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Key issues affecting quality of life and patient-reported outcomes in prostate cancer: an analysis conducted in 2128 patients with initial psychometric assessment of the prostate cancer symptom scale (PCSS)

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Abstract

Objective—Evidence-based quality of life (QL) questionnaires require the identification of issues of importance to patients. The primary aim of this study was to inform providers on patient-expressed issues while enhancing the content validity of instruments assessing quality of life (QL) and patient reported outcomes (PROs) in prostate cancer. The study provided additional psychometric properties for the new PRO and QL instrument, the Prostate Cancer Symptom Scale (PCSS).

Methods—An anonymous web-based survey of 2128 patients with prostate cancer was conducted with patients rating 18 QL items on a five-point scale.

Results—Most respondents (74%) were 55 to 74 years old, had early stage disease at diagnosis (81%) and were diagnosed within 2 years of the survey (81%). The top five rated issues were: overall QL, ability to perform normal activities, maintaining independence, ability to sleep, and not being a burden. These items were ranked as either “very important” or “important” by at least 88% of patients. None of the most highly ranked issues were symptoms. Instead, the highest ranked items were global issues reflecting the impact of symptoms on patients. In addition to the

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Competing Interests None declared.

Ethics approval Ethical approval was not sought at the time the survey was conducted as responses were fully anonymous, participation was elective and the study did not contain questions on sensitive topics. Participants’ informed consent was indicated by each individual’s willingness to complete the questionnaire.

Data Sharing Statement All primary data used for this study are available upon request via email to the corresponding author.

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enhanced content validity findings, good reliability results and initial support for construct validity are reported for the PCSS.

Conclusions—This is the largest survey providing patient-expressed background for content validity for QL and PRO measures. The findings of this study should aid development of newer practical questionnaires, such as the PCSS, which can be adapted to electronic platforms enhancing rapid and accurate PRO and QL evaluation.

Keywords

Quality of life evaluation; patient reported outcomes; prostate cancer; PCSS; psychometric properties

INTRODUCTION

Key concerns affecting patients with prostate cancer are essential when evaluating the impact of therapeutic and supportive care interventions. Major endpoints requiring evaluation include quality of life (QL) and patient-reported outcomes (PROs). While a large number of QL and PRO questionnaires have been developed,¹ few are used in clinical trials and even fewer are used in daily patient evaluation. Issues that limit the assessment of PROs include the practicality of incorporating this evaluation into trials and patient care, and the method of choosing items for inclusion in these measures. Concerns have been expressed about the limited participation of patients themselves during the development of these questionnaires. Appropriately, the FDA 2009 guidance for industry document stated that “... without adequate documentation of patient input, a PRO instrument’s content validity is likely to be questioned”.² The current study was initiated to gain, for the first time, the input of a large number of patients with prostate cancer to provide evidence for PRO measures in general and for the new quality of life and PRO instrument, the prostate cancer symptom scale (PCSS), in particular. In addition to PCSS, a number of other QL and PRO measures, comprehensively described in a previous systematic review,³ have been developed for prostate cancer patients. Although the present analysis was initiated to support the content validity of the PCSS, the results reported herein can be of value for other prostate cancer PRO instruments.

Somatic symptoms reflect physical well-being and are a component of overall quality of life.⁴⁵ However, quality of life and broad affective responses are multi-dimensional constructs influenced by the interaction of physical, psychological, social, and spiritual well-being,⁶ and therefore should be distinguished from physical symptom reporting. Previous work by our group has shown that patients with lung or breast cancer more highly value PRO aspects that evaluate global issues such as quality of life, maintaining independence, and performing normal activities, as opposed to specific symptoms.⁷⁸ The current project also assessed whether patients with prostate cancer similarly prioritize more global issues of concern compared with somatic symptoms.

