

# Validation of the French-Canadian version of the Expanded Prostate Cancer Index Composite (EPIC) in a French-Canadian population

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## Abstract

**Introduction:** This study aims to empirically validate the French-Canadian version of the Expanded Prostate Cancer Index Composite (EPIC), a measure of health-related quality of life for prostate cancer patients.

**Methods:** Two hundred fifty-one participants completed a battery of self-report scales, including the French-Canadian version of the EPIC, after having received radiation therapy or radical prostatectomy for prostate cancer.

**Results:** The internal consistency for the urinary incontinence, bowel, and sexual domains of the EPIC-26 was high (Cronbach's alpha coefficients from 0.80–0.92), while coefficients for the urinary irritation/obstruction (0.59) and hormonal (0.67) domains were lower. Item-total correlations ( $r_s=0.15-0.85$ ), and temporal stability ( $r_s=0.72-0.93$ ) generally supported the reliability of the instrument. The five-factor structure of the EPIC-26 was confirmed for the most part. The construct validity of the instrument was also supported by high correlations obtained between each domain and measures assessing similar constructs ( $r_s=-0.56-0.83$ ). The EPIC also showed an excellent sensitivity to change with significant differences obtained on EPIC scores (all  $p<0.05$ ) between pre- and post-prostate cancer treatment.

**Conclusions:** The psychometric qualities of the French-Canadian version of the EPIC are well-supported, thus providing a valid tool to assess health-related quality of life in prostate cancer patients.

## Introduction

Prostate cancer is the most common cancer in North American men. Approximately 161 360 cases were diagnosed in the U.S in 2017.<sup>1</sup> While some low-risk patients may

be put on active surveillance programs, intermediate- and high-risk prostate cancer usually requires treatment. Several options are available, including radical prostatectomy, external beam radiation therapy, and brachytherapy. While these treatment modalities have demonstrated their efficacy in treating prostate cancer, they are associated with some toxicity and long-term side-effects.<sup>2-4</sup> Health-related quality of life (HRQOL) is an important parameter of treatment success and is now typically assessed in standard practice.<sup>5</sup> It is also an important aspect to take into account when helping patients choose the most appropriate treatment option for their condition.

The Expanded Prostate Cancer Index Composite (EPIC), a self-report scale, was designed to measure HRQOL specifically among prostate cancer patients.<sup>6</sup> The original English version is composed of 50 questions encompassing four domains (urinary, bowel, sexual, and hormonal). Function and bother are assessed with different items within each domain, and the urinary domain comprises two additional subscales: incontinence and irritation/obstruction. Domain-specific standardized scores range from 0–100, a higher score indicating a better perceived quality of life. High Cronbach's alpha coefficients ( $>0.82$ , a measure of internal consistency ranging from 0–1) and a very good test-retest reliability ( $r_s>0.80$ ) were found for all domains. The EPIC-50 also has demonstrated an adequate validity with instruments assessing similar content (convergent validity) and other instruments assessing physical symptoms that are not specific to prostate cancer (divergent validity).<sup>6</sup> In addition, this evaluation tool has been found to be sensitive to change following prostate cancer treatment.<sup>7</sup>

A shorter 26-item version of EPIC (EPIC-26) was developed to facilitate its use in a wide range of prostate cancer research and practice settings. The EPIC-26 is highly correlated with the full questionnaire ( $r_s>0.96$  for all domains).<sup>8</sup> This abbreviated version comprises five domains rather than four: urinary incontinence, urinary irritation/obstruction, bowel, sexual, and vitality/hormonal. The EPIC-26 has shown high internal consistency (Cronbach's alpha=0.70–0.90) and test-retest reliabil-

ity at 2–4-week intervals ( $r_s=0.69-0.90$  for all five domains). Moderate to strong correlations were found between the sexual domain and the Sexual Health Inventory for Men (SHIM) and between the urinary domain and the Incontinence Symptom Index (ISI), thus supporting its convergent validity.<sup>9</sup>

Two systematic comparisons of available instruments supported the use of the EPIC for the assessment of prostate cancer-specific HRQOL.<sup>10,11</sup> The EPIC has been validated in several languages (i.e., Norwegian, Spanish, Korean).<sup>12-14</sup> A French version is available, but only the EPIC-50 was validated.<sup>15</sup> Validating the short version is critical, as this is the version most likely to be used in clinical contexts, as well as in randomized, controlled trials. Also, given significant cross-cultural language differences between French people and French-Canadians, a French-Canadian validation of the EPIC was needed.

