determine what elements of OAB should be addressed, the first step was to search available literature to answer the question "What is overactive bladder?" With the purpose of the questionnaire in mind, this first literature search encompassed searching for and reviewing OAB's most common symptoms, effects on quality of life, most common treatments, and any side effects to these treatments, including any themes or topics not yet considered.

Methods

To complete this first literature search, the keywords "overactive bladder" or "OAB" were used to find appropriate literature on the following databases and search engines: the UBC Library Homepage General "search bar," Cumulative Index to Nursing and Allied Health

Literature (CINAHL), and UptoDate. Manual searches for “overactive bladder” were completed in the following textbooks: Uphold and Graham’s “Clinical Guidelines in Family Practice,” and Dunphy, Winland-Brown, Porter, and Thomas’s (2011) “Primary Care: The Art and Science of Advanced Practice Nursing.” A general search at <http://www.google.ca> was completed to search for OAB definitions from government sponsored websites (for example, the Canadian Urologic Association [CUA]). Reference lists of relevant articles were searched to locate additional pertinent literature. Articles, chapters, or web-pages were only included if published since the year 2000. Searching the above databases, textbooks, and websites continued until a point of data saturation was achieved, and overall 28 pieces of literatures were reviewed. Of note, as this questionnaire was intended for patients with established OAB, it did not address screening questions used to aid with diagnosis.

Definition of Overactive Bladder

Overactive bladder was described in the literature as a syndrome, a complex, or constellation of symptoms, and *not* a disease (Carcio & Monaghan, 2015; Dunphy, Winland-Brown, Porter, & Thomas, 2011; Ellsworth, 2013a; Ellsworth 2013b; Ellsworth, 2014; Ellsworth, 2015; Epstein et al., 2006; Gormley et al., 2012; Gormley et al., 2014; Henderson & Drake, 2010; Lukacz, 2016; McVary & Saini, 2015; Uphold & Graham, 2013). The four most common symptoms of OAB were described as urgency, frequency, and nocturia, with or without the presence of urge incontinence (Abrams et al., 2002; Barkin, 2011; Bettez et al., 2012; Carcio & Monaghan, 2015; Dunphy et al., 2011; Ellsworth, 2013a; Ellsworth, 2014; Ellsworth, 2015; Epstein et al., 2006; Gormley et al., 2012; Gormley et al., 2014; Henderson & Drake, 2010; Lukacz, 2016; McVary & Saini, 2015; Schabert, Bavendam, Goldberg, Trocio, & Brubaker, 2009; White & Iglesia, 2016). Furthermore, urgency was described as the cornerstone or

hallmark symptom of OAB (Ellsworth, 2013a; Ellsworth, 2013b; Ellsworth, 2014; Ellsworth, 2015; Henderson & Drake, 2010). Urgency may be defined as the urge to void which cannot be (or is difficult to) defer, while urge incontinence denotes an involuntary loss of urine preceded by (or occurring at the same time as) urgency (Carcio & Monaghan, 2015; Ellsworth 2013a; Ellsworth, 2013b; Epstein, Gums, & Molina, 2006; Henderson & Drake, 2016; Singh & Khullar, 2015; Uphold & Graham, 2013). Frequency was consistently defined as voiding eight or more times in a period of 24 hours (Carcio & Monaghan, 2015; Ellsworth, 2013a; Ellsworth, 2013b; Ellsworth, 2014; Epstein et al., 2006; Gormley et al., 2012; Singh & Khullar, 2015). Nocturia was also consistently defined as occurring if an individual awoke more than twice during the night to void (Carcio & Monaghan, 2015; Ellsworth, 2013b; Singh & Khullar, 2015). Though the definition of OAB symptoms was overall consistent in the literature and therefore important to include in the questionnaire, also frequently mentioned was OAB's negative impact on quality of life for patients suffering with this complex of symptoms.

Effects on Quality of Life

The effect that OAB has on quality of life was discussed in the literature in a variety of ways. Quality of life was described as being reduced (Schabert et al., 2009), compromised (Gormley et al., 2014), negatively impacted (Barkin, 2011; Ellsworth, 2013b), substantially impaired (Henderson & Drake, 2010), greatly impacted (White & Iglesia, 2016) and detrimentally affected (Hou & Zimmern, 2015) by OAB. Some authors went on to describe these effects in more detail, stating that OAB could negatively impact a person's well-being (Ellsworth, 2013a; Plowright & Davila, 2015), have noteworthy consequences on physical, occupational, sexual, psychological, domestic, and social aspects of quality of life (Ellsworth, 2013a; Ellsworth, 2013b), could affect physical and social functioning and vitality (Ellsworth,

2015), and that it had enormous social and psychological ramifications (Uphold & Graham, 2013).

Consequences of OAB were also addressed in the literature. Overactive bladder puts sufferers at risk for anxiety, depression, sexual dysfunction, sleep disturbances, and urinary tract infections (UTIs; Dunphy et al., 2011; Ellsworth, 2013a; Ellsworth, 2013b; Ellsworth, 2014; McVary & Saini, 2015; Schabert et al., 2009). These consequences of OAB will be important to address in the questionnaire to ensure patient safety. Furthermore, the knowledge obtained from this first literature review has reinforced the need to address OAB's effects on quality of life in the questionnaire. In fact, the reason many patients seek medical attention is because of OAB's detrimental effects on quality of life, and not for physical symptoms (Corcos, 2015). These treatments will be discussed next.

Common Treatments (and Side Effects)

The literature distinguished between first- and second-line treatments for OAB (third- and fourth-line treatments will not be discussed). Of note, behavioural or lifestyle changes (including physical therapy, weight loss, smoking cessation) were frequently discussed as first-line therapy for OAB (American Urological Association [AUA], 2014; Barkin, 2011; Carcio & Monaghan, 2015; Bettez et al., 2012; Corcos, 2015; Ellsworth, 2013b; Ellsworth, 2014; Epstein et al., 2012; Gormley et al., 2012; Gormley et al., 2014; Henderson & Drake, 2010; Lukacz, 2016; Newman, 2015; Schabert et al., 2009; Uphold & Graham, 2013; White & Iglesia, 2016). Pharmacotherapy was either discussed in the literature as part of the first-line therapy with lifestyle changes (Carcio & Monaghan, 2015; Corcos, 2015; Dunphy et al., 2011; Ellsworth, 2013a; Henderson & Drake, 2010; Schabert et al., 2009), second-line treatment (AUA, 2014; Bettez et al., 2012; Ellsworth, 2014; Ellsworth, 2015; Gormley et al., 2012; Gormley et al., 2014; Lukacz,

2015; White & Iglesia 2016), or less frequently as the “mainstay” or “gold-standard” for OAB treatment (Dmochowski & Danford, 2015; Felicilda-Reynaldo, 2013; Plowright & Davila, 2015). Regardless of order, a combination of lifestyle modifications and pharmacotherapy constitute both first- and second-line treatment options for patients with OAB.