PRO evaluation is gaining recognition in clinical oncology⁹ and more cancer-specific instruments are being developed.¹⁰ The PCSS is designed to emulate the theoretical model¹¹ of the LCSS (the Lung Cancer Symptom Scale) which is a widely used measure

with well-validated psychometric properties in patients with lung cancer.^{711–13} The LCSS is a brief and practical questionnaire concentrating on the issues of greatest importance to patients. As such, the LCSS has been successfully migrated to an electronic platform (called the “eLCSS-QL”).¹⁴ This electronic platform can be used on tablets or other devices. The electronic methodology improves accuracy and reduces the burden on patients and staff in conducting PRO evaluation, while providing immediately available results for comparison over time. Using the electronic platform, the questionnaire requires only about 2 minutes to administer, and overall can save time in a busy clinic setting.¹⁴ Currently, few QL/PRO measures are used commonly either in research or in practice in patients with prostate cancer. The findings of this current study can add to the evidence-based foundation for enhancing existing instruments, and in developing newer measures, such as the PCSS. By providing a brief and practical measure, the PCSS may encourage more frequent quality of life assessment to aid in personalizing patient care and assessing interventions in clinical investigations.

METHODS

Participants and data collection

A cross-sectional, online electronic survey of patients with prostate cancer was conducted over a 3-day period. Patients were surveyed using the established patient base of the online NexCura, Inc. patient information resource. Patients who had previously registered in the NexCura website (www.nexcura.com) were routinely asked if it would be permissible to be contacted in the future. Those with prostate cancer and agreeing to be contacted, received invitation e-mails outlining the purpose of the survey, and that it would be performed anonymously. These patients who agreed to be included in the study then received the electronic survey related to prostate cancer. Participation was elective, responses were fully anonymous and no patient identifier was used at any time during the study.

Patients with either active disease or a history of prostate cancer were invited to be included in the survey. Caregivers were excluded from the survey. Participants' consent was indicated by each individual's willingness to complete and return the questionnaire. The ownership and mission of NexCura has evolved since the completion of this survey and at the time of this writing, the NexCura website is no longer active online.

Survey measures

Patients were asked first to complete a demographic form consisting of ten questions concerned with the socio-demographic profile and health-related information of patients. This included self-reporting of age group, time since prostate cancer diagnosis, stage at diagnosis, cancer recurrence and types of treatment received. To determine disease stage, patients were asked to choose among the following four options: “My prostate cancer was confined to my prostate (localized disease; no cancer outside the prostate capsule),” “My prostate cancer was spread outside of my prostate, but not to other organs in my body (the cancer may have spread to the nearby seminal vesicles, or other nearby tissues within the pelvic area),” “My prostate cancer was spread outside of my prostate to areas far from my prostate, such as lymph nodes or bone,” or “I do not know.” Based on these responses,

patients were classified as having early stage (stages I and II), locally advanced (stage III), or metastatic (stage IV) disease.

To determine the list of QL and PRO items to be evaluated and ranked by patients, a panel of 17 oncology professionals who focus on prostate cancer (medical oncologists, urologists and oncology nurses) reviewed the literature and existing PRO/QL instruments.^{15–18} The panel selected 18 items felt to be of the greatest importance based on the literature review and their experiences. These issues encompassed the physical, functional, psychological, social and spiritual domains of QL. Patients were also encouraged to submit items that they felt might supplement the survey. The 18 QL/PRO items were rated by patients on a 5-point categorical scale ranging from “not important at all” to “very important.” Categorical variables were compared using Fisher’s exact tests. A p-value of <0.05 was considered statistically significant. All statistical analyses were performed using the statistical program R (Foundation for Statistical Computing, Vienna, Austria).¹⁹

SEER database

The demographic characteristics of the present study’s cohort were compared to those of the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute. SEER includes data from approximately 28% of the US population²⁰. Using the SEER 1973–2010 database (April 2013 release), men with primary prostate cancer diagnosed from 2000–2010 were identified. The information retrieved included age and stage at diagnosis.

Continued Assessment of Psychometric Properties of the PCSS

The primary focus of this study was to analyze items of importance in prostate cancer to enhance evidence-based content validity for the PCSS using a large-scale online survey methodology. The Prostate Cancer Symptom Scale (PCSS) is an 18-item self-report instrument for measuring QL, major symptoms, and PROs of prostate cancer. It is a modification of the well-tested Lung Cancer Symptom Scale.^{711–13} As seen in the items tested, the PCSS measures major symptoms and global issues of concern to patients with prostate cancer. Additionally, it uses three of the global items as a prognostic 3-Item Global Index (related to total symptom distress, activity status, and overall QL).²¹

