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## Abstract

**Background:** Assessing data from large patient populations remains challenging in oncology clinical research. The PCSS is an electronic QL and PRO measure based on the LCSS (a validated lung cancer instrument).

**Methods:** We queried patients with prostate cancer who were previously enrolled in the web-based NexCura® patient information resource. Patients with prostate cancer ranked the importance of each of 18 issues on a 5-point scale. Issues included: general, prostate-specific, psychosocial and summative items. 2128 patients completed the anonymous internet-conducted survey over a 3-day period.

**Results:** Demographic groups included stage (NED = 1385; metastatic extent = 245), prior radical prostatectomy (1010), and current treatment (hormonal = 128, non-hormonal = 117). The 5 highest ranked items are listed in the table; by either the highest ranking (most important) or by the two highest ratings combined, and percent of patients.

	Rank by: Very Important	Rank by: Very Important + Important
Good QL	1 (76%)	1 (98%)
Maintaining Independence	2 (74%)	2 (97%)
Incontinence	5 (61%)	4 (90%)
Ability to sleep	6 (51%)	3 (84%)
Sexual Functioning	8 (44%)	5 (80%)

Ratings by disease category (NED or metastatic disease, hormonal or non-hormonal treatment) were similar. Patients gave low rankings to appetite (17% of 18 issues), and to hot flashes (14% of 18 issues) even in those receiving hormonal treatment.

**Conclusions:** This methodology was efficient in information gathering and analysis. Limitations include the possibility of a biased population in that patients must have access to the Internet, and have visited the nexcura.com website. This may influence why maintaining independence ranked near the top of all items. This represents the largest survey of patient opinions in prostate cancer and supports using this technology to assess content validity to obtain results rapidly from a large patient sample. Such patient rankings could also serve to assign weighting to each item in establishing an overall QL score.

## Background

Prostate cancer is often a highly symptomatic disease affecting all dimensions of quality of life. Both health care professionals and patients recognize the importance of quality of life and symptom control. Nonetheless, formal evaluation of quality of life using well-validated instruments is unusual in clinical trials and rare in typical patient management.

To address the issues of insufficient time and resources for performing the QL and patient reported outcome (PRO) evaluations, the PCSS-QL was designed to be used with an inexpensive handheld pocket pc. In the experience with this format in lung cancer, < 2 minutes of patient time was needed; no extra physician time was required.<sup>4</sup>

In a survey of oncologists concerning quality of life evaluation, reasons stated as barriers to performing such assessments were a perceived lack of validated instruments, and insufficient time and resources for carrying out the evaluation.<sup>5</sup>

There is general agreement that the most valid data for the content of QL assessment should be based on patient input. In the development of different QL instruments for patients with prostate cancer, the content validity processes have varied. Often, instruments have been based more on opinions of health care professionals rather than on patient experiences. This study was undertaken to obtain input from a large sample of patients to provide reliable information for the population in general and for important subsets of the population (such as extent of disease and treatment type).

Several instruments for evaluating quality of life (QL) and symptoms in patients with prostate cancer are available, including: QLQ-C30 + Prostate Module, FACIT, EPIC, PC-QoL, PROSQoL, UCLA-PCL and UCLA-PCF. These instruments vary in length (10 to 52 questions), content, format, and psychometric properties.

Due to the infrequent use of these instruments and stated barriers, our group began the development of a new instrument for prostate cancer (the "PCSS-QL") based on the structure, outcomes, and model of the validated lung cancer instrument, the LCSS.<sup>2,3</sup>

Content validity is usually supported by a panel of experts (in this case 16 urologists, medical oncologists and oncology nurses) involved in the particular construct of interest.<sup>5,6</sup> Additionally, a review of the literature often serves to help in establishing the list of items to be rated by the patients. After both a literature review and results were obtained from the expert panel, the survey was constructed for submission to patients.

The current study was undertaken as a new online method for obtaining patient input from a large sample as part of the validation process.

## Study Objectives

- To determine which quality of life issues are of importance to patients to aid in establishing content validity in a quality of life and patient reported outcomes questionnaire for patients with prostate cancer.
- To obtain information from a large sample of patients, thus allowing subgroup analysis representing treatment and extent of disease status.
- To determine among the issues, which are ranked as having the greatest importance.

