Quality of Life Research (2021) 30:2919–2928
https://doi.org/10.1007/s11136-021-02871-9

Mapping the Memorial Anxiety Scale for Prostate Cancer to the SF-6D

Daniel O. Erim[1] · Antonia V. Bennett[1,2] · Bradley N. Gaynes[3] · Ram Sankar Basak[4] · Deborah Usinger[1] · Ronald C. Chen[5]

Accepted: 3 May 2021 / Published online: 16 May 2021

Abstract

Purpose To create a crosswalk that predicts Short Form 6D (SF-6D) utilities from Memorial Anxiety Scale for Prostate Cancer (MAX-PC) scores.

Methods The data come from prostate cancer patients enrolled in the North Carolina Prostate Cancer Comparative Effectiveness & Survivorship Study (NC ProCESS, $N = 1016$). Cross-sectional data from 12- to 24-month follow-up were used as estimation and validation datasets, respectively. Participants' SF-12 scores were used to generate SF-6D utilities in both datasets.

Beta regression mixture models were used to evaluate SF-6D utilities as a function of MAX-PC scores, race, education, marital status, income, employment status, having health insurance, year of cancer diagnosis and clinically significant prostate cancer-related anxiety (PCRA) status in the estimation dataset. Models' predictive accuracies (using mean absolute error [MAE], root mean squared error [RMSE], Akaike information criterion [AIC] and Bayesian information criterion [BIC]) were examined in both datasets. The model with the highest prediction accuracy and the lowest prediction errors was selected as the crosswalk.

Results The crosswalk had modest prediction accuracy (MAE = 0.092, RMSE = 0.114, AIC = − 2708 and BIC = − 2595.6), which are comparable to prediction accuracies of other SF-6D crosswalks in the literature. About 24% and 52% of predictions fell within ± 5% and ± 10% of observed SF-6D, respectively. The observed mean disutility associated with acquiring clinically significant PCRA is 0.168 (standard deviation = 0.179).

Conclusion This study provides a crosswalk that converts MAX-PC scores to SF-6D utilities for economic evaluation of clinically significant PCRA treatment options for prostate cancer survivors.

Keywords SF-6D · MAX-PC · Prostate cancer-related anxiety · Crosswalk · Utility · Mapping

Introduction

There is increasing awareness of the importance of psychosocial outcomes in prostate cancer patients [1, 2]. Of note is prostate cancer-related anxiety (PCRA), a situational anxiety that adversely affects the quality of prostate cancer survivorship [3, 4]. PCRA can be assessed with a validated patient-reported outcome measure, the Memorial Anxiety Scale for Prostate Cancer, and published studies indicate that 1 in 10 prostate cancer patients and survivors (i.e., over 300,000 in the USA) experience clinically significant PCRA that requires behavioral care [3, 4]. PCRA severity increases with prostate cancer stage [5], and it has been associated with depressive disorders and productivity loss [6, 7]. While PCRA is measurable, its impact on patients' health-related quality of life (HRQOL) is largely unknown [6, 7], and therefore, clinical and health

✉ Daniel O. Erim
erim.daniel@alumni.harvard.edu

1 Lineberger Comprehensive Cancer Center, School of Medicine, The University of North Carolina, Chapel Hill, NC, USA

2 Department of Health Policy and Management, The University of North Carolina At Chapel Hill, Chapel Hill, NC, USA

3 Department of Psychiatry, The University of North Carolina, Chapel Hill, NC, USA

4 Department of Radiation Oncology, The University of North Carolina, Chapel Hill, NC, USA

5 Department of Radiation Oncology, The University of Kansas Cancer Center, Kansas City, KS, USA

policy importance of this measurable outcome (e.g., the value of PCRA interventions) is currently unclear.

