Published in final edited form as:
J Urol. 2011 September ; 186(3): . doi:10.1016/j.juro.2011.04.085.

Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP): Development and Validation of a Practical Health-Related Quality of Life Instrument for Use in the Routine Clinical Care of Prostate Cancer Patients

Peter Chang, MD[1,2], **Konrad M. Szymanski, MD, MPH**[3], **Rodney L. Dunn, MS**[4], **Jonathan J. Chipman, MS**[5], **Mark S. Litwin, MD, MPH**[6], **Paul L. Nguyen, MD**[7,8], **Christopher J. Sweeney, MBBS**[9], **Robert Cook, MD**[10], **Andrew A. Wagner, MD**[1,11], **William C. DeWolf, MD**[1,11], **Glenn J. Bubley, MD**[11,12], **Renee Funches, MD**[12], **Joseph A. Aronovitz, MD, PhD**[13], **John T. Wei, MD, MS**[3,†], and **Martin G. Sanda, MD**[1,11,†]

[1]Division of Urology, Department of Surgery Beth Israel Deaconess Medical Center, Boston, MA

[2]Division of Urology, Department of Surgery Brigham and Women's Hospital, Boston, MA

[3]Division of Urology, McGill University Health Centre, Montreal, QC, Canada

[4]Department of Urology, University of Michigan School of Medicine, Ann Arbor, MI

[5]Department of Biostatistics and Computational Biology Dana-Farber Cancer Institute, Boston, MA

[6]David Geffen School of Medicine and School of Public Health, University of California-Los Angeles, Los Angeles, CA

[7]Department of Radiation Oncology, Brigham and Women's Hospital, Boston, MA

[8]Department of Radiation Oncology Dana-Farber Cancer Institute, Boston, MA

[9]Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, Boston, MA

[10]Seven Hills Urology, Centra Health, Lynchburg, VA

[11]Harvard School of Medicine, Boston, MA

[12]Department of Medicine Beth Israel Deaconess Medical Center, Boston, MA

[13]Department of Radiation-Oncology, Beth Israel Deaconess Medical Center, Boston, MA

Abstract

Purpose—Measuring prostate cancer patient HRQOL in routine clinical practice is hindered by lack of instruments enabling efficient real-time, point-of-care scoring of multiple HRQOL domains. We sought to develop an instrument for this purpose.

Materials and Methods—The EPIC for Clinical Practice (EPIC-CP) is a one-page, 16-item questionnaire to measure urinary incontinence, urinary irritation, bowel, sexual, and hormonal HRQOL domains that we constructed by eliminating conceptually overlapping items from the 3 page EPIC-26, and revising the questionnaire format to mirror the AUA Symptom Index, thereby enabling practitioners to calculate HRQOL scores at point of care. We administered EPIC-CP to a

Address Correspondence to: Martin G. Sanda, MD Division of Urology Beth Israel Deaconess Medical Center 330 Brookline Ave – Rabb 440 Boston, MA 02215 Phone: 617-735-2100 FAX: 617-735-2110 msanda@bidmc.harvard.edu.
†Senior authorship shared by JTW and MGS

new cohort of PCa patients in community-based and academic oncology, radiation, and urology practices to evaluate the instrument's validity and ease of use for clinical practice.

Results—175 treated and 132 untreated PCa subjects completed EPIC-CP (N = 307). EPIC-CP domain scores correlated highly with respective domain scores from longer versions of EPIC ($r \geq 0.93$ for all domains). EPIC-CP showed high internal consistency (Cronbach's $\alpha = 0.64$-0.84) and sensitivity to PCa treatment-related effects ($p < 0.05$ in each of 5 HRQOL domains). Patients completed EPIC-CP efficiently (96% in <10 minutes, and 11% missing items). It was deemed 'very convenient' by clinicians in 87% of routine clinical encounters, and clinicians accurately scored completed questionnaires 94% of the time.

Conclusions—EPIC-CP is a valid instrument that enables patient-reported HRQOL to be measured efficiently and accurately at the point of care, and can thereby facilitate improved emphasis and management of patient-reported outcomes.

Keywords

Prostatic neoplasms/therapy; Quality of Life; Outcome Assessment (Health Care); Questionnaires

INTRODUCTION

As survivorship after prostate cancer (PCa) diagnosis continues to improve with advances in detection and treatment, the effects of PCa management modalities on health-related quality of life (HRQOL) are becoming increasingly important. Patterns in HRQOL change for each PCa treatment modality are well-recognized[1], but objective characterization and quantification of such changes is challenging, especially outside of the research realm in the flow of a busy clinical practice.

The 50-item Expanded Prostate Cancer Index Composite (EPIC)[2], a validated domain-specific patient-reported questionnaire derived from the UCLA-Prostate Cancer Index (UCLA-PCI)[3] designed to assess HRQOL after PCa treatment, was successfully reduced into a shorter 26-item form (EPIC-26)[4], but can still be too cumbersome to administer in the routine clinical setting. Its three-page length is daunting to patients, it often takes longer than 10-15 minutes to administer, and it requires transformation of question answers into a 0-100 scale to calculate domain scores.