Anticholinergic/antimuscarinic medications were the most frequently discussed classes of medication for the pharmaceutical management of OAB (AUA, 2014; Barkin, 2011; Carcio & Monaghan, 2015; Bettez et al., 2012; Dmochowski & Danford, 2015; Dunphy et al., 2011; Ellsworth, 2013a; Ellsworth, 2013b; Ellsworth, 2014; Ellsworth, 2015; Epstein et al., 2006; Felicilda-Reynaldo, 2013; Gormley et al., 2012; Gormley et al., 2014; Henderson & Drake, 2010; Hou & Zimmern, 2015; Lukacz, 2016; McVary & Saini, 2015; Plowright & Davila, 2015; Uphold & Graham, 2013; White & Iglesia, 2016). The side effects of these medications were repeatedly mentioned, namely, how common and bothersome these side effects can be. These side effects include constipation, dry mouth, blurred vision, headache, and dizziness (AUA, 2014; Barkin, 2011; Bettez et al., 2012; Carcio & Monaghan, 2015; Dmochowski & Danford, 2015; Dunphy et al., 2011; Ellsworth, 2013a; Ellsworth, 2013b; Epstein et al., 2006; Felicilda-Reynaldo, 2013; Gormley et al., 2014; Henderson & Drake, 2010; Kripke, 2007; Lukacz, 2016; McVary & Saini, 2015; Plowright & Davila, 2015; White & Iglesia, 2016; Uphold & Graham, 2013). These side effects can be so bothersome that patients cease treatment (Carcio & Monaghan, 2015; Ellsworth, 2013a; Ellsworth, 2013b; Henderson & Drake, 2010; McVary & Saini, 2015; Plowright & Davila, 2015; White & Iglesia, 2016). Because of this, and because pharmacotherapy is either first- or second-line therapy for OAB, it was important to address these medication side effects within the questionnaire. Schabert et al. (2009) surveyed 5392 patients with OAB and discovered another reason for medication discontinuation is unmet

treatment expectations. Interestingly, patient expectations were an unexpected theme to emerge from the literature.

Patient Expectations

The literature emphasized that patients need to understand it is unrealistic to expect to return to “normal” bladder function, or that OAB can be “cured” (Corcos, 2015; Ellsworth, 2013a; Ellsworth, 2013b; Ellsworth, 2014; Henderson & Drake, 2010; Hou & Zimmern, 2015). Furthermore, clinicians should address patients’ most bothersome symptoms (Ellsworth, 2013a; Ellsworth, 2013b) and work together to set mutual and achievable treatment goals (Corcos, 2015; Ellsworth, 2013b; Gormley et al., 2012); realistic expectations increase the chance of treatment adherence (Corcos, 2015; Hou & Zimmern, 2015). It was thus important to have items in the questionnaire which allowed patients to identify their most bothersome symptoms in order to set realistic treatment goals. However, before the questionnaire was designed, it was important to review existing questionnaires.

Literature Review 2: What Questionnaires for Overactive Bladder Already Exist?

As discussed above, OAB is primarily symptom-based and thus patient-reported outcomes are critical to understand its impact on quality of life and day-to-day functioning (Coyne et al., 2015). Furthermore, Singh and Khullar (2015) stated that questionnaires are the most effective way to assess a patient’s perspective on OAB. Therefore, this second literature review answered the question “what questionnaires for OAB already exist?” The purpose of this second literature review was to research and identify commonly used OAB questionnaires and to review how these questionnaires are used in practice. Also, this second literature review prevented inadvertent duplication of a questionnaire that already exists, and identified aspects of OAB that are not addressed in any existing questionnaire.

Methods

To complete this second literature search, the following keywords were used in various combinations: “overactive bladder” or “OAB” or “urinary” or “lower urinary tract symptoms” or “LUTS” and “questionnaire” or “assessment” or “tool.” Combinations of these keywords were in the UBC Library Homepage General “search bar” and CINAHL. UptoDate was also searched for relevant OAB tools and questionnaires. Titles of articles were scanned for relevance and abstracts of pertinent titles were read and assessed for relevance. Reference lists of pertinent articles reviewed were then searched to locate additional relevant literature. Articles and webpages were only included if published since the year 2000. Searching the above databases and websites continued until a point of data saturation was achieved, and overall 23 pieces of literatures were included in the second literature review.

OAB Questionnaires

This second literature search reinforced the importance of using patient-reported outcomes (PROs) – such as questionnaires – with conditions that are symptom based, such as OAB (Abrams, Avery, Zyczynski, Kozzp, & Coyne, 2004; Brubaker et al., 2011; Coyne et al., 2002; Coyne et al., 2005; Coyne et al., 2006; Coyne et al., 2015; Homma et al., 2006; Jeong, Homma, & Oh, 2014; Khullar et al., 2013; Matza et al., 2005; McKown et al., 2010; Piau et al., 2008; Pleil et al., 2005; Singh & Khullar, 2015). Thirteen relevant questionnaires regarding OAB will be discussed next, presented in no particular order.

OAB Questionnaire (OAB-q). The OAB-q was developed from focus groups, clinician input, and literature reviews (Abrams et al., 2004). It was validated through study on over 2500 patients and is used in both population and clinical research (Abrams et al., 2014; Coyne et al., 2006). It consists of 33 items: an 8-item bother scale and 25 health-related quality of life

(HRQL) items comprised of four subscales (coping, concern, sleep, and social interaction; Abrams et al., 2004; Matza et al., 2005; Pleil et al., 2005). Each of the 33 items is rated by patients through a 6-point Likert scale (Coyne et al., 2005; Matza et al., 2005). Responses are then summed into two separate scores ranging from 0-100, with higher symptom bother scores representing higher symptom bother, and higher HRQL scores representing better HRQL (Coyne et al., 2005; Matza et al., 2005; Pleil et al., 2005). It is appropriate for use in both continent and incontinent patients with mild to severe symptoms of OAB and has demonstrated reliability, validity, and responsiveness (Coyne et al., 2002; Coyne et al., 2006; Coyne et al., 2015; Coyne et al., 2005; Matza et al., 2005; Pleil et al., 2005). Although it achieves the highest level of evidence and recommendation, its length has been considered burdensome for patients and clinicians (Avery et al., 2007; Abrams et al., 2004; Coyne et al., 2015; Singh & Khullar, 2015).