The PCSS focuses on the physical and functional domains of QL, and captures the psychological, social, and spiritual domains in less depth. The patient is asked to focus on describing prostate cancer symptoms to limit co-morbidity aspects as much as possible. The time frame is the past day (last 24 hours), based on the rationale that the scale items represent states or conditions that may fluctuate, not enduring traits. The reading level required for the patient scale is second grade level. The PCSS uses an interval level visual analogue scale (VAS) to determine the intensity of patient responses. Each item is given an individual score equal to the length of the line, with zero = lowest rating (*best* status) and 100 = highest rating (*worst* status).^{7811–13} Scores are then reversed for two electronic summary reports to discuss with patients (scores for today’s visit and scores overtime).

Initial psychometric testing in addition to determination of large-scale content validity for the PCSS is reported. Support for content validity was initially obtained using the literature

and then a panel of healthcare experts in prostate cancer prior to asking the patients to rate all items. Initial reliability testing (for internal consistency) for the PCSS was calculated from the results of 45 men with prostate cancer who completed the PCSS (using the Cronbach's alpha test). Construct validity was assessed using classic validity testing guidelines,²² whereby the PCSS score is compared between two groups of patients known to have either very good or very poor health status. If the PCSS is sensitive to differences in disease status using the contrasted groups approach, then there should be a significant difference in the PCSS score between these two patient groups.

RESULTS

Demographic Data

The respondents' demographic profile and prostate cancer characteristics in comparison to the SEER cohort (627,464 individuals) are presented in table 1. A total of 2128 patients completed the survey; the majority of patients (74%) were 55 to 74 years old. Most patients (81%) had early stage disease at initial diagnosis and were diagnosed within 2 years of the survey. The staging and demographics of the 2128 patients in this survey were similar to that of the SEER cohort, although the patients in the present study were on average somewhat younger. The proportion of patients older than 75 years old was significantly lower in the present study compared with the SEER cohort ($p < 0.001$). Nearly half of the patients (48%) in the survey were treated with radical prostatectomy, and only 10% had not received any anticancer treatment. Even though most patients (81%) had early stage disease, this large survey still enlisted nearly 120 patients with metastatic cancer, providing a reasonably large sample of patients with this extent of disease.

Quality of life and PRO questions assessed for content validity

The QL and PRO survey results for the 2128 patients with prostate cancer are presented from the large online survey (table 2). These results were ranked by the percentage rating each item in either the top two categories ("very important" plus "important") or by only the top category ("very important"). Of the 18 items surveyed, 12 were symptoms, and 6 were global issues. The five most highly ranked issues are global items rather than specific symptoms, whether one looks at the ratings by either the top two categories or by only the "very important" category (with the one exception that "urinary incontinence" as a symptom was ranked #4 in the "very important" category). The global issues, such as maintaining quality of life (rated in the top two categories by 96% of patients), the ability to perform normal activities (95%), and maintaining independence (95%) received the highest ratings by patients. The highest rated symptoms were fatigue (87% of patients), urinary incontinence (87%), depression (80%), difficulties with urination (79%), and erectile dysfunction (77%). Patients were invited to suggest additional items. However, only a very small number of patients volunteered additional items, and none of these were indicated with sufficient frequency to add as additional items to the PCSS.

Quality of life and PRO findings are presented for subgroups of patients of interest (tables 3 and 4, and the text). Four subgroups were included: 1) patients who had or had not received radical prostatectomy, 2) patients with metastatic (stage IV) disease, 3) patients without

disease recurrence, and 4) patients who received hormone therapy following disease recurrence. No matter which subgroup is examined, the top 5 rated issues were ranked very similarly; they were all global impact items, and were rated by the patients as being of greater importance than any of the specific symptoms.