The AUA Symptom Index (AUA-SI)/International Prostate Symptom Score (IPSS) and the International Index of Erectile Function (IIEF-5)/Sexual Health Inventory for Men (SHIM) are examples of validated instruments that have become standard clinical tools in the management of lower urinary tract symptoms and erectile dysfunction, respectively.[5,6] A correlate for use specifically in patients with prostate cancer has not yet been realized. In fact, no validated tool measuring HRQOL in PCa patients currently exists in a form that would be practical for use in both community and academic clinical practices. Hence, we set out to develop and validate a shorter and more accessible HRQOL instrument designed specifically for use in the routine clinical care of prostate cancer patients: the Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP).*

*The complete EPIC-CP questionnaire can be found at http://www.bidmc.org/epic.

METHODS

Study populations

We performed initial psychometric analysis of EPIC-CP using the previously described EPIC-50/EPIC-26 Cohort[2,4], consisting of 252 subjects who had undergone brachytherapy, external radiotherapy, and radical prostatectomy. After institutional review board exemption was obtained because no protected health information was collected, we administered EPIC-CP from June to October, 2010 in an anonymous fashion to the EPIC-CP Validation Cohort, a new cross-sectional cohort (n=307) of PCa subjects of any stage in academic and community Radiation Oncology, Medical Oncology, Urology, and multidisciplinary clinics who were either as-of-yet untreated, on active surveillance, or were within one year of receiving any PCa treatment, either localized primary or systemic (Table 1). Those unable to read English were excluded.

Instrument Development

We developed EPIC-CP from item reduction and reformatting of EPIC-26.[4] We gathered input and feedback regarding EPIC-CP format and content from two focused project discussion and review sessions: one project review group comprised 6 urology faculty and 9 trainees, and a separate discussion and review from a multidisciplinary group of medical oncologists (3), radiation oncologists (3), and urologists (3 academic, 2 community).

EPIC-26 reduction strategy—We performed reduction of EPIC-26 with the goal and challenge of maintaining a balance between validity, clinical relevance, sensitivity, and a manageable and consistent number of questions (three) per health domain. Items were selected for retention using an iterative process. We preserved the overall bother items from the urinary, bowel, and sexual domains for content and consistency with previous versions of EPIC[2,4] and the UCLA-PCI.[3] As in EPIC-26, the overall urinary bother item in EPIC-CP is evaluated separately from the urinary incontinence and irritative/obstructive scales, as it can be influenced by either or both of these domains. We examined item-score correlations between individual EPIC-26 items and their respective domain scores[4], and selected questions with stronger item-score correlations. We resolved similar item-score correlations between two items in a domain by choosing the item with a higher prevalence of severity reported in a multicenter prospective trial on PCa treatment-related HRQOL effects.[7] Questions whose use in routine clinical practice was particularly prevalent were favored. If multiple items within a domain addressed a single or similar construct, we retained only one of those items.

In the urinary incontinence domain, the leaking bother question and the assessment of urinary control had the highest item-score correlations. We kept the question regarding number of pads per day despite its lower relative item-score correlation because of its prevalence in clinical practice. In the urinary irritation/obstruction domain, questions regarding dysuria, weak stream, and urinary frequency had the highest item-score correlations. In the bowel domain, we retained the overall bowel bother item for its high item-score correlation as well as for content, and the frequency and urgency items for their high item-score correlations. We dropped the hematochezia item because of its low correlation with the domain score. We recognized the importance of assessing rectal pain in patients who have undergone radiotherapy; therefore, we grouped this item with the urgency item, the combination of which often characterizes tenesmus in radiation proctitis. In the sexual domain, the correlation between bother and function ($r < 0.65$) has been shown to be lower than in other domains.[2] Therefore, we kept the overall sexual bother item for content despite its low correlation with the domain score. We preserved the question regarding the firmness of erections for its prevalence in clinical practice, and dropped the other items

concerning erections for their relative redundancy. The item regarding orgasm was kept for its conceptual difference from the already-retained items. In the vitality/hormonal domain, all item-score correlations were relatively low because of the domain's broad, systemic nature. We retained the depression and lack-of-energy items for their higher item-score correlations. We included and grouped hot flashes and breast problems because of their high prevalence, accompanying bother, and frequent need for symptomatic treatment in patients undergoing androgen deprivation therapy.[8-11]

The EPIC-CP scoring system—We designed EPIC-CP so that symptom scores for each domain (urinary incontinence, urinary irritative/obstructive, bowel, sexual, and vitality/hormonal) are calculated similarly as is done with the AUA-SI/IPSS,[5] (i.e. higher scores reflect worse symptom/bother severity) by simply adding together the numeric values (0 to 4) that correspond to patient responses in each of 3 questions comprising each HRQOL domain (Figure 1). Consequently, the minimum symptom score (best HRQOL) = 0 and the maximum symptom score (worst HRQOL) = 12 in each domain. For consistency, the values assigned to each question range from 0 (best) to 4 (worst) regardless of whether there were 4 or 5 response options per question. This design allows calculation of domain scores at the point of care without requiring time-consuming transformations to 0-100 ranges; it also allows calculating an overall HRQOL score by summing the five domain scores (maximum of 60). The overall urinary bother item (first question) is a stand-alone item not used in scoring any of the three-item domain scores because it relates to both urinary incontinence and irritation/obstruction.

