THE CHALLENGES ENCOUNTERED WITH DEVELOPING A VALID AND RELIABLE URINARY CONTINENCE ASSESSMENT FORM

ABSTRACT
The purpose of this study was to develop and validate a concise continence assessment form that can be completed by patients.

A prospective, descriptive, multi-site study was conducted at three major teaching hospitals over a 6 month period utilising a repeated measure design. The study was conducted over two stages: Stage One consisted of developing the face validity and user friendliness of the instrument; Stage Two consisted of establishing the test-retest reliability of the instrument.

This paper discusses the process and results of the instrument development project. It highlights the clinical and statistical difficulties experienced in the development of the continence assessment form.

INTRODUCTION
Incontinence is a complex, multi-factorial problem that requires in-depth patient assessment in order to determine appropriate treatment. Anecdotal information from a group of nursing continence care specialists indicated that the type of patient assessments conducted and information gathered varied across settings.

This variation in patient assessments and information gathered is problematic. Specifically, it tends to limit treatment outcome comparisons being made across sites because of the lack of comparable data collected using valid and reliable measurement scales. Given that the assessment of patients' continence status pre- and post-treatment provides a gauge for evaluating treatment outcomes, the use of a valid and reliable assessment form would ensure consistency in measuring patient progress and provide a means to test treatment efficacy and to develop evidence-based practice.

There are a number of limitations with current assessment forms. Specifically, streamlined assessment forms developed by Sampelle and colleagues 1 and Gunthorpe, Brown & Redman 3 provide valid and reliable instruments, but they are limited in that they only assess urinary incontinence in women and have not been tested on men. Other assessment forms used in studies are limited in that their developers have only established content validity and not instrument reliability 1-3.

Another item that needs to be considered in continence assessment is determining the level of bother caused by the symptoms experienced by the patients. It would seem that the development of any continence assessment form should include both patient symptoms and patients' bother/concern levels 5.

Developing a continence assessment form is a challenging exercise as continence is often a complex problem that can have a number of symptoms. It is important to ask the right questions that will assist with determining diagnosis and treatment. Given that hospitals are busy work environments, it would seem that the development of an instrument that can be completed by patients would be useful as it would assist continence nurses timewise and allow patients time to reflect on the level of symptoms and the degree of bother they pose.

There are a number of factors that need to be considered in the development of a self-administered continence assessment instrument. These include selecting appropriate assessment items to be included that will support accurate diagnosis and treatment, and ensuring that the measurement of these variables is reliable.

Objectives
The objectives of the study were to develop and validate a concise Continence Symptorns Assessment Form 6 (Form) that
can be completed by patients and to determine the reliability of the Form on a group of incontinent patients attending hospital outpatient clinics.

PATIENTS AND METHODS

Research design

A prospective, descriptive, multi-site study was conducted at three major teaching hospitals over a 6 month period utilising a repeated measure design. The study was conducted over two stages: Stage One consisted of developing the face validity and user friendliness of the instrument; Stage Two consisted of establishing the test-retest reliability of the instrument.

The study commenced after it was approved by three institutional Ethics Committees. The sample consisted of patients who were over 18 years of age, able to understand conversational English, and who had been referred to the clinical nurse specialist’s continence clinics in three teaching hospitals. Sixty patients from the three sites participated in Stage One of the study. Stage Two involved 170 consecutive patients who met the selection criteria and consented to participate in the study.

Procedure

Stage One

The Form was developed and based on expert opinions and items identified in the literature (Appendix A). Content validity was further established using a panel of continence (n=4) and research (n=2) authorities. To establish the user friendliness of the Form, a convenience sample of 60 patients who experienced continence problems were asked to complete both the Form and a questionnaire commenting on the Form’s clarity, ease of completion and length of time required to complete. Items found to be difficult to complete by the 60 patients were revised.

Stage Two

The reliability of the Form was conducted using test-retest methodology. Patients who were referred to the continence outpatient clinics were sent a plain language statement, the consent form and a Form 2 weeks prior to their scheduled clinic appointment and asked to return them via reply paid envelope.

On attending their clinic appointment, consenting patients were asked to complete another Form. At this first appointment, the continence nurse specialist assessed the patients to determine whether their condition had remained unchanged since filling in the Form at home. Only patients whose symptoms levels were consistent and chronic in nature were included in the study (n=170). Demographic information (e.g. age, gender, medical diagnosis) was obtained from the unit medical record of each patient.