This study aimed to translate the EPIC into French, as well as to assess its psychometric properties among a clinical sample of French-Canadian prostate cancer patients. For purposes of parsimony, only the results pertaining to the EPIC-26 will be described, as this is the format typically used in clinics, although validation analyses were performed for both formats (see Supplementary Tables 1–4 for results pertaining to the EPIC-50; available at [cuaj.ca](http://cuaj.ca)).

## Methods

### Language equivalence

An initial in-house French version of the EPIC-26 was developed and used for many years in the radiation oncology department of CHU de Québec-Université Laval. To verify its quality, this version was sent to two professional English–French translators whose native language is French, following recommendations by Haccoun.<sup>16</sup> Both translators assessed whether each of the items and response choices was correctly translated and suggested an alternative wording when needed. Based on the translators' suggestions, these items were then reformulated by our research team (JS, EV, MHS). Translators were also asked to translate into French the 24 additional items of the EPIC-50. One of the two proposed French versions of each item or a version combining the two proposed formulations was retained.

Next, English and French versions of all items were sent to two different English-French translators whose native language is French (Canadian) to assess to what extent each item was correctly translated. The same strategy as described above was used to reach a single translation.

### Pilot study

This preliminary French version of the EPIC-50 was tested among a sample of 10 prostate cancer patients. Participants

were recruited during a medical appointment at the radiation oncology department of CHU de Québec-Université Laval by a research assistant. Patients were eligible when they were scheduled to receive or were currently receiving radiation therapy. Patients provided informed consent prior to their participation. They were asked to complete the EPIC while verbalizing out loud any comment about the clarity of the items or the response choices to the research assistant, who noted down their comments.

Only the French translation of “dribbling/dripping,” used in one question and two response choices, was noted as lacking clarity by three participants, and was therefore slightly modified to yield the final version.

## Empirical validation

### Participants

French-Canadian prostate cancer patients were recruited at the radiation oncology and the uro-oncology departments of CHU de Québec-Université Laval from March 2014 to January 2015. Patients were solicited in person by a research nurse during a medical appointment at the clinic.

Inclusion criteria were: a) having received radiation treatments (external beam radiation therapy or brachytherapy) and/or a radical prostatectomy (RP) for prostate cancer in the past or being scheduled to receive radiation treatments (for sensitivity to change analyses only); b) having a life expectancy >1 year; and c) being readily able to read and understand French. This study was approved by the research ethics board of the CHU de Québec-Université Laval and patients provided informed consent prior to their participation.

### Measures

All of the following measures were validated in French or official French versions were used.

#### 1. International Prostate Symptom Score (IPSS)<sup>17,18</sup>

This seven-item questionnaire assesses irritative/obstructive urinary prostate symptoms. Items are scored on a scale ranging from 0 (“never”) to 5 (“almost always”). The total score ranges from 0–35, a lower score indicating a better functioning.

#### 2. Sexual Health Inventory for Men (SHIM)<sup>19</sup>

This questionnaire is an abbreviated five-item version of the 15-item International Index of Erectile Function.<sup>20</sup> It assesses erectile function and intercourse satisfaction. Scores range from 1–5 (item 1) or from 0–5 (items 2–5), with a total score ranging from 1–25. Higher values indicate a better sexual functioning.

### 3. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire – Prostate Cancer-Specific Module (PR25)<sup>21</sup>

This 25-item questionnaire assesses HRQOL of prostate cancer patients over the past week (20 items) or the last four weeks (five items). It comprises two functional scales (sexual activity and sexual functioning) and four symptom scales (urinary, bowel, hormonal treatment-related, incontinence aid). Items are scored on a Likert scale ranging from 1 (“not at all”) to 4 (“very much”). Standardized scores range from 0–100, a higher score indicating a better (functioning scales) or worse (symptom scales) quality of life.

#### Procedure

Participants taking part in the sensitivity to change study (n=51) were asked by the research nurse to complete the EPIC-50, along with the other self-report scales, at their initial consultation (prior to receiving radiation therapy), and to fill out the EPIC-50 a second time during a followup visit at the hospital (approximately three months after their treatment ended (mean 98.2 days; range 59–163).