Analysis and Validation

We first evaluated the EPIC-CP scoring system to previously-collected responses from the original EPIC-50/EPIC-26 Cohort (n = 252) that had been administered by mail survey[2,4]. Questions 2, 3, and 8 were transformed as 0, 25, 50, and 100%, as described above. The more severe answer was scored in combination questions (6a and 10a). We calculated item-score correlations between EPIC-CP items and their respective domain scores, and used the Pearson correlation coefficient to calculate the interscale correlations between the EPIC-CP, EPIC-26, and EPIC-50 domains, as well as between the EPIC-CP urinary irritative/obstructive domain and the AUA-SI. We used Cronbach's alpha coefficient to evaluate internal consistency.

After initial psychometric analysis, we evaluated EPIC-CP in the new EPIC-CP Validation Cohort (n = 307). No study personnel assisted in the distribution or completion of EPIC-CP. Questionnaires were administered in the office setting and practitioners provided demographic and cancer-related information for each subject. Subjects were asked how long EPIC-CP took to complete, and cancer practitioners rated the convenience of the instrument's use in the flow of clinical practice with a 4-point Likert item. We calculated mean, standard deviation, median, range, and the percentage of subjects scoring the minimum (floor) and maximum (ceiling) in each domain in all subjects who underwent any PCa therapy (n = 175). We used Cronbach's alpha to evaluate internal consistency, and estimated its variability by using confidence intervals from 500 bootstrap samples. To determine the sensitivity of EPIC-CP to PCa treatment effects, we used ANOVA to compare mean scores of treated subjects for each HRQOL domain against that of a group untreated subjects (on active surveillance or treatment not yet started; n = 132). All statistical analyses were performed using Statistical Analysis Systems software (SAS), version 9.2.

RESULTS

A complete, ready-to-use copy of EPIC-CP can be found at http://www.bidmc.org/epic. The questionnaire is formatted to fit on one page, contains 16 items, and retains the five EPIC HRQOL domains of urinary incontinence, urinary irritation/obstruction, bowel, sexual, and vitality/hormonal. Eight questions from the UCLA-PCI (including the bother items from the urinary, bowel, and sexual domains) and 6 questions from EPIC-50/EPIC-26 are preserved. Two items combine questions from EPIC-26. Each domain contains 3 questions scored 0-4, encompassing a domain score range of 0-12, with a lower score indicating more favorable HRQOL.

After rescoring the EPIC-50/EPIC-26 Cohort using EPIC-CP, we found that EPIC-CP domain summary scores correlated strongly with corresponding scores in previous versions of EPIC ($r \geq 0.93$ in all domains; Table 2). Score correlation between different domain was modest ($r < 0.50$ for all correlations; data not shown), indicating that the EPIC-CP domains are conceptually distinct and merit independent measure. The EPIC-CP urinary irritative/obstructive domain correlated well with the AUA-SI ($r = 0.81$).

We then externally validated EPIC-CP by administration to a new EPIC-CP Validation Cohort (Table 3), comprised of patients before or after treatment as well as some men on active surveillance. Survey completion rate was 89%, post-treatment subjects usually completed EPIC-CP within 6 months of primary treatment (median = 174 days), and treatment effects on response rates were not evident. Floor effects were evident in the urinary incontinence, bowel, and vitality/hormonal domains, but several subjects in these domains scored a near-maximum score of 11, demonstrating the capacity of EPIC-CP to capture a large range of side-effect severity. The urinary, bowel, and sexual domains demonstrated strong internal consistency (Cronbach's alpha = 0.72-0.84). While that of the vitality/hormonal domain was unsurprisingly lower, reflecting its broad, systemic nature (Cronbach's alpha = 0.64; 95% CI 0.54-0.73), 0.70 was included in its 95% confidence interval.

EPIC-CP demonstrated sensitivity to detect PCa treatment-related effects when domain scores of subjects who had undergone treatment were compared to untreated subjects (Table 4). Although this study was not designed to compare differences in HRQOL between primary PCa therapies, characteristic side effect patterns were observed when comparing specific primary treatment groups to untreated subjects. For example, subjects who underwent prostatectomy had highly significant deficits in the urinary incontinence and sexual domains (both $p < 0.0001$), and those who had external radiation experienced deficits in the urinary irritation/obstruction ($p = 0.0004$), bowel ($p = 0.0001$), and sexual domains ($p < 0.0001$). Vitality/hormonal domain changes approached significance for any treatment compared to non-treatment ($p = 0.08$), and subjects who had received hormonal therapy had worse EPIC-CP vitality/hormonal scores than those who had not ($p < 0.0001$).

