Development and Validation of the Bladder Cancer Index: A Comprehensive, Disease Specific Measure of Health Related Quality of Life in Patients With Localized Bladder Cancer

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Abbreviations and Acronyms

BCI = Bladder Cancer Index

FACT = Functional Assessment of Cancer Therapy

FACT-BI = FACT-Bladder

FACT-G = FACT-General

HRQOL = health related quality of life

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Purpose: We developed and validated a reliable, responsive multidimensional instrument to measure disease specific health related quality of life in bladder cancer survivors treated with local cancer therapy.

Materials and Methods: Instrument content was based on qualitative information obtained from a panel of bladder cancer providers and from patient focus groups. Draft items were piloted and revised, resulting in the 36-item Bladder Cancer Index consisting of urinary, bowel and sexual health domains. Internal consistency, test-retest reliability, convergent validity, concurrent validity and criterion validity were then assessed.

Results: Internal consistency was high at 0.77 to 0.91. Test-retest reliability was also high at 0.73 to 0.95. Correlations among the 3 domains were low ($r \leq 0.39$), indicating interscale independence. Health outcome discrimination was apparent in clinically distinct treatment groups. Moderate correlation was observed with existing external measures, indicating that the Bladder Cancer Index detects aspects of health related quality of life related to bladder cancer treatments that are not recorded by more general measures.

Conclusions: The Bladder Cancer Index is a robust, multidimensional measure of bladder cancer specific health related quality of life and to our knowledge is the first available validated instrument to assess health outcomes across a range of local treatments commonly used for bladder cancer.

Key Words: urinary bladder, bladder neoplasms, quality of life, questionnaires, survivors

For many of the greater than 70,000 American men and women diagnosed with bladder cancer each year[1] treatment is associated with a number of life altering consequences. While most patients present with noninvasive papillary tumors and are treated with endoscopic tumor resection, intravesical therapy and surveillance cystoscopy, a substantial number face more advanced disease requiring bladder removal and urinary diversion. Bladder cancer treatment imparts significant functional and HRQOL impairment across different disease and treatment settings. Consequently assessing the consequences associated with bladder cancer treatment has become increasingly important.

Despite significant interest in this area HRQOL assessment of bladder cancer survivors has been limited by a lack of reliable, responsive disease specific measures.[2–4] To date research has largely focused on the im-

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pact of bladder removal and urinary diversion.[5] However, disease and treatment related consequences in those who do not undergo cystectomy, representing most bladder cancer survivors, have been overlooked. In this prevalent group little is known regarding the impact of repeat, endoscopic and intravesical treatments. Even in those treated with cystectomy and urinary diversion comparisons of functional outcomes and HRQOL have been inconsistent and difficult to interpret.[6–9] In part this stems from issues related to inadequate methodology. For example, most previous groups have used generic, nondisease specific health measures or measures lacking formal validation, raising important concerns regarding responsiveness and reliability.[2,4,6,7,10] Given these shortcomings and the resulting gap in knowledge for this important disease, we developed and validated a reliable, responsive disease specific measure of HRQOL applicable across the disease and treatment spectrum of localized bladder cancer.

METHODS

Instrument Development

Initial instrument content was based on the results of literature review and input from a panel of physicians, oncology nurses and enterostomal therapists with extensive experience with various aspects of bladder cancer management. Content and format feedback from a development cohort of 62 bladder cancer survivors was then used to revise survey items. During this first phase new items were developed to address previously unrecognized areas of importance and existing items were refined to be inclusive across treatment groups. For example, items were revised to provide gender and urinary diversion neutral phrasing to improve the acceptability and applicability of questions. Revised items were then administered to a separate pilot cohort of 72 bladder cancer survivors and evaluated for response frequency, initial factor loading, item scale correlation and internal reliability. Based on these preliminary psychometric properties low performing items were eliminated and retained items were grouped by related constructs.

Validation Procedures

A validation cohort was chosen by taking a random cross-sectional sample of bladder cancer survivors across a range of disease stages (noninvasive and invasive cancer) and management approaches (endoscopic treatment, intravesical therapy, and extirpative surgery) from a prospective institutional bladder cancer database. A total of 693 patients treated between 1995 and 2004 were initially contacted, of whom 315 with a median age of 69 years (range 41 to 89) agreed to participate and returned study forms (45% participation). Study participants completed a battery of questionnaires, including SF-12®,[11] which measures general physical and mental health, FACT-G,[12] which measures physical, social, emotional and functional well-being in patients with cancer and FACT-Bl, an adaptation of the FACT-G module that measures additional aspects of HRQOL relevant to bladder cancer, in addition to candidate items retained from the instrument development phase. All questionnaires were self-administered, returned by mail and scored centrally by trained staff.