The Short Form 12 is a commonly used instrument to assess health-related quality of life, and scores can also be converted to a utility measure (i.e., SF-6D). Utilities inform estimates of quality-adjusted life expectancy, which provide insight into economic and health policy implications of medical conditions or health interventions [8, 9]. A growing number of studies have mapped (or cross-walked) utilities from patient-reported outcome (PRO) measures [10, 11]. However, to date, utilities have not been mapped from PRO measures that assess PCRA; doing so would facilitate economic evaluation of current or future PCRA interventions. To address this gap, we analyzed data from a population-based and sociodemographically diverse cohort of prostate cancer patients and identified a crosswalk that can be used to predict SF-6D utilities for patients with and without PCRA. These crosswalks may be applied in economic evaluations that use secondary data or mathematical forecasting models (including deterministic/probabilistic cohort- or patient-level simulation models).

Materials and methods

Data

We used data from participants in the North Carolina Prostate Cancer Comparative Effectiveness & Survivorship Study (NC ProCESS). NC ProCESS prospectively followed a population-based cohort of prostate cancer survivors who were enrolled soon after cancer diagnosis [12]. Patients with newly diagnosed localized prostate cancer were enrolled prior to cancer treatment, between January 2011 and June 2013, in collaboration with the North Carolina state cancer registry [12]. Details on study design and enrollment processes are described elsewhere [12]. Patient race, education, marital status, household income, employment and insurance were obtained by patient report at baseline. Cancer diagnostic information (e.g., aggressiveness of prostate cancer), age at diagnosis and treatment were abstracted from medical records. For our analyses, we used cross-sectional data from the 12- to 24-month follow-up surveys as estimation and validation datasets, respectively, and both datasets included contemporaneous assessments of patient-reported PCRA and HRQOL measures as described below.

Measures

Memorial Anxiety Scale for Prostate Cancer (MAX-PC)

The MAX-PC is a validated, 18-item, questionnaire for assessing PCRA severity [3, 4]. MAX-PC has three subscales for indicated PCRA subdomains: prostate cancer anxiety, PSA (prostate-specific antigen) testing anxiety (or PSA anxiety) and fear of recurrence. Each item has four possible responses that are scored ordinally (from 0 to 3), with higher scores indicating worse PCRA [3, 4]. Total scores range from 0 to 54, and patients with scores above 27 have clinically significant PCRA which usually requires behavioral care (e.g., hospitalization) [3, 4]. We used this information to create a binary indicator of clinically significant PCRA (set to 1 if MAX-PC score exceeds 27, 0 otherwise) in the estimation and validation datasets. Items 15 to 18 have responses in reverse (i.e., higher scores indicate less PCRA), so we reversed their scoring to maintain consistency with the rest of the instrument [7].

Short Form (SF) 6D

The SF-6D is a preference-based measure derived from converting SF-36 or SF-12 scores into a single summary score that preserves the descriptive richness and sensitivity to change of the original instruments [13–15]. The SF-6D derivation is based on a set of preference weights obtained from a sample of the general US population using standard gamble [13–15]. The scores, which range from 0 to 1, can be used as utilities to generate quality-adjusted life-years in cost–utility analyses [13–16]. An algorithm developed by researchers at the University of Sheffield was used to convert SF-12 data to SF-6D scores [13–16].

Others

Potential control covariates were participants' sociodemographic and clinical characteristics that have been shown to be associated with both PCRA and health-related quality of life and are also available in the estimation and validation datasets. These variables include age, race, educational attainment, marital status, income, employment status, health insurance coverage MAX-PC total score, National Comprehensive Cancer Network risk category, prostate cancer treatment type and year of prostate cancer diagnosis [3–6, 17–27].