The ease of using EPIC-CP in the clinical setting was tested by having urologists, radiation oncologists, medical oncologists, and nurse practitioners administer the questionnaire at the point of care in routine single-specialty academic or community practices as well as in the multidisciplinary clinic setting (number of evaluated practitioners = 12) without the direct assistance of study research personnel. Clinicians found the instrument convenient to use in the flow of their routine clinical practices (Table 5). Eighty-nine percent of subjects completely filled out EPIC-CP in the patient waiting room before their appointment without missing items, and 77% completed the form in less than five minutes. When calculating patient domain scores at the point of care, clinician-calculated scores were accurate in 94% of instances.

DISCUSSION

Validity is a vital characteristic of any instrument, but an instrument's clinical usefulness is determined more by the importance of what it measures and its practical clinical applicability. The AUA-SI[5] exemplifies such a tool: symptomatic benign prostatic hyperplasia is highly prevalent[12], and the ease of administering the AUA-SI's questions has allowed translation of its use in groundbreaking clinical trials[13-15] directly into the clinical setting.

While few would question the importance of HRQOL in PCa patients, it is not intuitively clear why objectively assessing it in a domain-specific fashion using a patient-reported questionnaire is of vital clinical interest. First, physicians rather notoriously tend to underestimate the severity of patients' post-treatment HRQOL deficits.[16-18] This discrepancy contributed to the development of validated patient-reported questionnaires specific to PCa patients, the first of which was the UCLA-PCI[3], the instrument from which EPIC in its various forms[2,4] was derived. Use of these questionnaires and others[19,20] in multicenter prospective studies specifically examining HRQOL changes after PCa treatment have helped elucidate characteristic side effect patterns after each major primary PCa treatment modality.[7, 21-24]

More recent efforts have sought to bring PCa HRQOL research closer to the bedside by identifying specific pre-treatment factors that may predict post-treatment HRQOL changes. Just as a patient's oncologic outcome is affected by cancer-related factors such as Gleason score, clinical stage, and PSA[25], the side effect profile that a patient experiences with a given treatment choice is heavily impacted by his individual pre-treatment, or baseline HRQOL.[26,27] This presents a unique gap between the research and clinical realms which, if bridged, has the potential to improve clinicians' ability to more accurately represent and convey the risks of PCa treatment to an individual patient. We designed EPIC-CP to bridge this gap. Its high correlation with longer EPIC versions and indirectly with the UCLA-PCI, reflects a compatibility that can facilitate translating HRQOL research findings to routine practice. Concurrent use of a general HRQOL instrument such as the SF-8 may allow easy linkage with disease-specific HRQOL.

Our development and validation of EPIC-CP has limitations. As is inherent and expected with further item reduction, the breadth of HRQOL assessment is decreased; however, EPIC-CP retains measure of 5 prostate cancer HRQOL domains, enabling prostate cancer patient-reported outcomes to be measured in the routine outpatient practice setting and to become a more standard part of routine clinical PCa care. The cross-sectional and anonymous nature of the EPIC-CP Validation Cohort did not allow for reliability testing or the assessment of EPIC-CP's ability to detect treatment-related changes over time. That other demographic variables (marital status, income, etc.) were not assessed, and that the cohort was nonrandomized, predominantly white, and mostly treated in the academic setting may limit the generalizability of our results. Potential treatment selection bias precludes use of this cross-sectional validation cohort for conclusive comparisons regarding treatment-specific effects on HRQOL. These limitations may be addressed through further study of EPIC-CP in the prospective setting.

CONCLUSIONS

Despite these limitations, this study demonstrates that EPIC-CP is a valid, sensitive, and practical tool that can be efficiently administered in the outpatient setting, thereby enabling patient HRQOL outcomes to be easily measured and documented at the point of care. Its ease of use provides an opportunity to incorporate HRQOL measures as a standard

component of routine prostate cancer clinical care, and to facilitate the implementation and documentation of patient-centered care.

Acknowledgments

The authors would like to acknowledge Irving Kaplan, MD, Brian Hoell, NP, Courtney Collins, Research Nurse, Mary Ellen Morrissey, Nurse Coordinator, Jodi Mechaber, NP, Robert Eyre, MD, and Paul Church, MD for their help with subject accrual. We would also like to thank Catrina Crociani, MPH for project management, Neha Mehta for data management, and Meredith M. Regan, ScD for her statistical expertise and supervision.

