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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 $\geq 0.82$) 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. 

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

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for localized prostate cancer: radical prostatectomy, external beam radiation, and brachytherapy.[3,4] Moreover, neoadjuvant or adjuvant hormonal therapy is commonly used to complement these primary interventions, yet consequent HRQOL effects have not been sufficiently characterized, largely because of the absence of validated HRQOL scales for measuring androgen-deprivation symptoms and related bother. We sought to develop a new HRQOL instrument that would address these significant components of prostate cancer HRQOL, built on the context of previously established domains of urinary, bowel, and sexual function.[5–7]

## MATERIAL AND METHODS

### *Instrument Development*

Content from the original University of California-Los Angeles Prostate Cancer Index (UCLA-PCI)[5] was expanded with guidance from a development cohort of localized prostate cancer patients and an expert panel comprised of urologic oncologists, radiation oncologists (including brachytherapy expertise), survey researchers, and prostate cancer nurses. Patient experts were unselected volunteers from our multidisciplinary urologic oncology clinics who had undergone the range of therapies represented in this study. These experts and patients as well as a review of the literature suggested a need to augment the UCLA-PCI with items to capture additional concerns relevant to brachytherapy, external beam radiation, radical prostatectomy, and androgen deprivation. Accordingly, the UCLA-PCI was supplemented with specific items addressing irritative and obstructive voiding symptoms (the original UCLA-PCI had queried principally incontinence only in urinary function assessment), hematuria, additional bowel symptoms (to improve the suboptimal bowel function scale from the original UCLA-PCI), and hormonal symptoms. Symptom-specific bother items corresponding to each symptom item were added to elicit multi-item bother scales for each HRQOL domain. Responses and comments from the development cohort were incorporated to derive the final instrument, the Expanded Prostate Cancer Index Composite (EPIC), which is given in Figure 1.

### *Study Population*

EPIC was validated via study of 252 subjects randomly selected from a larger cross-sectional cohort to provide equal representation of patients treated with radical prostatectomy, external beam radiation, or brachytherapy (with or without adjuvant hormonal therapy). This study was approved by the Institutional Review Board and all subjects provided informed consent. Sample size was based on having each cohort include as many available subjects as the smallest cohort. A 75% response rate, including written informed consent from each subject, was achieved for a mail survey that included EPIC, Medical Outcomes Study 36-item Short-Form Health Survey (SF-36), Functional Assessment of Cancer Therapy General module (FACT-G), Functional Assessment of Cancer Therapy Prostate module (FACT-P), American Urological Association Symptom Index (AUA-SI), and a satisfaction item. Details regarding the source cohort and survey methodology are described elsewhere.[8]

### *Measures and Statistical Analyses*

Exploratory factor analysis using varimax rotation identified discrete domains in EPIC to provide the basis for summary scoring. Response options for each EPIC item form a Likert scale, and multi-item scale scores were transformed linearly to a 0-to-100 scale, with higher scores representing better HRQOL. Reliability was assessed using test-retest in a cohort subset resurveyed 2 to 4 weeks apart[9]; internal consistency was measured with Cronbach's alpha coefficient. Pearson correlation coefficients ($r$) were calculated between individual domains to assess redundancy or conceptual independence. Criterion validity was measured by correlation of individual EPIC scales to summary scores of relevant validated instruments. Analyses were performed using SAS software (SAS Institute, Cary, NC).

## RESULTS

Relevant EPIC validation cohort characteristics appear in Table I. Unique features of this cohort include equal representation of subjects between brachytherapy, external beam radiation, and radical prostatectomy, as well as representation of patients who received hormonal therapy. These characteristics were sought to ensure adequate representation of side effects from each therapy. To determine valid EPIC item groupings for HRQOL domain scores, survey item responses were evaluated by factor analysis. This analysis identified primary HRQOL domains similar to those previously reported for the UCLA-PCI (Urinary, Bowel, and Sexual), and a new domain assessing hormonal concerns (such as breast tenderness, hot flashes, vitality, and patient bother related to these issues). In addition, the urinary items loaded onto two factors, leading to two novel, secondary urinary subscales that distinguish irritative/obstructive symptoms and incontinence as potentially discrete components of the overall urinary HRQOL domain.