Comparison of subgroups revealed that the importance of PRO issues was fairly congruent across all subgroups. There are some issues; however, differing by patient subgroup and merit attention, as seen in tables 3 and 4. Some variations by subgroup are seen in the ratings of specific symptoms. While hot flashes was the lowest ranked item by all groups, predictably a large difference was reported by those who received hormonal therapy (46% rated this item in the “very important” plus “important” categories) when compared with the whole group (34%), with those treated with radical prostatectomy (32%, $p=0.004$), or with those patients who are free of cancer (32%, $p=0.002$). When contrasted to the whole group, the 128 patients receiving hormonal therapy after disease recurrence reported less erectile dysfunction (77% for the whole group, and 48% in the hormone treated subset) or sexual difficulties (76% versus 48%). Urinary difficulties (69%) and incontinence (77%) were less often reported (10% lower ratings) by the hormone treated group than for any other subset ($p < 0.05$ in each instance). For all other issues, patients receiving hormone therapy rated each item similarly (within 5%) to the whole group. As previously reported,^{23,24} patients with stage IV extent (typically with bone metastases) ranked pain considerably higher than other groups. All urinary and sexual issues were rated more highly by patients reportedly free of disease when compared with those with metastatic prostate cancer.

As seen in table 4, the more than 1000 patients undergoing radical prostatectomy generally ranked most issues similarly to those not having this procedure. Three items differed by 4% or greater between these two groups. Patients experiencing radical prostatectomy expressed greater concerns regarding both sexual issues surveyed (9% differences with $p < 0.001$ in each instance). The surgically treated patients also expressed slightly greater concern with urinary incontinence (4% difference, $p = 0.004$).

Additional Assessment of Psychometric Properties of the PCSS including Reliability and Construct Validity Testing

In addition to determining patient generated content validity for the PCSS, support for reliability (internal consistency) and initial construct validity were good for this 18-item self-report instrument which measures QL, major symptoms, and PROs of prostate cancer. For reliability testing, the early content findings derived from the literature and reviewed by a panel of experts were then taken to a patient sample as part of a larger prospective evaluation.²⁵ This sample included 45 patients with advanced prostate cancer who completed the PCSS. Internal consistency, using Cronbach’s alpha, was 0.86, exceeding the acceptable reliability guideline of 0.70 for new measures.²²

Initial support for construct validity, using the contrasted groups approach, also was good for the PCSS. In a sample of 35 men with advanced castration resistant prostate cancer with similar demographic characteristics (median age 73): 74% Caucasian and 26% African-American, a median of 16 years of education, and 37% with incomes of $< \$40,000$ per year), two groups were divided into early and late disease trajectory groups using common

standards of disease status. The results indicated that the PCSS is measuring what it purports to measure and it is sensitive to group differences²² in that the 16 men with less advanced cancer (the earlier trajectory group) reported better QL (mean, 67.9) than the 19 men with more advanced disease (the later trajectory group) who reported a lower QL (mean, 57.9), using the electronic version.

DISCUSSION

The present survey is the largest study designed to assess patient input for issues of importance in prostate cancer. As such, it provides patient-generated evidence for content validity of PRO and QL measures in this malignancy. The web-based method enhanced the ability to collect responses from a large number of patients, and to do so rapidly. Cancer symptoms were less highly ranked compared with more global issues such as QL, maintaining independence and performing normal activities. Of interest, in recent similar assessments in both lung cancer and in breast cancer, patients also rated these global issues more highly than symptoms.⁷⁸ While the number, magnitude and type of specific symptoms may vary among individuals, all respondents ranked these three global issues as their main concerns. Symptoms remain important to patients (as demonstrated by 87% of patients ranking urinary incontinence highly); however, it must be recognized that it is the impact and distress of symptoms on overall QL and functioning that patients express at the top of the list. This is true for the whole group of over 2000 patients and for the various subsets, including those with metastatic disease.

The five-point categorical scale utilized in this survey allowed a strong separation in the ranking of issues, from 96% of patients to 34% when combining the top two categories, and 74% to 10% when considering only the top category ("very important"). Among common specific symptoms, fatigue and urinary problems were the highest ranked by patients, whereas hot flashes, diarrhea, constipation and appetite were consistently reported to be lower. Each of the 18 items ranked by the patients is worthy of attention. Even hot flashes, which was the lowest ranked item, was deemed to be either important or very important by about one third of patients. Not surprisingly, patients with advanced prostate cancer who often receive hormonal therapy were more likely than others to consider hot flashes as important. Documentation of this impact on such individuals is needed for dependable PRO evaluation, rather than relying on expert opinion, which is not always accurate. Of note, the expert panel members did not anticipate that global issues would be so clearly ranked at the top of the survey. Additional evaluation of the psychometric properties of the PCSS performed in the subgroup of patients with advanced prostate cancer showed good reliability and support for construct validity pointing towards the strong psychometric underpinning of the instrument. These assessments were intentionally performed in one specific patient subgroup (i.e., patients with advanced prostate cancer) to minimize measured or unmeasured differences between patients when assessing construct validity using the contrasted groups approach.