Statistical analyses

Univariate analyses were used to assess for associations between potential control covariates and SF-6D; variables with a p value < 0.05 were selected for multivariable analysis. We then used beta regression mixture models to evaluate SF-6D as a function of control covariates. Beta regression is a flexible approach for modeling and predicting variables between 0 and 1, while mixture modeling allows for specification of multimodal distributions (commonly seen with utilities) as combinations of simpler distributions (or

components) [28, 29]. We used beta regression mixture models because of their superior performance over other regression-based or machine learning techniques (including ordinary least squares, generalized ordered probit/logit models, generalized linear models, fractional regression, robust MM estimator and adjusted limited dependent variable mixture models) when generating utility crosswalks from PRO measures [30–35]. We assessed crosswalk performance using objective and subjective measures of prediction accuracy (i.e., mean absolute errors [MAE], root mean-squared error [RMSE], Akaike information criterion [AIC], Bayesian information criterion [BIC], the proportion of predictions that lie within ± 5 and ± 10% of observed SF-6D and correlations between observed and predicted SF-6D) [36].

Sensitivity analyses

We did the following during sensitivity analyses: we evaluated participants' data within categories of clinically significant PCRA status (due to plausible collinearity between MAX-PC and clinically significant PCRA status); we included all potential control covariates in the models; we increased the number of components in the beta mixture regression models; we switched to inflated beta mixture regression models; and we trimmed the crosswalk by dropping covariates with p value > 0.05 after multivariable analyses. All analyses were done using SAS® University Edition, Microsoft Excel® for Mac (version 16.47.1) and Stata® 13 for Mac.

Results

Descriptive statistics

Participants' characteristics are shown in Table 1. Among 1016 participants in the study, the mean age was 65 years. As a population-based cohort, there is sociodemographic diversity with 26% non-Caucasian, 31% with high school education or less and 36% with household income < $40,000. The mean MAX-PC scores was 10.1, and the prevalence of clinically significant PCRA at 12-month follow-up was 8.0%. Histograms of participants' SF-6D utilities are presented in Fig. 1, and they seem to follow a beta distribution.

The MAX-PC to SF-6D crosswalk and other models from sensitivity analyses

Summaries of observed SF-6D utilities in the estimation dataset are presented in Table 2. The mean observed utility for all participants was 0.817 (standard deviation [s.d.] = 0.122). The mean observed utility was higher for participants without clinically significant PCRA (mean = 0.830, s.d. = 0.122) than for those with clinically significant PCRA (mean = 0.662, s.d. = 0.132; p value > 0.05). The observed mean disutility was 0.168 (s.d. = 0.179). Summaries of predicted SF-6D utilities and prediction accuracy of each model under consideration are also presented in Table 2 (i.e., models A to F). The most accurate prediction model (i.e., the crosswalk) is a beta regression mixture model with two components and control covariates with p value < 0.05 from univariate analyses (i.e., model A [second column]). Model A had the lowest AIC (− 2707.5), the lowest BIC (− 2,595.6) and some of the best measures of prediction accuracy in the estimation and validation datasets (Table 3). Mean predicted utilities were 0.817 (s.d. = 0.057) for all participants, as well as 0.667 (s.d. = 0.050) and 0.830 (s.d. = 0.035) for participants with and without clinically significant PCRA, respectively. The mean predicted disutility was 0.163 (s.d. = 0.061). All other models (i.e., B to F) had worse measures of prediction accuracy in the estimation dataset. Note that models B to F were part of sensitivity analyses, and additional details on models A to F are provided in Online Appendix Tables 1–6.

Summaries of observed SF-6D utilities in the validation dataset are presented in Table 3. The mean observed utility for all participants was 0.809 (s.d. = 0.133). Again, the mean observed utility was higher for participants without clinically significant PCRA (mean = 0.817, s.d. = 0.129) than for those with clinically significant PCRA (mean = 0.698, s.d. = 0.146; p-value > 0.05). The observed mean disutility was 0.119 (s.d. = 0.195). Model A's prediction accuracy in the validation dataset was modest: 17.4% and 42% of predictions were within ± 5% and ± 10% of observed SF-6D utilities. Mean predicted utilities were 0.800 (s.d. = 0.042) for all participants, 0.808 (s.d. = 0.028) for participants without clinically significant PCRA and 0.681 (s.d. = 0.041) for participants with clinically significant PCRA. The mean predicted disutility was 0.127 (s.d. = 0.050). All other models (except model D) had worse measures of prediction accuracy in the validation dataset.