Characteristics of the EPIC domain summary scores and subscale scores were evaluated (Table II). Each of the four principal domain summary scores demonstrated robust internal consistency (Cronbach's alpha $\geq 0.82$ for each) and test-retest reliability ($r \geq 0.80$ for each). Individual items generally yielded high item-scale correlation ($r \geq 0.4$ in 47 of 50 items and $> 0.27$ in all). Following the paradigm that items measuring symptom severity (function items) complement items measuring symptom-related HRQOL impairment (bother items), subscales to discern function and bother (within each HRQOL domain) were derived based on item content. The consequent function/bother subscales retained satisfactory internal consistency and reliability, as did urinary incontinence versus irritative-obstructive subscales (Table II).

To ascertain whether these scores measure complementary HRQOL components, correlations between EPIC domain function and bother subscales were evaluated (Table III). As expected, function and bother subscales within each individual HRQOL domain exhibited strong correlation ($r =$

## URINARY DOMAIN

1. Over the **past 4 weeks**, how often have you leaked urine? More than once a day // About once a day // More than once a week // About once a week // Rarely or never
2. Over the **past 4 weeks**, how often have you urinated blood? More than once a day // About once a day // More than once a week // About once a week // Rarely or never
3. Over the **past 4 weeks**, how often have you had pain or burning with urination? More than once a day//About once a day//More than once a week// About once a week//Rarely or never
4. Which of the following best describes your urinary control **during the last 4 weeks**? No urinary control whatsoever // Frequent dribbling // Occasional dribbling // Total control
5. How many pads or adult diapers per day did you usually use to control leakage **during the last 4 weeks**? No pads // 1 pad per day // 2 pads per day // 3 or more pads per day

| How big a problem, if any, has each of the following been for you **during the last 4 weeks**? | No Problem | Very Small Problem | Small Problem | Moderate Problem | Big Problem |
|---|---|---|---|---|---|
| 6. Dripping or leaking urine ..... | 0 | 1 | 2 | 3 | 4 |
| 7. Pain or burning on urination..... | 0 | 1 | 2 | 3 | 4 |
| 8. Bleeding with urination..... | 0 | 1 | 2 | 3 | 4 |
| 9. Weak urine stream or incomplete emptying.. | 0 | 1 | 2 | 3 | 4 |
| 10 Waking up to urinate..... | 0 | 1 | 2 | 3 | 4 |
| 11. Need to urinate frequently during the day.... | 0 | 1 | 2 | 3 | 4 |

12. Overall, how big a problem has your urinary function been for you **during the last 4 weeks**? No problem // Very small problem // Small problem // Moderate problem // Big problem

## BOWEL DOMAIN

13. How often have you had rectal urgency (felt like I had to pass stool, but did not) **during the last 4 weeks**? More than once a day // About once a day // More than once a week // About once a week // Rarely or never
14. How often have you had uncontrolled leakage of stool or feces? More than once a day // About once a day // More than once a week // About once a week // Rarely or never
15. How often have you had stools (bowel movements) that were loose or liquid (no form, watery,mushy) **during the last 4 weeks**? Never// Rarely// About half the time// Usually// Always
16. How often have you had bloody stools **during the last 4 weeks**? Never // Rarely // About half the time // Usually // Always
17. How often have your bowel movements been painful **during the last 4 weeks**? Never // Rarely // About half the time // Usually // Always
18. How many bowel movements have you had on a typical day **during the last 4 weeks**? Two or less // Three to four // Five or more
19. How often have you had crampy pain in your abdomen, pelvis or rectum **during the last 4 weeks**? More than once a day // About once a day // More than once a week // About once a week // Rarely or never

| How big a problem, if any, has each of the following been for you **during the last 4 weeks**? | No Problem | Very Small Problem | Small Problem | Moderate Problem | Big Problem |
|---|---|---|---|---|---|
| 20. Urgency to have a bowel movement ..... | 0 | 1 | 2 | 3 | 4 |
| 21. Increased frequency of bowel movements | 0 | 1 | 2 | 3 | 4 |
| 22. Watery bowel movements..... | 0 | 1 | 2 | 3 | 4 |
| 23. Losing control of your stools.. | 0 | 1 | 2 | 3 | 4 |
| 24 Bloody stools ..... | 0 | 1 | 2 | 3 | 4 |
| 25. Abdominal/ Pelvic/Rectal pain.... | 0 | 1 | 2 | 3 | 4 |