As with all surveys, the present study has limitations and strengths. All collected data, including demographic information, were self-reported. It is an advantage that the web-based technology allows participation of a large number of patients; but, on the other hand, it

is only available to those with internet access, some degree of computer literacy, and the desire to learn more about their cancer. It may be that patients with higher disease severity are less likely to access the web and complete the survey. Patients using the NexCura website had to be able to communicate in English, and this website attracted a predominantly North American audience (88–91% of respondents), as determined in prior studies using the Nexcura platform.²⁶²⁷ The major strengths of the present survey include the large sample size and that all ratings are patient reported. In addition, the generalizability of the results is further supported by the demographic and disease characteristics of the surveyed patients which are similar to the overall population of patients with prostate cancer in the US, as seen in the SEER data displayed in table 1.²⁸ One notable exception is that patients participating in the present survey were younger than what would be expected based on the SEER data. Younger patients are more likely to have higher computer literacy and thus access the survey. It is unknown if older patients would share the same views.

The present survey provides evidence of the importance of specific PRO and QL issues as reported by over 2000 patients with prostate cancer. These results elucidate data for such evaluation from the patients' point of view that has not previously been available. Additionally, this large sample allows examination of the views of patients in a variety of subgroups including those currently free of disease as opposed to those with stage IV extent, as well as the opinions of those who had undergone radical prostatectomy. Review of the findings can be helpful for both the PCSS and other PRO and QL measures used in patients with prostate cancer.³ In particular, the present study demonstrates that an exclusive focus on symptom measures is incongruent with patient-expressed needs.

The study's findings contribute to the content validity of PRO measures for patients with prostate cancer. It provides enhanced psychometric properties for the new PCSS questionnaire: support of content validity by patients is indeed strong, based on findings of this large survey. In addition to reflecting the views of patients, the PCSS can provide a PRO and QL measure that is succinct and practical for use in patient care and clinical trial settings. This format lends itself to patient use on such electronic platforms as a modern tablet¹⁴ or via an application. These results add to the evidence in major cancers indicating that measures focusing solely on symptoms, without including items related to the impact of such symptoms on overall QL, fail to address PRO issues that are clearly deemed to be crucial by patients.⁷⁸

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References

1. PROQOLID [Online Patient-Reported Outcome and Quality of Life Instruments Database]. Secondary PROQOLID [Online Patient-Reported Outcome and Quality of Life Instruments Database]. <http://www.proqolid.org/>
2. US Department of Health and Human Services (USDHHS); Guidance for industry. Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Dec.2009

2009 Secondary US Department of Health and Human Services (USDHHS); Guidance for industry. Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. <http://www.fda.gov/downloads/Drugs/Guidances/UCM193282.pdf>.