Measures and Statistical Analysis

To provide a basis for summary scoring exploratory factor analysis we applied varimax rotation to identify discrete domains. Domain scores were calculated by standardizing each Likert scale item to a 0 to 100 scale and determining the mean of the standardized items that comprised the domain. Higher scores represented better health states. Domain scores were set to missing when more than 20% of the items in a domain were missing. Otherwise the domain score was calculated from nonmissing items.

To assess external reliability test-retest analysis was performed in a subgroup of 50 participants with assessments made 2 to 4 weeks apart. This subgroup was divided evenly among 4 predefined treatment groups, including group 1—native bladder managed by cystoscopy but no intravesical therapy, group 2—native bladder managed by cystoscopy and intravesical therapy, group 3—cystectomy managed by ileal conduit urinary diversion and group 4—cystectomy managed by continent urinary diversion. Participants were chosen by stratified randomization. Treatment groups were chosen to represent broad management groups across the spectrum of bladder cancer, including endoscopic based resection and surveillance, management by intravesical therapy, and surgical management by cystectomy and urinary diversion. Internal consistency was assessed using Cronbach's α coefficient for each domain and subdomain. Pearson correlation coefficients were calculated between domains to assess redundancy and/or conceptual independence. Correlation of HRQOL score differences between different treatment groups was used to assess concurrent validity. Criterion validity was assessed with correlation of individual instrument scales to summary scores of relevant validated instruments, for example FACT-Bl, and comparison of mean domain scores across disease stage. All analysis was done with SAS®, version 9.1.2. Two-sided statistical testing was performed at the 5% significance level. The study was approved by the University of Michigan institutional review board and all study participants provided consent.

RESULTS

Table 1 lists clinical and demographic characteristics in the validation cohort of 315 patients. Consistent with bladder cancer epidemiology, most patients were male and older. Noninvasive tumors were more common than muscle invasive disease but greater than 70% of cases consisted of high grade cancer. Approximately 40% of patients recruited for study were treated with endoscopic based therapy, including cystoscopy, transurethral tumor resection and ablation, and intravesical therapy. Of the remaining 60% of patients treated with cystectomy 122 (64.9% of those with cystectomy and 38.7%

Table 1. *Demographic and clinical characteristics in 315 patients in BCI validation cohort*

Characteristic	No. Pts (%)
Primary intervention:	
Endoscopy, no intravesical therapy	52 (16.5)
Endoscopy + intravesical therapy	75 (23.8)
Cystectomy + ileal conduit diversion	66 (21.0)
Cystectomy + orthotopic continent diversion	122 (38.7)
Gender:	
M	258 (81.9)
F	57 (18.1)
Race:	
White	290 (92.6)
Black	9 (2.9)
Other	14 (4.5)
Income level ($):	
30,000 or Greater	204 (68.0)
Less than 30,000	96 (32.0)
Education:	
College or advanced degree	116 (36.9)
High school	170 (54.1)
Less than high school	28 (8.9)
Living status:	
Married/life partner	254 (81.4)
Single/divorced	58 (18.6)
Disease stage:	
Nonmuscle invasive (Ta, Tis, T1)	166 (52.7)
Muscle invasive (T2–T4)	119 (37.8)
Unknown	30 (9.5)
Disease grade:	
Low	49 (15.6)
High	223 (70.8)
Unknown	43 (13.6)
Tumor histology:	
Transitional cell Ca	306 (97.1)
Other	8 (2.9)

of the overall cohort) underwent continent urinary diversion and 66 (35.1% and 21%, respectively) underwent ileal conduit diversion.

Factor analysis of item response distribution identified 3 primary HRQOL domains (urinary, bowel and sexual). In each domain function and bother subgroups were also identified according to item loading. The revised instrument used in the validation phase contained a total of 36 items distributed among the 3 primary domains, including 14 urinary, 10 bowel and 12 sexual items.