26. Overall, how big a problem have your bowel habits been for you **during the last 4 weeks**? No problem // Very small problem // Small problem // Moderate problem // Big problem

## SEXUAL DOMAIN

| How would you rate each of the following **during the last 4 weeks**? | Very Poor to None | Poor | Fair | Good | Very Good |
|---|---|---|---|---|---|
| 27. Your level of sexual desire..... | 1 | 2 | 3 | 4 | 5 |
| 28. Your ability to have an erection..... | 1 | 2 | 3 | 4 | 5 |
| 29. Your ability to reach orgasm (climax).. | 1 | 2 | 3 | 4 | 5 |

30. How would you describe the usual QUALITY of your erections **during the last 4 weeks**? None at all// Not firm enough for any sexual activity.// Firm enough for masturbation and foreplay only // Firm enough for intercourse
31. How would you describe the FREQUENCY of your erections **during the last 4 weeks**? I NEVER had an erection when I wanted one// I had an erection LESS THAN HALF the time I wanted one//I had an erection ABOUT HALF the time I wanted one// I had an erection MORE THAN HALF the time I wanted one// I had an erection WHENEVER I wanted one.
32. How often have you awakened in the morning or night with an erection **during the last 4 weeks**? Never// Less than once a week// About once a week// Several times a week// Daily
33. **During the last 4 weeks**, how often did you have any sexual activity? Not at all // Less than once a week // About once a week // Several times a week //Daily
34. **During the last 4 weeks**, how often did you have sexual intercourse? Not at all // Less than once a week // About once a week // Several times a week // Daily
35. Overall, how would you rate your ability to function sexually **during the last 4 weeks**? Very poor // Poor // Fair // Good // Very good

| How big a problem **during the last 4 weeks**, if any,has each of the following been for you? | No Problem | Very Small Problem | Small Problem | Moderate Problem | Big Problem |
|---|---|---|---|---|---|
| 36. Your level of sexual desire..... | 0 | 1 | 2 | 3 | 4 |
| 37. Your ability to have an erection..... | 0 | 1 | 2 | 3 | 4 |
| 38. Your ability to reach orgasm (climax).. | 0 | 1 | 2 | 3 | 4 |

39. Overall, how big a problem has your sexual function or lack of sexual function been for you **during the last 4 weeks**? No problem // Very small problem // Small problem // Moderate problem // Big problem

## HORMONAL DOMAIN

40. **Over the last 4 weeks,** how often have you experienced hot flashes? More than once a day // About once a day // More than once a week // About once a week // Rarely or never
41. How often have you had breast tenderness **during the last 4 weeks**? More than once a day // About once a day // More than once a week // About once a week // Rarely or never
42. **During the last 4 weeks,** how often have you felt depressed? More than once a day // About once a day // More than once a week // About once a week//Rarely or never
43. **During the last 4 weeks,** how often have you felt a lack of energy? More than once a day // About once a day // More than once a week // About once a week // Rarely or never
44. How much change in your weight have you experienced during the last 4 weeks, if any? Gained 10 pounds or more // Gained less than 10 pounds // No change in weight // Lost less than 10 pounds // Lost 10 pounds or more

| How big a problem **during the last 4 weeks**, if any,has each of the following been for you? | No Problem | Very Small Problem | Small Problem | Moderate Problem | Big Problem |
|---|---|---|---|---|---|
| 45. Hot flashes ..... | 0 | 1 | 2 | 3 | 4 |
| 46. Breast tenderness/enlargement..... | 0 | 1 | 2 | 3 | 4 |
| 47. Loss of body hair..... | 0 | 1 | 2 | 3 | 4 |
| 48. Feeling depressed..... | 0 | 1 | 2 | 3 | 4 |
| 49. Lack of energy ..... | 0 | 1 | 2 | 3 | 4 |
| 50. Change in body weight.... | 0 | 1 | 2 | 3 | 4 |

FIGURE 1. *Items comprising the Expanded Prostate Cancer Index Composite (EPIC) survey instrument.*