Increasing the number of components in the beta mixture regression models or switching to inflated beta mixture regression models either failed to converge or worsened prediction accuracy. When we trimmed the crosswalk by dropping covariates with p value > 0.05, measures of prediction accuracy marginally improved (e.g., AIC = − 2721.5 and BIC = − 2648.5; see Online Appendix Table 7). However, the trimmed crosswalk was unreliable as it frequently failed to converge.

Discussion

Using data from a diverse, population-based cohort of 1,016 prostate cancer patients who reported prostate cancer-related anxiety using the validated MAX-PC

Table 1 Characteristics of NC ProCESS participants in the estimation dataset ($N = 1016$)

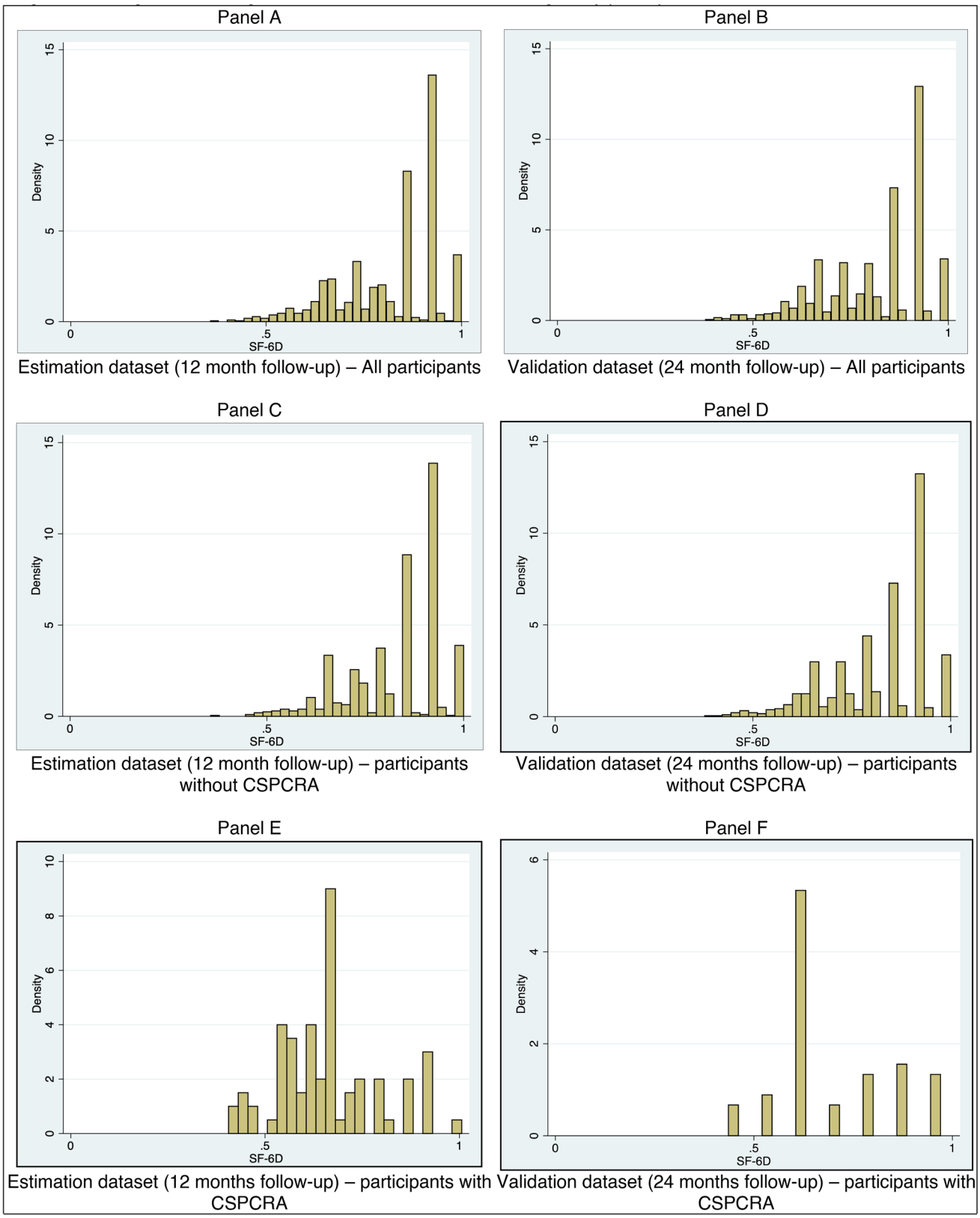
Characteristics	*N* (%) or mean (SD)	*P* values for univariate analyses
SF-6D utility (mean and SD)	0.82 (0.13)	Not applicable
Age, years (mean and SD)	65.6 (7.5)	0.22
Race		< 0.01
Caucasian American	747 (73.5%)	
African American/all other races	269 (26.5%)	
Educational attainment		< 0.01
High school or less		
At least some college	700 (68.9%)	
Marital status		< 0.01
Never married, divorced, widowed or separated	197 (19.4%)	
Married	819 (80.6%)	
Annual household income		< 0.01
< $40,000	351 (35.7%)	
$40,001–$70,000	284 (28.9%)	
> $70,000	348 (35.4%)	
Employment status		< 0.01
Unemployed, retired or not working due to disability	581 (57.2%)	
Employed	435 (42.8%)	
Health insurance status		< 0.01
Insured	982 (97.0%)	
Uninsured	31 (3.1%)	
MAX-PC total score (mean and SD)	10.13 (9.99)	< 0.01
Participants with clinically significant PCRA		< 0.01
No	920 (92.0%)	
Yes	80 (8.0%)	
NCCN risk categories		0.12
Low risk	493 (49.2%)	
Intermediate or high risk	509 (50.8%)	
Prostate cancer treatment type		0.28
Active surveillance/no treatment		
Radiation therapy		
Radical prostatectomy	421 (41.4%)	
Year of prostate cancer diagnosis		< 0.01
2011		
2012		
2013	104 (10.2)	