Funding: National Institutes of Health (R01 CA95662; RC1 CA146596, M Sanda, PI)

REFERENCES/BIBLIOGRAPHY

1. Litwin MS, Hays RD, Fink A, et al. Quality-of-life outcomes in men treated for localized prostate cancer. JAMA. 1995; 273:129–135. [PubMed: 7799493]
2. Wei JT, Dunn RL, Litwin MS, et al. 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. Urology. 2000; 56:899–905. [PubMed: 11113727]
3. Litwin MS, Hays RD, Fink A, et al. The UCLA Prostate Cancer Index: development, reliability, and validity of a health-related quality of life measure. Med Care. 1998; 36(7):1002–12. [PubMed: 9674618]
4. Szymanski KM, Wei JT, Dunn RL, et al. Development and Validation of an Abbreviated Version of the Expanded Prostate Cancer Index Composite Instrument for Measuring Health-Related Quality of Life Among Prostate Cancer Survivors. Urology. Nov; 2010 76(5):1245–50. Epub 2010 Mar 28. [PubMed: 20350762]
5. Barry MJ, Fowler FJ Jr, O'Leary MP, et al. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committeee of the American Urological Association. J Urol. 1992; 148(5):1549–57. [PubMed: 1279218]
6. Rosen RC, Cappelleri JC, Smith MD, et al. Development and evaluation of an abridged, 5-item version of the International Index of Erectile Function (IIEF) as a diagnostic tool for erectile dysfunction. Int J Impot Res. 1999; 11:319–326. [PubMed: 10637462]
7. Sanda MG, Dunn RL, Michalski J, et al. Quality of Life and Satisfaction with Outcome among Prostate-Cancer Survivors. NEJM. 2008; 358:1250–61. [PubMed: 18354103]
8. Spetz AC, Zetterlund EL, Varenhorst E, et al. Incidence and management of hot flashes in prostate cancer. J Support Oncol. Nov-Dec;2003 1(4):263–6. 269–70, 272–3. discussion 267-8, 271-2. [PubMed: 15334868]
9. Dobs A, Darkes MJ. Incidence and management of gynecomastia in men treated for prostate cancer. J Urol. Nov; 2005 174(5):1737–42. [PubMed: 16217274]
10. Smith MR, Goode M, Zietman AL, et al. Bicalutamide monotherapy versus leuprolide monotherapy for prostate cancer: effects on bone mineral density and body composition. J Clin Oncol. Jul 1; 2004 22(13):2546–53. [PubMed: 15226323]
11. Di Lorenzo G, Perdoná S, De Placido S, et al. Gynecomastia and breast pain induced by adjuvant therapy with bicalutamide after radical prostatectomy in patients with prostate cancer: the role of tamoxifen and radiotherapy. J Urol. Dec; 2005 174(6):2197–203. [PubMed: 16280763]
12. Sagnier PP, Girman CJ, Garraway M, et al. International comparison of the community prevalence of symptoms of prostatism in four countries. Eur Urol. 1996; 29(1):15–20. [PubMed: 8821684]
13. Lepor H, Williford WO, Barry MJ, et al. The efficacy of terazosin, finasteride, or both in benign prostatic hyperplasia. Veterans Affairs Cooperative Studies Benign Prostatic Hyperplasia Study Group. N Engl J Med. Aug 22; 1996 335(8):533–9. [PubMed: 8684407]
14. McConnell JD, Bruskewitz R, Walsh P, et al. The effect of finasteride on the risk of acute urinary retention and the need for surgical treatment among men with benign prostatic hyperplasia. Finasteride Long-Term Efficacy and Safety Study Group. N Engl J Med. Feb 26; 1998 338(9): 557–63. [PubMed: 9475762]

15. McConnell JD, Roehrborn CG, Bautista OM, et al. the Medical Therapy of Prostatic Symptoms (MTOPS) Research Group. The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. N Engl J Med. Dec 18; 2003 349(25):2387–98. [PubMed: 14681504]

16. Fowler FJ Jr. Barry MJ, Luet. Patient-reported complications and follow-up treatment after radical prostatectomy. The National Medicare Experience: 1988-1990 (updated June 1993). Urology. 1993; 42(6):622–9. al. [PubMed: 8256394]

17. Joly F, Brune D, Couette JE, et al. Health-related quality of life and sequelae in patients treated with brachytherapy and external beam irradiation for localized prostate cancer. Ann Oncol. 1998; 9(7):751–7. [PubMed: 9739442]

18. Sonn GA, Sadetsky N, Presti JC, Litwin MS. Differing perceptions of quality of life in patients with prostate cancer and their doctors. J Urol. Nov; 2009 182(5):2296–302. Epub 2009 Sep 16. [PubMed: 19758610]

19. Borghede G, Sullivan M. Measurement of quality of life in localized prostatic cancer patients treated with radiotherapy. Development of a prostate cancer-specific module supplementing the EORTC QLQ-C30. Qual Life Res. 1996; 5(2):212–22. [PubMed: 8998490]

20. Giesler RB, Miles BJ, Cowen ME, et al. Assessing quality of life in men with clinically localized prostate cancer: development of a new instrument for use in multiple settings. Qual Life Res. 2000; 9(6):645–65. [PubMed: 11236855]

21. Madalinska JB, Essink-Bot ML, de Koning HJ, et al. Health-related quality-of-life effects of radical prostatectomy and primary radiotherapy for screen-detected or clinically diagnosed localized prostate cancer. J Clin Oncol. 2001; 19(6):1619–28. [PubMed: 11250990]