Table 2 lists the results of reliability testing. For all 3 domains internal consistency reliability was high (Cronbach's α between 0.77 and 0.94), indicating that domain items were consistent in measuring urinary, bowel and sexual constructs. The percent of participants reporting maximum and minimum scores was relatively low across domains, indicating minimal to moderate floor and ceiling effects. For example, the scoring minimum and maximum percents were 0% and 22.7% for the urinary domain, 0% and 11.2% for the bowel domain, and 1.1% and 0.4% for the sexual domain. Also, test-retest correlation

Table 2. *BCI domain specific summary and subscale characteristics*

Domains	No. Items	Scoring Minimum %	Scoring Max %	Cronbach's α	Test-Retest Correlation
Urinary:	14	0	22.7	0.85	0.92
Function	6	1.4	40.2	0.85	0.90
Bother	8	0	33.7	0.83	0.92
Bowel:	10	0	11.2	0.82	0.87
Function	4	0	17.2	0.77	0.82
Bother	6	0	32.8	0.77	0.87
Sexual:	12	1.1	0.4	0.91	0.92
Function	7	22.0	0.4	0.94	0.95
Bother	5	2.5	19.2	0.81	0.73

testing revealed excellent external reliability across all domains with correlations between 0.73 and 0.95.

Interscale correlations between domain scales and subscales were used to evaluate the convergent and divergent validity of BCI function and bother scores (table 3). In each domain function and bother scores had moderate correlations (urinary, bowel and sexual subdomains r = 0.48, 0.45 and 0.56, respectively), indicating that each domain bother subscale quantified impairments related to symptoms measured by the function subscale. In contrast, correlations between the function and bother subscales of different domains were consistently weaker. Combined, interdomain and intradomain subscale correla-

Table 3. *Interscale correlation between BCI function and bother subscales, and other HRQOL instrument summary scores*