About 8% of observations were missing and were handled by listwise deletion [7]. Categories of ordinal variables are sorted in order of consecutively increasing integer value (starting from 0). Univariate analyses evaluated associations between SF-6D and indicated variables

MAX-PC Memorial Anxiety Scale for Prostate Cancer, *SD* standard deviation, *NCCN* National Comprehensive Cancer Network

instrument and quality of life on the SF-12 instrument, we created a crosswalk that predicts SF-6D utilities in patients with and without clinically significant PCRA. We also estimated the mean disutility associated with experiencing clinically significant PCRA. These findings have several implications on research and policy.

The observed mean disutility associated with clinically significant PCRA is 0.168 (s.d. = 0.179). This estimate is comparable to mean disutilities reported for anxiety disorders (up to 0.147) and for major depressive disorder (up to 0.215) [37–40], and this comparability is consistent with reports of PCRA's association with anxiety and depressive



CSPCRA, clinically significant prostate cancer related anxiety.

Fig. 1 Histograms showing distributions of Sf-6D utilities among study participants

Table 2 Characteristics of observed and predicted utilities as well as measures of prediction accuracy using the estimation dataset

Selection of control covariates	Only variables with p value < 0.05 in univariate analyses			All variables examined in univariate analyses		
Specification of clinically significant PCRA	As an extra control covariate	Used to stratify the analyses		As an extra control covariate	Used to stratify the analyses	
Strata	None	CSPCRA absent	CSPSCA present	None	CSPCRA absent	CSPSCA present
Model name	A	B	C	D	E	F
Number of model components	2	1	1	1	2	1
Number of control covariates	9	8	8	9	8	8
Observed utilities—all participants						
Mean (standard deviation)	0.817 (0.130)	–	–	0.817 (0.130)	–	–
Range	0.375–1.000	–	–	0.375–1.000	–	–
Observed utilities—CS PCRA absent						
Mean (standard deviation)	0.830 (0.122)	0.830 (0.122)	–	0.830 (0.122)	0.830 (0.122)	–
Range	0.357–1.000	0.357–1.000	–	0.357–1.000	0.357–1.000	–
Observed utilities—CS PCRA present						
Mean (standard deviation)	0.662 (0.132)	–	0.662 (0.132)	0.662 (0.132)	–	0.662 (0.132)
Range	0.406–1.000	–	0.406–1.000	0.406–1.000	–	0.406–1.000
Observed disutilities						
Mean (standard deviation)	0.168 (0.179)	0.168 (0.179)	0.168 (0.179)	0.168 (0.179)	0.168 (0.179)	
Estimated range[¶]	(− 0.376–0.793)	(− 0.376–0.793)	(− 0.376–0.793)	(− 0.376–0.793)	(− 0.376–0.793)	(− 0.376–0.793)
Predicted utilities—all participants						
Mean (standard deviation)	0.817 (0.057)	–	–	0.833 (0.076)	–	–
Range	0.532–0.884	–	–	0.423–0.924	–	–
Predicted utilities—CS PCRA absent						
Mean (standard deviation)	0.830 (0.035)	0.844 (0.043)	–	0.849 (0.045)		–
Range	0.697–0.883	0.686–0.910	–	0.676–0.924	0.695–0.886	–
Predicted utilities—CS PCRA present						
Mean (standard deviation)	0.667 (0.050)	–	0.671 (0.105)	0.634 (0.081)	–	
Range	0.532–0.748	–	0.399–0.875	0.423–0.776	–	0.429–0.843
Predicted disutilities						
Mean (standard deviation)	0.163 (0.061)	0.172 (0.114)	0.172 (0.114)	0.215 (0.093)	0.196 (0.089)	
Estimated range[¶]	–0.040–0.338	–0.049–0.413	–0.049–0.413	–0.067–0.496	–0.025–0.519	–0.025–0.519
Measures of prediction accuracy						
Mean absolute error	0.092	0.090	0.091	0.090	0.092	0.079
Root mean squared error	0.114	0.115	0.118	0.116	0.114	0.100

Table 2 (continued)

Selection of control covariates	Only variables with p value < 0.05 in univariate analyses			All variables examined in univariate analyses		
Specification of clinically significant PCRA	As an extra control covariate	Used to stratify the analyses		As an extra control covariate	Used to stratify the analyses	
Strata	None	CSPCRA absent	CSPSCA present	None	CSPCRA absent	CSPSCA present
AIC	− 2707.5	–1811.7	− 75.02	− 1866.8	− 2563.1	− 97.49
BIC	− 2595.6	− 1763.9	− 51.85	− 1799.0	− 2434.4	− 67.54
Within ± 5% of observed utilities	23.7%	27.1%	2.1%	30.6%	21.5%	2.1%
Within ± 10% of observed utilities	52.4%	49.5%	3.7%	52.9%	48.3%	3.6%
Pearson's correlation coefficient[‡]	0.493	0.329	0.526	0.480	0.363	0.613

[¶]Estimates were obtained using Monte Carlo simulation

[‡]This measures the correlation between observed and predicted SF-6D for indicated study participants, and all p values were ≤ 0.05

Regression coefficients and other characteristics are provided in the Online Appendix

CS PCRA clinically significant prostate cancer-related anxiety

disorders [3, 4, 7]. Nevertheless, from a deterministic economic evaluation perspective, the estimated disutility suggests that US payers may be willing to cover treatment options for clinically significant PCRA as long as annual per capita costs do not exceed US$600,000 (assuming a willingness-to-pay threshold of $100,000/QALY and that episodes of clinically significant PCRA lasts for several months if untreated). As cancer survivorship is an increasingly recognized important issue, especially in prostate cancer where most patients have a long survival after treatment, the current crosswalk provides foundational data needed for future studies that focus on interventions to address PCRA and assessments of the interventions' cost-effectiveness.

