

This is a **Sample** version of the

Expanded Prostate Cancer Index Composite Kit (EPIC-Kit)

The **full version** of the EPIC-Kit comes without 'sample' watermark.

The full complete EPIC-Kit version includes –

- EPIC Clinical Validity
- EPIC Scoring/ Administration instructions for all EPIC Segments and Domains.
- EPIC core questionnaire plus addons Short-forms etc.
- EPIC questionnaire domains ie -
 - Bowel Domain - Hormonal Domain
 - Sexual Domain - Urinary Domain

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DEVELOPMENT AND VALIDATION OF THE EXPANDED PROSTATE CANCER INDEX COMPOSITE (EPIC) FOR COMPREHENSIVE ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE IN MEN WITH PROSTATE CANCER

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ABSTRACT

Objectives. Health-related quality of life (HRQOL) is an increasingly important endpoint in prostate cancer care. However, pivotal issues that are not fully assessed in existing HRQOL instruments include irritative urinary symptoms, hormonal symptoms, and multi-item scores quantifying bother between urinary, sexual, bowel, and hormonal domains. We sought to develop a novel instrument to facilitate more comprehensive assessment of prostate cancer-related HRQOL.

Methods. Instrument development was based on advice from an expert panel and prostate cancer patients, which led to expanding the 20-item University of California-Los Angeles Prostate Cancer Index (UCLA-PCI) to the 50-item Expanded Prostate Index Composite (EPIC). Summary and subscale scores were derived by content and factor analyses. Reliability and validity were assessed by test-retest correlation, Cronbach's alpha coefficient, interscale correlation, and EPIC correlation with other validated instruments.

Results. Test-retest reliability and internal consistency were high for EPIC urinary, bowel, sexual, and hormonal domain summary scores (each $r \geq 0.80$ and Cronbach's alpha ≥ 0.82) and for most domain-specific subscales. Correlations between function and bother subscales within domains were high ($r > 0.60$). Correlations between different primary domains were consistently lower, indicating that these domains assess distinct HRQOL components. EPIC domains had weak to modest correlations with the Medical Outcomes Study 12-item Short-Form Health Survey (SF-12), indicating rationale for their concurrent use. Moderate agreement was observed between EPIC domains relevant to the Functional Assessment of Cancer Therapy Prostate module (FACT-P) and the American Urological Association Symptom Index (AUA-SI), providing criterion validity without excessive overlap.

Conclusions. EPIC is a robust prostate cancer HRQOL instrument that complements prior instruments by measuring a broad spectrum of urinary, bowel, sexual, and hormonal symptoms, thereby providing a unique tool for comprehensive assessment of HRQOL issues important in contemporary prostate cancer management. *UROLOGY* 56: 899–905, 2000. © 2000, Elsevier Science Inc.

As prostate cancer is increasingly diagnosed at early stages with favorable survival outcomes, the basis on which patients select primary therapy has shifted toward consideration of health-related

quality of life (HRQOL).^{1,2} However, no HRQOL instrument has previously been developed and validated in a setting concurrently representing each of the three most common current interventions

Supported by National Institutes of Health grants 5P30CA46598 and 1P50CA69568 (National Cancer Institute Prostate Cancer Specialized Projects of Oncology Research Excellence [SPORE]), American Cancer Society Clinical Career Development Award 96-77 (M.G.S.), Robert Wood Johnson Scholars Program (J.T.W.), and American Foundation for Urological Diseases Fellowship Award (J.T.W.).

From the Veterans Affairs Center for Practice Management and Outcomes Research; Ann Arbor Veterans Affairs Medical Center, the National Cancer Institute Special Project of Research

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Submitted: July 26, 2000, accepted (with revisions): August 17, 2000

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Scoring Instructions for the Expanded Prostate cancer Index Composite (EPIC)*

EPIC assesses the disease-specific aspects of prostate cancer and its therapies and comprises four summary domains (Urinary, Bowel, Sexual and Hormonal). Factor analysis supports dividing the Urinary Domain Summary Score into two distinct *Incontinence* and *Irritative/Obstructive* subscales. In addition, each Domain Summary Score has measurable *Function Subscale* and *Bother Subscale* components. Response options for each EPIC item form a Likert scale, and multi-item scale scores are transformed linearly to a 0-100 scale (see following page: EPIC scoring), with higher scores representing better HRQOL. A summary of EPIC Summary Score and Subscale characteristics are tabulated (from Ref. 1):

