

Development and validation of a short, easy-to-use questionnaire for diagnosing urinary incontinence and lower urinary tract symptoms in women: the Female Urinary Symptom Score

Ann Wagg University of Hertfordshire, Dr M O Wallis & Partners, Stevenage, UK, **Duncan Barron** HertNet/CRIPACC, University of Hertfordshire, Hatfield, UK, **Mike Kirby** Hertfordshire Primary Care Research Network Consortium (HertNet), The Nevells Road Surgery, Letchworth, UK and **Kate Corlett** Hanscombe House Surgery, Hertford, UK

We have developed the Female Urinary Symptom Score (FUSS), a symptom questionnaire for the evaluation of urinary incontinence and lower urinary tract symptoms in women and their effect on quality of life. The FUSS is a modified version of the International Prostate Symptom Score adapted for use in women. It consists of a simple questionnaire of only eight questions, which patients can answer quickly on a numerical scale. We performed a validation study of the FUSS by comparing it with the King's Health Questionnaire (KHQ), a well-validated but longer symptom questionnaire. We sent both questionnaires to 220 women between the ages of 45 and 65 years randomly selected from two general practices in the United Kingdom. Urinary symptom status was unknown; 149 (94%) of the FUSS questionnaires and 115 (73%) of the KHQs were completed correctly. Correlation was conducted on the scores of the 115 matched pairs and was high ($r = 0.83$). We sent another copy of the FUSS questionnaire to the same group of women after four weeks, and found that the test and re-test scores for FUSS were highly correlated ($r = 0.88$). We conclude that the FUSS is a simple, reliable and reproducible tool for the diagnosis of urinary symptoms in women. As it is brief, we believe that it will be useful in the primary care setting, enabling women to receive appropriate treatment and care as early as possible.

Key words: continence; questionnaire; women

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Introduction

Urinary incontinence is a common problem in middle-aged and older women. It is defined by the

Standardization Committee of the International Continence Society as, 'the complaint of any involuntary leakage of urine' (Abrams *et al.*, 2002). The Society also defines urinary storage symptoms as urgency, frequency and nocturia, as well as leakage (Abrams *et al.*, 2002). These can be distressing and debilitating, with a significant impact on a patient's quality of life. In addition the similar symptoms of overactive bladder are a major problem for

Address for correspondence: Ann Wagg, Senior Practice Nurse, University of Hertfordshire, Dr M O Wallis & Partners, 5 Stanmore Road, Stevenage SG1 3QA, UK. Email: ann.wagg@btinternet.com

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patients and healthcare providers across the globe and recently large epidemiological studies have produced remarkably consistent data on the prevalence of overactive bladder and the impact on quality of life (Milsom *et al.*, 2001; Stewart *et al.*, 2003; Hunskaar *et al.*, 2004).

Overall, it has been estimated that two to three million individuals in the United Kingdom are affected by urinary incontinence (Royal College of Physicians, 1995) and that half a million people over the age of 40 in the United Kingdom have urinary symptoms that are clinically significant, bothersome and socially disabling (Perry *et al.*, 2000). A large postal survey of 10 116 men and women aged over 40 years found that 20% of women had clinically significant urinary incontinence, defined as having symptoms at least several times a month. Only 9% of men had similar symptoms. In women, the prevalence of incontinence was highest in those in their early fifties, before declining in the women in their sixties and rising again in those over 75 years of age (Perry *et al.*, 2000). A number of other studies have estimated the prevalence of urinary incontinence in women of different age groups in the United Kingdom, reporting prevalences ranging from 8% to 58% (Burgio *et al.*, 1991; Brocklehurst, 1993; Perry *et al.*, 2000).

A recent postal survey involving women in almost 30 000 households in four European countries confirmed that this problem is not confined to the United Kingdom (Hunskaar *et al.*, 2004). Incontinence prevalence rates were 23% in Spain, 41% in Germany, 42% in the United Kingdom and 44% in France. Among the women in the United Kingdom, the most prevalent symptom was stress urinary incontinence, either in isolation or in combination with urge incontinence, being reported by 75% of the women with incontinence at all ages.