The remaining participants (n=200) completed the same battery of questionnaires at a followup appointment with their radiation oncologist or surgical urologist. A subgroup of these participants (n=75) was randomly selected to fill out the EPIC-50 on a second occasion, two weeks later, for test-retest reliability analyses. The randomization sequence was prepared by a biostatistician and the allocation sequence was concealed in opaque, sealed envelopes, numbered in advance, and opened sequentially. All research personnel were blind to the group allocation sequence. These randomly selected participants were given a copy of the EPIC-50 to take home and were instructed to complete it two weeks later and to return it by mail. Participants who did not return the questionnaire within four weeks were contacted by phone to remind them to complete and return it as soon as possible. A total of 68 participants returned the second questionnaire (median interval 21 days; range 7–41).

#### Statistical analyses

All data were double-entered and missing data, outliers, and distributions were examined using standard procedures.<sup>22</sup> No data imputation was performed and the alpha level was set at 5%, two-tailed. All analyses were conducted on both the full (EPIC-50) and the abbreviated (EPIC-26) scales using the SAS 9.3 software (2012, SAS Institute, Cary, NC, U.S.). EPIC-26 items were extracted from the 50-item version, as the items are the same. All results pertaining to the EPIC-26, the version most likely to be used in clinical and research settings, are discussed in this article. Detailed results about the 50-item version can be found in the Supplementary Tables (available at [cuaj.ca](http://cuaj.ca)).

#### 1. Reliability (internal consistency)

The Cronbach’s alpha coefficient<sup>23</sup> and item-total correlations were calculated for each EPIC domain using the full sample (n=251). An alpha >0.80 and item-total correlations >0.30 (moderate association<sup>24</sup>) were used to indicate an acceptable internal consistency.

#### 2. Test-retest reliability

Correlations were computed between EPIC scores obtained on each domain on two different occasions, separated by a 2–4-week interval. In addition, scores between the two administrations were compared using linear mixed models with one-time factor (two levels). A large correlation between the two time points ( $r > 0.50$ <sup>24</sup>) and a non-significant F-test were the criteria used to support the EPIC temporal stability.

#### 3. Construct validity (factor analysis)

A confirmatory factor analysis using SAS PROC CALIS (structural equation modelling) was performed using the full sample (n=251) in order to verify the reproducibility of the factor structure of the EPIC-26 (five domains: urinary incontinence, urinary irritation/obstruction, bowel, sexual, and vitality/hormonal symptoms) and the EPIC-50 (four domains: urinary, bowel, sexual, hormonal). Various indices were examined to ensure an acceptable goodness of fit with the factorial structure of the original English version.

#### 4. Convergent and divergent validity

The convergent validity of each domain of the EPIC-26 and EPIC-50 was evaluated by assessing its relationship with other measures of similar constructs: IPSS for the urinary irritation/obstruction domain; SHIM for the sexual domain; and PR25 for the other three domains (urinary incontinence, bowel, and vitality/hormonal domains). The divergent validity was evaluated by examining associations with different constructs, using the same questionnaires as for the convergent validity assessment (cross-correlations; e.g., between the urinary incontinence domain of EPIC and SHIM, which assesses sexual symptoms). Lower (or non-significant) Pearson correlations were expected as compared to convergent validity correlations.

#### 5. Sensitivity to change

In order to assess the capacity of the EPIC to detect changes in symptoms following treatment, 51 patients were asked to complete the EPIC-50 prior to the initiation of radiotherapy and approximately 12 weeks following its termination. A linear mixed model analysis with repeated measures was conducted. The presence of significant differences between pre- and post-treatment assessments on each domain was expected.

## Results

### Participant characteristics

A total of 251 prostate cancer patients were included. Of these, 51 participated in the sensitivity to change study, whereas 68 other men participated in the study's test-retest component.