Instrument

The Form consisted of 13 items that glean information on frequency, occurrence, amount of urine and faecal leakage experienced and level of bother. The items were developed from the literature and modified by an expert panel of continence consultants. For each item, patients were asked to rate the severity of the symptom experienced in terms of how bothersome it is. The five responses for each item were ‘no problem’, ‘slight problem’, ‘moderate problem’, ‘serious problem’ or ‘don’t know’. This paper focuses on the measurement of the urinary symptoms only.

Data analysis

Data were analysed using the Statistics for Social Sciences (SPSS) for Windows software package. Forms were matched through the use of numerical codes for patients involved in Stage Two of the study. The Form was tested for both reliability and validity using Cronbach’s Alpha to measure internal consistency. Test-retest analysis was also performed to assess the stability of the instrument over time. Only the urinary incontinence assessment section of the Form is reported in this study as there were less than seven participants who reported problems with faecal incontinence which is an inadequate sample size for determining test-retest reliability.

RESULTS

Stage One

Sixty three patients completed and returned the questionnaire regarding the Form. Results showed that 87% of patients (n=55) stated they found the Form easy to understand. However, responding to another question, 29% (n=18) stated they required assistance with filling in the Form. When asked how long it took to complete, 73% of patients stated less than 10 minutes. With regard to content validity, only 1% percent of questions had missing data and each of these were reviewed by the expert panel and revised accordingly. The following changes were made to the pilot Form:

- On the How much of a problem is this for you? questions, a ‘don’t know’ response was inserted throughout the Form.
- Question 2 was re-worded from How long are you able to hold on before having to go to the toilet? to How long after you get the urge are you able to hold on before having to go to the toilet during the day?

The modified Form was piloted again on a smaller sample of patients (n=10) from the continence outpatient clinics. Results showed that all items were completed with no comments made by patients relating to ambiguity. Based on these findings, the researchers proceeded with Stage Two of the study.

Stage Two

The total sample for Stage Two consisted of 170 patients aged between 18 and 96 years with a mean age of 65 years. Female
patients outnumbered males (74% vs 26%) and the majority of respondents were aged pensioners/retirees (69%).

Urinary incontinence symptoms were categorised as those experienced during the day and those experienced during the night (Table 1). For several items, patients were also asked to rate on a bother scale the impact of the incontinence symptom (Table 2).

Reliability
Internal consistency for the urinary scales was undertaken using Cronbach’s Alpha. The urinary incontinence scale consisted of items 1 to 9 inclusive of the ‘bother questions’. Additionally, items 2 and 7, which were negatively coded, were recoded before analysis was undertaken. An Alpha of 0.91 was achieved for the urinary incontinence scale. Test-retest was also undertaken using Spearman’s rho correlation coefficient and Kappa Statistic (Question 3) to assess the degree of stability of scores between measurement periods (Table 3).

DISCUSSION
This study attempted to develop a valid, reliable and user-friendly continence assessment form that was self-administered. Such a form, if proved successful, could provide a means by which to measure the efficacy of continence interventions and detect changes in continence status of patients being treated in outpatient continence clinics.

Although the instrument developed in this study was rated high in terms of face validity and user-friendliness and met the needs of the continence nurse specialists, it revealed poor test-retest scores on most items. Only three items on the urinary incontinence section met the 0.70 criterion for temporal stability. These were ‘How long after you get the urge are you able to hold on before having to go to the toilet in the day? During the day do you experience urine loss and How many times do you pass water/pee at night? The results of the internal consistency of the scale were encouraging as they indicate that the items assessed related to each other and patients’ responses obtained at the same time correlated highly with each other. It is recommended that these items should form the basis of any continence assessment form.

Interestingly, the continence nurse specialists who were part of the research team stated that the Form enhanced the assessment process as patients had time to reflect on the types of symptoms they were experiencing prior to being assessed. It may be useful for continence nurse specialists to consider using a self-administered assessment form for continence patients as it could enhance the assessment process because patients are given time to reflect more closely on their levels of symptoms.

While the overall findings of this study are disappointing in terms of the Form’s test-retest reliability, it does illustrate that

Table 1. Frequency and percentage of urinary incontinence symptoms experienced by patients during the day and night time.