The scale of the problem and its financial and social impact has only recently been appreciated. Despite recent publicity campaigns and the distribution of comprehensive guidelines on the detection and management of urinary incontinence, many cases remain undetected in older adults (Department of Health, 2001). The financial implications of incontinence are considerable. The annual cost to the National Health Service for urinary storage symptoms is estimated at £536 million per year, equivalent to 1% of the total National Health Service's budget (Turner *et al.*, 2004). In

addition, sufferers themselves spend £207 million per year (Turner *et al.*, 2004). Those with incontinence problems often buy incontinence pads themselves rather than asking for help and must bear the cost of extra laundering and clothing (Royal College of Physicians, 1995). In addition, the psychological costs to an individual with incontinence should not be underestimated. Many people may feel restricted in social activities and employment, sometimes to the point of exclusion, and many do not seek medical attention due to embarrassment or a false assumption that incontinence is an inevitable consequence of age or childbirth (Burgio *et al.*, 1994; Fultz *et al.*, 2003; Kinchen *et al.*, 2003; Hunskaar *et al.*, 2004).

A number of different symptom questionnaires have been developed to detect urinary incontinence and assess the impact it has on a patient's quality of life, including the King's Health Questionnaire (KHQ) (Kelleher *et al.*, 1997), the Bristol Lower Urinary Tract Symptom Questionnaire (Jackson *et al.*, 1996) and the Urogenital Distress Inventory and Incontinence Impact Questionnaire (Shumaker *et al.*, 1994). Although well validated, the time taken to complete these questionnaires and calculate the scores precludes their use in primary care. They attempt to measure the severity of symptoms and have the advantage of being non-invasive, inexpensive and, usually, self-administered. However, many questionnaires are long and time-consuming to complete or have not been validated. Others, such as the Nottingham Health Profile (NHP) (Hunt and McEwen, 1980) are too generic, difficult to interpret and not sensitive enough to identify specific conditions such as incontinence (Kind and Carr-Hill, 1987). Similarly, although Barber *et al.* (2005) found that short forms of two questionnaires (PFDI-20 and PFIQ-7) designed to assess quality of life in women with pelvic floor disorders were valid, reliable and responsive, they cover not only urinary incontinence, but also pelvic organ prolapse and faecal incontinence.

Although current guidelines recommend the identification of urinary symptoms in primary care (Department of Health, 2000; Thakar and Stanton, 2000), there is no appropriate tool for use in this setting, where consultations are usually brief. All questionnaires assessed were at least two pages in length, some longer. A responsive tool that can assess symptoms and record quality of life, but which can fit within the short time limits of a

primary care consultation is therefore needed. The ideal tool needs to be easy and quick to complete, but must yield accurate information. In addition, urinary symptoms may not be discussed in a consultation due to the patient's embarrassment or belief that her symptoms are not severe enough to merit attention. Availability of questionnaires in the waiting room may provide the trigger for the patient to self-assess and seek help.

We have developed a tool for use in primary care, called the Female Urinary Symptom Score (FUSS). This is an adapted version of the International Prostate Symptom Score (IPSS) (Barry *et al.*, 1992) that is modified for use in women. The IPSS was developed by the American Urological Association to evaluate the impact and severity of urinary tract symptoms in men with benign prostatic hyperplasia. The IPSS meets the criteria of being easy and quick and yielding accurate information and has been used successfully in women. However, it was not designed for women who do not have obstructive symptoms or intermittency (Desgrandchamps *et al.*, 1996). The aim of the present study, therefore, was to validate a female-specific version of the IPSS, the FUSS, in order to assess its relevance for use in primary care. Ethical approval was obtained from the local Research Ethics Committee.

A summary of the findings of this validation study has been published previously (Kirby *et al.*, 2006).