OAB-q short form (OAB-q SF). The OAB-q SF is a PRO questionnaire developed with the purpose of reducing the length of the OAB-q, thereby decreasing response burden (Coyne et al., 2004). The symptom bother scale was reduced from 8 to 6 items, and the HRQL scale was reduced from 25 to 13 items (Abrams et al., 2004; Coyne et al., 2004; Coyne et al., 2015). The OAB-q SF retains the psychometric properties of the original OAB-q, and possesses validity, reliability, and responsiveness; it is a pertinent tool which can be used to assess patient outcomes (Abrams et al., 2004; Coyne et al., 2004; Coyne et al., 2015). Coyne et al. (2015) described it as “an economical, efficient alternative to longer questionnaires that can be used...in routine clinical care and research settings with minimal participant burden” (p. 260). The OAB-q SF was adopted into the International Consultation on Incontinence Questionnaire (ICIQ) module on OAB, discussed next (Coyne et al., 2006).

ICIQ-OAB and ICIQ-OABqol. The ICIQ-OAB is a brief and robust questionnaire that

assesses the impact OAB symptoms have on quality of life and treatment outcomes (Bristol Urological Institute [BUI], 2014). It can also be used for screening purposes and constitutes Grade A evidence (BUI, 2014). It has been described as short and simple, aimed for use with general and specialized clinicians (BUI, 2014). It consists of four items (frequency, nocturia, urgency, urge urinary incontinence) that are scored from 0-16, with a higher score representing greater symptom severity (BUI, 2014). Each of the four items also contains a bother scale which is not incorporated into the overall score (BUI, 2014).

The ICIQ-OABqol is another valid, reliable, and responsive Grade A evidence-based questionnaire for patient with OAB that specifically focuses on patients' quality of life (BUI, 2014). It can be used both in research and within clinical practice, and after completion patients arrive at a score between 25-160, with a higher score indicating a higher impact OAB symptoms are having on quality of life (BUI, 2014).

King's health questionnaire (KHQ). The KHQ is another questionnaire focused on HRQL, consisting of 21 items (Coyne et al., 2006). It was the result of several years of research on over 1000 patients (Pleil et al., 2005). Nine domains (General Health Perceptions, Incontinence Impact, Role Limitations, Physical Limitations, Social Limitations, Personal Relationships, Emotions, Sleep/Energy, and Severity Measures) are summed to yield a patient score ranging from 0-100, with a higher score indicating worse quality of life and a separate symptom impact score from 0-30 (Coyne et al., 2006; Homma et al., 2006; Pleil et al., 2005). Each item is rated with either a 4- or 5-point Likert scale (Coyne et al., 2006). Though originally developed for women with urinary incontinence, it has demonstrated good psychometric properties among all patients with OAB (Coyne et al., 2006) and was recommended by Lukacz (2016) in UpToDate. However, it may not be applicable for use in OAB patients who do not

experience incontinence (Coyne et al., 2002; van der Vaart, de Leeuw, Roovers, & Heintz, 2003).

Patient perception of bladder condition (PPBC). The PPBC is a single-item global patient measure developed for patients with urinary problems (Coyne et al., 2006; Matza et al., 2005). This single-item “questionnaire” asks patients about their impression of their *current* urinary problems on a 6-point Likert scale ranging from “no problems at all” to “many severe problems” (Coyne et al., 2006). The PPBC can be initiated both before treatment and throughout, and answer changes can be monitored (Coyne et al., 2006). It has shown good validity and responsiveness to treatment among patients with OAB (Coyne et al., 2006; Matza et al., 2005). Its simplicity is an advantage in any clinical setting with limited resources and combines patients’ feelings about their symptoms, treatments, side effects, and quality of life into one question (Coyne et al., 2006). That being said, single-item questionnaires have limitations, particularly because they cannot provide the breadth of information that could be obtained from a multi-item questionnaire (Coyne et al., 2006), for example, which OAB symptom is most bothersome to a patient.

Indevus urgency severity scale (IUSS) and the OAB symptom composite score (OAB-SCS). The IUSS is a questionnaire that focuses primarily on urgency and constitutes a 4-grade response scale from questions asked about urgency severity every time a patient voids (Homma et al., 2006). Overall, it captures urgency severity per toilet void (Zinner et al., 2005). The IUSS has demonstrated validity, test-test reliability, and responsiveness, however it cannot be used in isolation to understand the full experience of patients with OAB during treatment (Zinner et al., 2005). To address this, the OAB-SCS was developed: it incorporates the IUSS scale (based on a patient’s voiding diary) and quantifies this into a single score (Homma et al.,

2006; Zinner et al., 2005). One of the advantages of the OAB-SCS is being able to differentiate between voiding “normally” versus voiding due to urgency (Homma et al., 2006; Zinner et al., 2005). The OAB-SCS has been shown to demonstrate responsiveness with antimuscarinic therapy (Homma et al., 2006). However, it is not convenient or simple to use, as an onerous voiding diary needs to be completed by the patient (Homma et al., 2006). Furthermore, there is no upper limit to the score, and it has not been tested for psychometric properties (Homma et al., 2006). Its intentions are for research purposes and use during clinical trials (Zinner et al., 2005).

OAB symptom score (OABSS). The OABSS was developed as an alternative to the difficult-to-score OAB-SCS (Homma et al., 2006). The OABSS is obtained after summing four symptom scores addressing daytime voiding, nocturia, urgency, and urge incontinence (Homma et al., 2006; Jeong et al., 2014). It can be used for both research and clinical practice for OAB patients (Homma et al., 2006). Though it has only been used in practice where the majority of patients were Japanese, it still has demonstrated responsiveness to treatment (Jeong et al., 2014). It has been translated into English but would require validation based on local patient population characteristics (Jeong et al., 2014). Furthermore, it has not been used in studies with a large number of participants (Homma et al., 2006).

Primary OAB symptom questionnaire (POSQ). The POSQ is a newly developed questionnaire comprised of five questions in total: four assess the amount patients have been bothered by each OAB symptom in the past two weeks (frequency, urgency, nocturia, and urge incontinence; Homma et al., 2006) and the fifth item addresses which symptom is most bothersome (Matza et al., 2005). It has demonstrated validity among patients with OAB (Matza et al., 2005).