## Methods

### Design and Patient Recruitment

- This methodological study used an online survey approach.
- The established patient base of the web-based NexCura® patient information resource was used to survey patients with prostate cancer. Patients who had previously visited the website ([www.nexcura.com](http://www.nexcura.com)), and had registered, are routinely asked if it is agreeable to contact them in the future. Such patients were then sent an invitation to participate anonymously in this survey. If a patient agreed, he or she then sent a survey form for completion. No patient identifier was collected at anytime.
- Selection criteria included any patient with current or a history of prostate cancer. Caregivers were excluded. Demographic stratifications included stage of disease, prior radical prostatectomy, and current treatment (none, hormonal, non-hormonal).

## Methods continued

### Design and Patient Recruitment continued

- Over a 3-day period, 2128 patients completed the anonymous web-conducted survey. With this large response, no further recruitment of patients was conducted.
- In addition to a patient information form to obtain demographics and health-related variables, patients were asked to rank 18 issues on a 5-point scale assessing the importance of each item. Issues included general, prostate-specific, psychosocial and summative items.

### Instruments and Scoring

Two instruments were used in this computer-assisted survey:

- Patient Information Form** – The investigators developed a 10-item form to obtain self-reported demographic and health-related information for the following: age, time since diagnosis, stage at diagnosis, recurrence since completion of treatment, and presence of metastatic prostate cancer disease. Demographic stratifications included stage of disease, prior radical prostatectomy, and current treatment (none, hormonal, and non-hormonal).

- Prostate Cancer Symptom Scale (PCSS-QL)** The investigators developed a 18-item quality of life measure. The initial content validity was based on a literature review and on the results of deliberations of an expert panel of 5 health care professionals. The final step in the content validity process was the survey of patients with prostate cancer. The plan is then to use an inexpensive hand-held pocket PC to enhance feasibility. The PCSS-QL is based on the LCSS (a validated lung cancer quality of life and symptom assessment instrument). Further information on the LCSS can be found at [www.lcss-ql.com](http://www.lcss-ql.com) and in references quoted in this poster.<sup>2,3,4</sup> In the instructions, patients were asked to rank 18 issues on a 5-point scale assessing the importance of each item (ranging from "Most Important" to "Not Important at All"). The items were in the following categories: general, prostate-specific, psychosocial, and three summative items (global symptomatic distress, global activity status, and global quality of life).

- Scoring of the results.** The results were scored in several ways to allow different uses of the information. First, a scoring system ranging from 0 to 400 was created, with the highest score indicating the greatest importance as assessed by the patients. The highest weighting was given to the "Most Important" category in calculating the total score. The total scores for all patients are listed in the results Tables 1 – 4, and the individual issues are ranged from 1\* to 18\* according to the weighted total score. Another demonstration of the results is by ranking in the "Most Important" category only; this too is listed in results Tables 1 – 4. Results Table 5 lists the findings by the percentage of patients who rated each item to be in the "Most Important" category, or in the combined "Most Important" plus "Important" (the second highest response) categories.

TABLE 1. Patient Characteristics (Available on 98% of the 2128 Patients)

AGE:		
< 45	1%	
45 – 54	1%	
55 – 64	44%	
65 – 74	31%	
> 74	8%	
TIME SINCE DIAGNOSIS:		
< 1 Year	42%	
1 – 2 Years	41%	
3 – 7 Years	13%	
> 7 Years	4%	
TREATMENT (all that apply):		
Radical Prostatectomy	48%	
Radiotherapy: External Beam	29%	
Brachytherapy	24%	
Hormonal Therapy	18%	
Chemotherapy	3%	
None	10%	
EXTENT OF DISEASE AT DIAGNOSIS:	PERCENT // (Number of Patients)	
Localized to Prostate	82% / 1725	
Metastatic or Locally Advanced	15% / 304	
Not known	3% / 67	

## Results

TABLE 2. The 12 Top Ranked Items By: All Patients and by Subgroups (no recurrent disease, and by status-post radical prostatectomy)