Methods

Development of the FUSS instrument

We developed the FUSS by adapting the IPSS to provide a short and easy-to-use questionnaire to assess urinary incontinence and lower urinary tract symptoms (LUTS) in women, as well as their effect on quality of life (Table 1).

The IPSS consists of eight Likert-type questions, graded on a five-point scale, to assess obstructive and irritative symptoms. The quality of life effect is assessed with a single question. We replaced two of the questions in the IPSS that deal with intermittency and weak stream with questions relating to stress incontinence and urge incontinence. Intermittency and weak stream are generally associated with obstruction which is mostly reported by men (Desgrandchamps *et al.*,

1996), while stress and urge incontinence are two of the most commonly reported voiding disorders in women (Perry *et al.*, 2000). A study comparing the unadapted IPSS in men and women found that men tended to score higher on the questions linked to obstructive symptoms, whereas intermittency and weak stream are rare symptoms in women; however they score higher for frequency and urgency (Chai *et al.*, 1993). Permission to adapt the questionnaire was obtained from the original author (O'Leary, 2000). We chose to change two questions following a discussion between continence advisors and general practitioners, in order to make the questionnaire more relevant to women with LUTS.

Question 3 was, 'over the past month or so, how often have you found you stopped and started again several times when you urinated?' This was replaced with, 'over the past month, how often have you lost urine on laughing, coughing or sneezing?' This was designed to detect stress incontinence.

Question 5 was, 'over the past month or so, how often have you had a weak urinary stream?' This was replaced with, 'over the past month, how often have you leaked urine before reaching the toilet?' This was designed to detect urge incontinence.

The FUSS (Table 1) consists of six questions that assess urinary symptoms, scored on a scale of zero to five. The total score on these six questions is used to grade the severity of symptoms into the following categories: mild (0–7), moderate (8–19) and severe (≥ 19). The responses to individual questions can also be used to differentiate between the symptoms of stress and urge incontinence and other storage symptoms, such as frequency, urgency and nocturia. A further question assesses the effect of symptoms on quality of life on a six-point scale. This provides information on the impact of the urinary symptom score on quality of life and gives an indication of the bother caused by the symptoms.

A focus group was held consisting of eight female patients to gain their views on the usefulness and acceptability of the questionnaire to help inform the development of the FUSS. The facilitator utilized a semi-structured schedule and transcripts were analysed for emerging themes. The conclusion was that the FUSS was a useful tool. The women were selected at random from a general practice, and their urinary status was unknown.

Table 1 The FUSS

Patient identification							
Date	Not at all	Less than one time in five	Less than half the time	About half the time	More than half the time	Almost always	Fill in your score
1. Incomplete emptying							
Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5	
2. Frequency							
Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
3. Stress incontinence							
Over the past month, how often have you lost urine on laughing, coughing or sneezing?	0	1	2	3	4	5	
4. Urgency							
Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5	
5. Urge incontinence							
Over the past month, how often have you leaked urine before reaching the toilet?	0	1	2	3	4	5	
6. Straining							
Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	
	None	Once	Twice	Three	Four times	Five times or more	
7. Nocturia							
Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5	
Total score							
	Delighted	Pleased	Mostly satisfied	Mixed	Mostly dissatisfied	Unhappy	Terrible
Quality of life due to urinary symptoms							
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that? (Please circle appropriate number)	0	1	2	3	4	5	6

Adapted from the IPSS (Barry *et al.*, 1992)*Primary Health Care Research & Development* 2007; **8**: 243–250

Validation of FUSS

We sent the FUSS questionnaire (Table 1) and the KHQ to 220 women aged between 45 and 65 years. The KHQ is a condition-specific tool for the assessment of LUTS and the effect on quality of life in women (Kelleher *et al.*, 1997; Reese *et al.*, 2003). It has questions across eight domains and a symptom severity scale. The National Institute for Health and Clinical Excellence (2006) found good evidence for test-re-test reliability for both symptom scoring and quality of life and it was recently used to evaluate a simple urinary symptom questionnaire published in the European Urology Journal (Basra *et al.*, 2006).