**TABLE I.** *Demographics of the EPIC validation cohort (n = 252)*

| | |
|---|---|
| Mean age ± SD | 67.2 ± 8.1 |
| Primary intervention | |
| Brachytherapy | 84 (33.3%) |
| External beam radiation | 84 (33.3%) |
| Radical prostatectomy | 84 (33.3%) |
| Neoadjuvant/adjuvant hormonal therapy | 91 (36.1%) |
| Median pretreatment PSA (ng/mL) | 6.7 (range 0.1–129.0) |
| Biopsy Gleason score distribution* | 242 |
| 2–6 | 141 (58.3%) |
| 7 | 81 (33.5%) |
| 8–10 | 20 (8.3%) |
| Clinical T-stage distribution* | 247 |
| T1 | 120 (48.6%) |
| T2 | 116 (47.0%) |
| T3 | 11 (4.4%) |
| Mean time since primary intervention ± SD (mo) | 25.7 ± 13.0 (range 3.6–51.5) |
| Race (% white) | 92.8 |
| Marital status (% currently married) | 88.8 |
| Relationships (% currently involved in a relationship) | 94.4 |
| Education (% completed high school) | 92.7 |

*KEY: EPIC = Expanded Prostate Index Composite; PSA = prostate-specific antigen.*
** Number of subjects for the Gleason score and T-stage analyses are less than the total cohort because Gleason score and T-stage data were not available for 10 and 5 patients, respectively.*

**TABLE II.** *Characteristics of EPIC domain-specific summary and subscale scores*

| HRQOL Domain | No. of Items | Mean Score (SD) | Scoring Minimum (%) | Scoring Maximum (%) | Test-Retest | Cronbach's alpha |
|---|---|---|---|---|---|---|
| HRQOL Domain Summary Scores | | | | | | |
| Urinary | 12 | 80.2 (17.5) | 0.0 | 6.6 | 0.88 | 0.88 |
| Bowel | 14 | 86.6 (15.7) | 0.0 | 16.0 | 0.84 | 0.92 |
| Sexual | 13 | 33.1 (23.6) | 7.6 | 0.0 | 0.91 | 0.93 |
| Hormonal | 11 | 86.6 (13.8) | 0.0 | 18.1 | 0.80 | 0.82 |
| Domain-Specific HRQOL Subscales | | | | | | |
| Urinary subscales | | | | | | |
| Function | 5 | 86.5 (16.7) | 0.4 | 40.2 | 0.83 | 0.69 |
| Bother | 7 | 75.8 (20.4) | 0.0 | 7.0 | 0.87 | 0.85 |
| Incontinence* | 4 | 83.2 (22.9) | 1.3 | 46.4 | 0.87 | 0.89 |
| Irritation/obstruction* | 7 | 79.7 (18.5) | 0.0 | 8.2 | 0.85 | 0.81 |
| Bowel subscales | | | | | | |
| Function | 7 | 87.9 (13.6) | 0.0 | 18.5 | 0.78 | 0.75 |
| Bother | 7 | 85.3 (18.8) | 0.0 | 32.4 | 0.85 | 0.90 |
| Sexual subscales | | | | | | |
| Function | 9 | 29.5 (24.0) | 15.3 | 0.0 | 0.90 | 0.92 |
| Bother | 4 | 41.1 (30.1) | 14.2 | 7.7 | 0.78 | 0.84 |
| Hormonal subscales | | | | | | |
| Function | 5 | 84.0 (15.3) | 0.0 | 20.9 | 0.79 | 0.51 |
| Bother | 6 | 88.7 (13.6) | 0.0 | 30.8 | 0.73 | 0.73 |

*KEY: EPIC = Expanded Prostate Index Composite; HRQOL = health-related quality of life.*
** Function items and bother items are combined in the urinary incontinence subscale and the urinary irritation/obstruction subscale. On the basis of factor analysis, these two subscales (urinary incontinence and urinary irritation/obstruction) represent alternative grouping of the urinary HRQOL domain items for scoring. One item, measuring global urinary bother, does not distinguish bother related to incontinence from that related to irritative/obstructive voiding, and so it is not included in either the urinary incontinence or the urinary irritation/obstruction subscales; therefore, 11 urinary items comprise these two subscales, whereas the urinary summary score includes 12 urinary items. Effect on scores of specific therapy, cancer severity, follow-up duration, and other factors are described elsewhere.[8]*

0.64 to 0.87), indicating that each domain's bother subscale quantifies utility or impairment related to that domain's symptoms quantified by the corresponding function subscale. In contrast, correlations between bother or function subscales among different HRQOL domains were consistently