<table>
<thead>
<tr>
<th>Day time</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micturition*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 6 times per day</td>
<td>71</td>
<td>44</td>
</tr>
<tr>
<td>≥ 7 times per day</td>
<td>91</td>
<td>56</td>
</tr>
<tr>
<td>Controlling urge*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can’t hold on</td>
<td>47</td>
<td>30</td>
</tr>
<tr>
<td>≤ 5 minutes</td>
<td>60</td>
<td>38</td>
</tr>
<tr>
<td>6–10 minutes</td>
<td>21</td>
<td>13</td>
</tr>
<tr>
<td>11–20 minutes</td>
<td>14</td>
<td>9</td>
</tr>
<tr>
<td>≥ 21 minutes</td>
<td>17</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Able to reach the toilet without wetting oneself</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>16</td>
<td>13</td>
</tr>
<tr>
<td>Mostly</td>
<td>55</td>
<td>43</td>
</tr>
<tr>
<td>Sometimes</td>
<td>46</td>
<td>36</td>
</tr>
<tr>
<td>Never</td>
<td>10</td>
<td>8</td>
</tr>
</tbody>
</table>

| Severity of incontinence episodes* | | |
| Make underwear/pad damp | 47 | 42 |
| Make underwear/pad wet | 42 | 37 |
| Wet outer clothing | 18 | 16 |
| Wet furniture | 6 | 5 |

| Night time | | |
| Micturition* | | |
| Not at all | 13 | 8 |
| 1–2 times per night | 69 | 44 |
| 3–6 times per night | 66 | 42 |
| ≥ 7 times per night | 9 | 6 |
| Controlling urge* | | |
| Can’t hold on | 47 | 30 |
| ≤ 5 minutes | 58 | 37 |
| 6–10 minutes | 21 | 13 |
| 11–20 minutes | 14 | 9 |
| ≥ 21 minutes | 16 | 10 |

| Able to reach the toilet without wetting oneself | | |
| Always | 30 | 27 |
| Mostly | 39 | 35 |
| Sometimes | 31 | 28 |
| Never | 12 | 10 |

| Severity of incontinence episodes* | | |
| Make underwear/pad damp | 44 | 49 |
| Make underwear/pad wet | 25 | 28 |
| Wet outer clothing | 13 | 14 |
| Wet furniture | 8 | 9 |

* Missing data
patients may have difficulties discerning actual levels of symptoms they experience. Alternatively, the findings could indicate that continence status is difficult to accurately measure as the number and levels of symptoms experienced by patients vary from day to day due to other contextual factors, such as the weather or having a full bladder, rather than the patient's actual condition.

This changing continence status poses a challenge for any researchers who are involved in continence instrument development. It may be useful to consider using fewer and more discriminating measurement levels of symptoms so that each response is easy to distinguish and patients are able to reliably state the level of symptom they are experiencing.

Another explanation for the poor test-retest reliability of the Form could be the small sample size. According to Streiner and Norman, for an expected reliability coefficient of 0.70, the desirable sample should be 130 participants. Although this study included 170 patients, not all of the patients completed the questionnaire twice. Therefore, it may be useful to repeat this study using a larger sample size.

**CONCLUSION**

Developing a valid and reliable urinary continence assessment form that can be completed by patients is a complex task, the importance of which should not be overlooked. Clearly, with the increasing pressure for health care professionals to demonstrate their role in improving patient outcomes there is a need to use a simple valid and reliable assessment form that provides a means by which to measure and make explicit patient outcomes. Unless such an instrument is developed and used, the role of continence health care specialists will continue to be poorly understood and recognised. To avoid this situation, further attention should be given to the development and

Table 2. Bother scale percentages of urinary incontinence symptoms.