One hundred and ten women in the study age range were randomly selected from each of the two general practices in the United Kingdom. One practice was in a large town and the other was in a semi-rural smaller town. Total scores on each instrument were compared for each woman and results from the two tests were correlated using Spearman's rho correlation.

We sent each woman the FUSS questionnaire again four weeks later, in order to assess the re-test reliability of the tool. Total symptom scores from the women who returned both FUSS questionnaires were correlated using Spearman's rho correlation.

Results

Of the 220 women who were sent the FUSS questionnaire and the King's Heath Questionnaire, 158 (72%) returned both. The FUSS questionnaire was completed more fully than the KHQ: 149 (94%) of the FUSS questionnaires and 115 (73%) of the KHQs were completed fully.

Correlation between the total scores of the two questionnaires was high in the 115 women who returned both ($r = 0.83$, $P < 0.001$). Individual correlation coefficients between similar items on the questionnaires are given in Table 2. They ranged from 0.56 for urgency to 0.86 for stress incontinence. Quality of life could not be compared between questionnaires, as there is no single quality of life score in the KHQ, although several questions relate to quality of life.

Of the 158 women who were sent the FUSS a second time, 137 (87%) responded; 131 (96%) of the returned questionnaires were filled in completely.

Table 2 Correlation coefficients for symptoms in the KHQ and the FUSS questionnaire

Symptom	Correlation coefficient (r)
Frequency	0.60
Stress incontinence	0.86
Urgency	0.56
Urge incontinence	0.64
Nocturia	0.64
Overall	0.81

Table 3 Distribution of scores on the FUSS questionnaire during the test and re-test

FUSS score	Symptom severity	Test, n (%)	Re-test, n (%)
0–7	Mild	95 (60)	85 (62)
8–18	Moderate	53 (33)	43 (32)
≥19	Severe	10 (7)	9 (6)
	Total	158 (100)	137 (100)

The distributions of the total FUSS scores in the test and re-test are shown in Table 3.

At re-test, 103 (79%) of the 131 women were placed in the same category as on the first test. Moreover, all the transfers were to the adjacent category. Thus 71 (91%) of the 78 patients whose first test was classified as 'mild' were allocated to 'mild' on re-test, and the remainder were allocated to 'moderate'. Similarly, all of the individuals who were categorized as 'mild' at re-test had either 'mild' (88%) or 'moderate' (12%) symptoms at the first test. There were no cases where an individual moved from 'mild' to 'severe' or vice versa. The correlation between total scores was high ($r = 0.88$, $P < 0.001$). Individual correlation coefficients for symptoms in the test and re-test are given in Table 4, ranging from 0.56 for straining to 0.89 for quality of life.

Findings from the focus group revealed that none of the eight women had difficulty in understanding the questions comprising the FUSS. One woman felt that the use of a total score meant it would be unclear where a specific problem lay but was happy after it was explained that the score would not be viewed in isolation by the health care professional. Another woman commented that the quality of life terminology was extreme, with 'delighted' and 'terrible' at either end of the quality

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Table 4 Correlation coefficients for symptoms in the test and re-test of the FUSS

Symptom	Correlation coefficient (<i>r</i>)
Incomplete emptying	0.75
Frequency	0.74
Stress incontinence	0.79
Urgency	0.72
Urge incontinence	0.81
Straining	0.56
Nocturia	0.60
Quality of life	0.89
Overall	0.88

of life scale. No other problems were noted. The women felt that it would be reasonable to receive the questionnaire through the post and that they would have completed and returned it. They also felt that they would complete the questionnaire in the surgery if necessary, and that it would be used to diagnose symptoms.