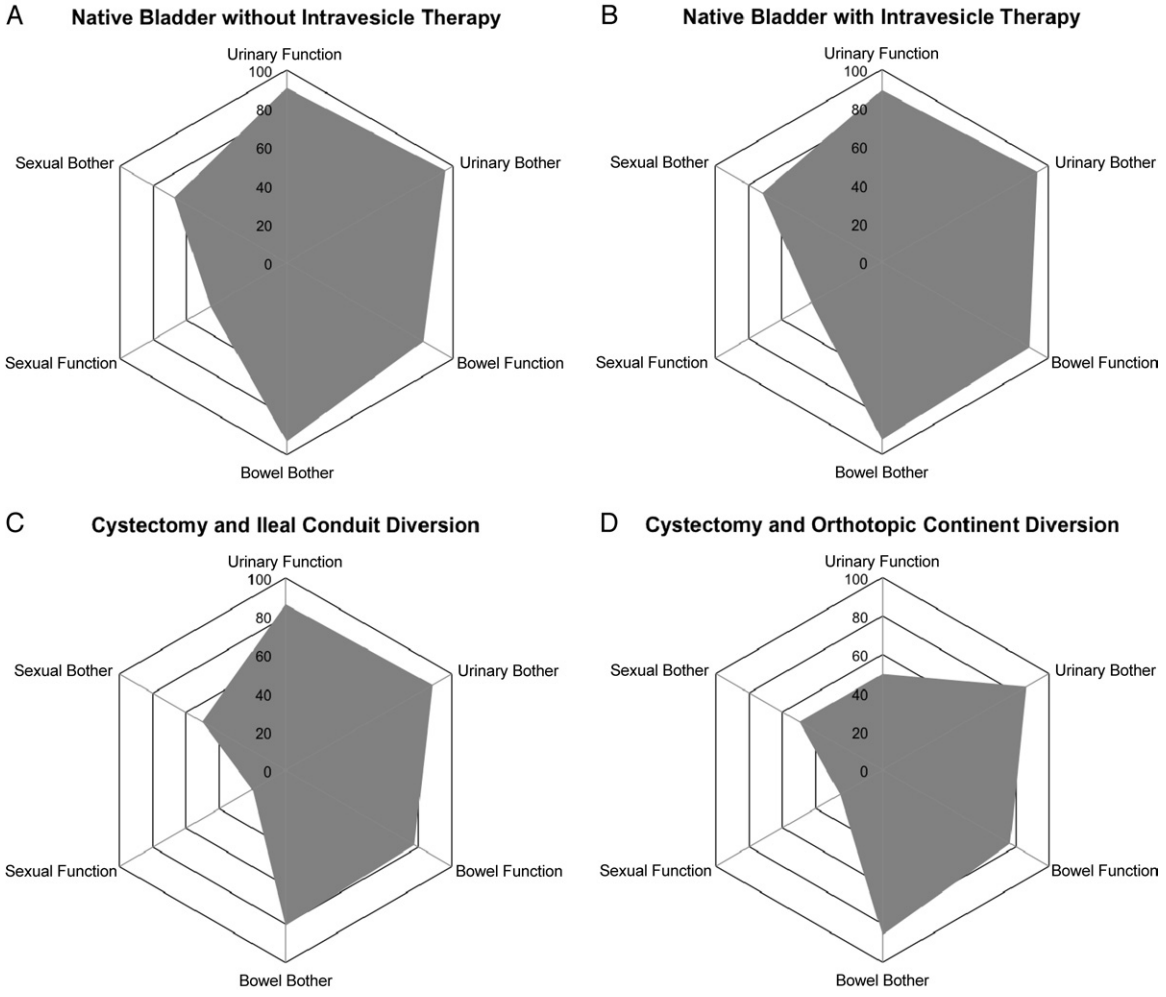
	Urinary		Bowel		Sexual	
	Function	Bother	Function	Bother	Function	Bother
Urinary:						
Function	1.0	—	—	—	—	—
Bother	0.48	1.0	—	—	—	—
Bowel:						
Function	0.24	0.26	1.0	—	—	—
Bother	0.21	0.39	0.45	1.0	—	—
Sexual:						
Function	0.18	0.23	0.17	0.21	1.0	—
Bother	0.23	0.31	0.18	0.23	0.56	1.0
FACT-G domain:	0.20	0.60	0.23	0.44	0.29	0.32
Physical well-being	0.16	0.56	0.20	0.50	0.25	0.24
Social + family well-being	0.17	0.40	0.19	0.17	0.15	0.27
Emotional well-being	0.07	0.41	0.14	0.29	0.13	0.19
Functional well-being	0.21	0.51	0.19	0.40	0.36	0.27
FACT-BI additional concern domain	0.40	0.49	0.24	0.22	0.42	0.23
FACT-BI	0.28	0.63	0.26	0.42	0.36	0.33
SF-12 composite summary:						
Physical	0.07	0.32	0.11	0.30	0.30	0.19
Mental	0.15	0.34	0.15	0.26	0.17	0.19

The underlined numbers are the interscale correlation coefficients comparing function and bother scores within each domain (for example, urinary function compared the urinary bother).

tions indicated that the urinary, bowel and sexual domains measured conceptually discrete components of HRQOL.

Mean domain scores differed significantly among treatment groups. Generally lower domain scores (relatively lower health function) were more common in the setting of more invasive intervention (see figure). For example, urinary, bowel and sexual scores were consistently lower in cystectomy groups than in native (endoscopically managed) bladder groups. The magnitude of this observed treatment related effect was greatest for the sexual and urinary domains, for which known functional consequences associated with extirpative surgical resection and urinary diversion are common, such as sexual dysfunction, and changes in urine storage and drainage. For instance, sexual function scores were lowest in the cystectomy groups compared to the native bladder groups, as were urinary function scores (table 4).

Table 3 also shows the correlation with other relevant HRQOL measures. As expected, BCI function and bother subscales correlated only modestly with the generic (noncancer specific) physical and mental composite summary domains of SF-12 (r = 0.07 to 0.34). Moderate to strong correlation was observed between several domains of the FACT and BCI subscales. In particular the urinary bother subscale correlated strongly with the physical and functional domains of FACT-G and FACT-Bl. BCI subscales correlated more strongly with cancer specific (FACT-G) and modified (FACT-Bl) measures than with noncancer specific scales. Mean BCI scores also differed consistently by disease stage, as indicated by incrementally lower urinary, bowel and sexual scores for higher disease stages (table 5).



Spider graphs stratified by treatment group. *A,* native bladder without intravesical therapy. *B,* native bladder with intravesical therapy. *C,* cystectomy and ileal conduit urinary diversion. *D,* cystectomy and ileal neobladder urinary diversion. Shaded areas include mean scores across BCI domains in treatment group. Changes in shaded areas indicate characteristic HRQOL differences in treatment group.