Urgency questionnaire (UQ). The UQ contains 19 questions (15 five-point Likert scale

items and 4 visual analog scales) focusing on urgency (Homma et al., 2006; Matza et al., 2005). The Likert-style items comprise four subscales of nocturia, fear of incontinence, time to control urge, and impact on daily activities while the visual analog scales assess the severity, intensity, impact, and discomfort urinary urgency has on the patient (Matza et al., 2005). Of note, this was the only questionnaire found that utilizes a visual analog scale. However, while urgency is a hallmark symptom of OAB, it may not be the most bothersome to a patient with OAB, and thus this questionnaire's focus on urgency may not be appropriate for all patients with OAB. Nevertheless, it has demonstrated reliability, validity, and responsiveness (Matza et al., 2005).

Self-assessment goal achievement (SAGA). The SAGA was developed to help patients to identify their goals of treatment (either behavioural or pharmacological) and assess their achievement of these goals; its use is for patients with lower urinary tract symptoms (LUTS), including OAB (Brubaker et al., 2011; Khullar et al., 2013). Patients are asked to rate the importance of several fixed goals (derived from previous research) and to write down five individual goals (Khullar et al., 2013). It was designed for both clinical and research use (Brubaker et al., 2011; Singh & Khullar, 2015) and has demonstrated validity and ease-of-use among patients (Khullar et al., 2013). The information obtained by this questionnaire can promote discussion between patients and their health care providers, and can help to develop an individualized treatment plan for patients with LUTS; it is designed to be administered both prior to and throughout treatment (Brubaker et al., 2011; Khullar et al., 2013). It has been described “as a communication tool” (Khullar et al., 2013, p. 1530) with the potential to improve patient-clinician interactions (Singh & Khullar, 2015). The questionnaire is one of few containing open ended questions, the advantage being that patients have the opportunity to mention bothersome symptoms beyond LUTS.

OAB-satisfaction questionnaire (OAB-S). The OAB-S is a questionnaire consisting of 51 items in total: 10 items each on control expectations, impact on daily living, OAB control, satisfaction with control, 6 items addressing OAB medication tolerability, and 5 single-item assessments of the patient's fulfillment (Piault et al., 2008). This questionnaire was developed to assess patients' overall satisfaction with OAB pharmacological treatment (Piault et al., 2008). It is unclear whether the OAB-S can be used in both clinical and research settings, and has only demonstrated validity in studies within the United States (Piault et al., 2008). Its initial intention was to also address non-pharmacological treatments for OAB (such as physical therapy) but this is not addressed, and the authors note another item would need to be added (Piault et al., 2008). Regardless, it was the only questionnaire found in this literature review to specifically address medication side effects. Despite its long length, each of the 5 scales could be separated and administered individually if time constraints are present (Piault et al., 2008).

Global assessment of treatment benefit, satisfaction with treatment, and willingness to continue treatment (BSW). The BSW is a 3-item assessment administered by the clinician to assess patients' perception of treatment benefits, satisfaction with treatment, and willingness to continue treatment (Pleil et al., 2005). The clinician asks three yes/no questions and then probes further, for example, if the patient is willing to continue treatment, is s/he "a little bit willing" or "very willing" to continue treatment (Pleil et al., 2005). The underlying assumption is that when answering questions, patients will consider all factors related to their OAB (symptoms, treatments, quality of life, side effects of any medications, and so on; Pleil et al., 2005), which may not always be the case. Single-item measures can again miss details that would have been uncovered with multi-item questionnaires (Coyne et al., 2006; Pleil et al., 2005). The BSW has demonstrated validity in patients with OAB, and has the potential to be used with other chronic

conditions or diseases (Pleil et al., 2005). Despite the ease of use that accompanies single-item questionnaires, as this is administered by the clinician it could be argued that this does not save the clinician (likely working in a busy practice) much time.

Discussion

The above search was not exhaustive for possible questionnaire relevant for OAB patients for several reasons. For example, the OAB-q has been modified into six versions, each intended for a different patient population, desired length of questionnaire, and follow-up period (for example, different versions exist if the patient is following up at 1 week versus 4 weeks; Pfizer, 2016). Furthermore, within the literature, OAB is frequently grouped into discussions of incontinence.

The term OAB was sometimes discussed synonymously with urge incontinence, even though incontinence is not always present (Coyne, Matza, Thompson, Jumadilova, & Bavendam, 2007). Again, numerous questionnaires exist that are intended for different patient populations: women with incontinence, patients with urinary incontinence (men and women), older persons with urinary incontinence, elderly women with urinary incontinence, and so on. For example, the ICIQ is a highly recommended questionnaire which evaluates patient perspective on urinary incontinence (Abrams et al., 2010). It has been described as simple and robust; it can be used in both clinical research and practice, has high levels of validity, reliability, and sensitivity, and is easy to complete (Avery et al., 2004). It has been modified into 13 modules depending on the patient's most bothersome symptom (Pfizer, 2016). Two of these modules were discussed above (the ICIQ-OAB and ICIQ-OABqol). Other editions include the ICIQ-VA for vaginal symptoms, the ICIQ-B3 for bowel symptoms, the ICIQ-MLUTS for urinary symptoms in males, the ICIQ-N for nocturia (ICIQ-N) and the ICIQ-Nqol to assess nocturia quality of life (Abrams et al., 2010).

Health care providers must decide which questionnaire to use based on (1) whether the patient is male or female (2) whether the patient experiences incontinence or not (3) his or her age, and (4) his or her most bothersome symptom. Altogether, numerous questionnaires exist with significant overlap – for example, if a female patient has OAB and her most bothersome symptom is nocturia, which questionnaire is best, the ICIQ-OAB or the ICIQ-N?

Another point of confusion is that the 2014 AUA Guidelines (Gormley et al., 2014) recommend the use of validated symptom questionnaires for patients with OAB such as the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ). These questionnaires were originally developed in 1994, and were among the first to include questions addressing both urinary symptoms and health-related quality of life questions (van der Vaart et al., 2003). However, they were developed from a highly-selective population of women, and though modified and validated more recently in 2003 by van der Vaart et al., these questionnaires remain intended for female patients and focus primarily on incontinence.

Many questionnaires already exist that can be used in research settings. First and foremost, the questionnaire developed here was designed with patients in mind, and for ease of clinician use. The next step, however, was to determine what constitutes an ideal patient questionnaire so that it can be used in practice by primary care clinicians and Urologists.

Literature Review 3: Ideal Patient Questionnaire

Much research has already been done on what constitutes an ideal survey or questionnaire. The purpose of this third literature review was to determine what makes a successful patient questionnaire, and common mistakes to avoid during design.