22. Smith DP, King MT, Egger S, et al. Quality of life three years after diagnosis of localised prostate cancer: population based cohort study. BMJ. 2009; 339:b4817. [PubMed: 19945997]

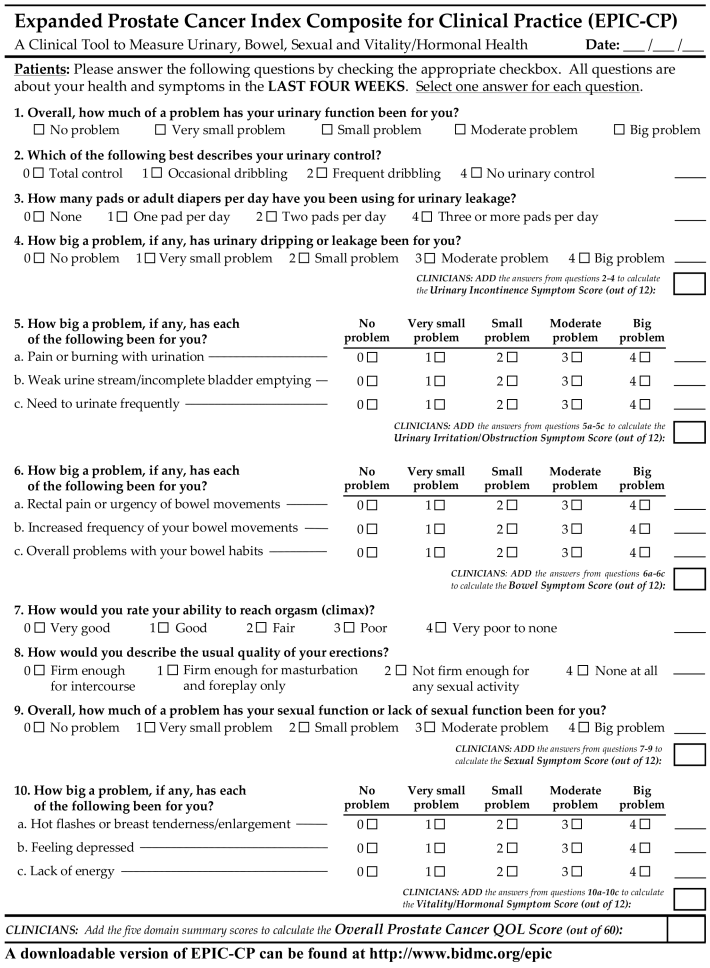
23. Pardo Y, Guedea F, Aguiló F, et al. Quality-of-Life Impact of Primary Treatments for Localized Prostate Cancer in Patients Without Hormonal Treatment. J Clin Oncol. Oct 4.2010 [Epub ahead of print].

24. Potosky AL, Legler J, Albertsen PC, et al. Health outcomes after prostatectomy or radiotherapy for prostate cancer: results from the Prostate Cancer Outcomes Study. J Natl Cancer Inst. Oct 4; 2000 92(19):1582–92. [PubMed: 11018094]

25. D'Amico AV, Whittington R, Malkowicz SB, et al. Biochemical outcome after radical prostatectomy, external beam radiation therapy, or interstitial radiation therapy for clinically localized prostate cancer. JAMA. Sep 16; 1998 280(11):969–74. [PubMed: 9749478]

26. Chen RC, Clark JA, Talcott JA. Individualizing quality-of-life outcomes reporting: how localized prostate cancer treatments affect patients with different levels of baseline urinary, bowel, and sexual function. J Clin Oncol. Aug 20; 2009 27(24):3916–22. Epub 2009 Jul 20. [PubMed: 19620493]

27. Stanford JL, Feng Z, Hamilton AS, et al. Urinary and sexual function after radical prostatectomy for clinically localized prostate cancer: the Prostate Cancer Outcomes Study. JAMA. 2000; 283(3): 354–60. [PubMed: 10647798]



Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP)

A Clinical Tool to Measure Urinary, Bowel, Sexual and Vitality/Hormonal Health **Date:** ___ /___ /___

Patients: Please answer the following questions by checking the appropriate checkbox. All questions are about your health and symptoms in the **LAST FOUR WEEKS**. Select one answer for each question.