3. Rnic K, Linden W, Tudor I, Pullmer R, Vodermaier A. Measuring symptoms in localized prostate cancer: a systematic review of assessment instruments. *Prostate cancer and prostatic diseases*. 2013; 16:111–22. [PubMed: 23381695]
4. Roth AJ, Weinberger MI, Nelson CJ. Prostate cancer: psychosocial implications and management. *Future oncology*. 2008; 4:561–8. [PubMed: 18684066]
5. Ochayon L, Zelker R, Kaduri L, Kadmon I. Relationship between severity of symptoms and quality of life in patients with breast cancer receiving adjuvant hormonal therapy. *Oncology nursing forum*. 2010; 37:E349–58. [PubMed: 20797943]
6. Hamming JF, De Vries J. Measuring quality of life. *The British journal of surgery*. 2007; 94:923–4. [PubMed: 17636515]
7. Gralla RJ, Hollen PJ, Msaouel P, Davis BV, Petersen J. An evidence-based determination of issues affecting quality of life and patient-reported outcomes in lung cancer: results of a survey of 660 patients. *Journal of thoracic oncology*. 2014; 9:1243–8. [PubMed: 25122420]
8. Shapira I, Gralla R, Davis B, et al. How Important Is Cognition for Women with Breast Cancer? Results of a Web-Based Study of 1071 Breast Cancer Patients Used To Augment Content Validity of the Breast Cancer Symptom Scale (BCSS) a New Health-Related Quality of Life Instrument. *Cancer Research*. 2009; 69:5049. [PubMed: 19491269]
9. Gotay CC, Kawamoto CT, Bottomley A, Efficace F. The prognostic significance of patient-reported outcomes in cancer clinical trials. *J Clin Oncol*. 2008; 26:1355–63. [PubMed: 18227528]
10. Hamoen EH, De Rooij M, Witjes JA, Barentsz JO, Rovers MM. Measuring health-related quality of life in men with prostate cancer: A systematic review of the most used questionnaires and their validity. *Urol Oncol*. 2015; 33:69 e19–28.
11. Hollen PJ, Gralla RJ, Kris MG, Cox C. Quality of life during clinical trials: conceptual model for the Lung Cancer Symptom Scale (LCSS). *Supportive care in cancer*. 1994; 2:213–22. [PubMed: 8087439]
12. Hollen PJ, Gralla RJ, Kris MG, et al. Measurement of quality of life in patients with lung cancer in multicenter trials of new therapies. Psychometric assessment of the Lung Cancer Symptom Scale. *Cancer*. 1994; 73:2087–98. [PubMed: 8156514]
13. Earle, C., Weeks, J. The science of quality-of-life measurement in lung cancer. In: Lipscomb, J. Gotay, C., Synder, C., editors. *Outcomes assessment in cancer: measures, method, and applications*. Cambridge: Cambridge University Press; 2005. p. 171
14. Hollen PJ, Gralla RJ, Stewart JA, Meharchand JM, Wierzbicki R, Leighl N. Can a computerized format replace a paper form in PRO and HRQL evaluation? Psychometric testing of the computer-assisted LCSS instrument (eLCSS-QL). *Supportive care in cancer*. 2013; 21:165–72. [PubMed: 22684988]
15. Sommers SD, Ramsey SD. A review of quality-of-life evaluations in prostate cancer. *Pharmacoeconomics*. 1999; 16:127–40. [PubMed: 10539394]
16. Litwin MS, Hays RD, Fink A, Ganz PA, Leake B, Brook RH. The UCLA Prostate Cancer Index: development, reliability, and validity of a health-related quality of life measure. *Med Care*. 1998; 36:1002–12. [PubMed: 9674618]
17. 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. [PubMed: 18774706]
18. Wei JT, Dunn RL, Litwin MS, Sandler HM, Sanda MG. 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]
19. R: A language and environment for statistical computing [program]. Vienna, Austria: R Foundation for Statistical Computing; 2012.
20. Surveillance, Epidemiology, and End Results (SEER) Program. National Cancer Institute, Division of Cancer Control and Population Services, Surveillance Research Program, Surveillance Systems Branch. Secondary Surveillance, Epidemiology, and End Results (SEER) Program. National

Cancer Institute, Division of Cancer Control and Population Services, Surveillance Research Program, Surveillance Systems Branch. www.seer.cancer.gov

21. Gralla RJ, Hollen PJ, Symanowski JT, Msaouel P, Kohn N, Lesser M. Improving clinical prognostic categories beyond performance status: Enhancing accuracy in survival prediction with a three-item patient-reported outcome (PRO) index from the LCSS in lung cancer and mesothelioma. *J Clin Oncol*. 2014; 32:5s. (suppl; abstr 8065).
22. Nunnally, JC., Bernstein, IH. *Psychometric theory*. 3. New York: McGraw-Hill; 1994.
23. Msaouel P, Pissimissis N, Halapas A, Koutsilieris M. Mechanisms of bone metastasis in prostate cancer: clinical implications. *Best Pract Res Clin Endocrinol Metab*. 2008; 22:341–55. [PubMed: 18471791]
24. Smith HS. Painful osseous metastases. *Pain Physician*. 2011; 14:E373–403. [PubMed: 21785487]
25. Hollen PJ, Gralla RJ, Jones RA, et al. A theory-based decision aid for patients with cancer: results of feasibility and acceptability testing of DecisionKEYS for cancer. *Supportive care in cancer*. 2013; 21:889–99. [PubMed: 23052911]
26. Markman M, Petersen J, Montgomery R. An examination of characteristics of lung and colon cancer patients participating in a web-based decision support program. *Internet-based decision support programs. Oncology*. 2005; 69:311–6. [PubMed: 16293971]
27. Markman M, Markman M, Petersen J, Belland A. Clinical features of American versus non-American gynecologic cancer patients requesting information from a proprietary web-based decision-support program. *Journal of cancer research and clinical oncology*. 2006; 132:439–43. [PubMed: 16538516]
28. Howlader, N., Noone, A., Krapcho, M., et al. SEER Cancer Statistics Review, 1975–2010. National Cancer Institute; Bethesda, MD: 2013. Secondary SEER Cancer Statistics Review, 1975–2010, National Cancer Institute. Bethesda, MD http://seer.cancer.gov/archive/csr/1975_2010/