ITEM	ALL PATIENTS (N = 2128)		NO RECURRENT DISEASE (n = 1385)	RADICAL PROSTATECTOMY (n = 1010)
	Rank by: Total Score	Rank by: "Most Important"		
Quality of Life	1 (371)	1	1	1
Maintaining Independence	2 (369)	2	2	2
Perform Normal Activities	3 (366)	3	3	3
Burden to Others	4 (347)	4	4	4
Urinary Incontinence	5 (345)	5	5	5
Ability to Sleep	6 (341)	6	6	6
Being Fatigued	7 (324)	10	10	10
Being Depressed	8 (315)	7	8	8
Erectile Dysfunction	9 (314)	8	7	7
Problems with Urination	10 (305)	12	11	11
Distress from Symptoms	11 (304)	14	14	14
Having Pain	12 (302)	11	13	11

## Results continued

TABLE 3. The 12 Top Ranked Items By: All Patients and by Subgroups (metastatic disease, and by receiving hormonal treatment for recurrent disease)

ITEM	ALL PATIENTS (N = 2128)		METASTATIC DISEASE (n = 117)	HORMONAL TREATMENT (n = 128)
	Rank by: Total Score	Rank by: "Most Important"		
Quality of Life	1	1	1	1
Maintaining Independence	2	2	2	2
Perform Normal Activities	3	3	5	5
Burden to Others	4	4	3	4
Urinary Incontinence	5	5	9	8
Ability to Sleep	6	6	4	3
Being Fatigued	7	10	6	7
Being Depressed	8	7	7	6
Erectile Dysfunction	9	8	15	15
Problems with Urination	10	12	14	13
Distress from Symptoms	11	14	12	11
Having Pain	12	11	8	9

TABLE 4. The 6 Lowest Ranked Items By: All Patients and by Subgroups (no recurrent disease, and by status-post radical prostatectomy)

ITEM	ALL PATIENTS (N = 2128)		NO RECURRENT DISEASE (n = 1385)	RADICAL PROSTATECTOMY (n = 1010)
	Rank by: Total Score	Rank by: "Most Important"		
Having Anxiety	13 (302)	12	11	11
Difficulty with Sexuality	14 (301)	9	9	9
Having Diarrhea	15 (275)	15	15	15
Having Constipation	16 (274)	16	16	16
Having a Good Appetite	17 (265)	17	17	17
Having a Hot Flashes	18 (238)	18	18	18

TABLE 5. The 6 Lowest Ranked Items By: All Patients and by Subgroups (metastatic disease, and by receiving hormonal treatment for recurrent disease)

ITEM	ALL PATIENTS (N = 2128)		METASTATIC DISEASE (n = 117)	HORMONAL TREATMENT (n = 128)
	Rank by: Total Score	Rank by: "Most Important"		
Having Anxiety	13	12	10	10
Difficulty with Sexuality	14	9	14	14
Having Diarrhea	15	15	11	12
Having Constipation	16	16	13	16
Having a Good Appetite	17	17	17	18
Having a Hot Flashes	18	18	18	17

TABLE 6. Percentage of the 2128 Patients Rating the Items in the Top 2 Categories of Importance

ITEM	RESPONSE CATEGORY	
	Very Important	Very Important + Important
Quality of Life	76%	98%
Maintaining Independence	74%	97%
Perform Normal Activities	66%	97%
Burden to Others	65%	90%
Urinary Incontinence	61%	90%
Ability to Sleep	51%	94%
Being Depressed	45%	82%
Erectile Dysfunction	42%	80%
Difficulty with Sexuality	41%	73%
Being Fatigued	40%	89%
Having Pain	35%	78%
Problems with Urination	35%	81%
Having Anxiety	35%	78%
Distress from Symptoms	32%	80%
Having Diarrhea	30%	71%
Being Constipated	23%	67%
Maintaining an Appetite	13%	64%
Having Hot Flashes	10%	35%

## Conclusions

- This is the largest survey of self-reported patient issues and concerns for prostate cancer. Subgroups by treatment status and extent of disease were easily identified and provide useful comparisons to the full sample. Even when a subgroup was a small percentage of the total, the number of patients was generally > 100.