Discussion and conclusions

The FUSS questionnaire is a short, easy-to-use questionnaire that can be used to assess urinary symptoms in women. Our results show that the questionnaire is acceptable and easily understood by women, and that it gives results that are well correlated with the KHQ in a cohort of 115 women. The KHQ is a multi-item severity score which includes all the items in Table 4 and correlation was above 0.5 in all cases. Test–re-test analysis also demonstrated that the questionnaire is reproducible, since answers were well correlated across the sample after a delay of one month.

The KHQ includes 21 questions relating to symptoms of urinary incontinence and their impact on quality of life in eight domains plus a severity scale (Kelleher *et al.*, 1997). In a study of 239 women referred for urinary investigations, the questionnaire was shown to be valid for the assessment of quality of life in women with urinary incontinence (Reese *et al.*, 2003). Although shorter than similar tools, such as the Bristol Female Lower Urinary Tract Symptoms questionnaire (Jackson *et al.*, 1996), it is still four pages long. Consequently, its use is generally restricted to specialist clinics, where it is given to the patient to complete before seeing the specialist. In contrast, the FUSS questionnaire consists of only eight

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questions, which are answered simply on a numerical scale. As the FUSS is only one page in length, it can be completed more quickly than the KHQ. The FUSS questionnaire therefore has the potential to be a more useful tool for use in primary care consultations. We believe that this questionnaire can be used widely to provide a valid and simple way to case-find and assess LUTS in women. Primary care professionals would then have an opportunity to offer the patient appropriate investigation and treatment.

One drawback of the FUSS questionnaire may be its use of a single question to assess quality of life, which could lead to an over- or underestimation of the impact of symptoms. Also quality of life related to symptoms will change depending on status at the time. However consistency and validity for the individual patient allows the health care professional to assess the amount of bother caused and the consequent effect on quality of life related to LUTS.

A number of other tools have been developed for the assessment of urinary symptoms in women. For example, Resnick *et al.* (1994) developed a questionnaire that evaluates faecal and urinary incontinence, but not other forms of LUTS such as frequency or their effect on quality of life. Bo (1994) designed two instruments to evaluate female stress incontinence and its impact on social activity. One presented thirteen situations where leakage might occur, such as on coughing or sneezing, while the second listed nine social activities that might be affected by the possibility of leakage, such as aerobics. Similar tools include the Urological Distress Inventory and Incontinence Impact Questionnaire (Shumaker *et al.*, 1994), which have been used in combination to determine the effect incontinence has on quality of life. Although these tools have good reliability and validity and are highly recommended (Naughton *et al.*, 2004), their length may preclude their use in primary care.

Jackson *et al.* (1996) developed the Bristol Female Lower Urinary Tract Symptoms questionnaire, which is comprehensive and has good psychometric validity and reliability. However, it is 12 pages long, so would have a significant impact on consultation time. This would be problematic in the primary care environment. Swithinbank *et al.* (1999) used this questionnaire in a postal survey of women over 18 years of age in a large British city,

achieving an 80% response rate. This suggests that this tool may be useful when it can be completed at home, but it is too long to be used in the primary care setting. In contrast to the FUSS questionnaire, many assessment tools suffer from a lack of validation, excessive length or a failure to include questions on quality of life.

The range of tools available and lack of a clear definition of incontinence has complicated the studies reporting the prevalence of urinary symptoms in women. Coupled with reluctance by patients to report symptoms, the use of a variety of different tools has contributed to the wide variation in the prevalence of urinary symptoms reported in different studies (Thom, 1998; Cheater and Castleden, 2000). We therefore believe that the FUSS questionnaire will be a useful research tool. Indeed, we are conducting an intervention study using the FUSS questionnaire to identify women with urinary incontinence, LUTS and impaired quality of life due to their urinary symptoms in general practice in the United Kingdom.

Implications for practice:

- The FUSS is a rapid, simple questionnaire to assess urinary symptoms and their effect on quality of life in women.
- The FUSS is a useful tool for use in primary care, since it provides a measure of urinary symptoms and incontinence, and is quick to complete, reliable and reproducible.

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