Table 1

Demographics of the study participants (N=2128) and comparison to SEER data.

		Survey respondents (N=2128)	SEER cohort (N=627,464)
Age (years)	< 35	0	0.02%
	35 – 44	19 (1%)	0.6%
	45 – 54	325 (15%)	9%
	55 – 64	928 (44%)	30%
	65 – 74	653 (31%)	36%
	> 75	171 (8%)	24%
	Missing data	32 (2%)	
Extent of prostate cancer at the time of diagnosis	I don't know	48 (2%)	4.5%
	Early stage (stage I – II)	1725 (81%)	80%
	Locally advanced (Stage III)	238 (11%)	11%
	Metastatic disease (Stage IV)	117 (6%)	4%
Time since initial diagnosis	0 – 6 months ago	379 (18%)	
	6 – 12 months ago	483 (23%)	
	1 – 2 years ago	864 (41%)	
	2 – 4 years ago	194 (9%)	
	4 – 7 years ago	84 (4%)	
	7+ years ago	86 (4%)	
	Missing data	38 (2%)	
Disease recurrence	No	1385 (65%)	
	Yes	195 (9%)	
	Does not apply (initial treatment regimen not yet completed)	513 (24%)	
	Missing data	35 (2%)	
Treatment	Radical prostatectomy	1011 (48%)	
	Brachytherapy	383 (18%)	
	External beam radiation therapy	579 (27%)	
	Hormonal therapy	504 (24%)	
	Chemotherapy	60 (3%)	
	Cryotherapy	42 (2%)	
	Alternative/complementary medicine	170 (8%)	
	No therapy	214 (10%)	

SEER: Surveillance, Epidemiology, and End Results program of the National Cancer Institute [28]

Table 2

Importance of quality of life issues among all study participants (N=2128).

	Ranked as either “important” or “very important” *	Ranked as “very important” **
Quality of life	2043 (96%) [1]	1577 (74%) [1]
Ability to perform normal activities	2022 (95%) [2]	1366 (64%) [3]
Maintaining independence	2021 (95%) [3]	1534 (72%) [2]
Ability to sleep	1948 (92%) [4]	1057 (50%) [6]
Not being a burden to others	1878 (88%) [5]	1353 (64%) [4]
Fatigue	1845 (87%) [6]	828 (39%) [10]
Urinary incontinence	1842 (87%) [7]	1251 (59%) [5]
Depression	1709 (80%) [8]	958 (45%) [7]
Difficulties with urination	1683 (79%) [9]	732 (34%) [12]
Difficulty achieving or maintaining an erection	1641 (77%) [10]	904 (43%) [8]
Symptom distress	1624 (76%) [11]	653 (31%) [14]
Sexual difficulties	1622 (76%) [12]	840 (40%) [9]
Anxiety	1603 (75%) [13]	717 (34%) [13]
Pain	1588 (75%) [14]	734 (35%) [11]
Diarrhea	1481 (70%) [15]	630 (30%) [15]
Constipation	1408 (66%) [16]	485 (23%) [16]
Appetite	1342 (63%) [17]	270 (13%) [17]
Hot flashes	713 (34%) [18]	204 (10%) [18]

The top 10 symptoms ranked as either “important” or “very important” are separated from the lower ranked issues by a dashed line. Numbers in brackets indicate each item’s rank.