**TABLE III.** *Interscale correlations between EPIC function and bother subscales*

| | Urinary Function | Urinary Bother | Bowel Function | Bowel Bother | Sexual Function | Sexual Bother | Hormonal Function | Hormonal Bother |
|---|---|---|---|---|---|---|---|---|
| Urinary function | 1.00 | | | | | | | |
| Urinary bother | 0.69 | 1.00 | | | | | | |
| Bowel function | 0.27 | 0.30 | 1.00 | | | | | |
| Bowel bother | 0.29 | 0.39 | 0.87 | 1.00 | | | | |
| Sexual function | 0.25 | 0.32 | 0.21 | 0.21 | 1.00 | | | |
| Sexual bother | 0.15 | 0.25 | 0.24 | 0.22 | 0.64 | 1.00 | | |
| Hormonal function | 0.29 | 0.36 | 0.41 | 0.37 | 0.24 | 0.23 | 1.00 | |
| Hormonal bother | 0.33 | 0.43 | 0.44 | 0.48 | 0.26 | 0.25 | 0.84 | 1.00 |

*KEY: EPIC = Expanded Prostate Index Composite.*
*Underlines denote correlation of symptom severity in a specific domain (as measured by Function subscale) with impairment specific for that domain (as measured by Bother subscale).*

**TABLE IV.** *Interscale correlations between EPIC HRQOL summary scores and other relevant HRQOL instrument summary scores*

| HRQOL Instrument Scale | EPIC-Urinary | EPIC-Bowel | EPIC-Sexual | EPIC-Hormonal | AUA-SI | FACT-P | FACT-G | SF-12 MCS | SF-12 PCS |
|---|---|---|---|---|---|---|---|---|---|
| EPIC-Urinary | 1.00 | | | | | | | | |
| EPIC-Bowel | 0.36 | 1.00 | | | | | | | |
| EPIC-Sexual | 0.32 | 0.25 | 1.00 | | | | | | |
| EPIC-Hormonal | 0.41 | 0.46 | 0.28 | 1.00 | | | | | |
| AUA-SI | 0.77 | 0.42 | 0.29 | 0.43 | 1.00 | | | | |
| FACT-P | 0.58 | 0.51 | 0.44 | 0.61 | 0.57 | 1.00 | | | |
| FACT-G | 0.40 | 0.42 | 0.31 | 0.66 | 0.41 | 0.71 | 1.00 | | |
| SF-12 MCS | 0.33 | 0.25 | 0.17 | 0.56 | 0.27 | 0.45 | 0.66 | 1.00 | |
| SF-12 PCS | 0.34 | 0.49 | 0.27 | 0.48 | 0.40 | 0.64 | 0.55 | 0.18 | 1.00 |

*KEY: EPIC = Expanded Prostate Index Composite; HRQOL = health-related quality of life; AUA-SI = American Urological Association Symptom Index; FACT-P = Functional Assessment of Cancer Therapy Prostate module; FACT-G = Functional Assessment of Cancer Therapy General module; SF-12 MCS = Medical Outcomes Study Short Form 12 Mental Component Score; SF-12 PCS = Medical Outcomes Study Short Form 12 Physical Component Score.*

weaker (each $r < 0.5$), indicating that the urinary, sexual, bowel, and hormonal domains measure conceptually discrete HRQOL components. Interscale correlation between each of the overall urinary, bowel, sexual, and hormonal summary scores (in which function and bother items are combined) also supported this paradigm (Table IV). The urinary incontinence and irritative subscales were also found to measure complementary urinary HRQOL components ($r = 0.39$) and were distinct from other domain measures ($r \leq 0.4$ in each comparison).

Correlation between HRQOL domain scores from EPIC and HRQOL scores of other instruments was then assessed (Table IV).[10–13] Correlations were poor between EPIC domain scores and summary scores of HRQOL instruments not specific for prostate cancer (eg, SF-36 and FACT-G), confirming the need for disease-specific survey instruments. Moderate correlation between each EPIC domain and FACT-P (reflecting content of hormonal, urinary, sexual, and bowel items in FACT-P), as well as strong correlation between AUA-SI and the EPIC irritative/obstructive urinary subscale, provided evidence for EPIC criterion validity. Lower interscale correlations between EPIC domains and SF-36 or SF-12 (than between EPIC and FACT-G or FACT-P) supports concurrent use of EPIC with SF-12 for efficient and comprehensive assessment of HRQOL among prostate cancer patients.