HRQOL Domain	Number of items	Mean Score (sd)	Test-retest reliability	Internal consistency reliability
<u>HRQOL Domain Summary Scores</u>				
Urinary	12	80.2 (17.5)	0.88	0.88
Bowel	14	86.6 (15.7)	0.84	0.92
Sexual	13	33.1 (23.6)	0.91	0.93
Hormonal	11	86.6 (13.8)	0.80	0.82
<u>Domain-Specific HRQOL Subscales</u>				
Urinary Subscales				
Function	5	86.5 (16.7)	0.83	0.69
Bother	7	75.8 (20.4)	0.87	0.85
Incontinence*	4	83.2 (22.9)	0.87	0.89
Irritative/Obstructive*	7	79.7 (18.5)	0.85	0.81
Bowel Subscales				
Function	7	87.9 (13.6)	0.78	0.75
Bother	7	85.3 (18.8)	0.85	0.90
Sexual Subscales				
Function	9	29.5 (24.0)	0.90	0.92
Bother	4	41.1 (30.1)	0.78	0.84
Hormonal Subscales				
Function	5	84.0 (15.3)	0.79	0.51
Bother	6	88.7 (13.6)	0.73	0.73

* A single global urinary bother item, which does not distinguish bother related to incontinence from that related to urinary obstruction, is not included in the Urinary Incontinence or Urinary Irritative/Obstructive subscales; therefore, 11 urinary items comprise these 2 subscales whereas the Urinary Summary Domain includes 12 items.

EPIC can be used alone or combined with other instruments, including the AUA-SI, FACT-P, and Medical Outcomes Study SF-12 or SF-36. Inter-scale correlation between EPIC and these instruments has indicated that efficient (yet comprehensive) HRQOL assessment can be achieved by co-administering EPIC with SF-12.⁴ Concurrent use of the AUA-SI can also provide useful complementary clinical information.⁵ The following scoring instructions therefore assume that EPIC will be co-administered with SF-12 and the AUA-SI, with these 3 instruments combined according to the following format:

SF-12 General Health Function Survey (first 12 items):	Items 11-22
EPIC (subsequent 50 items excluding 7 AUA-SI items):	Items 23-34, 42-79
AUA Symptom Index (7 items embedded in EPIC Urinary Section):	Items 35-41

**This is the end of the EPIC scoring instructions sample version.
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EPIC

The Expanded Prostate Cancer Index Composite

This questionnaire is designed to measure Quality of Life issues in patients with Prostate cancer. To help us get the most accurate measurement, it is important that you answer all questions honestly and completely.

Remember, as with all medical records, information contained within this survey will remain strictly confidential.

Today's Date (please enter date when survey completed): Month _____ Day _____ Year _____

Name (optional): _____

Date of Birth (optional): Month _____ Day _____ Year _____

URINARY FUNCTION

This section is about your urinary habits. Please consider **ONLY THE LAST 4 WEEKS**.

1. Over the **past 4 weeks**, how often have you leaked urine?

- More than once a day..... 1
- About once a day..... 2
- More than once a week..... 3 (Circle one number)
- About once a week..... 4
- Rarely or never..... 5

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2. Over the **past 4 weeks**, how often have you urinated blood?

- More than once a day..... 1
- About once a day..... 2
- More than once a week..... 3 (Circle one number)
- About once a week..... 4
- Rarely or never..... 5

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3. Over the **past 4 weeks**, how often have you had pain or burning with urination?

- More than once a day..... 1
- About once a day..... 2
- More than once a week..... 3 (Circle one number)
- About once a week..... 4
- Rarely or never..... 5

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4. Which of the following best describes your urinary control **during the last 4 weeks**?

- No urinary control whatsoever..... 1
- Frequent dribbling..... 2 (Circle one number)
- Occasional dribbling..... 3
- Total control..... 4

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5. How many pads or adult diapers per day did you usually use to control leakage **during the last 4 weeks?**

- None 0
- 1 pad per day..... 1
- 2 pads per day..... 2 (Circle one number)
- 3 or more pads per day..... 3

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6. How big a problem, if any, has each of the following been for you **during the last 4 weeks?**

(Circle one number on each line)

	<u>No Problem</u>	<u>Very Small Problem</u>	<u>Small Problem</u>	<u>Moderate Problem</u>	<u>Big Problem</u>	
a. Dripping or leaking urine	0	1	2	3	4	28/
b. Pain or burning on urination.....	0	1	2	3	4	29/
c. Bleeding with urination.....	0	1	2	3	4	30/
d. Weak urine stream or incomplete emptying.....	0	1	2	3	4	31/
e. Waking up to urinate.....	0	1	2	3	4	32/
f. Need to urinate frequently during the day	0	1	2	3	4	33/

7. Overall, how big a problem has your urinary function been for you **during the last 4 weeks?**

- No problem..... 1
- Very small problem..... 2
- Small problem..... 3 (Circle one number)
- Moderate problem..... 4
- Big problem..... 5

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**This is the end of the EPIC core questionnaire sample version.
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