<table>
<thead>
<tr>
<th>Bother rating (%)</th>
<th>1 (No)</th>
<th>2 (Slight)</th>
<th>3 (Moderate)</th>
<th>4 (Serious)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of micturition*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 6 times per day</td>
<td>37</td>
<td>25</td>
<td>26</td>
<td>12</td>
</tr>
<tr>
<td>≥ 7 times per day</td>
<td>10</td>
<td>21</td>
<td>32</td>
<td>34</td>
</tr>
<tr>
<td>Controlling the urge*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 10 minutes</td>
<td>7</td>
<td>18</td>
<td>32</td>
<td>43</td>
</tr>
<tr>
<td>≥ 11 minutes</td>
<td>48</td>
<td>24</td>
<td>28</td>
<td>0</td>
</tr>
<tr>
<td>Severity of incontinence episodes*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underwear/pad damp</td>
<td>9</td>
<td>59</td>
<td>18</td>
<td>14</td>
</tr>
<tr>
<td>Underwear/pad wet</td>
<td>3</td>
<td>10</td>
<td>45</td>
<td>42</td>
</tr>
<tr>
<td>Wet outer clothing</td>
<td>0</td>
<td>6</td>
<td>27</td>
<td>67</td>
</tr>
<tr>
<td>Wet furniture</td>
<td>0</td>
<td>0</td>
<td>17</td>
<td>83</td>
</tr>
<tr>
<td>Night time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of micturition*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 6 times per day</td>
<td>23</td>
<td>29</td>
<td>30</td>
<td>18</td>
</tr>
<tr>
<td>≥ 7 times per day</td>
<td>0</td>
<td>11</td>
<td>33</td>
<td>56</td>
</tr>
<tr>
<td>Controlling the urge*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 10 minutes</td>
<td>11</td>
<td>26</td>
<td>29</td>
<td>34</td>
</tr>
<tr>
<td>≥ 11 minutes</td>
<td>38</td>
<td>41</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td>Severity of incontinence episodes*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underwear/pad damp</td>
<td>15</td>
<td>25</td>
<td>50</td>
<td>10</td>
</tr>
<tr>
<td>Underwear/pad wet</td>
<td>8</td>
<td>8</td>
<td>53</td>
<td>31</td>
</tr>
<tr>
<td>Wet outer clothing</td>
<td>0</td>
<td>0</td>
<td>75</td>
<td>25</td>
</tr>
<tr>
<td>Wet furniture</td>
<td>0</td>
<td>0</td>
<td>25</td>
<td>75</td>
</tr>
</tbody>
</table>

* Missing data = 'don’t know' response given in <3% of cases.

Table 3. Test-retest correlations of urinary incontinence symptoms.

<table>
<thead>
<tr>
<th>Questionnaire item number</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How many times do you pass water/pee in the day?</td>
<td>88</td>
<td>0.586</td>
</tr>
<tr>
<td>1b. How much of a problem is this for you?</td>
<td>85</td>
<td>0.635</td>
</tr>
<tr>
<td>2a. How long after you get the urge are you able to hold on before having to go to the toilet in the day?</td>
<td>87</td>
<td>0.718</td>
</tr>
<tr>
<td>2b. How much of a problem is this for you?</td>
<td>85</td>
<td>0.699</td>
</tr>
<tr>
<td>3. During the day do you experience urgency to pass water/pee?</td>
<td>75</td>
<td>0.749</td>
</tr>
<tr>
<td>4. During the day do you make it to the toilet without wetting yourself?</td>
<td>56</td>
<td>0.591</td>
</tr>
<tr>
<td>5a. Is the urine loss/pee enough to...</td>
<td>54</td>
<td>0.602</td>
</tr>
<tr>
<td>5b. How much of a problem is this for you?</td>
<td>56</td>
<td>0.655</td>
</tr>
<tr>
<td>6a. How many times do you think you pass water/pee at night?</td>
<td>84</td>
<td>0.722</td>
</tr>
<tr>
<td>6b. How much of a problem is this for you?</td>
<td>83</td>
<td>0.597</td>
</tr>
<tr>
<td>7a. How long are you able to hold on before having to go to the toilet at night?</td>
<td>83</td>
<td>0.598</td>
</tr>
<tr>
<td>7b. How much of a problem is this for you?</td>
<td>80</td>
<td>0.630</td>
</tr>
<tr>
<td>8. At night do you make it to the toilet without wetting yourself?</td>
<td>47</td>
<td>0.598</td>
</tr>
<tr>
<td>9a. At night is the urine loss/pee enough to...</td>
<td>41</td>
<td>0.532</td>
</tr>
<tr>
<td>9b. How much of a problem is this for you?</td>
<td>44</td>
<td>0.697</td>
</tr>
</tbody>
</table>
Appendix A. Care Nursing Research Network, Continence Symptoms Assessment Form

In preparation for your continence appointment could you please complete the following assessment form.

Please COLOUR in the circles with black pen. Please complete every part of the form.