Participants were between 46 and 89 years old (mean 68.7; standard deviation [SD] 7.39). The majority were married/cohabiting (73.3%) and retired from work (73.4%). Forty percent of the sample had a personal annual income lower than \$40 000 CAN. Thirty-four percent (n=86) of the total sample were treated with a combination of external beam radiotherapy and brachytherapy, 18% (n=46) with radiotherapy only, and 16% (n=39) with brachytherapy only, while 21% (n=53) received a combination of RP and radiotherapy, and the remaining 11% (n=27) had RP only. Similar proportions were found in the sample that participated in the test-retest substudy (36.0% radiotherapy and brachytherapy; 13.3% radiotherapy only; 18.7% brachytherapy only; 18.7% RP and radiotherapy; 13.3% RP only). Among the total sample, 46.2% of participants (n=116) received hormone therapy (current use 21.6%). The median time since the initial cancer diagnosis was 34.6 months (range 0.3–320), and median time since the end of treatment was 35 months (range 1–233 months). Fifteen percent of the participants had had a prostate cancer recurrence before their study participation.

### Descriptive statistics

Table 1 shows the descriptive statistics for each EPIC-26 domain. Mean scores ranged from 34.9 for the sexual function subscale to 92.4 for the bowel bother subscale, a higher score indicating a better functioning (Supplementary Table 1 for EPIC-50 available at [cuaj.ca](#)).

### 1. Reliability

#### a. Internal consistency

Table 1 also shows the Cronbach's alpha coefficients and item-total correlations obtained for each EPIC-26 domain (Supplementary Table 1 for EPIC-50). Coefficients obtained for the urinary incontinence, bowel, and sexual domains were high (from 0.84–0.92), while coefficients for the urinary irritation/obstruction (0.59) and hormonal (0.67) domains were lower. Items with the lowest item-total correlations were #4c (hematuria;  $r=0.15$ ), #6d (bloody stools;  $r=0.33$ ), #12 (overall sexuality problem;  $r=0.31$ ), and #13b (breast problems;  $r=0.11$ ).

#### b. Test-retest reliability

Large correlations were found between EPIC-26 mean scores obtained at the first assessment and 2–4 weeks later ( $r$ s ranging from 0.72–0.93) and no significant differences were found between the two administrations (all  $p>0.40$ ; Table 2 [and Supplementary Table 2 for EPIC-50; available at [cuaj.ca](#)]).

### 2. Construct validity

#### a. Confirmatory factor analysis

A structural equation model with five latent variables (the five postulated factors of the original EPIC-26) and all 10 pairwise covariances between the five latent variables was estimated using the maximum likelihood method. An adequate fit with the empirical variance-covariance matrix of the 26 items was found,  $X^2(n=251; df=284) 560.03; p<0.001$ , chi-square/df ratio=1.97, Standardized Root Mean Square Residuals (SRMSR) 0.069, Bentler Comparative Fit Index (CFI) 0.919, and Normed Fit Index 0.850. Correlations obtained between latent factors ranged from 0.23–0.48, with stronger correlations found between urinary incontinence and urinary irritation/obstruction scales,  $r=0.69$ , and between bowel and hormonal scales,  $r=0.51$  (see standardized loadings in Table 3). Only two items were weakly associated ( $B<0.30$ ) with their postulated factor: item #4c of the urinary irritation/obstruction scale (hematuria),  $B=0.201$ , and item #13b of the hormonal scale (breast problems),  $B=0.155$ .

For the EPIC-50, a structural equation model with four latent variables and all six pairwise covariances between the

**Table 1. Descriptive statistics obtained on the EPIC-26 and results of internal consistency analyses (n=251)**

Domains	n	Mean score (T1)	SD	Median	Range	Cronbach's alpha	Range r(tot)
Urinary incontinence	241	86.39	21.84	100.00	0–100	0.889	0.74–0.84
Urinary irritation/obstruction	241	87.42	13.97	93.75	12.5–100	0.594	0.15–0.51
Urinary overall problem	250	78.60	27.02	87.50	0–100	NA	NA
Bowel	245	92.38	12.86	100.00	0–100	0.837	0.33–0.77
Sexual	246	34.87	28.77	25.00	20.83–100	0.887	0.31–0.85
Hormonal	246	89.92	14.10	95.00	0–100	0.670	0.11–0.74

EPIC: Expanded Prostate Cancer Index Composite; SD: standard deviation; r(tot): item-total correlations; NA: not applicable (only one item).