Methods

To complete this third literature search the following keywords were used in various

combinations: “questionnaire*” or “survey” or “tool” and “ideal” or “design.” These keyword combinations were in the UBC Library Homepage General “search bar” and CINAHL. Searches in CINAHL were narrowed further by limiting the “major subject” to “Questionnaires – methods.” “Questionnaire” and “design” were also specifically searched as being present in the titles of articles. A general search was also completed using these keywords and the phrase “How to Design a questionnaire” at <http://www.google.ca>. Titles of articles, web pages, and books were then scanned for relevance and abstracts of relevant titles were read.

This literature search was more challenging: most articles focused on the development of a specific questionnaire, for example, patient satisfaction on a particular hospital oncology unit. Most articles which discussed the development of particular questionnaires did not address how the questionnaire was actually designed. As such, the majority of articles and books utilized for this third literature search were found after scanning the reference lists of the most relevant pieces of literature. Articles, books, and web-pages were only included if peer-reviewed or published by established academic institutes, and were published since the year 2000. Searching the above databases and websites continued until a point of data saturation was achieved, and overall 15 pieces of literatures were included in this third literature review.

Questionnaire Design

The following represents the most commonly discussed topics in the literature pertaining to questionnaire design and the points most relevant for this manuscript. Caution must be exercised when using available research for health care or patient related questionnaires; for example, many articles focused on achieving a high response-rate from participants when questionnaires are mailed out (Meadows, 2003). Of note, the literature referred to those who fill out questionnaires as “respondents” (versus patients) and those designing questionnaires were

referred to as “researchers.” These terms will be used here.

Using previously validated questionnaires. Various authors advised researchers to complete a thorough literature review on the topic being studied prior to designing a questionnaire, and to determine how relevant concepts have already been measured or studied (Grimmer & Bialocerkowski, 2005; Marshall, 2005). A common and unexpected theme to emerge from the literature was the recommendation to use a previously validated questionnaire, that is, using an “off the shelf” questionnaire when conducting research (Richardson, 2005, p. 48). Using a questionnaire that has already been published and validated has the potential to save time and resources (Booth, 2003; Marshall, 2005). A number of “standard surveys” already exist and have been developed for various studies of human behaviours, including quality of life (Grimmer & Bialocerkowski, 2005). Furthermore, if using a previously validated questionnaire for research purposes, it might be easier to be published and make comparisons across populations and other studies (Booth, 2003; Marshall, 2005; Harrison, 2007). As Harrison (2007) advised, “don’t reinvent the wheel.” Conversely, the decision to develop a new questionnaire should be carefully considered only after thorough assurance that no such questionnaire already exists, and if the decision is made to *not* use an existing questionnaire, this must be justified (Grimmer & Bialocerkowski, 2005; Harrison, 2007; McCoach, Gable, & Madura, 2013; Meadows, 2004). If choosing to use an existing questionnaire, it must be used with the appropriate patient population, intended purpose, and measure the same intended constructs (Richardson, 2005; Song, Son, & Oh, 2015).

Word choice and question length. Another common discussion in the literature on questionnaire design arose regarding wording and language. First, it was stressed that vague, ambiguous words, or words with multiple definitions, should be avoided (Artino, La Rochelle,

Dezee, & Gehlbach, 2014; Grimmer & Bialocerowski, 2005; Harrison, 2007; Leung, 2001; Meadows, 2003; Richardson, 2005). Second, questions should be short, specific, and to the point; it was recommended to keep question length between 12-20 words, or 1-2 clauses (Boynton & Greenhalgh, 2004; Leung, 2001; Marshall, 2005; Meadows, 2003; Song et al., 2015). The longer the question is, the more confusing it is, and the more information respondents must take in the more likely they are to make a mistake (Dillman, Smyth, & Christian, 2014; Harrison, 2007; Song et al., 2015). Third, the use of overly complicated words, medical jargon, or abbreviations can cause confusion (Dillman et al., 2014; Marshall, 2005; Richardson, 2005; Song et al., 2015). Abbreviations that seem obvious to the questionnaire designer may not be obvious to the respondent (Dillman et al., 2014). Dillman et al. (2014) mentioned that a good rule to follow is that a word containing 6 or 7 letters can generally be substituted for a shorter one.

Order of questions and sensitive items. The use of language and words becomes complicated when talking about sensitive topics or asking respondents sensitive questions (examples in the literature included breaking the law or personal medical questions). Using short, brief questions to address sensitive topics can be perceived as threatening or abrupt, while longer sentences may be preferred and elicit more truthful responses (Boynton & Greenhalgh, 2004; Marshall, 2005). Obtaining a truthful answer after asking a sensitive question is difficult and may produce no response at all (Leung, 2001). How someone responds to questions can also be influenced or impacted by previous questions (Harrison, 2007). Thus it is advised to begin questionnaires with general questions that are easier to answer (as the respondent may initially feel unsure about completing the questionnaire) and end with detailed or personal questions (Harrison, 2007; Leung, 2001; Marshall, 2005; McColl, Jacoby, Thomas, & Soutter, 2002;

Rattray & Jones, 2007; Richardson, 2005; Song et al., 2015). There was an overall consensus in the literature to ask sensitive questions near the end of the questionnaire (Harrison, 2007; Marshall, 2005; Meadows, 2003). The rationale for this is that once a respondent has already invested time completing a questionnaire, s/he is unlikely to stop at the end (Marshall, 2005; Richardson, 2005).

Closed- and open-ended questions. Closed-ended questions, also known as forced-choice questions, constitute questions where respondents are offered a list or choices of answers (Dillman et al., 2014; Marshall, 2005; Meadows, 2003; Richardson, 2005). These choices can be ordered or unordered, and vary from marital status, age, level of satisfaction, or 5- to 7- point Likert response scales (Artino et al., 2004; Dillman et al., 2014; Song et al., 2015). Closed-ended questions are easy and quick for respondents to answer (Leung, 2001; Dillman et al., 2014; Fowler, 2009; Meadows, 2003; Song et al., 2015) and when well-designed, they ensure all respondents answer questions in the same way (Harrison, 2007). However, they may cause frustration with respondents if researchers have not considered all possible answers (Boynton & Greenhalgh, 2004). One way to correct this is the use of a partially closed-ended question, which includes a set of answers and an “other” response, allowing participants to specify their own answer if not present (Dillman et al., 2014; Grimmer & Bialocerkowski, 2005).