## COMMENT

Existing HRQOL instruments that have been validated for use in prostate cancer studies are limited in evaluating contemporary prostate cancer therapies.[5–7,10–15] These limitations include lack of irritative and obstructive urinary symptom assessment (complementing concurrent incontinence assessment), lack of multi-item scales for measuring function-related bother, and lack of validated, multi-item summary scores to specifically measure hormonal therapy effects and their related bother.[5–7,10–15] To address these limitations, a broad-based modification of the UCLA-PCI was performed to derive the EPIC. The EPIC instrument showed satisfactory survey characteristics in validation analyses. Test-retest reliability and internal consistency for the urinary, bowel, sexual, and

hormonal domain summary scores and subscale scores compared favorably to those reported for the original UCLA-PCI. Factor analyses and item content assessments indicated that a valid approach to HRQOL measurement (with EPIC) can focus either on domain-specific summary scores for the urinary, bowel, sexual, and hormonal domains or on subscale scores (whereby the urinary domain is divided into incontinence and irritative/obstructive subscales, or whereby each domain is divided into function and bother components).

Although EPIC is useful for measuring HRQOL concerns specific to prostate cancer, comprehensive assessment of HRQOL in prostate cancer patients can be broadened by the concurrent use of more general HRQOL instruments. For this purpose, we found that both SF-36 and SF-12 can provide complementary information regarding general HRQOL related to prostate-specific impairment. The SF-12 may suffice for this purpose because strong correlation was observed between SF-12 and SF-36 in their respective physical and mental component summaries ($r > 0.95$). When used in combination with general HRQOL instruments, EPIC is sensitive for distinguishing specific HRQOL effects between radical prostatectomy, external beam radiation, and brachytherapy.[8] In addition, EPIC is sensitive to HRQOL effects of primary prostate cancer control compared to progression.[8]

Although the proportion of minority subjects in this validation study was only 7.2%, this proportion of nonwhites is consistent with the U.S. demographics that show that only 5.8% of American men older than 55 years of age are African American.[16,17] However, the source cohort of 902 patients with localized prostate cancer did include a substantial number of nonwhite participants (n = 59),[8] and to determine whether EPIC is reliable among nonwhites, responses of all nonwhite participants in the source cohort was assessed. Robust internal consistency of EPIC summary scores (urinary, bowel, sexual, and hormonal) was conserved among nonwhites (Cronbach's alpha >0.74 for each summary score). In addition, race did not significantly affect HRQOL scores when controlling for cancer severity by analysis of covariance,[8] supporting EPIC validity among nonwhites including African Americans.

The prostate domains of EPIC are longer than the original UCLA-PCI; however, patient compliance in completing the survey was satisfactory (response rates >75%). When coadministered with SF-12, EPIC length is comparable to other combined HRQOL instruments, such as the UCLA-PCI coadministered with SF-36, European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (QLQ-C30) with EORTC-Prostate, or FACT-G with FACT-P.[5,13,14] EPIC differs from FACT-P in providing distinct, domain-specific summary scores for urinary, bowel, sexual, and hormonal symptoms. Although a preliminary, 19-item version of an EORTC prostate appendix sought to measure similar concerns, validation of the initial version of EORTC-P did not include radical prostatectomy patients, and EORTC-P was subsequently modified to a longer instrument whose validation has not been hitherto reported. Finally, EPIC coadministered with SF-12 is unique in its predominant focus on prostate cancer-related HRQOL concerns, whereas general HRQOL items dominate other validated composite instruments.

Accurate prostate cancer HRQOL assessment remains primarily a function of survey content. Prior prostate cancer HRQOL instruments have typically combined a brief prostate module with longer, general HRQOL instruments such as SF-36 or FACT-G. We instead sought to develop a more comprehensive prostate HRQOL instrument that could be used with a brief assessment of general HRQOL (SF-12) to capture the subtle symptoms that differentiate various therapies. For this purpose, the UCLA-PCI was expanded to include items to assess irritative, obstructive symptoms, and symptoms intimately related to androgen deprivation therapy. This new instrument (EPIC) provides a valid and robust tool for a comprehensive assessment of prostate cancer HRQOL.

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