latent variables was estimated. A poor fit with the empirical variance-covariance matrix of the 50 items was found,  $X^2(n=251; df=1165) 4538.6, p<0.001$ , chi-square/df ratio 3.90; Standardized Root Mean Square Residuals (SRMSR) 0.099, Bentler Comparative Fit Index (CFI) 0.582, and Normed Fit Index 0.512. Seven items were weakly associated with their postulated factor: items #2 ( $B=0.26$ ), #3 ( $B=0.27$ ), and #8 ( $B=0.28$ ) of the urinary scales, item #18 (0.23) of the bowel scale, and items #41 ( $B=0.24$ ), #44 ( $B=0.25$ ) and #46 ( $B=0.20$ ) of the hormonal scale (Supplementary Table 3; available at [cuaj.ca](http://cuaj.ca)).

### b. Convergent and divergent validity

As seen in Table 4 (Supplementary Table 4 for EPIC-50; available at [cuaj.ca](http://cuaj.ca)), the correlations obtained between scores on EPIC-26 domains and those found on questionnaires measuring similar constructs were high ( $r$ s between 0.56 and 0.83; all  $p<0.05$ ). In contrast, the correlations obtained with questionnaires/subscales measuring different constructs were consistently weaker. For instance, the correlation obtained between the EPIC-26 sexual domain and the urinary, bowel, and hormonal subscales of the IPSS or the PR25 were lower ( $r$ s between -0.19 and 0.36) than with the SHIM or the PR25 sexual subscales ( $r$ s between 0.63 and 0.83).

### c. Sensitivity to change

As shown in Table 2 (Supplementary Table 2 for EPIC-50; available at [cuaj.ca](http://cuaj.ca)), scores obtained on each EPIC-26 domain significantly decreased after radiotherapy treatment (all  $p<0.01$ ), suggesting a worsening of HRQOL.

## Discussion

The objective of this study was to validate empirically the French-Canadian version of the EPIC. Overall, the psychometric properties found in this study are similar to those of the original English version.<sup>6,8</sup> Hence, results suggest that this French version is a reliable and valid instrument for assessing prostate cancer-related symptoms.

Test-retest correlations at an interval of 2–4 weeks were high across all domains, suggesting an excellent reliability. Cronbach's alpha coefficients for the urinary incontinence, bowel, and sexual domains were high, whereas they were lower for the urinary irritation/obstruction and hormonal domains, suggesting weaker internal consistency for these two scales. These lower coefficients seem to be due to two more problematic items, that is hematuria (urinary – irritation/

**Table 3. Confirmatory factor structure of EPIC-26**

Item	#item EPIC-50	#item EPIC-26	Standard loading
Urinary – incontinence			
Leaking >1 time per day	1	1	0.855
Frequent dribbling	4	2	0.825
Any pad use	5	3	0.764
Leaking problem	6	4a	0.938
Urinary – irritation/obstruction			
Dysuria	7	4b	0.491
Hematuria	8	4c	0.201
Weak stream	9	4d	0.559
Frequency	11	4e	0.717
Overall urinary problem	12	5	0.928
Bowel			
Urgency	20	6a	0.864
Frequency	21	6b	0.760
Fecal incontinence	23	6c	0.697
Bloody stools	24	6d	0.357
Rectal pain	25	6e	0.558
Overall bowel problem	26	7	0.810
Sexual			
Poor erections	28	8a	0.912
Difficulty with orgasm	29	8b	0.847
Erections not firm	30	9	0.838
Erections not reliable	31	10	0.908
Poor sexual function	35	11	0.818
Overall sexuality problem	39	12	0.326
Hormonal			
Hot flashes	45	13a	0.479
Breast problems	46	13b	0.155
Depression	48	13c	0.685
Lack of energy	49	13d	0.938
Weight change	50	13e	0.448

All loadings were significant at  $p<0.05$ . EPIC: Expanded Prostate Cancer Index Composite