Table 4. *Mean BCI scores by treatment group*

Domains	Mean ± SD Native Bladder	Mean ± SD Native Bladder/Intravesical Therapy	Mean ± SD Cystectomy/Ileal Conduit	Mean ± SD Cystectomy/Ileal Neobladder	p Value
Urinary:					
Function	88.3 ± 19.6	87.7 ± 20.7	85.7 ± 22.5	51.3 ± 27.1	<0.001
Bother	96.0 ± 8.1	93.6 ± 11.5	88.5 ± 13.5	85.9 ± 15.6	<0.001
Bowel:					
Function	82.3 ± 17.4	87.8 ± 14.6	78.6 ± 20.7	77.0 ± 19.0	<0.001
Bother	90.3 ± 13.3	91.1 ± 13.8	81.9 ± 18.6	86.0 ± 15.2	0.002
Sexual:					
Function	38.9 ± 30.0	40.0 ± 34.6	14.4 ± 18.3	30.5 ± 25.8	<0.001
Bother	67.3 ± 30.1	67.9 ± 31.5	48.6 ± 29.9	53.2 ± 28.0	<0.001

DISCUSSION

Using an iterative process and standard psychometric methods we developed and validated a disease specific HRQOL instrument applicable to a range of disease and treatment settings commonly encountered in nonmetastatic bladder cancer cases. Consisting of 36 items in 3 principal domains and 6 overall subdomains, the BCI showed satisfactory survey characteristics on validation analysis. Internal and external reliability were excellent, as indicated by Cronbach's α between 0.77 and 0.91, and test-retest correlations between 0.73 and 0.95. Interscale correlations were relatively low, supporting measurement independence among urinary, bowel and sexual domains. Mean domain scores also varied appropriately according to clinical treatment groups, further supporting the discriminatory ability of the BCI to differentiate clinically meaningful differences among various treatment groups.

Patient reported outcomes such as health status are important, well recognized components of quality cancer care.[12] For health care providers involved in the care of bladder cancer survivors the quality of life impact of cancer directed therapy, such as bladder removal and urinary diversion, has been a longstanding topic of concern. Unfortunately previous studies in this area have been limited.[2–4] Shortcomings in existing HRQOL measures relate to a lack of relevant content, such as multi-item scales for measuring treatment related dysfunction and bother as well as to undefined instrument reliability and responsiveness. Also, there is a paucity of quality of life studies in the noncystectomy population, representing the largest segment of bladder cancer survivors. Together the lack of a validated, universally adopted quality of life measure for bladder cancer has limited progress and questions on the HRQOL impact of different bladder cancer treatments remain unanswered.

Table 5. *Mean BCI scores by disease stage*

Domains	Ta	T1/is	T2	T3	T4	p Value
No. Pts*	52	114	101	15	3	
Urinary:	91.8	81.8	80.1	80.9	66.7	<0.001
Function	88.4	67.8	66.1	74.4	58.3	<0.001
Bother	94.2	89.3	86.8	85.9	70.8	0.008
Bowel:	90.8	83.8	82.8	79.4	76.4	0.006
Function	87.4	82.0	77.8	73.8	61.8	0.004
Bother	91.7	85.2	86.3	83.1	86.1	0.14
Sexual:	50.8	40.9	38.2	26.2	25.7	0.011
Function	38.9	31.7	26.2	10.8	3.6	0.003
Bother	66.3	54.3	54.6	47.8	50.7	0.15

* Stage missing or unknown in 30 participants.

The BCI addresses many of these limitations. BCI content is bladder cancer specific, targets symptoms commonly associated with bladder cancer treatment and is responsive (sensitive) to differences among treatment modalities.[13] Mean domain scores differed by treatment in a clinically consistent manner, indicating discrimination according to relevant clinical groups. Furthermore, correlation with other HRQOL measures showed that the BCI measures previously under recognized aspects of HRQOL, in addition to components consistent with external criterion. The BCI does not limit HRQOL assessment to cystectomy subgroups,[14] can be applied in invasive and noninvasive disease settings, measures HRQOL effects of endoscopic, intravesical and surgical (cystectomy) treatments, and is characterized by gender and urinary diversion neutral questions, further increasing its applicability.