1. Overall, how much of a problem has your urinary function been for you?
☐ No problem ☐ Very small problem ☐ Small problem ☐ Moderate problem ☐ Big problem

2. Which of the following best describes your urinary control?
0 ☐ Total control 1 ☐ Occasional dribbling 2 ☐ Frequent dribbling 4 ☐ No urinary control ____

3. How many pads or adult diapers per day have you been using for urinary leakage?
0 ☐ None 1 ☐ One pad per day 2 ☐ Two pads per day 4 ☐ Three or more pads per day ____

4. How big a problem, if any, has urinary dripping or leakage been for you?
0 ☐ No problem 1 ☐ Very small problem 2 ☐ Small problem 3 ☐ Moderate problem 4 ☐ Big problem ____

CLINICIANS: ADD the answers from questions **2-4** *to calculate the* ***Urinary Incontinence Symptom Score (out of 12):*** ☐

5. How big a problem, if any, has each of the following been for you?	**No problem**	**Very small problem**	**Small problem**	**Moderate problem**	**Big problem**	
a. Pain or burning with urination	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	____
b. Weak urine stream/incomplete bladder emptying	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	____
c. Need to urinate frequently	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	____

CLINICIANS: ADD the answers from questions **5a-5c** *to calculate the* ***Urinary Irritation/Obstruction Symptom Score (out of 12):*** ☐

6. How big a problem, if any, has each of the following been for you?	**No problem**	**Very small problem**	**Small problem**	**Moderate problem**	**Big problem**	
a. Rectal pain or urgency of bowel movements	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	____
b. Increased frequency of your bowel movements	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	____
c. Overall problems with your bowel habits	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	____

CLINICIANS: ADD the answers from questions **6a-6c** *to calculate the* ***Bowel Symptom Score (out of 12):*** ☐

7. How would you rate your ability to reach orgasm (climax)?
0 ☐ Very good 1 ☐ Good 2 ☐ Fair 3 ☐ Poor 4 ☐ Very poor to none ____

8. How would you describe the usual quality of your erections?
0 ☐ Firm enough for intercourse 1 ☐ Firm enough for masturbation and foreplay only 2 ☐ Not firm enough for any sexual activity 4 ☐ None at all ____

9. Overall, how much of a problem has your sexual function or lack of sexual function been for you?
0 ☐ No problem 1 ☐ Very small problem 2 ☐ Small problem 3 ☐ Moderate problem 4 ☐ Big problem ____

CLINICIANS: ADD the answers from questions **7-9** *to calculate the* ***Sexual Symptom Score (out of 12):*** ☐

10. How big a problem, if any, has each of the following been for you?	**No problem**	**Very small problem**	**Small problem**	**Moderate problem**	**Big problem**	
a. Hot flashes or breast tenderness/enlargement	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	____
b. Feeling depressed	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	____
c. Lack of energy	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	____

CLINICIANS: ADD the answers from questions **10a-10c** *to calculate the* ***Vitality/Hormonal Symptom Score (out of 12):*** ☐

CLINICIANS: Add the five domain summary scores to calculate the ***Overall Prostate Cancer QOL Score*** *(out of 60):* ☐

A downloadable version of EPIC-CP can be found at http://www.bidmc.org/epic

Figure 1.

Table 1

Patient and Disease Characteristics of the EPIC-CP Validation Cohort (n=307)*

Age at enrollment – median (IQR)	65 (59-70)
Race – no. (%)	
White/Caucasian	245 (79.8)
African-American	28 (9.1)
Other/Unknown	34 (11.1)
PSA (ng/mL) – median (IQR)	5.7 (4.4 – 8.2)
Clinical T-stage – no. (%)	
cT1	194 (63.2)
cT2	68 (22.1)
cT3-T4	20 (6.5)
cTX	19 (6.2)
Biopsy Gleason Score – no. (%)	
6 or less	117 (38.1)
7	125 (40.7)
8-10	47 (15.3)
Clinical Setting – no. (%)	
Medical Oncology	54 (17.6)
Radiation Oncology	88 (28.7)
Urology	74 (24.1)
Multidisciplinary clinic	81 (26.4)
Primary Treatment – no. (%)	
Radical Prostatectomy	64 (20.9)
External beam radiotherapy	63 (20.5)
Brachytherapy	38 (12.4)
Hormonal therapy only	10 (3.3)
Active surveillance	32 (10.4)
Untreated	100 (32.6)
Hormonal therapy as part of Primary Treatment – no. (%)	
No	258 (84.0)
Yes	49 (16.0)

* May not sum to total patients because of occasional missing values

Abbreviations: IQR=interquartile range; PSA=prostate-specific antigen

Table 2

Correlation between individual items and total scores for EPIC-26 and EPIC for Clinical Practice (EPIC-CP), and correlations of domain summary scores of EPIC-CP with previous versions of EPIC upon rescoring of the EPIC-50/EPIC-26 Cohort