**Table 2. Results of test-retest and sensitivity to change analyses**

Domains	Mean score (T1)	Mean score (T2)	F-test	r (T1 vs. T2)
<b>Test/retest analyses (n=68)</b>				
Urinary incontinence	84.42	84.63	0.04, $p=0.83$	0.93
Urinary irritation/obstruction	87.31	86.47	0.69, $p=0.41$	0.78
Urinary overall problem	77.76	78.55	0.11, $p=0.74$	0.72
Bowel	92.02	92.61	0.50, $p=0.48$	0.86
Sexual	30.76	30.46	0.06, $p=0.81$	0.92
Hormonal	89.63	89.70	0.00, $p=0.95$	0.75
<b>Sensitivity to change analyses (n=51)</b>				
Urinary incontinence	95.10	88.19	6.77, $p=0.010$	0.46
Urinary irritation/obstruction	87.93	81.59	8.21, $p=0.006$	0.45
Urinary overall problem	81.86	69.61	9.46, $p=0.003$	0.46
Bowel	94.00	86.54	11.48, $p=0.001$	0.33
Sexual	50.58	29.92	25.59, $p<0.001$	0.47
Hormonal	91.20	82.29	19.70, $p<0.001$	0.52

**Table 4. Correlations between domains of EPIC-26, IPSS, SHIM, and PR25**

Domain	IPSS total (n=206)	IPSS QoL (n=203)	SHIM (n=203)	PR25-SAC <sup>f</sup> (n=199)	PR25-SFU <sup>f</sup> (n=117)	PR25-URI <sup>s</sup> (n=204)	PR25-BOW <sup>s</sup> (n=200)	PR25-HTR <sup>s</sup> (n=204)	PR25-AID <sup>s</sup> (n=40)
Urinary incontinence	-0.44	-0.39	0.27	0.16	0.27	<b>-0.65</b>	-0.34	-0.28	<b>-0.70</b>
Urinary irritation/obstruction	<b>-0.76</b>	<b>-0.56</b>	0.21	0.17	0.25	<b>-0.71</b>	-0.38	-0.31	-0.31 NS
Urinary overall problem	<b>-0.68</b>	<b>-0.61</b>	0.24	0.19	0.30	<b>-0.78</b>	-0.26	-0.25	<b>-0.71</b>
Bowel	-0.52	-0.35	0.18	0.14	0.26	-0.49	<b>-0.65</b>	-0.37	-0.30 NS
Sexual	-0.21	-0.34	<b>0.83</b>	<b>0.63</b>	<b>0.72</b>	-0.34	-0.25	-0.36	-0.19 NS
Hormonal	-0.47	-0.34	0.24	0.19	0.35	-0.45	-0.56	<b>-0.62</b>	-0.37

Correlations used for convergent validity are in bold. All correlations are significant at  $p < 0.05$  unless otherwise specified. AID<sup>s</sup>: incontinence aid (symptom scale); BOW<sup>s</sup>: bowel (symptom scale); EPIC: Expanded Prostate Cancer Index Composite; HTR<sup>s</sup>: hormonal treatment-related (symptom scale); IPSS: International Prostate Symptom Score; PR25: Prostate cancer-specific module of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; SAC<sup>f</sup>: sexual activity (functioning scale); SFU<sup>f</sup>: sexual functioning (functioning scale); SHIM: Sexual Health Inventory for Men; URI<sup>s</sup>: urinary (symptom scale).

obstruction) and breast problems (hormonal), which seem to assess different constructs than their respective domains. They were also not frequently reported in our sample.

The five-factor structure of the original EPIC-26 was in large part confirmed,<sup>8</sup> with the same two items being weakly correlated with their postulated factor (hematuria and breast problems). The four-factor structure of the EPIC-50 was less sound, with poor fit indices and seven items that loaded less strongly with their respective factor. These include three items in the urinary domain (two hematuria items and one dysuria item), one in the intestinal domain (bowel movements frequency), and three in the hormonal domain, the latest being the least strongly loaded with their postulated factor. It is interesting to note that these findings are consistent with those of Anota et al,<sup>15</sup> who, although they did not perform a confirmatory factor analysis, found that the hormonal domain of their French version presented a poor construct validity overall. Similarly, the authors of the Korean version of the EPIC-50 also observed some disparity in the factorial structure of this subscale.<sup>14</sup> Together, these findings question the composition of the hormonal subscale.

The convergent validity of the EPIC was also well-supported. Indeed, for each of the five domains of the EPIC-26, the highest correlations (all  $> 0.55$ ) were found with instruments measuring similar constructs, whereas lower correlations (all  $< 0.55$ ) were consistently found with instruments measuring different constructs. Clearly, the French version of the EPIC accurately measures distinct domains that are relevant to prostate cancer-related quality of life.

