

# WORKING P A P E R

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## Development, Validation and Testing of an Epidemiological Case Definition of Interstitial Cystitis/Painful Bladder Syndrome

### Supplementary Tables

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Table 1. Final Median and Agreement Ratings of IC/PBS Case Definition Panel

Criteria with Strong Evidence	IC/PBS	OAB	ENDO	VULVO
Patient reports pain by location				
Presence of pain somewhere in pelvic area (suprapubic to upper thighs)	4A*	-5A*	4A*	5U
Bladder pain	5A*	-5A*	1A	0U
Suprapubic pain	5A*	-5A*	2A	0U
Urethral pain	2A	-5U	0A	1A
Vulvar pain	0U	-5U	0U	5A*
Vaginal pain	1A	-5U	2U	4A
Rectal pain	0A	-5U	0A	0A
Pain in lower back	0A	0U	1A	0A
Pain in inner thighs	0A	-2U	0A	0A
Pain awakening at night	5A	-4A	0U	0U
Localized pain below waist (always same area)	4A	-5U	3U	4A
Migratory pain (location varies over time)	0U	-5U	1A	-1U
Patient reports type of pain				
Cramping/Bladder spasms	3A	3U	-3U	0U
Pain, pressure & discomfort	5A*	0U	4A*	3A
Varies from mild/moderate-severe/excruciating	3U	-4U	4A	3U
Patient reports pain worsens				
When bladder is full	5A*	0U	-3U	-3U
During urination (burning)	1A	-4U	-3U	-2U
After bladder is emptied	-2U	-4U	-2U	0U
With vaginal intercourse, on entry	2U	0U	2U	5A
During vaginal intercourse, deep penetration	3A	0U	4A	4A
When vulvar area is touched	-3U	0U	0U	5A*
During tampon insertion	0U	0U	1A	4A
Just before menstruation begins	2U	0U	1U	0A
During menstruation	-2U	0U	5A*	0A
When bowels are full	0A	0U	0A	0A
Soon after consuming acidic or spicy foods, caffeine, or alcohol	4A	0U	0U	0U
When patient is under stress	4A	3A	1A	2A
When wearing constrictive clothing	0U	0U	0A	4U
Patient reports pain improves				
After menstrual period	0U	0U	3A	0
After bladder is emptied (within 5 - 30 minutes)	5U*	0U	0A	0U
Patient reports urgent need to urinate				
To relieve pain	5A*	-5A*	-3U	-2U
To avoid incontinence	-5U*	5A	-3U	0U

Patient reports frequent need to urinate				
During the daytime	5A*	4A*	0U	0A
Waking her up from sleep at night	5A*	4A	0U	0A
Patient reports other symptoms				
Unable to become pregnant after 1 yr of trying	0A	0A	2U	0A
Urge incontinence	-3U	5A	0A	0A
Stress incontinence	0A	0A	0A	0A
Difficulty starting urine flow	0U	0A	0A	0A
Difficulty emptying bladder	2U	0A	0A	0A
Patient reports events preceded onset				
Dysmennorrhea	0A	0A	4A*	0A
UTI treated with no improvement	4A	0U	0A	0U
Incident of holding urine for a long period (e.g. airplane flight)	0A	0A	0A	0A
Pelvic surgery	0A	0U	0A	0A
Blunt trauma to the abdomen	0A	0A	0A	0A
STD, PID	0A	0A	0A	0A

Notes:

Median values of +4 and +5 are strong evidence for the disease, and values of -4 and -5 are strong evidence against the disease

A = agreement among panelists and U = undetermined

\* = rated as necessary for diagnosis

IC/PBS = interstitial cystitis/painful bladder syndrome; OAB = overactive bladder; ENDO = endometriosis; VULV = vulvodynia.

Table 2. Necessary Symptoms based on RICE Case Definition Panel Discussion

Condition	Necessary Symptoms	Evidence Against
Interstitial Cystitis/Painful Bladder Syndrome	<ol style="list-style-type: none"> <li>1. Pain, pressure, and/or discomfort                             <ol style="list-style-type: none"> <li>a. In pelvic area (suprapubic to upper thighs)</li> <li>b. Worsens as bladder fills and/or is diminished by emptying the bladder</li> </ol> </li> <li>2. Frequent urination (over 24-hours, includes daytime and nighttime)</li> </ol>	<ol style="list-style-type: none"> <li>1. Pain pressure, and/or discomfort only occurs during menstruation</li> <li>2. Urge incontinence/ concern about urge incontinence</li> </ol>
Overactive Bladder	<ol style="list-style-type: none"> <li>1. Urgency</li> </ol>	<ol style="list-style-type: none"> <li>1. Urgency to relieve pain</li> <li>2. Pain in pelvic area (suprapubic to upper thighs, including bladder/ suprapubic pain)</li> </ol>
Endometriosis	<ol style="list-style-type: none"> <li>1. Pain, pressure, and/or discomfort                             <ol style="list-style-type: none"> <li>a. In pelvic area (suprapubic to upper thighs)</li> <li>b. during menstruation (dysmenorrhea)</li> </ol> </li> </ol>	
Vulvodinia	<ol style="list-style-type: none"> <li>1. Vulvar pain not related to bladder filling</li> </ol>	