- Responses were fairly similar among subgroups with functional issues being rated as among the most important.

- Some differences appeared with those with metastatic disease who rated sexual and urinary issues lower than patients without recurrent prostate cancer, and not unexpectedly rated pain control as more important.

- Surprisingly, appetite and hot flashes (even in those receiving hormonal treatment) were rated as less important issues, and the ability to sleep was rated highly by all.

- Strong support for content validity for the PCSS-QL was obtained through this large panel of patients with prostate cancer who ranked their quality of life concerns. These data are similar to those of a 16-member panel of health professionals in a previous survey conducted for this content validity process.

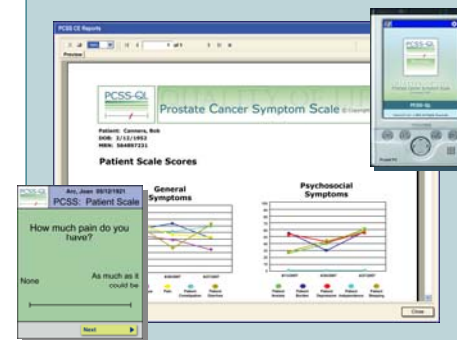
- A prospective trial completing the psychometric evaluation of the PCSS-QL is now in progress.

- This trial uses the pocket pc assistance to aid in feasibility as was previously confirmed with the LCSS-QL in patients with lung cancer (high patient and staff acceptability, requirement of only 2 minutes of patient time and no additional physician time)<sup>5</sup>

- This approach of using a computer-assisted survey for patients already registered on a site-specific web address may serve as a model for rapidly assessing large patient samples with other malignancies. Based on the large response over just 3 days, it appears that patients are willing to provide input about their cancer experience. Brevity of the scale and avoiding patient identifiers may have helped this large and rapid response.

- While it is most helpful to have a large patient sample, there are limitations to be considered with this approach. As a web-based methodology, it clearly tends to select those patients with computer availability and familiarity. In using patients who have previously registered with the NexCura® website, there could be a selection bias for those who seek out information. This may partially explain why the issue of maintaining independence was so highly rated by all patient subgroups.

## Examples of Pocket PC Screens and Computer Reports



## References

- Morris, J., Perez, D., & McNoe, B. (1998). The use of quality of life data in clinical practice. *Quality of Life Research*, 7, 85-91.
- Hollen, P.J., Gralla, R.J., & Kris, M.G. (1995). An Overview of the Lung Cancer Symptom Scale [Monograph, pp. 57-63]. *Quality of Life Symposium, 7th World Conference on Lung Cancer*, Colorado Springs, Colorado, June, 1994.
- Hollen, P.J., Gralla, R.J., Kris, M.G., & Potanovich, L.M. (1993). Quality of life assessment in individuals with lung cancer: Testing the Lung Cancer Symptom Scale (LCSS). *European Journal of Cancer*, 29A, S51-S56.
- Hollen, P.J., Gralla, R.J., Kris, M.G., Cox, C., Belani, C.P., Grunberg, S.M., Crawford, J., & Neuhart, J.A. (1994). 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*, 73, 2087-98.
- Gralla, R.J., Hollen, P.J., Leigh, N.B., Mehrarhand, J.M., Krieger, H., & Solow, H. A Prospective Evaluation of the Attitudes of Patients, Physicians and Nurses after using a Computer-Assisted Quality of Life Instrument (LCSS-QL) as Part of a Multicenter Clinical Trial in Non-Small Cell Lung Cancer. *Journal of Clinical Oncology*, 2006 ASCO Annual Meeting Proceedings Part I, Vol. 24, No. 18S (June 20 Supplement), 2006: 6123.
- Nunnally, J.C., & Bernstein, I.H. (1994). *Psychometric theory* (3rd edition). New York: McGraw-Hill.
- Hulley, S.B., Cummings, S.R., Browner, W.S., Grady, D., Healt, N., Newman, T.B. (2001). *Designing clinical research* (2nd edition). Philadelphia: Lippincott, Williams, & Wilkins.

For a copy of this poster, please go to: [www.lcss-ql.com](http://www.lcss-ql.com)

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