Another type of question is the open-ended question which allows respondents to answer any way they choose, usually responding within a blank box or space (Dillman et al., 2014; Harrison, 2007; Marshall, 2004; Rattray & Jones, 2007; Richardson, 2005; Song et al. 2015). These types of responses can add richness and depth to information being collected that may have been missed with closed-ended questions (Boynton & Greenhalgh, 2004; Dillman et al., 2014; Fowler, 2009; Harrison, 2007; Leung, 2001; Meadows, 2003). However, respondents tend

to skip open-ended questions because they are time-consuming and require more work and mental analysis to answer (Dillman et al., 2014; Harrison, 2007; McCoach et al., 2013; Richardson, 2005). As such, they should be used sparingly (Dillman et al., 2014; Meadows, 2003). Used in conjunction however, closed- and open-ended questions can improve questionnaire quality. Shifting the format between questions (for example, from open to closed-ended, or between different types of closed-ended questions) versus utilizing only one type of question can not only measure a range of different constructs but adds variety for respondents, maintaining their interest (Dillman et al., 2014; Leung, 2001; Rattray & Jones, 2007). It is considered advisable to vary the question format within a single questionnaire (Dillman et al., 2014; Leung, 2001).

Use of scales in closed-ended questions. The term “scales” refers to the choice of answers in closed-ended questions: mutually exclusive items that are used to assess and quantify the same underlying construct, for example, satisfaction (Dillman et al., 2014). Respondents must determine where to answer along a continuum (Dillman et al., 2014). A 5-point scale may offer answers such as “very dissatisfied,” “somewhat dissatisfied,” “neither satisfied nor dissatisfied,” “somewhat satisfied,” or “very satisfied” (Artino et al., 2004; Boynton & Greenhalgh, 2004; Marshall, 2005). Caution must be taken with the development of scales, particularly when assuming there is an equal interval between choice; in the previous example, it must be assumed that the same amount of satisfaction separates “very satisfied” from “somewhat satisfied” as does “very dissatisfied” and “somewhat dissatisfied” (Dillman et al., 2014). Likert scales assume that the strength, quantity, or intensity of a response is linear and on a continuum (Rattray & Jones, 2007). The use of Likert-type response scales is the most common and popular way to collect information from a questionnaire, for example the well-established and

well-known Likert Scale of Strongly Disagree, Disagree, Not Sure, Agree, Strongly Agree (Artino et al., 2004; McDowell & Newell, as cited in Grimmer & Bialocerkowski, 2005; McCoach et al., 2013; Rattray & Jones, 2007). Scales can be burdensome to develop but can help researchers define a particular concept (McIver & Carmines, as cited in Artino et al., 2004). In general, between 5 and 7 points (or choices) is thought to be best, as using too few reduces the reliability of answers and using too many causes the answers to become ambiguous or lose meaning (Artino et al., 2004; Dillman et al., 2014; Harrison, 2007). Conversely, the use of vague quantifiers can confuse respondents. For example, if a question asking about the frequency of an action (such as episodes of incontinence per day) only offers the choices “never, sometimes, or often,” respondents may feel differently about the quantity that constitutes “often” (Fowler, 2009; Harrison, 2007; Rattray & Jones, 2007).

Proper labelling of scale and response options. Common mistakes regarding the visual labelling of closed-ended questions were frequently discussed in the literature. Questionnaire designers were cautioned against labelling only the beginning and end points of scale choices (leaving the middle options unlabeled) because respondents will interpret unlabeled options differently (Artino et al., 2004; Dillman et al., 2014). Instead, all points should be labelled with clear words and should not include numbers (Artino et al., 2004; Harrison, 2007). Using both numbers and words to label responses, even if the rationale is clear to the researcher, can confuse respondents and increase response time, particularly with the use of negative numbers (Artino et al., 2004; Dillman et al., 2014). The addition of numbers changes how the scale is interpreted (Artino et al., 2004; Dillman et al., 2014). Finally, all items in a visual scale should be evenly spaced, either consistently horizontal or consistently vertical; any unequal visual spacing can attract respondents to choose one particular item over another and can shift the visual “midpoint”

of the scale (Artino et al., 2004; Dillman et al., 2014; Marshall, 2005)

Avoiding double-barreled questions. It was stressed in the literature that respondents have trouble answering questions if the question addresses more than one idea (Artino et al., 2004; Harrison, 2007; Leung, 2001; Marshall, 2005; Bowling, as cited in Rattray & Jones, 2007). Questions should only address one idea at a time, particularly if they require two separate answers (Artino et al., 2004; Harrison, 2007; Leung, 2001; Marshall, 2005; Bowling, as cited in Rattray & Jones, 2007). An example of this is the question “Are you satisfied with the care you received from your doctors and nurses?” as it asks about doctors *and* nurses; respondents may have a different opinion on the care they received from these two health professionals (Meadows, 2003). Questions that contain multiple ideas are called “double-barreled” (if they contain two) or triple-barreled (if they contain three; Dillman et al., 2014; Leung, 2001; Meadows, 2003). The use of multiple items in a question reflects poor question design and can confuse respondents (Grimmer & Bialocerkowski, 2005; Song et al., 2015).

Balancing the use of agreement questions. A phenomenon called “acquiescence” was noted frequently in the literature, and is “the tendency to endorse any assertion made in an item, regardless of its content” (Artino et al., 2004, p. 468; Dillman et al., 2014; Harrison, 2007; Marshall, 2004; Rattray & Jones, 2007; Richardson, 2005). This phenomenon is somewhat culturally based as it is generally easier to agree with someone than disagree (Dillman et al., 2014). These respondents have been referred to as “yea sayers” (Boynton & Greenhalgh, 2004). Asking patients about their level of agreement with a statement is also thought to cause participants to consider their responses less thoroughly (Artino et al., 2004). To combat this, it is advised to alternate between questions asking respondents how much they agree with a statement and how much they agree with a negatively phrased statement, or to use construct-specific items

(Boynton & Greenhalgh, 2004; Leung, 2001; Marshall, 2004; Rattray & Jones, 2007; Dillman et al., 2014; Harrison, 2007; Richardson, 2005).

Length of questionnaire. Although repeatedly discussed in the literature as something to consider, the overall length of a questionnaire does not, surprisingly, have an agreed-upon length (Leung, 2001; McColl et al., 2002; Richardson, 2005). What was stressed instead, however, was to ensure that enough items or questions are present so that the construct can be accurately measured (Artino et al., 2004). That being said, longer questionnaires can potentially lead to carelessness if respondents become fatigued (Leung, 2001; Meadows, 2003), however long questionnaires can be completed successfully if respondents see the value (Richardson, 2005). Regardless, Richardson (2005) recommends confining questionnaires to two pages of A4 sized paper for busy healthcare practitioners.