Moreover, the French-Canadian version of the EPIC proved to be sensitive to clinical changes associated with prostate cancer treatment. All domain scores significantly decreased following radiotherapy, which is consistent with the bulk of evidence published on this instrument showing its good sensitivity.<sup>25</sup> Also, the magnitude of the differences observed between pre- and post-treatment data were all above the thresholds for a clinically relevant change (minimally important difference) proposed by Skolarus et al for this instrument.<sup>26</sup> This indicates that the French-Canadian version of the EPIC can be routinely used in clinics to track

changes in patient-reported HRQOL associated with prostate cancer treatment.

The large sample size is a strength of this study, as well as the assessment of the translation quality and of various psychometric properties using rigorous and recognized procedures. On the other hand, no information was available on the number of patients who were approached in each clinic to document the participation rate, thus questioning the representativeness of the sample. Our sample, which received a variety of treatments alone and in combination, was fairly representative of the population of prostate cancer patients, although recruiting a fully representative sample is a challenge in the context of this cancer; however, a representative sample is not critical to study the psychometric properties of an instrument, since correlations between items, and the internal structure of the instrument, are not expected to vary according to medical treatment options. Besides, the fact that EPIC scores significantly deteriorated after radiation therapy, a treatment usually associated with less sudden side effects than RP, provides convincing evidence of its sensitivity to clinical change.

## Conclusion

The French-Canadian version of the EPIC, particularly its short-form (EPIC-26), is a reliable and valid measure of HRQOL in prostate cancer patients and can be used for both clinical and research purposes. The availability of this instrument in French will facilitate the assessment and management of patient-reported outcomes in francophone clinics and research settings.

**Competing interests:** Dr. Vigneault has been an advisor for AbbVie and Sanofi; and a speaker for Sanofi. Dr. Foster has been an advisor for AbbVie, Ferring, and Sanofi-Aventis. Dr. Fradet has been an advisor for Amgen, Astellas, Astra Zeneca, Bayer, Janssen, and Sanofi; has received payment/grants/honoraria from Astellas, Astra Zeneca, Bayer, Janssen, and Sanofi; and has participated in clinical trials supported by Astellas, Astra Zeneca, Bayer, Janssen, Merck, Roche, and Sanofi. The remaining authors report no competing personal or financial interests.