Quality-of-life domain and individual EPIC-CP questionnaire item	Item number		Item-scale correlation		Domain score correlations of EPIC-CP with previous versions of EPIC	
	EPIC-26	EPIC-CP	EPIC-26	EPIC-CP	EPIC-50	EPIC-26
Urinary domains						
Overall urinary problem (1) *	5	1	n/a	n/a		
Incontinence subscale (3)					0.96	0.96
Frequent dribbling *	2	2	0.77	0.75		
Any pad use *	3	3	0.66	0.66		
Leaking problem *	4.a	4	0.83	0.76		
Irritation/obstruction subscale (3)					0.98	0.97
Dysuria †	4.b	5.a	0.65	0.61		
Weak stream †	4.d	5.b	0.67	0.69		
Frequency †	4.e	5.c	0.61	0.62		
Bowel domain (3)					0.97	0.94
Urgency or rectal pain ‡	6.a/6.e	6.a	0.77/0.65	0.81		
Frequency †	6.b	6.b	0.81	0.80		
Overall bowel problem *	7	6.c	0.83	0.77		
Sexual domain (3)					0.95	0.93
Difficulty with orgasm *	8.b	7	0.68	0.63		
Erections not firm *	9	8	0.79	0.62		
Overall sexuality problem *	12	9	0.50	0.35		
Vitality or hormonal domain (3)					0.97	0.94
Hot flashes or breast problems ‡	13.a/13.b	10.a	0.38/0.31	0.29		
Depression †	13.c	10.b	0.62	0.60		
Lack of energy †	13.d	10.c	0.58	0.62		

* These 8 items (1, 2, 3, 4, 6c, 7, 8, 9 were original UCLA-PCI3 items retained for generalizability and clinically significant assessment; item 5 in EPIC-26 and item 1 in EPIC-CP are the UCLA urinary bother item; because this item related to both incontinence and irritative/obstructive scale in factor analyses and conceptual content, it was not included in either irritative/obstructive nor urinary incontinence scale, but was retained to enable assessment of overall urinary bother, which could be influenced by either or both of these domains.

† These items were retained from both EPIC-50 and EPIC-26

‡ Two items from EPIC-26 were combined in order to preserve conceptual content in EPIC-CP.

Table 3

Domain characteristics of EPIC for Clinical Practice (EPIC-CP) in 175 subjects treated for prostate cancer in the EPIC-CP Validation Cohort

EPIC-CP HRQOL Domain	Mean (SD)	Median (IQR)	Range	Scoring Minimum (%)	Scoring Maximum (%)	Cronbach's alpha (95% CI)*
Urinary						
Incontinence	1.76 (2.27)	1.0 (0.0-3.0)	0.0-11.0	42.2%	0.0%	0.81 (0.77-0.86)
Irritation/obstruction	2.79 (2.62)	2.0 (1.0-4.0)	0.0-12.0	19.0%	1.1%	0.72 (0.63-0.77)
Bowel	1.65 (2.48)	0.0 (0.0-2.0)	0.0-11.0	51.4%	0.0%	0.84 (0.78-0.88)
Sexual	6.47 (3.92)	7.0 (3.0-9.5)	0.0-12.0	8.8%	12.6%	0.80 (0.74-0.84)
Vitality/hormonal	2.43 (2.57)	2.0 (0.0-4.0)	0.0-11.0	29.9%	0.0%	0.64 (0.54-0.73)

Domain summary scores range from 0 to 12, with 0 = best possible score and 12 = worst possible score

* 95% confidence intervals estimated from 500 bootstrap samples

Table 4

Sensitivity of EPIC for Clinical Practice (EPIC-CP) to HRQOL differences associated with prostate cancer treatment – unadjusted mean domain scores by treatment group compared to a group of untreated subjects in the EPIC-CP Validation Cohort

	Treatment group Mean (SD)			
HRQOL Domain *	**Any treatment (n=175)**	**Active surveillance (n=32)**	**All Untreated (n=132)**	**p-value**†
Urinary				
Overall Urinary Bother	1.32 (1.29)	1.25 (1.32)	1.11 (1.17)	0.14
Incontinence	1.76 (2.27)	0.87 (1.41)	1.06 (1.85)	0.004
Irritation/obstruction	2.79 (2.62)	2.28 (2.22)	2.16 (1.99)	0.02
Bowel	1.65 (2.48)	0.94 (1.63)	1.11 (1.88)	0.04
Sexual	6.47 (3.92)	4.16 (3.12)	3.73 (3.20)	<0.0001
Vitality/Hormonal	2.43 (2.57)	1.88 (2.14)	1.92 (2.38)	0.08
Total score	14.66 (9.00)	9.77 (7.40)	9.59 (7.75)	<0.0001

*Domain scores range from possible 0 to 12, with 0 = best score and 12 = worst score. Overall urinary bother item is scored separately from the urinary domain scores, and is scored from a possible 0 to 4, with 0 = best score and 4 = worst score.

†Mean domain scores of subjects who received any treatment (n = 175) were compared using ANOVA to a group of all untreated subjects, a combined group of untreated and active surveillance (n=132). For the hormonal/vitality domain, patients who received hormonal therapy had worse scores than men who were either untreated or had undergone primary treatment without hormonal therapy.

Table 5

Ease of using EPIC-CP in routine clinical practice (n = 307)

Time taken for patient to fill out EPIC-CP	
Less than 5 minutes	77%
5 to 10 minutes	19%
10-15 minutes	2%
Greater than 15 minutes	<1%
Convenience of EPIC-CP administration in routine clinical practice by clinician	
Very convenient	87%
Somewhat convenient	12%
Somewhat inconvenient	<1%
Very inconvenient	0%
Patient completed all questions	89%