Development of The OASIS Questionnaire

A brief, patient-completed OAB questionnaire designed solely for outpatient visits that addresses all aspects of OAB care does not exist. Furthermore, no questionnaire described above asked about patients' progress or response to lifestyle modifications, which are often cited as first line treatment for OAB. This reiterates and reinforces the purpose of this manuscript, and after careful consideration of the information obtained from the above literature reviews, the OASIS Questionnaire: Overactive-Bladder Assessment of Symptoms, Interventions, and Satisfaction was developed (see Appendix A). The following considerations were made when designing the questionnaire.

First, the OASIS Questionnaire includes questions addressing each of the four main OAB symptoms, lifestyle/non-pharmacological treatments, medication side effects, quality of life, OAB risks, goals of treatment, current urinary status, and satisfaction with current urinary status

for a total of 14 items. Second, Marshall (2005) describes that the viable alternative to using an existing, published, validated questionnaire is to instead extract items from existing, valid surveys. Though not as time-saving, this approach is more effective than developing a new questionnaire (Marshall, 2005). This approach was taken here. Third, discussing OAB symptoms and/or medication side effects is a sensitive topic and as such these items were placed towards the end of the questionnaire (Harrison, 2007; Leung, 2001; Marshall, 2005; McColl, Jacoby, Thomas, & Soutter, 2002; Rattray & Jones, 2007; Richardson, 2005; Song et al., 2015). Regarding questionnaire length, as patients will likely be filling this out in a busy waiting room with limited time to complete it, the length was maintained at two A4 pages as recommended by Richardson (2005). Additionally, many of the questions adapted from previous questionnaires used scoring systems, and thus Likert responses were accompanied by numbers; indeed, many questionnaires discussed above were scored. The decision was made to not score the OASIS Questionnaire as it is unlikely that busy clinicians will have time to sum a score during each patient visit. Finally, the patient was not asked to answer questions on demographics as it was felt this would potentially jeopardize patient confidentiality if filling it out in a public waiting room. The following is a breakdown of how each question was determined.

Question Design

The purpose of the first question was to obtain a global impression of how the patient's OAB has changed since beginning treatment (either pharmaceutical or non-pharmaceutical). None of the OAB questionnaires discussed in the second literature review asked if the patient felt s/he had improved (the OAB-S asked if the patient felt medication had improved day to day life; Piault et al., 2008). Instead, Question #1 was adapted and modified from the Patient Global Impression of Improvement scale (Yalcin & Bump, 2003). The original question asked patients

to “Check the one box that best describes how your urinary tract condition is now, compared with how it was before you began taking medication in this study” with seven Likert-style responses. It was felt that seven choices might be too many (Artino et al., 2004; Dillman et al., 2014; Harrison, 2007), and so “much better” and “much worse” were eliminated. Finally, “your urinary tract condition” was changed to “your OAB” and “before you began taking medication in this study” was changed to “before you began treatment.” The final version of Question #1 is as follows:

1. Check the one box that best describes how your OAB is now, compared with how it was before you began treatment:

- ☐ Very much better
- ☐ A little better
- ☐ No change
- ☐ A little worse
- ☐ Very much worse

Continuing to ask more general questions at the beginning of a survey or questionnaire, Question #2 was taken from the Patient Perception of Bladder Condition (PPBC). While the first question asked about overall improvement, the second question asks how the patient’s urinary status is presently. This question combines patients’ overall feelings about all aspects of treatment (including symptoms and quality of life) into one question on their current status (Coyne et al., 2006; Matza et al., 2005). The original PPBC question asked about the respondent’s “bladder condition” and thus all instances of this were changed to “OAB.”

Question #2 is as follows:

2. Which of the following statements describes your OAB best at the moment?

- ☐ My OAB does not cause me any problems at all.
- ☐ My OAB causes me some very minor problems.
- ☐ My OAB causes me some minor problems.
- ☐ My OAB causes me (some) moderate problems.
- ☐ My OAB causes me severe problems.

- ☐ My OAB causes me many severe problems.

Questions #3 and #4 addressed quality of life concerns known to face patients with OAB. Specifically, Question #3 was modified from question (7) of the OAB-S questionnaire (Piault et al., 2008). While Question #3 addressed how OAB overall can affect a patient's quality of life, Question #4 was modified and adapted from the King's Health Questionnaire (KHQ). As stated above, patients with OAB are at risk for depression and anxiety, thus question 6A and 6B from the KHQ were modified here. Specifically, the scale response was changed to match the scale used for Question #3, and the term "bladder problem" was changed to "OAB." The final editions of Questions #3 and #4 are as follows:

3. How much do your OAB symptoms interrupt your day to day life?

- ☐ A lot ☐ Moderately ☐ Somewhat ☐ A little ☐ Not at all

4. Does your OAB ever affect your emotions, for example making you feel depressed or anxious?

- ☐ A lot ☐ Moderately ☐ Somewhat ☐ A little ☐ Not at all

Question #5 was modified from the Self-Assessment Goal Achievement (SAGA) questionnaire. Again, as patients often have unrealistic expectations about their treatment for OAB (Corcos, 2015; Ellsworth, 2013a; Ellsworth, 2013b; Ellsworth, 2014; Henderson & Drake, 2010; Hou & Zimmern, 2015), it was important to include a question addressing patient-specific goals on this questionnaire. Question #5 is the only open-ended question, and is as follows:

5. Though OAB cannot be cured, it can be managed. What is one goal you have for your OAB treatment?

Question #6 was adapted from the "Global assessment of treatment benefit, satisfaction with treatment, and willingness to continue treatment" (BSW) questionnaire. Specifically, the second BSW question regarding "Satisfaction" was utilized here. The original BSW

questionnaire was designed to be administered by an interviewer and focused on treatment satisfaction and read: “Taking all things into account, are you satisfied with your treatment?” It was therefore adapted with the intent to be self-completed by patients. The term “treatment” was changed to “OAB.” Question #6 is as follows:

6. Taking all things into account, are you satisfied with how your OAB is now?

If YES, are you:

- ☐ A little satisfied
☐ Very satisfied

If NO, are you:

- ☐ A little dissatisfied
☐ Very dissatisfied

Question #7 is an original question, as no previous OAB questionnaire mentioned lifestyle modifications or behavioural treatments for OAB. As these were frequently discussed in the literature as either first line treatment, or to be used in combination with medication as first line treatment, it was felt to be important to address. The five lifestyle modifications discussed in this question were adapted from Newman (2011). Furthermore, as lifestyle modification have proven benefit with little risk involved, patients were prompted to ask about these treatments.