Table 3 RICE Case Definition Questionnaire Items

1. In the past 3 months, have you ever had a feeling of pain, pressure, or discomfort in your lower abdomen or pelvic area -- that is, the part of your body that is above your legs and below your belly button?

<1> YES

<2> NO

2. In the past 3 months, have you had a feeling of a strong urge or feeling that you had to urinate or "pee" that made it difficult for you to wait to go to the bathroom?

<1> YES

<2> NO [goto Q4]

3. Would you say this urge to urinate is mainly because of pain, pressure or discomfort or mainly because you are afraid you will not make it to the toilet in time to avoid wetting?

<1> PAIN, PRESSURE, DISCOMFORT, OR

<2> FEAR OF WETTING

4. In the past 3 months, before you urinate, as your bladder starts to fill, does your feeling of pain, pressure, or discomfort usually:

<1> Get worse,

<2> Get better, or

<3> Stay the same?

5. In the past 3 months (when you were having symptoms), how many times on average have you had to go to the bathroom to urinate during the day when you are awake?

ENTER NUMBER OF TIMES: \_\_\_\_\_

6. In the past 3 months, have you had one or more urinary tract or bladder infections that were diagnosed by a doctor or nurse?

<1> Yes-- One

<2> Yes-- More Than One

<3> No [goto Q9]

7. Were you treated with antibiotics for urinary tract or bladder infection(s)?

<1> YES

<2> NO [goto Q9]

8. Did all of your symptoms disappear (each time) after you took antibiotics?

<1> YES

<2> NO

9. Have you ever been diagnosed with a medical condition called endometriosis?

<1> YES

<2> NO - END

10. Were you diagnosed (with endometriosis) with a laparoscopy under anesthesia, that is, a scope that allowed your doctor to look inside your abdomen, after you were put to sleep?

<1> YES

<2> NO - END

11. Did you ever have hormone injection to treat endometriosis, such as depolupron?

<1> YES

<2> NO

Table 4. Sensitivity and Specificity of IC/PBS case definitions

Definition	Source	IC/PBS cases identified as IC/PBS (sensitivity) (%)	Non-IC/PBS cases correctly excluded from the definition (specificity) (%)	Non-IC/PBS cases incorrectly identified as IC/PBS (false positives) (%)
Pain, pressure or discomfort in the pelvic area Daytime frequency 10+ OR urgency due to the pain, pressure or discomfort	RICE Study	91	42	58
Pain, pressure or discomfort in the pelvic area which worsens as the bladder fills Daytime frequency 10+ OR urgency due to pain, pressure discomfort Symptoms do not resolve with antibiotics No Lupron treatment for endometriosis	RICE Study	56	79	21
Pain, pressure or discomfort in the pelvic area which worsens as the bladder fills and/or is relieved by urination Daytime frequency 10+ OR Nocturia 2+	International Continence Society	65	72	28
Interstitial Cystitis Symptoms Index 7+	Boston Area Community Health Study	81	49	51
Interstitial Cystitis Symptoms Index 12+	Boston Area Community Health Study	48	85	15

Burning, pain, discomfort or pressure in pubic or bladder area - fairly often, usually, almost always Duration 3+ months	Boston Area Community Health Study	68	58	42
Pain increasing as the bladder fills OR pain relieved by urination– fairly often, usually, almost always Duration 3+ months	Boston Area Community Health Study	45	73	27
Pain increasing as the bladder fills OR pain relieved by urination– fairly often, usually, almost always Duration 3+ months	Boston Area Community Health Study	19	95	5
Frequency (urinating again < 2 hours after you finished urinating – fairly often, usually or almost always OR frequent urination - fairly often, usually or almost always OR daytime frequency 8+) Urgency (difficulty postponing urination – fairly often, usually, almost always OR strong urge or pressure to urinate immediately with little warning – fairly often, usually or almost always Nocturia 2+				
Burning, pain, discomfort or pressure in the pubic or bladder area – a few times, fairly often, usually, almost always Interstitial Cystitis Symptoms Index 7+	Leppilahti et al	73	66	34
Burning, pain, discomfort or pressure in the pubic or bladder area – a few times, fairly often, usually, almost always Interstitial Cystitis Symptoms Index 12+	Leppilahti et al	48	85	15