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## References

1. American Cancer Society. Cancer Facts & Figures 2017. Available at <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2017.html>. Accessed November 2, 2017.
2. Cooperberg MR, Broering JM, Carroll PR. Risk assessment for prostate cancer metastasis and mortality at the time of diagnosis. *J Natl Cancer Inst* 2009;101:878-87. <https://doi.org/10.1093/jnci/djp122>
3. Klein EA, Ciezki J, Kupelian PA, et al. Outcomes for intermediate risk prostate cancer: Are there advantages for surgery, external radiation, or brachytherapy? *Urol Oncol* 2009;27:67-71.
4. Donovan JL, Hamdy FC, Lane JA, et al. Patient-reported outcomes after monitoring, surgery, or radiotherapy for prostate cancer. *N Engl J Med* 2016;375:1425-37. <https://doi.org/10.1056/NEJMoa1606221>
5. Bottomley A, Therasse P. Quality of life in patients undergoing systemic therapy for advanced breast cancer. *Lancet Oncol* 2002;3:620-8. [https://doi.org/10.1016/S1470-2045\(02\)00876-8](https://doi.org/10.1016/S1470-2045(02)00876-8)
6. 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. [https://doi.org/10.1016/S0090-4295\(00\)00858-X](https://doi.org/10.1016/S0090-4295(00)00858-X)
7. Wei JT, Dunn RL, Sandler HM, et al. Comprehensive comparison of health-related quality of life after contemporary therapies for localized prostate cancer. *J Clin Oncol* 2002;20:557-66. <https://doi.org/10.1200/JCO.2002.20.2.557>
8. Szymanski KM, Wei JT, Dunn RL, et al. Development and validation of an abbreviated version of the Expanded Prostate Cancer Index Composite instrument (EPIC-26) for measuring health-related quality of life among prostate cancer survivors. *Urology* 2010;76:1245-50. <https://doi.org/10.1016/j.urol.2010.01.027>
9. Hedgepeth RC, Labo J, Zhang L, et al. Expanded Prostate Cancer Index Composite vs. Incontinence Symptom Index and Sexual Health Inventory for Men to measure functional outcomes after prostatectomy. *J Urol* 2009;182:221-7. <https://doi.org/10.1016/j.juro.2009.02.155>
10. Rieck K, Linden W, Tudor I, et al. Measuring symptoms in localized prostate cancer: A systematic review of assessment instruments. *Prostate Cancer Prostatic Dis* 2013;16:111-22. <https://doi.org/10.1038/pcan.2013.1>
11. Schmidt S, Garin O, Pardo Y, et al. Assessing quality of life in patients with prostate cancer: A systematic and standardized comparison of available instruments. *Qual Life Res* 2014;23:2169-81. <https://doi.org/10.1007/s11136-014-0678-8>
12. Fossa SD, Storås AH, Steinsvik EA, et al. Psychometric testing of the Norwegian version of the Expanded Prostate Cancer Index Composite 26-item version (EPIC-26). *Scand J Urol* 2016:1-6.
13. Ferrer M, Garin O, Pera J, et al. [Evaluation of the quality of life of patients with localized prostate cancer: Validation of the Spanish version of the EPIC]. *Med Clin (Barc)* 2009;132:128-35. <https://doi.org/10.1016/j.medcli.2008.01.001>
14. Chung KJ, Kim JJ, Lim SH, et al. Development and validation of the Korean version of Expanded Prostate Cancer Index Composite: Questionnaire assessing health-related quality of life after prostate cancer treatment. *Korean J Urol* 2010;51:601-12. <https://doi.org/10.4111/kju.2010.51.9.601>
15. Anota A, Mariet AS, Maingon P, et al. Cross-cultural adaptation and validation of the French version of the Expanded Prostate Cancer Index Composite questionnaire for health-related quality of life in prostate cancer patients. *Health Qual Life Outcomes* 2016;14:168. <https://doi.org/10.1186/s12955-016-0571-y>
16. Haccoun RR. Une nouvelle technique de vérification de l'équivalence de mesures psychologiques traduites. *Revue Québécoise de Psychologie* 1987;8:30-9.
17. Cockett ATK, Aso Y, Denis L, et al. Recommendations of the International Consensus Committee concerning: 1. Prostate Symptom Score (IPSS) and Quality of Life Assessment. In: Cockett ATK, Aso Y, Chatelain C, et al., eds. Proceedings of the International Consultation on Benign Prostatic Hyperplasia (BPH). Paris, France 1992:279-88.
18. Gregoire JP, Moisan J, Labrecque M, et al. [Validation of a French adaptation of the International Prostatic Symptom Score]. *Prog Urol* 1996;6:240-9.
19. 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-5) as a diagnostic tool for erectile dysfunction. *Int J Impot Res* 1999;11:319-26. <https://doi.org/10.1038/sj.ijir.3900472>
20. Rosen RC, Riley A, Wagner G, et al. The International Index of Erectile Function (IIEF): A multidimensional scale for assessment of erectile dysfunction. *Urology* 1997;49:822-30. [https://doi.org/10.1016/S0090-4295\(97\)00238-0](https://doi.org/10.1016/S0090-4295(97)00238-0)
21. van Andel G, Bottomley A, Fossa SD, et al. An international field study of the EORTC QLQ-PR25: A questionnaire for assessing the health-related quality of life of patients with prostate cancer. *Eur J Cancer* 2008;44:2418-24. <https://doi.org/10.1016/j.ejca.2008.07.030>
22. Tabachnick BG, Fidell LS. Using multivariate statistics 6th ed. New-York: Allyn & Bacon; 2012.
23. Cronbach LJ. Essentials of psychological testing. 4th ed. New-York: Harper & Row Publishers; 1984.
24. Cohen J. Statistical power analysis for the behavioral sciences. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.
25. Lee TK, Breau RH, Mallick R, et al. A systematic review of Expanded Prostate Cancer Index Composite (EPIC) quality of life after surgery or radiation treatment. *Can J Urol* 2015;22:7599-606.
26. Skolarus TA, Dunn RL, Sanda MG, et al. Minimally important difference for the Expanded Prostate Cancer Index Composite Short Form. *Urology* 2015;85:101-5. <https://doi.org/10.1016/j.urol.2014.08.04>

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