Hypothesis / aims of study
Urinary urgency is the cardinal symptom of overactive bladder syndrome (OAB), directly driving frequency, nocturia, and urge incontinence. The experience of urgency is however highly subjective, and dependent on its context. Despite its importance in our understanding of OAB, it has therefore proved challenging to measure urgency reliably [1]. The PPIUS is a scale designed for measurement of urinary urgency during completion of a bladder diary [2,3]. This study establishes its test-retest reliability, and its normal values in women without urgency, in order to complete its validation.

Study design, materials and methods
In two centres female volunteers, aged 18 and above, were screened with the ICIQ-FLUTS Long Form questionnaire, to exclude those with bothersome lower urinary tract symptoms. Other exclusion criteria included previous continence or vaginal surgery, use of anti-muscarinic or other bladder medication, grade II or above pelvic organ prolapse, and either history of urinary tract infection in the previous month, or positive urinalysis. Included participants completed two separate 7-day bladder diaries, scoring the intensity of urgency at each void on a 5-point scale:

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No urgency: I felt no need to empty my bladder but did so for other reasons</td>
</tr>
<tr>
<td>1</td>
<td>Mild Urgency: I could postpone voiding for as long as necessary without fear of wetting myself</td>
</tr>
<tr>
<td>2</td>
<td>Moderate Urgency: I could postpone voiding for a short while without fear of wetting myself</td>
</tr>
<tr>
<td>3</td>
<td>Severe Urgency: I could not postpone voiding but had to rush to the toilet in order not to wet myself</td>
</tr>
<tr>
<td>4</td>
<td>Urge Incontinence: I leaked before arriving at the toilet</td>
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</table>

As in previous studies using the PPIUS, voids rated as “3 Severe Urgency” were considered as corresponding to the ICS standardised definition of urgency, as a “sudden compelling desire to pass urine which is difficult to defer”. Reliability was assessed using intraclass correlation (ICC). The effect of demographic variables on scores was assessed using multivariate linear regression. Analyses were performed using SPSS version 16.0.

Results
40 volunteers were recruited, of mean age 46.7 (range 23-67), and mean parity 1.47 (range 0-4). Mean urgency score was 0.87 (95% confidence intervals 0.21 to 1.53). Mean scores were normally distributed (Kolmogorov-Smirnov 0.96) (Figure 1). No participant reported any urge incontinence episode on either diary. Mean urgency episodes/week (voids rated as 3 “Severe Urgency”) was 0.46 (95% confidence intervals 1.42 to 2.34) (Figure 2). ICC for mean urgency score from the two diaries was 0.92 indicating excellent reliability. ICC for urgency episode frequency was 0.72 indicating good reliability. Multivariate linear regression showed a significant positive effect of age (F=8.54, p=0.006) on urgency episodes, but no effect on mean urgency scores (F=0.04, p=0.843). Multivariate linear regression showed no effect of parity on urgency episodes (F=0.42, p=0.519), or on mean urgency scores (F=0.16, p=0.696).

Interpretation of results
The test-retest reliability of the PPIUS assessed using a 7-day bladder diary is good, and it discriminates well between asymptomatic controls and previously reported values for patients with OAB. These data define the upper limit of normality in women for mean urgency scores and urgency episodes. The relationship between age and urgency episodes suggests however that it may be appropriate to define distinct age related cut-offs for the normal limit of urgency episodes. At least as rated with the PPIUS, these data confirm that urgency episodes, although infrequent, are not in themselves necessarily pathological.

Concluding message
The PPIUS is now validated for women, and can be used in both clinical and research practice. We recommend its adoption by the ICS Clinical Trials Subcommittee as the standard measure of urgency.

References
1. BJU Int (2005) 95 ; 335-340
2. Int Urogynecol J (2006) 17 (Suppl 2) ; S88 (052)
3. Int Urogynecol J (2007) 18 (Suppl 1) ; S67 (115)
Specify source of funding or grant: Unrestricted educational grant from Astellas Pharma

Is this a clinical trial?: No

What were the subjects in the study?: HUMAN

Was this study approved by an ethics committee?: Yes

Specify Name of Ethics Committee: King’s College Hospital Research Ethics Committee, St Mary’s Hospital Research Ethics Committee

Was the Declaration of Helsinki followed?: Yes

Was informed consent obtained from the patients?: Yes