While we applied a standard psychometric approach characterized by iterative content development and validation, our results should not be interpreted without considering several limitations. We performed a cross-sectional evaluation of a cohort of bladder cancer survivors in different phases of recovery. Consequently we could not adjust for baseline assessment or track longitudinal changes in HRQOL effects with time. Because participants were surveyed at different followup times, it is possible that aspects of HRQOL sensitive to change were not detected based on the sampling, which would be most problematic in those treated with less permanent therapy, such as endoscopic (cystoscopy and transurethral resection) and intravesical therapy. This error would limit our ability to detect

differences in shorter term HRQOL but the long-term and late term effects of different treatment groups would be less likely affected.

Other sampling limitations were apparent in the relatively low number of female patients and patients with a native bladder (noncystectomy) in the study cohort. However, women have bladder cancer less commonly and our enrollment approximates national estimates.[1] Assessing criterion validation was also limited by the lack of available disease specific instruments targeting the cystectomy and noncystectomy bladder cancer population. This is reflected in low to moderate correlation among BCI subdomains and other, more general HRQOL instruments, such as FACT and SF-12. Finally, other important HRQOL aspects, such as patient perception of body image, were not included as a BCI core domain, given the availability of previously developed body image scales[15] that may be co-administered with BCI.

Outcome studies of bladder cancer cases have been limited by the lack of a validated disease specific measure. The BCI addresses this gap and provides researchers with a robust measure of urinary, sexual and bowel outcomes. The BCI is applicable across genders and forms of urinary diversion, making it ideal for comparative effectiveness trials. BCI construct validity will be established as more studies adopt its use across other clinical populations.

CONCLUSIONS

The BCI is a reliable, multidimensional measure of bladder cancer specific HRQOL and to our knowledge it is the first available validated instrument to assess health outcomes across a range of local treatments commonly used to manage bladder cancer. The BCI is responsive to treatment related functional and HRQOL differences, and can be used clinically and in research to quantify patient centered outcomes in bladder cancer survivors. Additional HRQOL research using the BCI in larger bladder cancer populations and in longitudinal settings will provide additional information and understanding concerning outcomes experienced by bladder cancer survivors.

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EDITORIAL COMMENT

To date our understanding of HRQOL outcomes in patients with bladder cancer has been hampered by the lack of a truly versatile, validated, reliable questionnaire that individually addresses the domains most likely affected by the disease and its treatment. With the development of the BCI these authors address this methodological shortcoming and contribute to the field of urological outcome research. Unlike prior instruments, such as the FACT-Bl and FACT-Vanderbilt Cystectomy Index of Cookson et al, which provide a single summary score for HRQOL (reference 14 in article), BCI provides an individual score in each distinct domain for a more detailed, comprehensive portrait of the survivorship experience. There is little

doubt in my mind that BCI is now the gold standard to assess HRQOL in bladder cancer cases.

With that said, while I believe that BCI is a major advance, I do not believe that it is perfect nor that it will ultimately be the final HRQOL questionnaire for this condition. I have serious concerns that in an effort to create an instrument that can be used for each gender, in patients with all stages of bladder cancer and all types of urinary diversions the authors may have missed some important HRQOL aspects that are unique to a specific gender or diversion type. For example, the concerns of a man undergoing ileal loop conduit diversion, ie body image changes, appliance malfunction, erectile and ejaculatory dysfunction etc, are likely to be quite different from those of a woman undergoing urinary neobladder replacement, ie stress incontinence, need to catheterize, dyspareunia etc. While BCI captures some of this, it lacks the detail to provide the full picture. If I am correct and certain elements of HRQOL unique to particular patient subsets have been missed, future versions of BCI must incorporate these additional elements into existing or new domains.

Luckily there is a precedent for updating and improving HRQOL instruments for urological malignancies. UCLA-PCI[1] was originally the gold standard for HRQOL assessment in localized prostate cancer cases, although it failed to capture irritative symptoms or side effects of hormonal therapy. With time as it became clear that these domains were highly relevant to prostate cancer survivors, researchers, of whom many are on the research team that created the BCI, developed the Expanded Prostate Cancer Index Composite, which captured these missing domains.[2] I am confident that BCI developers and other researchers will continue to explore and improve the BCI in a similar manner.

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