Our crosswalk's predictive performance is similar to what has been reported in the literature. For example, Brazier and colleagues reviewed twenty eight studies with 119 models and reported MAE between 0.01 and 0.19 (0.092 here) and RMSE between 0.08 and 0.20 (0.114 here) [10]. With respect to SF-6D crosswalks, most researchers focused on disease- (or gender-) specific quality of life measures: extensive overlap between indicated measures and SF-6D was expected to boost crosswalks' predictive performances (and thus lower MAE, RMSE, AIC and BIC). Examples of these measures and crosswalk performance are summarized in Online Appendix Table 8. Comparable measures of strong prediction accuracy may be seen in SF-6D crosswalks for PRO measures that assess disease severity (see Online Appendix Table 8). Similarities in prediction accuracies of crosswalks for PROs that assess aspects of quality of life or disease severity (including MAX-PC) challenge the paradigm requiring a high degree of conceptual overlap between PRO measures and SF-6D utilities when generating crosswalks [10]. Additionally, this paradigm may inadvertently preclude identification, diffusion and coverage of innovative and cost-effective treatment options for understudied diseases/health conditions.

This study has several limitations. First, we used cross-sectional data from fixed timepoints (i.e., 12- and 24-month follow-up). Given that all participants were enrolled shortly after prostate cancer diagnosis [12], we didn't have sufficient "between variation" in duration of prostate cancer survivorship. It matters because PCRA is negatively associated with time since prostate cancer diagnosis and health-related quality of life (see Online Appendix Fig. 1 for more details) [7, 25]. This suggests that our crosswalks prediction accuracy may decline over time, and that longitudinal datasets (with sufficient "between variation" in duration of prostate cancer survivorship) may provide further insight. On the other hand, our population-based cohort is a strength and may provide more generalizable results than limited institutional cohorts. Another limitation is that we acknowledge there is modest conceptual overlap between the MAX-PC questionnaire and SF-6D; however, as described earlier, the predictive performance of the current crosswalk is similar to others reported in the literature.

Our models yielded predicted utilities with narrower variances than observed utilities. This phenomenon is not uncommon and may be due to modest overlap between PCRA and HRQOL, missing covariates in the crosswalk, a regression to the mean, or because the crosswalks' coefficients were treated as fixed (rather than random) vectors when making predictions [36, 41, 42]. Irrespective of its cause, crosswalk users need to be mindful of this phenomenon and make recommended statistical adjustments

Table 3 Characteristics of observed and predicted utilities and measures of prediction accuracy in the validation dataset