Question #7 reads as follows:

7. Lifestyle modifications can help with urinary symptoms. Please check all that you have tried. *If you would like more information on the following topics, please ask your healthcare provider.*

- | | | | | |
|---|---------------------------------------|--------------------------------------|--|--|
| <input type="checkbox"/> Physical therapy | <input type="checkbox"/> Stop smoking | <input type="checkbox"/> Weight loss | <input type="checkbox"/> Monitoring fluid intake | <input type="checkbox"/> Avoiding foods and drinks that irritate the bladder |
|---|---------------------------------------|--------------------------------------|--|--|

Questions #8-12 were taken from the OAB-q short form edition (OAB-q SF), specifically, questions 1-6 regarding the symptom bother scale. These questions ask the patient about nocturia, frequency, urgency, and urge incontinence (without using those specific medical jargon terms). Furthermore, the visual layout of this question allows the clinician to quickly assess the patient’s most bothersome symptom(s). The only change was that question 4 from the

OAB-q SF was deleted as it was felt to be similar to question 5, and was deleted for the sake of saving space. The timeline of 4 weeks was felt to be appropriate and thus was not modified.

Questions #8-12 are as follows:

Questions 8-12 ask about how bothered you have been by bladder symptoms over the past 4 weeks. Please answer every question as best you can.

<i>During the past 4 weeks, how bothered were you by...</i>	Not at all	A little bit	Some-what	Quite a bit	A great deal	A very great deal
8. An uncomfortable urge to urinate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. A sudden urge to urinate with little or no warning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Accidental loss of small amounts of urine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Waking up at night because you had to urinate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Urine loss associated with a strong desire to urinate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Question #13 was designed as a safety question to monitor patients with OAB for the presence of a UTI, which they can be at risk for. The question was taken from Culligan and Heit (2000) who discussed key questions that should be asked when evaluating patients for the presence of urinary incontinence. Nevertheless, it is relevant here. The Likert response scale adapted for this question was taken from Artino et al. (2004). Question #13 is as follows:

13. Does it hurt when you urinate?

- ☐ Almost never
- ☐ Once in a while
- ☐ Sometimes
- ☐ Often
- ☐ Almost always

The final question addressed medication side effects, and was intentionally ordered last given its sensitive nature. If patients are not taking medication, this also avoids the confusion that can accompany skipping questions. It was adapted from question 8 of the OAB-S questionnaire (Piault et al., 2008). The original question asked “Since you started your medication, how much have you been bothered by each of the following side effects?” “Since you started” was changed to “in the past 4 weeks” to remain consistent with Questions #8-12. Question #14 is as follows:

14. In the past 4 weeks, how much have you been bothered by each of the following medication side effects? *Please skip this question if you do not take medication.*

	I did not have this side effect	It bothered me a lot	It bothered me moderately	It bothered me somewhat	It bothered me a little	It did not bother me at all
Constipation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dry Mouth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Drowsiness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Headache	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nausea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Blurry Vision	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Future Directions and Conclusion

This questionnaire will be presented as part of an oral presentation at the annual 2017 Graduate Students in Nursing Association (GSNA) student research symposium. The purpose of this presentation will be to distribute the questionnaire and receive feedback from other health care professionals. Next steps for this project also include distributing the OASIS Questionnaire to Urologists and primary care practitioners for feedback on its use in clinical practice. Taking this further, research could be done to demonstrate the OASIS Questionnaire’s responsiveness to

treatment. For example, the OASIS Questionnaire could be administered to patients in a research setting along with the OAB-q (with established validity and responsiveness) to determine if the OASIS also had any of these psychometric properties.

The OASIS Questionnaire was designed to be patient-centered, allowing patients to easily track their progress throughout treatment, with real-world intent to be filled out in a busy clinician's office. It was also designed with busy physicians, nurse practitioners, and specialists in mind, to allow these professionals to quickly assess the progress and status of their patients with OAB. It is hoped that this questionnaire will improve the lives of patients and clinicians alike. The field of Urology is of personal interest to this author, who hopes to use this questionnaire in practice after graduation.

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Appendix A

The OASIS Questionnaire
Overactive-Bladder Assessment of Symptoms, Interventions, and Satisfaction

This questionnaire will help monitor your overactive bladder (OAB) condition over time.

Please take the time to answer each question.

- 1. Check the one box that best describes how your OAB is now, compared with how it was before you began treatment:**

- ☐ Very much better
☐ A little better
☐ No change
☐ A little worse
☐ Very much worse

- 2. Which of the following statements describes your OAB best at the moment?**

- ☐ My OAB does not cause me any problems at all.
☐ My OAB causes me some very minor problems.
☐ My OAB causes me some minor problems.
☐ My OAB causes me (some) moderate problems.
☐ My OAB causes me severe problems.
☐ My OAB causes me many severe problems.

- 3. How much do your OAB symptoms interrupt your day to day life?**

- ☐ A lot ☐ Moderately ☐ Somewhat ☐ A little ☐ Not at all

- 4. Does your OAB ever affect your emotions, for example making you feel depressed or anxious?**

- ☐ A lot ☐ Moderately ☐ Somewhat ☐ A little ☐ Not at all

- 5. Though OAB cannot be cured, it can be managed. What is one goal you have for your OAB treatment?**

- 6. Taking all things into account, are you satisfied with how your OAB is now?**

If YES, are you:

- ☐ A little satisfied
☐ Very satisfied

If NO, are you:

- ☐ A little dissatisfied
☐ Very dissatisfied

- 7. Lifestyle modifications can help with urinary symptoms. Please check all that you have tried.**

If you would like more information on the following topics, please ask your healthcare provider.

- ☐ Physical therapy ☐ Stop smoking ☐ Weight loss ☐ Monitoring fluid intake ☐ Avoiding foods and drinks that irritate the bladder

Appendix A Continued

The OASIS Questionnaire
Overactive-Bladder Assessment of Symptoms, Interventions, and Satisfaction

Questions 8-12 ask about how bothered you have been by bladder symptoms over the past 4 weeks.

Please answer every question as best you can.

<i>During the past 4 weeks, how bothered were you by...</i>	Not at all	A little bit	Some-what	Quite a bit	A great deal	A very great deal
8. An uncomfortable urge to urinate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. A sudden urge to urinate with little or no warning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Accidental loss of small amounts of urine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Waking up at night because you had to urinate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Urine loss associated with a strong desire to urinate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. Does it burn or hurt when you urinate?

- ☐ Almost never
- ☐ Once in a while
- ☐ Sometimes
- ☐ Often
- ☐ Almost always

14. In the past 4 weeks, how much have you been bothered by each of the following medication side effects? Please skip this question if you do not take medication.

	I did not have this side effect	It bothered me a lot	It bothered me moderately	It bothered me somewhat	It bothered me a little	It did not bother me at all
Constipation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dry Mouth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Drowsiness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Headache	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nausea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Blurry Vision	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>