* This column shows the rankings by the top 2 categories;

** this column shows the rankings by the single top category

Table 3

Quality of life issues ranked as either “very important” or “important” by patients with metastatic (stage IV) prostate cancer and those without disease recurrence.

	All patients (N=2128)	Patients with stage IV prostate cancer (n=117)	Patients without disease recurrence (n=1385)
Quality of life	2043 (96%) [1]	113 (97%) [1]	1346 (97%) [1]
Ability to perform normal activities	2022 (95%) [2]	112 (96%) [2]	1333 (96%) [2]
Maintaining independence	2021 (95%) [3]	111 (95%) [3]	1326 (96%) [3]
Ability to sleep	1948 (92%) [4]	107 (92%) [5]	1286 (93%) [4]
Not being a burden to others	1878 (88%) [5]	106 (91%) [6]	1229 (89%) [5]
Fatigue	1845 (87%) [6]	108 (92%) [4]	1218 (88%) [7]
Urinary incontinence	1842 (87%) [7]	88 (75%) [9]	1222 (88%) [6]
Depression	1709 (80%) [8]	89 (76%) [8]	1134 (82%) [9]
Difficulties with urination	1683 (79%) [9]	85 (73%) [10]	1108 (80%) [11]
Difficulty achieving or maintaining an erection	1641 (77%) [10]	64 (55%) [16]	1154 (83%) [8]
Symptom distress	1624 (76%) [11]	81 (69%) [13]	1071 (77%) [12]
Sexual difficulties	1622 (76%) [12]	62 (53%) [17]	1131 (82%) [10]
Anxiety	1603 (75%) [13]	85 (73%) [11]	1061 (77%) [13]
Pain	1588 (75%) [14]	91 (78%) [7]	1034 (75%) [14]
Diarrhea	1481 (70%) [15]	77 (66%) [15]	973 (70%) [15]
Constipation	1408 (66%) [16]	78 (67%) [14]	920 (66%) [16]
Appetite	1342 (63%) [17]	83 (71%) [12]	867 (63%) [17]
Hot flashes	713 (34%) [18]	53 (45%) [18]	436 (32%) [18]

Numbers in brackets indicate each item's rank by the corresponding patient subgroup

Table 4

Quality of life issues ranked as either “very important” or “important” by patients who have undergone radical prostatectomy compared with those who have not.

	All patients (N=2128)	Radical prostatectomy (n=1011)	No radical prostatectomy (n=1117)
Quality of life	2043 (96%) [1]	978 (97%) [1]	1065 (95%) [1]
Ability to perform normal activities	2022 (95%) [2]	967 (96%) [2]	1055 (94%) [3]
Maintaining independence	2021 (95%) [3]	962 (95%) [3]	1059 (95%) [2]
Ability to sleep	1948 (92%) [4]	934 (92%) [4]	1014 (91%) [4]
Not being a burden to others	1878 (88%) [5]	903 (89%) [5]	975 (87%) [6]
Fatigue	1845 (87%) [6]	869 (86%) [7]	976 (87%) [5]
Urinary incontinence	1842 (87%) [7]	898 (89%) [6]	944 (85%) [7]
Depression	1709 (80%) [8]	829 (82%) [8]	880 (79%) [8]
Difficulties with urination	1683 (79%) [9]	813 (80%) [11]	870 (78%) [9]
Difficulty achieving or maintaining an erection	1641 (77%) [10]	826 (82%) [9]	815 (73%) [13]
Symptom distress	1624 (76%) [11]	778 (77%) [12]	846 (76%) [11]
Sexual difficulties	1622 (76%) [12]	815 (81%) [10]	807 (72%) [14]
Anxiety	1603 (75%) [13]	778 (77%) [12]	825 (74%) [12]
Pain	1588 (75%) [14]	741 (73%) [14]	847 (76%) [10]
Diarrhea	1481 (70%) [15]	699 (69%) [15]	782 (70%) [15]
Constipation	1408 (66%) [16]	673 (67%) [16]	735 (66%) [16]
Appetite	1342 (63%) [17]	632 (63%) [17]	710 (64%) [17]
Hot flashes	713 (34%) [18]	324 (32%) [18]	389 (35%) [18]

Numbers in brackets indicate each item's rank by the corresponding patient subgroup.