Selection of control covariates	Only variables with p value < 0.05 in univariate analyses			All variables examined in univariate analyses		
Specification of clinically significant PCRA	As an extra control covariate	Used to stratify the analyses		As an extra control covariate	Used to stratify the analyses	
Strata	None	CS PCRA absent	CS PSCA present	None	*CS PCRA absent*	*CS PSCA present*
Model name	A	B	C	D	E	F
Number of control covariates	9	8	8	9	8	8
Observed utilities–all participants						
Mean (standard deviation)	0.809 (0.133)	–	–	0.809 (0.133)	–	–
Range	0.378–1.000	–	–	0.378–1.000	–	–
Observed utilities—CS PCRA absent						
Mean (standard deviation)	0.817 (0.129)	0.817 (0.129)	–	0.817 (0.129)	0.817 (0.129)	–
Range	0.378–1.000	0.378–1.000	–	0.378–1.000	0.378–1.000	–
Observed utilities—CS PCRA present						
Mean (standard deviation)	0.698 (0.146)	–	0.698 (0.146)	0.698 (0.146)	–	0.698 (0.146)
Range	0.406–1.000	–	0.406–1.000	0.406–1.000	–	0.406–1.000
Observed disutilities						
Mean (standard deviation)	0.119 (0.195)	0.119 (0.195)	0.119 (0.195)	0.119 (0.195)	0.119 (0.195)	0.119 (0.195)
Estimated range[¶]	–0.438–0.626	–0.438–0.626	–0.438–0.626	–0.438–0.626	–0.438–0.626	–0.438–0.626
Predicted utilities—all participants						
Mean (standard deviation)	0.800 (0.042)	–	–	0.808 (0.055)	–	–
Range	0.569–0.862	–	–	0.496–0.894	–	–
Predicted utilities—CS PCRA absent						
Mean (standard deviation)	0.808 (0.028)	0.811 (0.035)	–	0.818 (0.038)	0.809 (0.028)	–
Range	0.703–0.862	0.675–0.889	–	0.654–0.894	0.703–0.863	–
Predicted utilities—CS PCRA present						
Mean (standard deviation)	0.681 (0.041)	–	0.702 (0.086)	0.654 (0.055)	–	0.688 (0.068)
Range	0.569–0.751	–	0.484–0.848	0.496–0.758	–	0.562–0.820
Predicted disutilities						
Mean (standard deviation)	0.127 (0.050)	0.110 (0.093)	0.110 (0.093)	0.164 (0.067)	0.120 (0.073)	0.120 (0.073)
Estimated range[¶]	–0.020–0.257	–0.106–0.355	–0.106–0.355	–0.015–0.361	–0.073–0.316	–0.073–0.316
Measures of prediction accuracy						
Mean absolute error	0.104	0.106	0.114	0.105	0.104	0.109
Root mean squared error	0.125	0.128	0.145	0.128	0.125	0.133
Within ± 5% of observed utilities	17.4%	17.0%	17.0%	17.5%	17.3%	17.0%
Within ± 10% of observed utilities	42.0%	40.8%	39.6%	45.5%	41.8%	26.4%
Pearson's correlation coefficient[‡]	0.327	0.164	0.317	0.269	0.257	0.432

[¶]Estimates were obtained using Monte Carlo simulation

[‡]This measures the correlation between observed and predicted SF-6D for indicated study participants, and all p values were ≤ 0.05

CS PCRA clinically significant PCRA

[42]. Unlike prior crosswalk studies, we did not include interaction or higher order (e.g., squared) terms as control covariates for three reasons: indicated terms are likely to worsen prediction accuracy (i.e., the bias-variance trade-off) [43]; our study goal prioritized prediction accuracy over bias; and indicated terms make crosswalks difficult to use routinely. Lastly, we caution against clinical interpretation of our disutility estimates and causal interpretation of our regression estimates.

Conclusion

Using data collected from a population-based cohort of prostate cancer patients, we present a crosswalk that convert MAX-PC scores into SF-6D utilities for patients with and without clinically significant PCRA. This crosswalk facilitates economic evaluation of current and future PCRA interventions for cancer survivors.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11136-021-02871-9.

Author contributions DOE contributed to conception and design, data acquisition, data analyses and interpretation, drafting the manuscript, critical review of the manuscript for scientific and factual content and statistical analysis. AVB, BNG and RCC were involved in conception and design, data analyses and interpretation, critical review of the manuscript for scientific and factual content and supervision. RSB performed data analysis and interpretation, and critical revision of the manuscript for scientific and factual content. DU contributed to data acquisition, critical review of the manuscript for scientific and factual content and supervision.

Funding This research was funded by the Agency for Healthcare Research and Quality (AHRQ), US Department of Health and Human Services (DHHS) as part of the DEcIDE program, contract HHSA290200500401 and the Patient-Centered Outcomes Research Institute® (PCORI) Award (CER 1310–06543).

Availability of data and material The data that support the findings in this study are available from the NC ProCESS management team. Restrictions apply to the availability of these data, which are used under license for this study.

Code availability The Stata® codes used in this study are available from the corresponding author.

Declarations

Conflict of interest None to declare.

Ethical approval This study was exempted from IRB review by the UNC Office of Human Research Ethics/Institutional Review Board (17-0183).

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