1a) How many times do you pass water/pee in the day?
   - Not at all
   - 1-2 times per day
   - 3-6 times per day
   - 7-10 times per day
   - 11 or more times per day

1b) How much of a problem is this for you?
   - No problem
   - Slight problem
   - Moderate problem
   - Serious problem
   - Don’t know

2a) How long after you get the urge are you able to hold on before having to go to the toilet in the day?
   - Can’t hold on
   - 1-5 minutes
   - 6-10 minutes
   - 11-20 minutes
   - 21-30 minutes
   - Longer than 30 minutes

2b) How much of a problem is this for you?
   - No problem
   - Slight problem
   - Moderate problem
   - Serious problem
   - Don’t know

3) During the day do you experience urine loss (wet yourself)?
   - No – Please go to Question 6
   - Yes

4) During the day do you make it to the toilet without wetting yourself?
   - Always
   - Mostly
   - Sometimes
   - Never
   - Don’t know

5a) Is the urine lost/pee enough to:
   - Make underwear/pad damp
   - Make underwear/pad wet
   - Wet outer clothing
   - Wet the furniture

5b) How much of a problem is this for you?
   - No problem
   - Slight problem
   - Moderate problem
   - Serious problem
   - Don’t know

6a) How many times do you think you pass water/pee at night?
   - Not at all
   - 1-2 times per night
   - 3-6 times per night
   - 7-10 times per night
   - 11 or more times per night

6b) How much of a problem is this for you?
   - No problem
   - Slight problem
   - Moderate problem
   - Serious problem
   - Don’t know

7) How long after you get the urge are you able to hold on before having to go to the toilet at night?
   - Can’t hold on
   - 1-5 minutes
   - 6-10 minutes
   - 11-20 minutes
   - 21-30 minutes
   - Longer than 30 minutes

7b) How much of a problem is this for you?
   - No problem
   - Slight problem
   - Moderate problem
   - Serious problem
   - Don’t know

8) At night do you make it to the toilet without wetting yourself?
   - Always
   - Mostly
   - Sometimes
   - Never
   - Don’t know

9a) At night is urine loss/pee enough to:
   - Make underwear/pad damp
   - Make underwear/pad wet
   - Wet outer clothing
   - Wet furniture/bed

9b) How much of a problem is this for you?
   - No problem
   - Slight problem
   - Moderate problem
   - Serious problem
   - Don’t know

10) Do you experience leakage from the back passage (fistees)?
   - No
   - Yes

11) How much leakage from the back passage would you lose each day?
   - Teaspoon
   - Tablespoon
   - Half a cupful
   - A cupful

11b) How much of a problem is this for you?
   - No problem
   - Slight problem
   - Moderate problem
   - Serious problem
   - Don’t know

12a) How often do you experience leakage from the back passage during the day?
   - Once a month
   - Once a week
   - 2-3 times a week
   - Once a day
   - 2-5 times a day
   - More than 6 times a day
   - Never

12b) How much of a problem is this for you?
   - No problem
   - Slight problem
   - Moderate problem
   - Serious problem
   - Don’t know

13a) How often do you experience leakage from the back passage at night?
   - Once a month
   - Once a week
   - 2-3 times a week
   - Once a day
   - 2-5 times a day
   - More than 6 times a day
   - Never

13b) How much of a problem is this for you?
   - No problem
   - Slight problem
   - Moderate problem
   - Serious problem
   - Don’t know

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widespread implementation of an easy to use valid and reliable continence assessment form that could be the basis for developing evidence based practice in continence care.

ACKNOWLEDGEMENTS
This study was supported by a research grant from the Olive Anstey Nursing Fund Inc. We would like to thank Ms Jan Low for administrative support and Siobhan Bowler for her editorial comments.

REFERENCES

A BRIDGE JUST FAR ENOUGH!

Thanks to TENA Queensland, the Brisbane icon, the Story Bridge, played a major part in Continence Awareness Week in the Queensland capital!

The person responsible within the council for allocating space on the Story Bridge wasn’t sure that Brisbane’s public was ready to be informed about ‘incontinence’ or ‘bladder weakness’. Once we convinced him of the importance of addressing this issue we were then faced with the cost of having a banner made specifically to meet the specifications of the Story Bridge (cost of $650). Space and colour restrictions meant our banner couldn’t be as ‘in your face’ as we would have liked but this picture shows the result...

The most amusing part of this story is that the team responsible for attaching the banner to the bridge thought our banner belonged to the AMA (of all groups) and hung the banner about 10 days before Continence Awareness week. I made a phone call to make sure they were going to re-hang the banner for the correct week and they said that they were going to leave ours in place (too bad for the AMA) and did so for a grand total of about 4 weeks.

All in all, the staff from the CFA who run the 1800 number have said they received calls from a number of people requesting more information. Luckily no one was injured taking down the number!